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The Pharmacy of the Developing World:
India, Patent Law and Access to Essential Medicines

Hafiz Aziz ur Rehman

A thesis submitted for the Degree of Doctor of Philosophy
at the ANU College of Law
The Australian National University

January 2011
Statement of Originality

I certify that the thesis entitled *The Pharmacy of the Developing World: India, Patent Law, and Access to Essential Medicines* submitted for the degree of Doctor of Philosophy at the Australian National University is an original work, which is the result of my own independent intellectual effort. Where reference is made to the work of others, due acknowledgement is given. I also certify that any material in the thesis that has been accepted for a degree or diploma by any other university or institution is identified in the text.

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Acknowledgments

I am greatly indebted to my supervisor, Dr Matthew Rimmer, for his continued support during my PhD candidature. I would also like to thank members of my supervisory panel, Dr Thomas Alured Faunce and Dr Hitoshi Nasu for their valuable suggestions and comments.

This work was made possible by the financial support of the AusAID and I am thankful for the award of an Australian Development Scholarship. The International Islamic University, Islamabad, has been a model employer by fully supporting and facilitating my study leave at the ANU College of Law.

My stay at the Australian National University has been made all the more enjoyable by my various friends. I am particularly thankful to Shah Faisal, Muhammad Fahim, Khalid Chauhan and Ajmal Jhangir for their constant help and support.

Finally, it is with deepest gratitude that I acknowledge the support of my family. Without the patience, understanding and love of my wife Munazza and children – Hasan, Husain and Rahmah – I would be lost.

I dedicate this dissertation to my parents; they have contributed more to my life than I have ever let them know.
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Abstract

In a critical evaluation of the influence of the TRIPS Agreement 1994 on India's patent regime, this thesis considers whether India can retain its pre-eminent role as the pharmacy of the developing world. Using Amartya Sen's conception of justice, development as freedom and capability approaches as thematic foundation, I have problematised key domestic and international developments in the area of patent law and access to essential medicines.

With the help of original case studies, this work provides an in-depth and thorough analysis of major controversies which are currently dominating the global discourse about patents and access to medicines. The Gleevec patent saga in India highlights the problem of evergreening in patent law; the tensions between the right to health and the right to property; and the role of international law. The next case study – the Pfizer, Natco controversy – highlights the limitations and shortcomings of the World Trade Organization's rules on compulsory licensing for exports. The Indian experience shows that implementation of the Waiver Decision 2003 is extremely cumbersome and India's domestic regulations have also failed to address this problem. The third case study of this thesis deals with the detention of generic drugs in transit and border enforcement measures, and shows that barriers to access to essential medicine are sometimes operating beyond the limits of patent laws and domestic regulations.

In addition to calling for a modernisation of Indian patent law, this thesis also considers new models of medical innovation in the Indian context. It maintains that the ongoing debate in India about the regulation of publicly funded research should be fully informed about the consequences of excessive patenting. India should consider adopting open source drug discovery models by facilitating and participating in patent pools.
Two alternative models of medical innovation – the Health Impact Fund and Prizes – are discussed in the Indian context to show how India can maintain its pre-eminence in the pharmaceutical manufacturing sector.

This study concludes that a number of multilateral and bilateral initiatives mandating TRIPS-Plus standards have the potential to further compromise India’s access to a medicines regime. It is argued that the Indian government should resist entering into any TRIPS-Plus trade agreement, which could limit its ability to manufacture cheap and affordable generic drugs. The World Trade Organization should reconsider the mandate of the *Doha Declaration on TRIPS and Public Health 2001* in the light of domestic experiences to provide a readily available and easy to implement export mechanism. The World Health Organization should take a leadership role in promoting and implementing alternative models of medical innovation. The thesis also recommends that the World Intellectual Property Organization needs to substantively implement its Development Agenda in order to promote access to medicines.
Chapter 1
Introduction

I. Introduction

In the foreword of a collection of short stories, poems, photographs and essays, *AIDS Sutra: Untold Stories from India*, Professor Amartya Sen referred to the disturbing prevalence of HIV/AIDS in India, notwithstanding the country's international role in providing access to affordable treatment of this epidemic. He writes that:

> There is a peculiar – and rather bitter – irony in the fact that no country has done more than India in cheapening the production cost of known antiretroviral drugs (CIPLA is something of a world leader in this), and yet most HIV affected people in India cannot afford to get and use these drugs. India's role in supplying cheap lifesaving drugs to the world is, of course, to be much applauded (if anything demands cooperation across the national boundaries today, the global AIDS epidemic surely does), but this country itself should also have a more effective system of delivery and use within its borders. There are, to be sure, the barriers of organization and medical assistance, but the costs of the drugs, even when lowered by domestic production, tend to be well beyond the means of the less affluent patients.¹

The concern raised by Sen clearly depicts the typical role of India as a leading manufacturer of affordable generic drugs while the Indian populace suffer epidemics, poor health infrastructure and extreme poverty. Despite its domestic limitations and

poor health services, India has emerged as an important player in the global pharmaceutical market and its generic drug industry is tipped to be the most reliable source of affordable essential medicines across the world.

The relevance and importance of Indian generic drugs is evident from the fact that:

Most of the ARVs currently available at affordable prices come from India. In 2008, an estimated 3 million people in low and middle income countries received ARV therapy for HIV/AIDS. It is estimated that approximately 60% of the ARVs come from India, including up to 80% of first-line treatments.\(^2\)

For this crucial role, India is often described as the pharmacy of the developing world.\(^3\)

Recognising the crucial role of Indian generic drugs in the implementation of major humanitarian projects, it is pertinent to raise questions about the sustainability and future of these supplies amidst rapid legal, political and economic transformations taking place in India. The most significant change in this regard is the implementation of the *Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS Agreement 1994)*\(^4\) which has changed India’s longstanding tradition of prohibiting


\(^{4}\) *Marrakesh Agreement Establishing the World Trade Organization*, opened for signature 15 April 1994,
patents on pharmaceutical products. India’s decision to accept the *TRIPS Agreement 1994* and consequently amend its domestic laws to provide stronger patent protection to pharmaceutical products, has very significant and long-term implications for the global access to medicines regime. It will eventually change the existing structures and arrangements for obtaining cheaper and affordable generic drugs from India. The ability of Indian drug manufacturers to produce generic drugs will be significantly compromised under the new patent law.

This thesis considers the prospects for India’s future as the pharmacy of the developing world in a post-TRIPS world. In doing so, it has sought answers to three important questions. First, what are the key policy and legal changes which India has introduced since the adoption of the *TRIPS Agreement 1994* affecting the existing state of access to medicines regime, and how have domestic political and systemic influences shaped the outcome of legislative changes? Second, how are India’s new laws responding to implementation and enforcement challenges, and to what extent have these laws managed to accommodate the exceptions and safeguard provisions of the *TRIPS Agreement 1994*? Third, how does India interact within the international system to advocate legal transformation of the kind required to address the needs of developing countries, and what policy options is India adopting in the process of internalisation of a global patent regime?

**II. Development as Freedom**

The problematisation of patents and access to medicines issue needs a holistic approach which can define key constituents of this problem and its possible solutions. From the perspective of this thesis, a comprehensive theoretical framework is required which can

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1867 UNTS 3 (entered into force 1 January 1995) annex 1C (‘Agreement on Trade-Related Aspects of Intellectual Property Rights’).
explain three key questions dominating the discourse on patents and access to medicines. First, what is the precise nature of the access to medicines problem and its possible nexus with the patent regime, and how may the sufferings of individual patients be linked with the mainstream discourse on human rights and development? Second, what are the best means to address this problem both at the level of developed and developing countries, and how can individual and collective social responsibilities be allocated in this regard? Third, what future policies and strategies should be adopted at national and international levels to promote affordable and equitable access to essential medicines?

In an attempt to devise a defining and holistic theoretical framework, I have mainly relied upon Professor Amartya Sen’s theory of development as freedom. In his seminal book, Development as Freedom, Professor Sen provides an expansive and articulate view of development and the capability approach. His development as freedom model can be briefly summarised with the help of the following four points.

First, Sen’s conception of development goes beyond the accumulation of wealth and economic growth and emphasises that poverty is indeed a deprivation of basic capabilities rather than living in a state of low income. He states that:

Development has to be more concerned with enhancing the lives we lead and the freedom we enjoy. Expanding the freedoms that we have reason to value not only makes our lives richer and more unfettered, but also allows us to be fuller social persons, exercising our own volitions and interacting with – and influencing – the world in which we live.⁵

⁵ Ibid. 14.
These freedoms, according to Sen, can be either constitutive or instrumental. The constitutive freedoms are valued on their own as they enable individuals to lead the type of lives they have reason to value. On the contrary, instrumental freedoms have functional value in contributing to the achievement of constitutive freedoms. Sen also provides a non-exclusive list of five basic types of freedoms – including political freedoms; economic facilities; social opportunities, such as access to health and access to education; transparency guarantees, and protective security.

Amartya Sen's conception of development and freedoms has great relevance from the perspective of this thesis. India needs to learn a lot from Sen's views on development which go much beyond economic growth and wealth generation. These views are particularly helpful for India at a time when we often see the dilemma of Indian policy makers struggling to balance its role both as an emerging global economy and a poor developing country. This problem is evident from the case studies in this thesis which establish that India lacks a coherent, consistent and pro-poor policy on patents and access to medicines. India should understand that the development process is complex and painstakingly long-term, and a quick rush to a strong patent regime will not help its poor consumers.

The implementation of a stricter patent regime in India may affect several substantive freedoms which are highly regarded by Professor Sen. Individual freedoms associated with social opportunities will inevitably suffer with the introduction of a product patent regime resulting in high drug prices. The lack of transparency in global patent law rule-making and standards development is squeezing political freedoms. In the process of

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6 Ibid. 36.
7 Ibid. 38-40.
implementing TRIPS-plus intellectual property standards, the freedoms constituting transparency guarantees are often compromised and neglected by contracting parties.

The second feature of Sen’s conception of development as freedom is about functionings and capabilities. Driving the notion of functionings from Aristotelian roots, Sen describes it as the various states of being which an individual may value. Basic functionings include values such as being free from diseases, adequately nourished, and having access to reasonable shelter. Among the complex functionings, Sen includes the individual’s desire for self-respect and other higher values of society. The ability of an individual to achieve desired functionings in his or her capability, is a key component of Sen’s developmental framework. He notes that:

[T]here is a strong case for judging individual advantage in terms of capabilities that a person has, that is, the substantive freedom he or she enjoy to lead the kind of life he or she has reason to value. In this perspective, poverty must be seen as the deprivation of basic capabilities rather than merely a lowness of income, which is the standard criterion of identification of poverty.

From the perspective of patents and access to medicines, Sen’s capability approach is relevant for two reasons. With the implementation of the TRIPS Agreement 1994 and other intellectual property instruments, the individual’s capabilities are severely undermined in the area of access to affordable health and prevention of diseases. There is no doubt that a patent regime is one factor among many others which contribute towards the state of un-freedom which poor patients face in the developing world. However, it is becoming increasingly more relevant and serious in terms of systemic consequences as it is not generally addressed through development policies. Sen

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8 Ibid. 74-75.

9 Ibid. 87.
ascribes great importance to individuals’ capabilities\textsuperscript{10} and insists that the state of freedom can be effectively calculated and measured at that level. Thus, the economic performance of a country like India is not relevant here when its poor population is not living up to its capabilities.

Second, the individual’s capabilities, according to Sen, are a function of both process and endowment.\textsuperscript{11} Processes are institutions that give freedom such as political and civil rights, and endowments are the individual’s personal and social circumstances. This distinction is extremely important for us. A system may apparently have adequate processes which ensures the individual’s attempts to harness their capabilities, but the actual personal and social circumstances of individuals may not allow them to materialise their objectives. At a national level, the case of Indian patent law is a perfect example in this regard. The \textit{Patents Act 1970} (India) contains some prominent safeguard provisions in the form of compulsory licensing, opposition proceedings, and parallel importation. Thus, the process is aptly laid down. However, the actual use of these safeguards (the endowment aspect) suggests that some of these provisions work well while others fail to deliver. In the case of opposition proceedings, the political and economic circumstances work well for some of the leading Indian pharmaceutical firms.

\begin{itemize}
\item \textsuperscript{10} Patents and the access to medicines problem can be approached both as individual and collective capabilities. Though Sen’s own conception is confined to an individual’s capabilities, this notion is now widened to see how collective capabilities influence the process to development. See: Peter Evans ‘Collective Capabilities, Culture, and Amartya Sen’s Development as Freedom’ (Summer 2002) 37(2) \textit{Studies in Comparative International Development} 54-60. Also see: Solava S. Ibrahim, ‘From Individual to Collective Capabilities: The Capability Approach as a Conceptual Framework for Self-help’ (November 2006) 7(3) \textit{Journal of Human Development and Capabilities} 397-416.
\item \textsuperscript{11} Aaron Cosbey, \textit{A Capability Approach to Trade and Sustainable Development: Using Sen’s Conception of Development to Re-Examine the Debates} (Manitoba, Canada: International Institute for Sustainable Development and the Swiss Agency for Development and Cooperation, November 2004) 12.
\end{itemize}
On the contrary, compulsory licensing provisions could not be used for a multiplicity of reasons as discussed in this thesis. At the international level, the failure of the Waiver Decision 2003 can also be analysed in this context. The individual circumstances of developing countries often prevent them from invoking the cumbersome compulsory licensing scheme envisaged under the Waiver Decision 2003.

The third important feature of Amartya Sen’s development as freedom approach is his articulation of a ‘goal-rights system’. Sen is not satisfied with both libertarian and utilitarian views of rights and he advances his own consequentialist approach as follows:

I have argued, elsewhere, against the necessity of opting for one or the other approach in this dichotomy, and have presented arguments for a consequential system that incorporates the fulfilment of rights among other goals. It shares with utilitarianism a consequentialist approach (but differs from it in not confining attention to utility consequences only), and it shares with a libertarian system the attachment of intrinsic importance to rights (but differs from it in not giving it complete priority irrespective of other consequences). Such a “goal-rights system” has many attractive properties as well as versatility and reach.12

This is an important observation and intellectual construct which can be potentially used in justifying some alternative models of pharmaceutical innovation. The proponents of prize models and the Health Impact Fund13 often extend similar justifications to override adverse consequences of patent rights. However, their accounts, as we discuss in this

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thesis, are limited to particular solutions unlike Sen’s theoretical framework which contextualises his ‘goal-rights system’ in a broader perspective, providing a useful analytical platform for this work. Sen does not offer specific comments on the nature of patent rights and their limitations in his book, *Development as Freedom*. However, his dissatisfaction with the existing state of global access to medicines and the role of patents therein is quite clear from his evidence before the United Kingdom’s House of Common’s Treasury Committee. Answering a question about the institutional reforms needed to share the benefits of globalisation fairly, he said that:

I think institutional reform has to be of many different kinds ... To give one example, patent law would be one of them. The patent law issue is interesting ... quite often this has been seen as being basically confrontational to the richer countries’ interest, because they introduced pharmaceuticals and so on. The picture is a bit complicated now, partly because of the dynamism of the nature of the world economy. For example, India, which we were discussing earlier, which began primarily as an importer of drugs, has ended up now being one of the bigger producers of drugs. So in some ways the identification of interests have got much more muddied over time.\(^{14}\)

He further noted that:

If you look at the patent laws, I think they are very unsatisfactory and the WTO reforms, which have tried to do something, have not really got as far as they could have got. To see the issue of equity and incentive at loggerheads with each other, I do not think is the right way of thinking about it. Just consider one of the issues. That is why for many of us, including, as I was mentioning earlier, Oxfam and

Médecins Sans Frontières, there exist drugs, for example for AIDS, which people cannot afford and cannot therefore buy in the poorer parts of the world, and the question is that you can produce them at an extremely low cost, but you may be prevented from doing that on grounds of loyalty and patent rights.\(^{15}\)

Sen’s stance on the limitations of patent rights and their impact on the access to medicines regime has been made conspicuously clear in these statements. He favours a wide range of solutions ranging from differential drug prices to more radical changes in the pharmaceutical innovation system.\(^{16}\) This approach is perfectly justified in the light of his consequentialist theory of rights.\(^{17}\)

The fourth explanatory feature of Sen’s development as freedom approach deals with his position on ‘market versus state and efficiency versus equity’.\(^{18}\) Here, he again adopts a middle course by allocating relevant importance and roles to both institutions. The role of the market in wealth generation cannot be neglected and substituted and reliance on the market in this regard is fully justified. He also recognises that markets can sometimes become counterproductive and need stringent regulations. For this regulatory reason, the role of the state is always important.\(^{19}\) Sen’s point also strengthens the argument, which this thesis has developed, about the critical role of the Indian government, and for that purpose governments of other developing countries, in

\(^{15}\) Ibid.

\(^{16}\) Ibid.


accelerating the cause of access to essential medicines. In a situation where market 
forces have failed to direct sufficient resources for the research and development of 
drugs needed in the developing countries, the primary responsibility lies with 
governments to offset its negative impacts.

The work of Amartya Sen, who won the Nobel Prize in 1998, was applauded by Kofi A. 
Annan in the following words:

The world’s poor and dispossessed could have no more articulate or insightful a 
champion among economists than Amartya Sen. By showing that the quality of 
our lives should be measured not by our wealth, but by our freedom, his writings 
have revolutionized the theory and practice of development.  

This thesis is an original application of Amartya Sen’s development as freedom model 
in the context of patent law and access to medicines. It argues that Sen’s conception of 
freedom provides an appropriate analytical basis to study the role of India as the 
pharmacy of the developing world. The key components of this thesis – Indian patent 
law and its development, the application of safeguard provisions and enforcement 
issues, the regulation of publically funded research and alternative models of 
pharmaceutical innovation, the emergence of TRIPS-plus standards and the WIPO 

Development Agenda – can be sufficiently explained with the help of Sen’s theorisation. 

There is evidence that some scholars have recently used Sen’s model to understand the 
changing dynamics of the global intellectual property movement. Madhavi Sunder 
presents a theory of cultural analysis of intellectual property, noting:

I draw upon Amartya Sen’s and Martha Nussbaum’s capabilities approach to 
human development, the social relations approach to property, and what I call a

“New Enlightenment” analysis of culture, in which the core values of Enlightenment-reason, democracy, freedom of expression, and the call, in Kant’s words, to “think for [one]self” are extended to the cultural sphere. My reinterpretation of intellectual property applies to suburban American fan fiction authors and rural Indian weavers alike: all seek greater capacity for accessing and participating in crafting new knowledge of the world. In turn, these cultural capabilities structure our social relations.  

This work, however, does not specifically analyse the issue of patents and access to medicines but mainly deals with theoretical justifications of the intellectual property system. Other scholars have also used Sen’s discourse in areas such as the developmental dimensions of intellectual property and the regulation of biotechnologies. Arguably, such an approach has great explanatory power in making sense of the conflicts over patent law and access to essential medicines in India.

III. Indian Patent Law and Access to Medicines

The academic interest in India’s patent law and pharmaceutical policy is a longstanding phenomenon and there is no dearth of literature on this topic. Several accounts of the historical development of Indian patent law and its different phases have been recorded, and India is one of a few developing countries which have attracted considerable research and academic interest in this regard.


The United States patent scholar, Professor Janice M. Mueller, has highlighted the historical evolution of Indian patent law with an aim to elaborate the rationale of recent changes in a specific policy perspective. While discussing different stages of patent law development in India, Mueller concludes that India will continue facing substantive policy challenges in balancing its role as an emerging economy and a leading developing country. India’s ‘mosaic view’ of patents is a direct outcome of multiple, sometimes conflicting, influences and India has managed to develop a patent law which is fairly balanced in its outlook. Mueller goes one step further and concludes that Section 3(d) of the Patents Act 1970 (India) is the most controversial provision, and its ‘negative impact on an important form of indigenous innovation should not be ignored’. Mueller considers that Indian law is adequately equipped with multiple safeguard provisions which the Indian government can use to facilitate access to medicine programs. The specific reference in this regard is made to the compulsory licensing provisions.

Sudip Chaudhuri acknowledges that the traditional wisdom of not granting product patents in developing countries is still applicable and the Indian pharmaceutical industry presents a peculiar case in this regard. He highlights the innovative capabilities of

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25 Ibid. 558.


Indian pharmaceutical firms and argues that some leading Indian firms will build capabilities to develop drugs both for regulated and non-regulated markets. The technological advancement which Indian companies have demonstrated in the case of HIV/AIDS medicines will continue strengthening a particular segment of the pharmaceutical market.

In another study, Sudip Chaudhuri argues that India needs to initiate public-private partnerships for the development of new drugs in India. He thinks that the Indian patent regime goes beyond the requirements of the *TRIPS Agreement 1994*, and safeguard provisions such as compulsory licences should be effectively utilised to overcome the problems associated with drug patents. This approach fails to address the practical limitations which developing countries have traditionally faced in using the safeguard provisions of the *TRIPS Agreement 1994*. Furthermore, any suggestion to implement a public-private initiative needs to explore innovative options which can resolve issues of the patent rights of leading pharmaceutical companies.

Continuing this theme, Padmashree Gehl Sampath confirms that several Indian pharmaceutical companies face difficulties with India’s TRIPS compliance and ‘product patent protection in India is emerging to be a very decisive factor in determining access to medicines, both in India and other third countries in Africa’.

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explores the relationship between innovation and pharmaceutical exports in the case of Indian generic companies. The issue of domestic innovation and the technological capabilities of Indian pharmaceutical companies is further discussed by Biswajit Dhar and K. K. Gopakumar. They argue that Indian firms have successfully launched some extraordinary research and development projects.

Martin J. Adelman and Sonia Baldia argue that a phased and full implementation of the *TRIPS Agreement 1994* will eventually benefit Indian consumers, scientist and industry. This view is, nevertheless, confronted in other studies. Jayashree Watal calculates the welfare losses which India will bear on the eve of the full implementation of patent provisions of the TRIPS Agreement. These losses will mainly emerge from price increases which, according to Jayashree Watal, could be offset by an effective use of price control and compulsory licensing. These studies, however, do not provide a systematic policy solution which India should employ to design its long term strategy dealing with existing and future challenges in the area of patents and access to medicines.

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Protection and Emerging Firm Strategies in the Indian Pharmaceutical Industry’ (undated) Institute of New Technologies, United Nations University, 5 at http://www.who.int/intelectualproperty/studies/PadmashreeSampathFinal.pdf


Shamnad Basheer argues that most of the recent changes in Indian patent law contain a positive outlook from the public interest perspective and in this regard India has successfully implemented the obligation of the TRIPS Agreement 1994. The exceptions and safeguard provisions of Indian patent law will help Indian companies to continue production of affordable generics.\(^3\) He has, however, pointed out elsewhere that some safeguard provisions, such as Section 3(d) and the requirement for the use of local workers, are susceptible to a WTO dispute settlement challenge, and India needs to adopt detailed and clear guidelines in this regard.\(^6\)

Amy Kapczynski clearly applauds this provision of the Patents Act 1970 (India) and insists that these safeguard provisions should be evaluated and understood in the context of pharmaceutical patents and the problem of evergreening.\(^7\) She further notes that:

The Indian example shows that TRIPS leaves developing countries with a more diverse and wide-ranging set of flexibilities at the formal level than the existing literature typically suggests. If India implemented its adopted flexibilities to their full potential, it could generate significant scope for competition in the pharmaceutical sector without ever issuing a compulsory license ... Rather than reject TRIPS, Indian government actors have engaged in creative acts of legal


interpretation that take extensive advantage of known TRIPS flexibilities, and that have also generated new ones. In the process, India has paved the way for new interpretive disagreements over the meaning of TRIPS. The dynamic has clearly operated beyond India as well.\(^\text{38}\)

This is indeed a very positive evaluation of the Indian patent regime with ambitious expectations attached to the implementation of relevant provisions. This thesis, on the other hand, establishes that not all safeguard provisions have been effectively used and interpreted in India and there are strong political and economic constraints which inhibit a robust implementation process. Despite having very strong compulsory licensing provisions, India has so far failed to use this channel both for domestic and export purposes. An overemphasis on the potential of Indian patent law is perhaps misplaced and lacks evidence.

In 1997, Jean O. Lanjouw concluded that implementation of a product patent regime in India will not lead to ‘heartless exploitation of the poor’.\(^\text{39}\) The reason attributed in this regard is not the merit of the patent system. It is about the extreme poverty in India where poor patients were already not receiving medicines despite the low prices of generics. The debate about product patent, according to Jean O. Lanjouw, is irrelevant for 70% of the population living without access to pharmaceuticals. However, the role of the pharmaceutical sector and the implementation of a product patent regime should be now re-evaluated in the light of two factors. First, during the last decade or so, the Indian government has launched several treatment access programs and the situation has

\(^{38}\) Ibid. 1642-1643.

improved in many cases, though the overall impact may still be incremental. Second, the impact of the product patent regime in India should not be solely worked out within its limited geographical boundaries. Indian generics may not reach the poorest segment of its own population but they play a crucial role in international humanitarian aid and access to medicine projects. Neglecting this aspect will eventually be a bad news for those poor patients who benefit from Indian exports.

Padmashree Gehl Sampath thinks that the product patent regime will be a decisive factor in determining access to medicines both within India and outside. On the issue of the relevance of compulsory licensing and access to medicine, she notes that:

Theoretically, compulsory licensing, as provided for under the TRIPS Agreement, or merely the threat of its use, could be used as a price leveraging instrument in developing countries. But the introduction of product patent protection in countries such as India may have far-reaching consequences on access to medicines at affordable prices in a large number of developing and least developed countries. Indian pharmaceutical firms, have in the past, offered strong price competition through the production of cheaper generic versions of drugs patented elsewhere.40

Cheri Grace also notes considerable challenges which India will face amidst the implementation of a product patents' regime. There could be devastating consequences from the perspective of public health and access to medicines, and India may use the flexibilities of the TRIPS Agreement 1994 to overcome some of these problems.

However, the practical usage and implementation of these safeguard provisions is a big question according to Cheri Grace. K Balasubramaniam also concludes that compulsory licensing and parallel importation are not a permanent solution and mostly beyond the capacity of developing countries. The need for a long term and sustainable solution to the problem of patents and access to medicines, is still felt. This thesis supports the underlying rationale of this argument with the help of case studies showing the practical limitations of compulsory licensing and other safeguard provisions.

IV. The TRIPS Agreement and Trade Law

While studying India’s role as the pharmacy of the developing world, I have focused upon the changes wrought to Indian patent law by the TRIPS Agreement 1994.

The inadequacies of the TRIPS Agreement 1994 have become evident during the implementation process and, contrary to popular perception, the Indian regime will show less promising results when it comes to the global access to medicines campaign. The situation is further aggravated by India’s domestic political and economic policies geared towards trade liberalisation and deregulation. The role of different bilateral and multilateral trade and intellectual property negotiations is further negatively impacting the state of access to medicines.


A substantial part of the patents and access to medicines problem is linked with the TRIPS Agreement 1994. Fredrick M. Abbott highlights the balancing nature of the TRIPS Agreement 1994 and asserts that despite its turbulent history, the TRIPS Agreement 1994 can be interpreted and used in a manner consistent with the expectations of the developing world. He advocates a broader understanding of the TRIPS Agreement 1994 in a human rights context and asserts that:

Throughout the history of international IPRs regulatory system, rights granted to creators have been subject to balancing against other social interests. This balancing has typically taken place at the national or regional level in the framework of a constitution. The TRIPS Agreement has largely removed IPRs regulation from the traditional constitutional framework, giving broad rights to producers and exceptional rights to public. The most evident means for resurrecting and maintaining a balance is for WTO Members to apply their constitutions to the application of TRIPS Agreement rules. The national and regional constitution will in most cases advance individual and group human rights … Yet in some cases the national constitution and its application will also require protection at the multilateral level, and it is here that the AB (Appellate Body) will need to step in to identify and apply relevant human rights principles that will maintain a reasonable semblance of balance.43

He further notes that ‘implementation of the TRIPS Agreement potentially conflicts with human rights, both core and relative’.


44 Ibid. 314.
Abbott maintains that the right to health has been confirmed in the *Doha Declaration on the TRIPS Agreement and Public Health* (*Doha Declaration 2001*)\(^4^5\) establishing that the TRIPS rules be flexible in terms of national policy to the extent that human rights interests can be accommodated.\(^4^6\) I have used Abbott’s analytical framework in Chapter 4 to elaborate the scope and contents of the *Doha Declaration 2001* and the WTO General Council Decision of 30 August 2003 (*Waiver Decision 2003*).\(^4^7\) It is important to note that Abbott’s rights-based approach adequately describes several provisions of the *TRIPS Agreement 1994* and the adoption of the *Doha Declaration 2001*. However, post *Doha Declaration 2001* developments and the complicated nature of the final outcome pose several questions about a smooth reading of the *TRIPS Agreement 1994* as a balancing act.

Peter Drahos also points to the role which India has historically played in developing its domestic patent law and to influence international intellectual property standards.\(^4^8\) He argues that India adopted a patent law earlier than some European countries but its delicate balance was a key factor in fostering industrial development in some sectors. However, after the *TRIPS Agreement 1994* some developing countries including India were worse off than in the past. Relying upon the notions of regulatory ritualism and

\(^{45}\) *Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc WT/MIN(01)/DEC/2 (14 November 2001) at http://www.wto.org/english/tratop_e/trips_e/min01_e/mindecl_trips_e.htm


rules complexity, Peter Drahos maintains that developing countries have lost the gains of the *Doha Declaration 2001* in subsequent negotiations.49 He does not share the same level of excitement and expectation which other commentators have shown with regard to the outcome of the *Doha Declaration 2001* and the *Waiver Decision 2003*.

Peter Drahos also discusses the possibility of a developing countries alliance which can collectively negotiate global intellectual property standards. This alliance, a developing country quad comprising India, Brazil, China and Nigeria, can enhance the negotiation capacity and bargaining position of developing countries and it would ultimately help in designing balanced domestic patent regimes. This proposal, however, fails to appreciate the internal political and economic dynamics of India which are evident from India’s bilateral and multilateral trade negotiations.

Professor Rochelle C. Dreyfuss assigns a great importance to the flexibilities of the *TRIPS Agreement 1994*. She thinks that a group of leading developing countries, like India, have demonstrated that the *TRIPS Agreement 1994* does not necessarily contain a one-size-fits-all approach, and it is evident from recent amendments in Indian patent law.50

Professor Jerome H. Reichman shares the position of optimism and constructive engagement advocated by Abbott.51 He thinks that the *TRIPS Agreement 1994* was

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51 Frederick M. Abbott and Jerome H. Reichman, ‘The Doha Round Public Health Legacy: Strategies for
definitely a huge undertaking for developing countries which were not ready to adopt stricter and higher intellectual property standards. Reichman argues that developed countries should halt the process of further harmonisation of a global patent regime by allocating more time and resources for developing countries. The trade bilateralism and the widening of the intellectual property negotiation agenda through data exclusivity and patent term extension, is a bad strategy on the part of developed countries and they may end up losing existing common grounds for negotiations.52 Reichman notes that:

The system needs to survive the shocks and pitfalls likely to be encountered in the post-transitional phase of the TRIPS Agreement. Let me, therefore end with a plea for restraint and for a more cooperative and less confrontational approach than that which has sometimes characterized relations between developed countries during the transitional phase. Once the developing countries see that they, too, have a big stake in the global intellectual property system, the long-term prospects for that system would become bright, indeed. In the long-term we should expect the economic stimulus of the TRIPS standards to influence business and investment decisions everywhere, without regard to those North-South divisions inherited from the Cold War that seems increasingly anachronistic in principle, if

not in practice. The trick, however, is to reach that long-term understanding without capsizing the vessel on which we collectively embarked in 1994.\(^5\)

With the benefit of a little hindsight we can now evaluate the optimism which was attached to the *TRIPS Agreement 1994*. It is evident from the failure of the *TRIPS Agreement 1994* to facilitate the access to medicines regime, and with the subsequent emergence of the TRIPS-plus agenda, that developed countries could not follow the advice of restraint and cooperation. Instead, we have seen a rigorous and fresh round of patent law harmonisation aimed at narrowing the policy space afforded under the *TRIPS Agreement 1994*.

V. Innovation

The patent law and access to medicines debate is not complete without suggesting appropriate solutions to resolve the problems of affordable access amidst the crisis of pharmaceutical innovation. Delivering essential medicines to the poorest population of the world is a moral obligation but who precisely bear this responsibility? The answer to this question is not simple as most of the governments in developing countries lack adequate resources to fulfil their legal and constitutional obligations. Pharmaceutical innovation and drug development is in the private domain and dominated by companies based in the most affluent countries. These firms have as such no moral obligation to ensure access to essential medicines in the developing world. These firms often tend to focus on producing drugs which are needed in developed countries and a large segment of poor patients living in developing countries are missed out. This particular dilemma is aggravating the problem of access to medicines in the developing world.

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\(^{53}\) Jerome H. Reichman, “The TRIPS Agreement Comes of Age: Conflict or Cooperation with the Developing Countries?” (2000) 32 *Case Western Reserve Journal of International Law* 441-470, 469.
William W. Fisher and Talha Syed approach this problem as follows:

Each year, roughly nine million people in the developing world die from infectious diseases. The large proportion of those deaths could be prevented, either by making existing drugs available at low prices in developing countries, or by augmenting the resources devoted to the creation of new vaccines and treatments for the diseases in question.54

To overcome this problem, they need to identify a package of reforms that would result in lowering the drug process in developing countries. This package will include measures aimed at limiting firms’ patent rights, re-prioritising pharmaceutical research and development strategies and stimulating the role of governments in drug development and distribution. Who will bear the cost of this reform package? For William W. Fisher and Talha Syed the answer to this question is straightforward: the developed countries’ residents and they advance plenty of historical, social and moral reasons in this regard.55

Thomas Pogge also considers this question in his discourse on the Health Impact Fund. He contextualises the problem of access to medicines in a poverty and human rights framework and argues that it is in the self-interest of developed countries to allocate resources for reforms such as the Health Impact Fund. Pogge’s earlier suggestion of imposing a Global Resources Dividend (GRD) tax provides sufficient moral arguments to build a case for financing an alternative model of pharmaceutical innovation.56


55 Ibid. 585.

56 Thomas Pogge, ‘A Global Resources Dividend’ in David A. Crocker and Toby Linden (Eds), Ethics of
Professor Joseph E. Stiglitz has long been advocating the use of prizes as motivation in an alternative model of pharmaceutical innovation. My work in Chapter 7 is partly built upon his arguments about the limitations of the patent system and the relevance of a prize model. In a recent article with Arjun Jayadev, Professor Joseph E. Stiglitz maintains that:

Most importantly, the prize fund mechanism is a way in which to provide a certain guaranteed return to an innovator to cover the (considerable) costs of production. Under such a system, a guaranteed prize (let us say US $1 billion) will be provided to the first producer of a viable therapy for a neglected disease. Once produced and paid for by the prize, the drug can be provided at cost. Drugs that provide little additional therapeutic value will be provided compensation from the fund, but at a substantially reduced amount. Such a program can be funded either by industrialized countries or philanthropic organizations.\(^7\)

One possible limitation of the prize model is its implementation cost which is expected to be far above the reach of developed countries. Stiglitz suggests that such a model can be implemented through a mutual financing of developing countries suffering from a particular neglected disease. However, the likelihood of such partnerships are quite low. There are two possible solutions which can help in overcoming this problem. First, the

cost should be allocated solely to affluent countries and the justifications in this regard can be borrowed from William W. Fisher and Talha Syed.\textsuperscript{58} Second, the use of miniature prize models should be encouraged instead of one large prize initiative. It will minimise cost related risks and constraints and developing countries will willingly consider participating in this system. James Love has suggested some miniature prize models and I have preferred this solution in this thesis in the context of India and the access to medicine problem.\textsuperscript{59}

Two more solutions, open source drug discovery and patent pools, are discussed in this thesis in the purview of equitable licensing and publicly funded research. I have used the theoretical construct of Yochai Benkler to develop a case for reforms in the existing Indian policies of proprietary ownership. Benkler presents a compelling case for commons-based peer production utilising the creative input and skills of a large number of people who work and participate for all sorts of intrinsic reasons beyond commercial gains and profit-making.\textsuperscript{60} Benkler first introduced this idea in his seminal paper, ‘Coase’s Penguin’\textsuperscript{61}, and elaborated a comprehensive theory of social production in his book, \textit{The Wealth of Networks}. In his book, Benkler briefly discussed the possibilities of


social production of essential medicines to meet the needs of developing countries. However, the details and practical arrangements in this regard were largely missing from earlier accounts of Benkler’s work. Professor Arti Rai took a lead by proposing an open source drug discovery model in the form of the Tropical Disease Initiative. I have used these theoretical frameworks to justify and develop a case for open source drug discovery in the Indian context.

This thesis also discusses the potential of patent pools in resolving the problem of access to essential medicines. Several commentators have sporadically discussed the option of creating a patent pool in the Indian context but this thesis for the first time comprehensively conceives a case for a patent pool and its implications for India. Using the theoretical foundations of Michael A. Heller and Rebecca S. Eisenberg, I have argued that India should actively consider participating in patent pool initiatives both for its domestic needs and pharmaceutical exports. In 1998, Michael A. Heller and Rebecca S. Eisenberg coined the term ‘tragedy of anticommons’ to demonstrate the problem of excessive patenting in the field of biomedical and pharmaceutical research. They argued that the tragedy of anticommons lies in under-utilisation of resources resulting in millions of poor patients living without access to secure life-saving drugs. Patents create barriers not only to access the patented products but also to develop and improve related technologies which are the crucial, and in some cases exclusive, means


64 Michael A. Heller and Rebecca S. Eisenberg, ‘Can Patents Deter Innovation? The Anticommons in Biomedical Research’ (1 May 1998) 280 (5364) *Science* 698-701 at http://www.sciencemag.org/cgi/content/full/280/5364/698
of scientific research and development. Heller further discusses various options of overcoming the problem associated with the tragedy of anticommons.

VI. Comparative Law

This thesis is fundamentally focused on India and the case studies which are presented in this work provide an explanation of access to medicines related implication of ongoing policy and legislative developments in India. In doing so, I have drawn up comparative analysis of laws and cases in the light of jurisprudence developed in other jurisdictions. The reference to the laws and cases of the United States are frequently used in the analysis to show similarities, differences and future policy options. The reason for using the Unites States as a comparator is due to its leadership role in shaping global intellectual property norms. This role has not always been appreciated by developing and least developing countries. The policies employed by the United States have been instrumental in the development and the adoption of bilateral and multilateral intellectual property frameworks. Moreover, the domestic developments in the Unites States and cases dealing with patents are also providing a lead in determining the future direction of patent law. The trade flows between India and the United States are also increasing and emerging bilateral ties between both countries will definitely redefine existing regulatory framework in India. To forecast India’s future role as the pharmacy of the developing world, it is important to evaluate how India will adjust its domestic policies while solidifying its partnership with the United States.

The United States is, however, not the single comparator used in this thesis for

65 Ibid.

comparative analysis. This thesis does explore the historical origins of Indian patent law – and highlights the imperial role of the United Kingdom in shaping principles, rules, and practices in this area. I have also referred to legislation and case law of the United Kingdom especially in Chapter 2, *The Making of Modern Indian Patent Law*, to provide historical linkages of Indian patent regime with early patent laws of the United Kingdom.

This thesis also explores contemporary European conflicts involving access to medicines. In Chapter 5, *Patent Enforcement, Border Measures and Access to Essential Medicines*, I have extensively dealt with the European case law to analyse the implications of the EU Border Regulation on access to medicines. As this issue is closely linked with the detention of generic drugs by the European Custom authorities, so it was appropriate to provide an overview of the case law and legal opinions of different European courts.

Chapter 8, India, *TRIPS-Plus Free Trade Agreements and the Future of Access to Essential Medicines*, focuses on TRIPS-plus regimes and its impact on India. I have deliberately selected United States as a comparator in this chapter despite the fact that the EU is currently negotiating a free trade agreement with India. This is done for following reasons. First, the EU does not have any standard FTA template which can be used as an analytical tool to judge the scope and implications of TRIPS-plus demands. The scope and depth of EU’s economic partnership agreements and FTAs are varying and it is difficult to identify a single European approach on TRIPS-plus issues. Second, this chapter is primarily dealing with the impact of TRIPS-plus measures on access to medicines. The position of the European Union on TRIPS-plus is diverse and relatively mild. To provide a complete analysis of TRIPS-plus measures in Indian context, it was
important to compare with a full-fledged TRIPS-plus regime and the United States is the only comparator in this regard. Third, although the EU is negotiating a free trade agreement with India, the discussions remain unresolved. There has been no official text released which can illuminate the IP provisions and their impact. In the absence of a uniform and standard practice of the EU, it is even hard to presume how India would deal with such framework. So for the sake of predictability and in-depth analysis of TRIPS-plus measures, I have focused on the Unites States approach towards FTAs.

VII. Structure and Chapter Outline

This thesis examines the future of India as the pharmacy of the developing world in the light of some core case studies, and the analysis of key national and international developments influencing the debate of patents and access to medicines. The thematic focus is, therefore, on Indian law, international rules governing patents and access to medicines and the future dimensions of this debate. This thesis focuses, in particular, upon the time period between 2005 and 2010, in order to evaluate the implementation of the TRIPS Agreement 1994 in India. The law is stated as at December 2010.

The original contribution of this thesis lies in its case studies which provide a solid basis for evaluating the efficacy and robustness of the international patent regime. These case studies show the complex dynamics of the process of internalisation which developing countries such as India, face in the course of the legislative and enforcement process. This thesis also uniquely elaborates the structural problems of the international patent regime in the context of India, and the access to medicines debate. Building upon the existing literature, this thesis for the first time contextualises the application of the World Trade Organization's rules related to TRIPS and access to medicine, and concludes that India has so far failed to use the flexibilities of the system. The blame
partly goes both to India and the World Trade Organization for the lack of political will and the severity of relevant rules. This thesis further fills an important gap in the existing literature on the Indian patent regime. It has for the first time studied the scope and relevance of alternative models of pharmaceutical innovation in the Indian context. The regulation of publicly funded research in India is also discussed in the thesis to suggest an appropriate policy response in the form of equitable licensing arrangements.

Chapter Two, ‘The Making of Modern Indian Patent Law’, traces the historical evolution of Indian patent law and its significance in the emergence of the domestic pharmaceutical industry. With a brief introduction relating to the earlier patent regime in India, this chapter focuses on developments taking place after India signed the *TRIPS Agreement 1994*. I have, thereafter, discussed key amendments in the patent law with an in-depth focus on the *Patents (Amendment) Act 2005* (India). Unlike other works on Indian patent law, this thesis traces the legislative history of the *Patents (Amendment) Act 2005* (India) in the light of Parliamentary debates and argues that the existing state of the Indian patent regime should be construed in India’s typical political context. The chapter concludes that, contrary to general perception, the Indian Parliament failed to devise an holistic and long term patent policy for the country. Most of the debate on Indian patent law is dominated by a few politically more sensitive issues and there is a general lack of clarity and understanding about systematic implications of the patent regime on the pharmaceutical sector and access to essential medicines.

Chapter Three focuses on the judgment of the Chennai High Court in *Novartis AG v. Union of India*, highlighting the interpretation of Indian patent law and international treaty standards. This case, which mainly deals with the legality of Section 3(d) of the *Patents Act 1970* (India), depicts the precise nature of the tension which developing countries are experiencing in the process of implementation of the *TRIPS Agreement 1994*. Examining the legality of Section 3(d) in the light of patent law, constitutional
provisions and the threshold of the *TRIPS Agreement 1994*, reveals that developing
countries can gain from intelligently designing national patent regimes. The chapter
concludes that India should retain and proactively apply the requirements of Section
3(d) to discourage evergreening of patents. It will help to smooth the transition to a
product patent regime in India with relatively less adverse impacts on access to
medicines.

Chapter Four considers the Pfizer-Natco controversy, establishing the limitations of
WTO rules in the compulsory licensing of patents for humanitarian purposes. Indian
pharmaceutical exports play a very important role in the global access to medicines
campaign and among the potential threats to this source is the introduction of a product
patent regime in India. With the help of the Natco compulsory licensing controversy, I
argue here that both the international law framework and Indian patent law have failed
to devise a workable and efficient access to medicine regimes to facilitate drug exports
to countries with little or no pharmaceutical manufacturing capacity. The futility of the
*Waiver Decision 2003* is evident from the Natco compulsory licensing saga when an
Indian manufacturer failed to export medicine to a neighbouring least-developing
country, Nepal. The chapter concludes that the objectives of the *Doha Declaration 2001*
cannot be achieved, without substantial reforms to the *Waiver Decision 2003*.

Chapter Five considers the impact of strategies for patent enforcement and border
measures, upon the ease of access to medicines in developing countries. First, I discuss
the case, *Roche v. Cipla*, in highlighting some of the contentious issues of patent law
enforcement in the domestic context. This case mainly involves the grant of injunctive
relief in an alleged case of non-authorised manufacturing of Roche’s patented drug,
Tarceva. Cipla, the defendant in this case, maintained that injunctive relief should not be
granted in this case for a variety of reasons including the exorbitant price of Roche’s
patented drug. Upholding the position of Cipla in this case, the Delhi High Court laid
down detailed criteria for granting injunctive relief in patent infringement matters including the public health implications of such cases. In the light of recent cases in the United States, I have argued that this position is fully consistent with the TRIPS Agreement 1994 and other jurisprudential norms. The second part of this chapter explores the impact of recent instances of seizure of Indian generic exports by European customs authorities. These developments are clearly against the spirit of the Doha Declaration 2001 and developing countries should resist this trend both at bilateral and multilateral forums.

In Chapter Six, I consider the relevance of equitable licensing, open source drug discovery and patent pools in the context of India and access to essential medicines. The chapter starts with a critical analysis of the Bayh-Dole Act 1980 (US) to show that this model is not appropriate for India. Indian policy makers should develop a regulatory framework suitable to the needs of Indian industry and poor consumers. In its existing form, the Protection and Utilisation of Public Funded Intellectual Property Bill 2008 (India) fails to accommodate the concerns of patient groups, human rights activists and the community of academics and scholars. As an alternative to the proprietary model of publicly funded research, I further discuss in this chapter, the relevance of the open source drug discovery initiative with respect to India. Using Yochai Benkler’s peer production and commons-based social production framework, a case is developed to implement open source drug discovery projects in India as an alternative to patent-based incentives. India’s comparative advantage in the form of highly skilled labour, information technology expertise and a scientific workforce can play a decisive role in this regard.

The final part of Chapter Six deals with the proposal for creating patent pools to address the problem of pharmaceutical research and development in the area of neglected and tropical diseases. Drawing upon Heller and Eisenbergs’ theory of the tragedy of
anticommons, I argue in this chapter that India can benefit from the proposed patent pool both at international and national levels. Any successful implementation of a patent pool, such as the one suggested by the UNITAID, will eventually strengthen India’s role as the pharmacy of the developing world. The chapter finally argues that a delicate mix of open source innovation strategy and patent pools should shape India’s future patent policy and any attempt to prescribe a strong patent regime must be discouraged.

Chapter Seven presents two alternative models of medical innovation designed to promote the discovery of drugs needed for the treatment of poor patients. The first model discussed in this chapter deals with prizes, particularly as depicted by Professor Joseph Stiglitz and James Love. There are many promising features of a prize model which can help in overcoming the problems of patents. For the first time, this thesis contextualises the prize model in an Indian perspective and argues that India will substantially gain from successful implementation of the prize system. The second alternative model elaborated in this chapter deals with the Health Impact Fund developed by Professor Thomas Pogge I discuss the meaning and relevance of this model for India with a conclusion that India may be reluctant to participate in a global Health Impact Fund. The main constraint is this regard is its huge implementation cost which will become a disadvantage for developing countries.

Chapter Eight contends that TRIPS-plus intellectual property standards may compromise the interests of developing countries and poor patients in having access to affordable medicines and health-care. These TRIPS-plus standards, which mainly reflect the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 (US), shrink the policy space which India is enjoying under the TRIPS Agreement 1994. The potential impact of typical TRIPS-plus provisions – patent term extensions, patent-regulatory approval linkage, data exclusivity and restrictions on compulsory licensing and parallel importation – are discussed in this chapter to suggest
an appropriate policy response for India. India should refrain from signing a TRIPS-Plus free trade agreement with any of its trading partners as it will hinder the global access to medicines campaign.

Chapter Nine presents an overall conclusion and a set of recommendations for key stakeholders. The future of the Indian access to medicine regime largely depends upon several factors and developments which are discussed in this thesis. Unless the Indian government seriously revisits its policy options, Indian generic drugs will face a setback amidst the implementation of new patent law. The flexibilities and safeguard provisions of Indian patent law cannot effectively work in isolation and there is a pressing need to reform global patent norms and practices to provide better incentives and a regulatory structure for access to essential medicines. Existing approaches taken at multilateral forums have failed and should be completely revamped. The chapter then provides policy recommendations to the Indian Government, the World Trade Organization, the World Health Organization and the World Intellectual Property Organization, to streamline and coordinate their efforts in the area of patents for access to medicines.
Chapter 2
The Making of Modern Indian Patent Law

I. Introduction

Paradoxically, the more the past is neglected, the more control it is able to wield over the future.

Brad Sherman and Lionel Bently, The Making of Modern Intellectual Property Law

On May 6, 1981, the ex-Prime Minister of India, Mrs Indira Gandhi delivered a keynote address at the thirty-fourth World Health Assembly of the World Health Organization, lamenting the problem of the lack of affordable and equitable access to patented medicines and pharmaceutical drugs:

Affluent societies are spending vast sums of money understandably on the search for new products and processes to alleviate suffering and to prolong life. In the process, drug manufacture has become a powerful industry, subject to the same driving considerations of other big industries, that is, concentration on profit, fierce competition and recourse to hard-sell advertising. Medicines, which may be of the utmost value to poorer countries, can be bought by us only at exorbitant prices, since we are unable to have adequate independent bases of research and production. This apart, sometimes dangerous new drugs are tried out on populations of weaker countries although their use is prohibited within the countries of manufacture. It also happens publicity makes us victims of habits and practices which are economically wasteful or wholly contrary to good health ...

My idea of a better ordered world is one in which medical discoveries would be free of patents and there would be no profiteering from life or death.68

This utopian vision of a ‘better ordered world’ evoked the Patents Act 1970 (India) which excluded pharmaceutical drugs from the scope of patentable subject matter. This session of World Health Assembly resulted in the adoption of the Global Strategy for Health for All.69

It is, however, paradoxical to observe that Indian patent law underwent a paradigm shift in the same decade. On September 12, 1989, India announced that it would principally accept the international enforcement of intellectual property rights within the framework of the Uruguay Round Negotiations.70 This major shift in the Indian stance was perhaps the most significant development in the negotiation history of the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS Agreement 1994). Between 1986 and 1989, the developing countries led by India and Brazil vehemently resisted the inclusion of intellectual property rights in multilateral trade negotiations under the auspices of the General Agreement on Tariffs and Trade (GATT). However, in 1989, India abandoned its long lasting opposition and agreed to negotiate trade related intellectual property rights within the Uruguay Round context.71 This process


71 Ibid.
culminated in the form of the *TRIPS Agreement 1994* which ultimately wrought drastic changes to Indian patent law.

The history of Indian patent law is rich, complex and multifaceted. It demonstrates the intricacies of the Indian political and legal systems which had undergone a massive transformation since independence. Professor Amartya Sen comments on the diversity of Indian culture and history and notes that:

> India is an immensely diverse country with many distinct pursuits, vastly disparate convictions, widely divergent customs and a veritable feast of viewpoints. Any attempt to talk about the culture of the country, or about its past history or contemporary politics, must inescapably involve considerable selection.  

This observation is fully applicable in the case of the history of Indian patent law which is often simplistically narrated and interpreted without considering the widely divergent political and social factors underpinning the development of India’s modern patent regime.

Modern Indian patent law requires an understanding of its historical origins. Unfortunately, most of the literature dedicated to the history of Indian patent law often tends to simplify the context in which Indian patent law ultimately developed and shaped. The most popular account is a post-colonial narrative which explains Indian patent law as a response to India’s post-independence policy shift. In this regard, commentators and authors discuss the impact of earlier laws on the pharmaceutical

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sector. While these narratives are partly true they have failed to consider the intricacies of political discourse which dominated the process of patent law development. Today, for this reason, we are very much familiar with an earlier judicial committee’s report but little is known about the political process which precipitated a national consensus on this issue. As Professor Brad Sherman and Professor Lionel Bently have observed, the evolution of patent law should not be seen as the pre-destined outcome of higher philosophical discourse.\textsuperscript{74} It should instead be construed in the light of a complex mixture of social, political and economic developments.

Professor Amartya Sen argues that India has a longstanding tradition of public discussion and reasoning which forms the very core of Indian democracy.\textsuperscript{75} He suggests that this tradition has been extremely useful in building and shaping today’s India. This construction of Amartya Sen, the Argumentative Indian, is clearly reflected in the process of development of Indian patent law. A historical account of Indian patent law shows how different stakeholders have eventually shaped Indian patent law as a continuous process of public discourse and political process.

This chapter seeks to build upon a tradition of critical historiography of intellectual property. In a review essay for the \textit{Sydney Law Review}, Kathy Bowrey and Natalie Fowell have called for the writing of nuanced histories of intellectual property, which are attentive to both the particulars of history and the limits of positive law:

\begin{quote}
The weight of the present, where global decisions about intellectual property loom large, is bound to filter into our understanding of history and our human
\end{quote}


responses. It is also difficult to escape from current understandings of the world, technology, the built environment, communications, social organisation and progress. But, at the same time, we are hoping for the human element we supply as writers and readers of intellectual property law to be more than antipathy or empathy toward particular policy winners and losers. An understanding of history should also lead to a more nuanced understanding of legal power and its relation to politics – including of law’s essential incompleteness, limits and complications in readily securing political objectives. For this reason, we think we need to understand more critically what it is about the construction of the present global institution of intellectual property that presses so much on us, that we have begun to read legal history as primarily just a record of policy choices, identifying winners, losers and compromises.76

Accordingly, this chapter engages in a critical reading of the histories of Indian patent law, and attends to the interplay between domestic national politics and international trade negotiations, and the relationship between law and power.

This chapter charts the historical evolution of Indian patent law, highlighting key landmarks in the political debate and legislative change. Given the diversity of political opinions, the debates about amendments in India patent law were intense and passionate. Among the typical stakeholders who rigorously participated in the discussions and public consultations were business organisations, patients’ rights groups, local and international non-governmental organisations, political workers and community activists. The political environment which has shaped the patent statute in India deserves a better understating across the party lines. The dynamics of political

coalitions which prompted important policy debates about the relevance of patent law could not find appropriate space in academic literature. The role of the Indian Parliament in the adoption of the most recent amendments in Indian patent law has been generally ignored and an overwhelming focus is on transnational and non-political actors. Part II of this chapter deals with the colonial and post-colonial era of Indian patent law, and considers early developments of Indian patent law under British rule and further reforms initiated after Indian independence in 1947. This part discusses key features of the *Patents Act 1970* (India). Part III considers the changes which emerged after 1994 when India signed the *TRIPS Agreement 1994*. In this part, I have separately discussed first, the *Patents (Amendment) Act 1999* (India), and second, the *Patents (Amendment) Act 2002* (India), amendments to the *Patents Act 1970* (India). Part IV specifically deals with the most recent amendments in Indian Law – the *Patents (Amendment) Act 2005* (India).

II. Evolution of Indian Patent Law: Impact of Nehru’s Socialist Economy

A. The Colonial Era of Indian Patent Law

India has its own established tradition of patent law and policy. Although the initial patent regime was a legal transplantation of British colonial law, the Indian legal system has since developed and implemented local reforms and innovations.

After the Great Indian Rebellion, the British Empire gained full control of India in 1857, and introduced massive legal and institutional reforms. The first Indian patent statute was passed by the Legislative Council of India in 1856 which was based on the *Patent Law Amendment Act, 1852* (United Kingdom).77 The Act VI of 1856 introduced

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77 Controller General of Patents, Designs and Trademarks-Government of India, History of Indian Patent
certain exclusive privileges to inventors of new manufactures for a period of 14 years. This Act was subsequently repealed in 1857 because it had been enacted without the approval of the British Crown. A new law was enacted on March 19, 1859 with the sanction of the Crown which introduced a broader definition of the terms ‘invention’ and ‘manufacture’.78

In 1872, the Patents and Designs Protection Act (India)79 was promulgated which was later amended through the Protection of Invention Act 1883 (India) to introduce an amendment to novelty with regard to the international exhibition held in Calcutta, India in 1883-84.80 A major step was taken in 1888 towards the consolidation of patent laws in India when all three enactments, the Acts of 1859, 1872 and 1888, were repealed with the promulgation of the Inventions and Designs Act 1888 (India).81 This law shifted the administration of patent-related matter from the Home Department to the Department of Revenue and Agriculture. The Act also elaborated the specification of invention requirement in terms of best mode disclosure and enablement.82 It is pertinent to note that the Inventions and Designs Act 1888 (India) was modelled on the British Patent Law Amendment Act of 1852 (United Kingdom) despite the fact that a revised patent system had already been implemented in the United Kingdom as a result of Patents, System (4 January 2010) at http://www.patentoffice.nic.in/ipr/patent/patents.htm.

80 Tanuja V. Garde, ‘India’ in Paul Goldstein et al (eds), Intellectual Property in Asia: Law, Economics, History and Politics (Berlin: Springer, 2009), 58.
82 Tanuja V. Garde, ‘India’ in Paul Goldstein et al (eds), Intellectual Property in Asia: Law, Economics, History and Politics (Berlin: Springer, 2009), 58.
Designs and Trademarks Act 1883 (United Kingdom). The reason behind this was explained in 1910 when further amendments were considered and it was stated with regard to the Inventions and Designs Act 1888 (India) that the ‘time was not yet ripe in (India) for introducing the English practice in its entirety as the volume of patent work was then small’. 

In 1911, the colonial Patents and Designs Act 1911 (India) was enacted. This law provided for the first time the establishment of a patent administration system in India in the form of the Controller of Patents. By that time, India had already developed a reasonable industrial base with the expansion of the technology sector. Although India continued to be thriving as an agriculture based economy, it increasingly developed an industrial manufacturing base. At the time of World War I, India was ranked fourteenth among the industrialised countries with most of the industrial activity in textile, food processing and metals sectors. It was then realised that the process of patent filing in India should be upgraded in light of the Patents and Designs Act of 1907 (United Kingdom).

The Patents and Designs Act 1911 (India) created a priority system between India and the United Kingdom to facilitate Indian patent applications. The term of patent was fixed at sixteen years from the date of filing with a possibility for extension of up to

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83 Ibid.

84 For a comprehensive analysis of Indian economic history: Tapan Raychaudhuri, Irfan Habib and Dharma Kumar, *The Cambridge Economic History of India* (Cambridge: Cambridge University Press, 1982).


86 Section 78A of the Patents and Designs Act 1911 (India)
seven years. Under the Act, the word ‘patent’ was substituted for the term ‘exclusive privileges’ which was earlier used, and it also provided for the compulsory examination of patent applications. Under the Act, the *Patents and Designs Rules 1912* (India) were framed for the first time to streamline the functioning of the Indian Patent Office. The *Patents and Designs Act 1911* (India) was amended several times to establish reciprocal arrangements between British India and the United Kingdom for the mutual protection of inventions and designs. The Act continued until the enactment of new laws in 1970.

The *Patents and Designs Act 1911* (India) was an important precursor of future developments in the area of Indian patent policy. The Indian pharmaceutical industry could not benefit from the provisions of this law and its progress was effectively stalled by multinational pharmaceutical companies. According to Sudip Chaudhuri, the *Patents and Designs Act 1911* (India) was used to prevent Indian drug companies from manufacturing products which were invented abroad. The patent filing record also shows that the Indian domestic pharmaceutical industry rarely benefited from the opportunities incorporated in the law. Out of a total 1,099 patent applications filed in 1930, 80% were filed by foreigners. The accumulative total reached 2,610 patent applications at the time of independence in 1947 when the Indian population was almost

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87 Section 14 of the *Patents and Designs Act 1911* (India)


400 million. The basic drug manufacturing which later became a hallmark of the Indian drug industry was virtually non-existent before World War II.

B. The Nationalist Era of Indian Patent Law

A new era of economic development and policy framework followed after the declaration of Indian independence in 1947. Jawaharlal Nehru and the Indian National Congress took charge of the newly created independent state of India.

Under the leadership of Jawaharlal Nehru and Indira Gandhi, the Indian Government engaged in extensive social and economic policy-making. Soon after resuming the charge of prime ministership, Jawaharlal Nehru introduced the mechanism of centralised planning in the form of the Planning Commission of India which charted the government’s investments in the agricultural and industrial sectors. The Industrial Policy Resolution 1956 (India) recommended the growth of diverse manufacturing and heavy industries. A focus on the pharmaceutical industry emerged in this context.

In the sphere of social policy, Jawaharlal Nehru’s administration faced multiple challenges. A large number of Indians were living in rural areas and the health care system was completely inadequate to meet the requirements of the masses. Drug prices were high and almost all critical medicines such as insulin and penicillin were imported

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91 Ibid.


in the absence of local manufacturing. According to India's first Five Year Plan 1952, multinational companies controlled more than 90% of the drug industry. India had the largest reservoir of epidemic diseases and it was reported that these diseases accounted for 5.1% of total deaths. In 1961, US Senator Estes Kefauver remarked that Indian drug prices ranked among the highest in the world. The provision of effective and affordable medicines became a top priority agenda of the government. There were mainly two restraints in this regard. First, the absence of large scale local manufacturing of pharmaceuticals as the market was dominated by foreign companies. Second, price control mechanisms were absent and multinational firms were leading the trend according to their priorities.

In order to address such concerns, the Indian Government appointed a Patent Inquiry Committee in 1948. The Committee headed by Justice Bukshi Tek Chand submitted its report in 1949 which was introduced in Parliament in 1953. However, this report lapsed when a Patent Bill could not be passed in light of the Committee’s recommendations with the dissolution of Lok Sabha. Justice Bukshi Tek Chand Report analysed the


failure of the Indian patent system to stimulate innovation and proposed the introduction of a compulsory licensing regime in India. These recommendations were similar to that of the Swan Committee Report in the United Kingdom.\textsuperscript{99}

Although this report could not be adopted, India’s future patent policy was largely informed from the recommendations of the Justice Bukshi Tek Chand Report. All of its recommendations were further elaborated and expanded in another influential report which is known as the Shri Justice N. Rajagopala Ayyangar Report.\textsuperscript{100} This landmark 1959 report studied comparative patent regimes and identified several policy recommendations to overhaul the Indian patent system. The operational part of the Ayyangar Report can be summarised as follows:

(i) identification of the types of inventions for which patent protection should be available;

(ii) determination either to prohibit the granting of Indian patents to foreign entities or to require working of such patents in India; and

(iii) determination to withstand international pressures on India to join international intellectual property conventions such as the Paris Convention, which required national treatment.\textsuperscript{101}


This report is largely believed to be the most influential document in the history of Indian patent law as it shaped the future direction of Indian patent law which provided a cutting edge to the local pharmaceutical industry.

The Ayyangar Report evaluated the effectiveness of the Indian patent regime in an historical context. Adopting a comparative methodology, the Committee’s Report frequently refers to the evolution of patent regimes in countries like United States, United Kingdom, Germany and Australia. The report attends to patent reforms and revisions in other Commonwealth countries, such as Australia. It is, however, interesting to note that the substantive part of the Ayyangar Report was not very well informed from the Australian experience. Most of its analysis on the patentability of pharmaceuticals and chemical substances was confined to European jurisprudence.

Ayyangar rejected the notion that India should completely abandon a patent-based incentive strategy and observed that:

> With all the handicaps which the system involves in its applications to under-developed countries, there are no alternative methods for achieving better results. As present there is no country in the world that does not adopt the patent system of rewarding inventors ... Even a country which has adopted a socialistic economic system such as U.S.S.R the law makes provision for the grant of patents in the same manner as in the rest of Europe ... I consider that the Patent system is the most desirable method of encouraging inventors and rewarding them.

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This clearly shows that an attempt was made to devise an innovative solution within the framework of a patent system. Although Jawaharlal Nehru had already introduced a semi-socialistic economic model in India, there was no popular demand for the abolition of the existing patent system. Such situation did not even appear later when Indira Gandhi tightened the State’s grip over economic activity under her socialist agenda.

One of the key recommendations of the Ayyangar Report was about the patentability of pharmaceutical products and chemical substances. After studying the historical evolution of pharmaceutical patents in several European countries, Ayyangar recommended that patents on pharmaceutical product chemical substances should not be granted in India following the German tradition of process patents and the law of the People’s Republic of China.\(^{104}\)

Despite two successive reports developing an arguably convincing case for patent law reforms in India, the Indian Parliament could not immediately adopt such appropriate legislative measures. With the death of Jawaharlal Nehru on May 27, 1964, the Indian National Congress went through a leadership crisis which was finally resolved in January 24, 1966 when his daughter Indira Gandhi finally became Prime Minister.\(^{105}\) Indira Gandhi gradually assumed a strong leadership role and enacted a new patent law on September 19, 1970 which had repealed the *Patents and Designs Act 1911* (India). The new legislation, the *Patents Act 1970* (India) came into force on April 20, 1972.\(^{106}\) The *Patents Act 1970* (India) brought a major policy shift in the Indian patent regime and India delinked itself from the colonial legacy of patent law. This law was extensively debated in both Houses of the Indian Parliament. A joint Select Committee

\(^{104}\) Ibid. Paragraph 60-61.


\(^{106}\) The *Patents Act 1970* (India), Act 39 of 1970 at [http://www.patentoffice.nic.in/ipr/patent/patents.htm](http://www.patentoffice.nic.in/ipr/patent/patents.htm)
thoroughly scrutinised this law in light of the reports of Justice N. Rajagopala Ayyangar and Justice Bukshi Tek Chand.\textsuperscript{107}

There were two stated objectives of the \textit{Patents Act 1970} (India): the development of a national pharmaceuticals industry and the provision of affordable access to medicines for Indian consumers. To achieve these objectives, the \textit{Patents Act 1970} (India) imposed substantial limits on patent rights to encourage indigenous inventions and secure their production in India on a commercial scale. Pharmaceutical products were declared non-patentable. Drug companies were permitted to patent only a single process for making a pharmaceutical.\textsuperscript{108} A patentee could not block competition by patenting all possible processes for manufacturing a drug. Moreover the term for pharmaceutical process patents was reduced to five years from the grant of the patent or seven years from application filing, whichever was less.\textsuperscript{109} For the first time in the history of India, the \textit{Patents Act 1970} (India) introduced broad compulsory licensing provisions in respect of pharmaceutical process patents.\textsuperscript{110} Within three years of the grant, the patents were deemed ‘licenses of right’, meaning that anyone could use the process if a royalty was paid.\textsuperscript{111}

After the enactment of the \textit{Patents Act 1970} (India), Indian pharmaceutical firms thrived and greatly increased their market share within a few years. According to Jean O.


\textsuperscript{108} Section 5 of the \textit{Patents Act 1970} (India), Act 39 of 1970 at http://www.patentoffice.nic.in/ipr/patent/patents.htm

\textsuperscript{109} Section 24B of the \textit{Patents Act 1970} (India).

\textsuperscript{110} Section 84 of the \textit{Patents Act 1970} (India).

\textsuperscript{111} Section 86 of the \textit{Patents Act 1970} (India).
Lanjouw, the number of patents granted in India ‘fell by three quarters from 3,923 in 1970-71 (of which 629 were to Indian applicants, 3,294 to foreign applicants) down to 1,019 in 1980-81 (349 Indian, 670 foreign)’. In 1970, Indian companies held only 15% of the local market as compared to 85% by foreign firms. In terms of total sales turnover/sale in 1970, only two firms in the top ten firms were Indian and the rest were subsidiaries of multinational companies. By 1982, Indian firms had increased their market share to 50%, and by 1999, Indian firms were holding 61% of the market share. This trend was to become a lasting feature of the pharmaceutical market in India.

Commentators are almost unanimous that the Patents Act 1970 (India) was the most important single policy measure which provided a solid foundation for the emergence to the Indian pharmaceutical sector. It would be, however, simplistic to presume that the Patents Act 1970 (India) had alone changed the complete structure of the pharmaceutical industry in India. There are at least two additional factors which are often ignored in the context of patent policy and pharmaceuticals.

First, early developments in the domestic pharmaceutical scene started with the setting up of government-owned pharmaceutical companies in 1960s. The initial precursor in this regard was the establishment of Hindustan Antibiotics Limited which was


inaugurated in 1954 with the support of WHO and UNICEF. The Indian Drugs & Pharmaceutical Limited was established in 1961 and thereafter twelve companies were setup all over the India to locally manufacture active pharmaceutical ingredients. Such companies provided a catalyst for the private sector in pharmaceutical drugs.

The second factor was India's strict price control regime under the *Drug Price Control Order 1970 (India)*, which helped bring the drug prices within the means of a wider range of Indian patients. Most of the multinational companies decided to limit their operations in India after strict price control was introduced in 1970.

III. India and the TRIPS Agreement 1994: Some Early Responses

After the promulgation of the *Patents Act 1970 (India)*, India staunchly defended its position on the non-patentability of pharmaceutical products and compulsory licensing for two decades. Throughout the 1970s and 1980s, India participated as an active member of the Group of 77 which took a lead role in the negotiation of the *International Code of Conduct for Technology Transfer* from the platform of United Nations Conference on Trade and Development (UNCTAD). The failure of these

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negotiations in 1985 was a substantial disappointment for developing countries, such as India. In the meantime, India refused to sign the *Paris Convention for the Protection of Industrial Property of 1883* and vehemently resisted any move to change its patent law.

A watershed shift occurred in 1989 when India was willing to discuss intellectual property rights as part of the Uruguay Round trade negotiations. At the time of signing of the *TRIPS Agreement 1994*, the Indian National Congress was in power and the P. V. Narasimha Rao led government was severely criticised domestically for its ‘compromising stance’ on an important issue of national sovereignty.

Scholars have put forward a range of rationales to explain the shift in India’s stance on the TRIPS Agreement during the Uruguay Round Negotiations. Peter K. Yu comments that four narratives and discourses are put forward to explain the origins of the *TRIPS Agreement 1994*. The first, bargain narrative is the most widely accepted explanation which suggests that the *TRIPS Agreement 1994* as a package deal of WTO was a win-win situation for developing countries like India. Under this theory, India benefited from certain agreements and accepted a compromised deal in other sectors realising the overall impact of the new regime for its economy and development.

The second discourse provided a coercion-based theory to explain India’s position to sign the *TRIPS Agreement 1994*. Professor Jagdish Bhagwati observes that:

> TRIPS does not involve mutual gain; rather, it positions the WTO primarily as a collector of intellectual property-related rents on behalf of multinational

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corporations (MNCs). This is a bad image for the WTO and in the view of many, especially the non-governmental organizations, reflects the “capture” of the WTO by the MNCs.\textsuperscript{121}

India’s bilateral relationships with the United States and its placement on a priority Watch List of Section 301, are also mentioned in this regard.

The third set of explanations about India’s engagement with the TRIPS Agreement 1994 provided a narrative of ignorance, which presumed that Indian negotiators could not fully appreciate the implications of a global intellectual property regime and they had ultimately failed to protect India’s interest.\textsuperscript{122} This narrative was particularly popular within India where politicians and public servants were generally blamed for their failure to safeguard India’s interest during the Uruguay Negotiations.

The final narrative is about self-interest theory which was also widely accepted among commentators. This narrative suggests that India among other developing countries wilfully agreed to sign the TRIPS Agreement 1994 because it had realised the relevance and importance of an intellectual property regime for its economic future. Professor Edmund Kitch has provided a detailed account of this narrative in his analysis of the patent policy of developing countries.\textsuperscript{123}

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\textsuperscript{123} Edmund Kitch, ‘Policy Consideration: The Patent Policy of Developing Countries’ (Fall, 994) 13 \textit{UCLA Pacific Basin Law Journal} 166.
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With the benefit of hindsight, and a close reading of Parliamentary debates in India, I would contend that India’s decision to sign the *TRIPS Agreement 1994* is best explained by two theories – the bargain theory and the self-interest theory.

A. *Patents (Amendment) Act 1999 (India)*

The first amendment to the *Patents Act 1970 (India)* was a direct outcome of WTO dispute settlement proceedings between India and the United States.

As a signatory to the Uruguay Round Agreements, India had decided to avail itself of the benefit of a maximum transition period which was allowed under the *TRIPS Agreement 1994*. With the status of a developing country, India had flexible timelines to implement its obligations under the *TRIPS Agreement 1994*. The first timeline in this regard was the creation of a mechanism for receiving mailbox applications by January 1, 1995.\(^ {124}\)

To meet this obligation, Shankar Dayal Sharma, then President of India, promulgated *Patents (Amendment) Ordinance, 1994 (India)*. This Ordinance sought amendments in the *Patents Act 1970 (India)* and provided that patent applications for pharmaceutical and agricultural chemical products would be accepted. However, these applications would be handled only after 1\(^{st}\) January, 2005.\(^ {125}\) The Ordinance also established an Exclusive Marketing Regime (EMR) for applications filed under the amended provisions of the *Patents Act 1970 (India)*.\(^ {126}\)

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\(^{124}\) Article 70 (9) of the *TRIPS Agreement 1994*.

\(^{125}\) Patents (Amendment) Ordinance, 1994 (India) at http://www.wipo.int/clea/en/text_pdf.jsp?lang=EN&id=2390

The *Patents (Amendment) Ordinance, 1994* (India) lapsed on March 26, 1995 when the Indian Parliament failed to pass follow-on legislation which was mandated under Article 123(1) of the Indian Constitution. In March 1995, the Lok Sabha passed a *Patents (Amendment) Bill 1995* (India) to give permanent status to the *Patents (Amendment) Ordinance, 1994* (India). This Bill, however, could not be passed in the Upper House of the Indian Parliament, the Rajya Sabha. In the Rajya Sabha, the Bill was referred to the Select Committee of the House which could not report before the dissolution of Lok Sabha in May 1995. The Bill ultimately lapsed.\(^{127}\)

In May, 1996, the Office of the United States Trade Representative added India to its Priority Watch List and stated that:

> India fails to provide patent protection for pharmaceutical or agricultural chemical products. It also has not legislatively established mailbox and marketing exclusivity systems in accordance with Article 70(8) and 70(9) of the TRIPS Agreement. Therefore, the United States will initiate formal consultations under WTO dispute settlement procedures in Geneva in the near future.\(^{128}\)

In July, 1996, the United States formally initiated World Trade Organization dispute settlement proceedings against India and a WTO Dispute Panel was formed on November 20, 1996.\(^{129}\) The United States alleged violations of Article 70 (8) and Article

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70 (9) of the *TRIPS Agreement 1994*. The Panel reported its findings to the WTO Dispute Settlement Body on September 5, 1997 and found that India had failed to comply with its obligations under Article 70(8)(a) and in the alternative, paragraph 1 and 2 of the Article 63 of the *TRIPS Agreement 1994*. On India’s request, the Appellate Body released its report on December, 19, 1997 and it upheld the findings of the Panel Report regarding Articles 70(8) and 70(9) of the *TRIPS Agreement 1994*. However, the Appellate Body reversed the findings of the Panel Report regarding paragraph 1 and 2 of the Article 63 of the *TRIPS Agreement 1994*. It was concluded that:

The Appellate Body upheld the Panel’s finding that India’s filing system based on “administrative practice” for patent applications for pharmaceutical and agricultural chemical products was inconsistent with Art. 70.8. The Appellate Body found that the system did not provide the “means” by which applications for patents for such inventions could be securely filed within the meaning of Art. 70.8(a), because, in theory, a patent application filed under the administrative instructions could be rejected by the court under the contradictory mandatory provisions of the existing Indian laws: the Patents Act of 1970 .... The Appellate Body agreed with the Panel that there was no mechanism in place in India for the grant of exclusive marketing rights for the products covered by Art. 70.8(a) and thus Art. 70.9 was violated.

http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds50_e.htm

130 Ibid.


132 Ibid.
Although some commentators such as Jerome Reichman\textsuperscript{133} have praised the balanced outcome of this dispute, the Indian political reaction to the adjudication was fierce. Mr Kushabhau Thakre, president of the Bharatiya Janata Party, demanded that India should leave the WTO.\textsuperscript{134} Given the political and economic policies of Bharatiya Janata Party, this demand was unusual as the party was committed to economic reforms and trade liberalisation.\textsuperscript{135}

Finally, India enacted the \textit{Patents (Amendment) Act 1999} (India) with a retroactive effect starting from January 1, 1995. It provided for the creation of the mailbox provision to receive patent applications which would not be examined before January 1, 2005.\textsuperscript{136} The \textit{Patents (Amendment) Act 1999} (India) also established an exclusive marketing regime.\textsuperscript{137} One of the innovative features of the law was related to compulsory licensing provision. Pursuant to Section 24C, any time after the expiry of

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\item \textsuperscript{133} Jerome Reichman, ‘Securing Compliance with the TRIPS Agreement after US v India’ (1998) 1 (4) \textit{Journal of International Economic Law} 585-601. He observes that: ‘The decision of the WTO Appellate Body in India-Mailbox case was a critical step in affirming the WTO-consistency of pursuing national and regional policies which take advantage of the absence of strict harmonization of IPRs standards at the worldwide level. The India-Mailbox decision suggests that the WTO will accord substantial deference to national and regional rules which manifest good faith compliance with the basic standards of the TRIPS Agreement.’


\item \textsuperscript{135} Julia Brummer, \textit{India’s Negotiation Position at the WTO}, Dialogue on Globalization: Briefing Papers (Geneva: Friedrich Ebert Stiftung, November 2005) 4 at \url{http://library.fes.de/pdf-files/bueros/genf/50205.pdf}


\item \textsuperscript{137} Section 24A of the \textit{Patents (Amendment) Act 1999} at \url{http://www.patentoffice.nic.in/ipr/patent/patact_99.PDF}
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two years from the date of approval by the Controller for exclusive marketing rights to sell or distribute under Section 24B, any person interested may make an application to the Controller alleging that the reasonable requirements of the public with respect to the exclusive marketing rights have not been satisfied or that the product enjoying exclusive marketing right is not available to the public at a reasonable price and pray for the grant of a Compulsory Licence.

The enforcement of exclusive marketing rights granted under the *Patents (Amendment) Act 1999* (India) was always a point of concern for applicants. Eli Lilly’s exclusive marketing right of Cialis was stayed by the Calcutta High Court and it could not be enforced. According to the sources of the Indian Patent Office, a total of 8,926 mailbox applications were filed for examination.

**B. Patents (Amendment) Act 2002 (India)**

The second deadline for India to amend its patent law was January 1, 2000 when a five year transition period ended. A comprehensive package of amendments was introduced in the form of *Patents (Amendment) Act 2002* (India) which had changed several provisions of the *Patents Act 1970* (India).

In 2002, the government of the Bharatiya Janata Party led National Democratic Alliance was quite stable and the Prime Minister, Atal Bihari Vajpayee, successfully introduced several economic reforms. After 1998, the Bharatiya Janata Party abandoned its

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opposition to patent law reforms and the party was confident to move its next legislative agenda after successful adoption of the *Patents (Amendment) Act 1999* (India).\(^{140}\)

Although some sections of the Indian National Congress were arguing against any change in the *Patents Act 1970* (India), the predominant view in the party was in favour of new legislative changes.\(^{141}\) The only bloc opposing the patent law amendments comprised the Communist Party of India (Marxist) and the Communist Party of India. The *Patents (Second Amendment) Bill* (India) was introduced in the Rajya Sabha in 1999 and was referred to a Joint Parliamentary Committee of both Houses of Parliament.\(^{142}\) In its 39 meetings over a period of two years, the Committee reviewed 42 memoranda and heard testimonies from 52 witnesses and 19 individuals and organisations.\(^{143}\) With the consensus of both mainstream parties, the *Patents (Amendment) Act 2002* (India) was passed by the Parliament.

In the social realm, several non-governmental organisations played an important role in the improvement and adoption of patent law amendments. The National Working Group on Patent Law was established in 1998 and it played a key role in mobilising civil society response to law amendments in India. In 2005, when a third amendment was made in *the Patents Act 1970* (India), many local and international non-governmental organisations were active in lobbying efforts. However, the pioneering work of the National Working Group on Patent Law was instrumental during the second round

\(^{140}\) Anitha Ramanna, ‘India’s Patent Policy and Negotiations in TRIPs: Future Options for India and other Developing Countries’ (Paper presented at the National Conference on TRIPs: Next Agenda for Developing Countries, Hyderabad, India, October 11-12, 2002) at http://www.ipronline.org/icts/docs/ResourcesTRIPSanitharamanna.doc

\(^{141}\) Ibid.


\(^{143}\) Ibid.
amendment in the patent law. In 2000, international advocacy groups such as Médecins Sans Frontières, Oxfam and the Consumer Project on Technology (now called Knowledge Ecology International) started working with local groups and non-governmental organisations to understand the broader impact of Indian patent law. An important development occurred when the *Doha Declaration on the TRIPS Agreement and Public Health 2001* was adopted in the 4th Ministerial Conference of the WTO. It has given rise to the pro-reform stance among local non-governmental organisations and with the support of their international partners, these organisations started extensive lobbying for appropriate amendments in the patent law. The establishment of the Fourth People’s Commission under the Chairmanship of I. K. Gujral was a major step in this regard, which is discussed in next section.

The position of the pharmaceutical industry also evolved gradually and the most critical voices against patent law reforms had been diluted over a period of time. Anitha Ramanna comments that a few large pharmaceutical firms in India revised their stance because of a belief that they could benefit from the new patent system:

> We can partly explain the rise of a pro-IPR stance among Indian industry by noting that firms with the ability to transform their potential into patents became votaries of reform. Those firms with greater sales, export competition and R&D investment are the firms that are in a position to transform their capacity into

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145 *Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc WT/MIN(01)/DEC/2 (14 November 2001) at [http://www.wto.org/english/tratop_e/minist_e/min01_e/mindecl_trips_e.htm](http://www.wto.org/english/tratop_e/minist_e/min01_e/mindecl_trips_e.htm)

gains from patents and therefore shifted their interests towards promoting rather than opposing patent reform.\textsuperscript{147}

The commentator concludes: "Domestic firms, while supporting the patent reform, have also attempted to influence the policy process to promote their interests in generic manufacturing."\textsuperscript{148}

In this context, the \textit{Patents (Amendment) Act 2002} (India) was passed by the Parliament. An overview of debates in the Lok Sabha reveals the concerns and issues which were raised when the bill was tabled in the Parliament. At the time of presenting the \textit{Patents (Amendment) Act 2002} (India) in the Lok Sabha, Shri Murasoli Maran, the Minister of Commerce and Industry observed that:

\begin{quote}
It is now necessary for us to set aside the international and internal "pharma politics" and look at the future. The Indian drug and pharma industry has made the fullest use of the Patents Act of 1970 and we now are not only the net-exporter of generic medicines but also emerging as the new leader of the knowledge-based drug industry in the world, following software and IT. Now it is the time for the rest of the industry to come out of its "reverse engineering" mode and move forward into the era of innovative "research and development" mode, clinching the opportunities.\textsuperscript{149}
\end{quote}

This is an important statement showing the confidence of the government on the proposed changes and their possible implications for the Indian pharmaceutical

\textsuperscript{147} Ibid. 7

\textsuperscript{148} Ibid. 7

industry. There is, however, a clear reflection of ‘shining India’ rhetoric which the Bharatiya Janata Party had introduced in 2002-03 after the success of the Indian information technology boom. The law was passed with the bipartisan support of the Bharatiya Janata Party and the Indian National Congress as a result of lengthy consultations in the Joint Standing Committee.

The members of the Indian National Congress supported this law in the Lok Sabha but some of them raised certain critical issues. Shri Mani Shankar Aiyar, Congress’s Member of Parliament from Mayiladuthurai, who later became Union Cabinet Minister for Petroleum and Natural Gas in 2004, stated that:

We need to take advantage of the international patents regime to become front-runners in the exercise of pushing forward our own new technology but at the same time we need to recognise that if our death rates have collapsed ... between 1970 and 2002, ... it is because of the Patents Act of 1970. If we do not exercise the utmost care, there is the danger that in respect of HIV AIDS or some other epidemic we might find ourselves in India in the same situation in which South Africa found itself not so long ago.\(^{150}\)

The dilemma of the Indian National Congress was evident from this statement. The party had justifiably been taking pride in the success of the Indian pharmaceutical industry achieved in part due to the Patents Act 1970 (India). In political terms, it was a difficult decision for the Indian National Congress to support this legislation especially after the decision of the Left parties to oppose this Bill.

To overcome any potential political backlash, Congress proposed several amendments in the law. Referring to the *Doha Declaration on the TRIPS Agreement and Public Health 2001*, Shri Mani Shankar Aiyar demanded that the Minister 'continue to strive to protect the Indian national interest especially in the public health sphere, in the TRIPS Council as well as in the WTO'.\textsuperscript{151} The Minister of Commerce and Industry, Murasoli Maran, played a key role in mobilising developing countries against the position of G7 countries during the ministerial meeting in Doha.\textsuperscript{152}

Shri Rupchand Pal Hoogly of the Communist Party of India (Marxist) wrote a dissenting note in the Joint Standing Committee. He raised several objections on the proposed law in his Lok Sabha speech:

It was said that *TRIPS Agreement 1994* is a part of the WTO agreement. It was to provide better health opportunities, better scientific research, better agricultural production, sharing of technologies and transfer of technologies, but, today, we find that it has never happened in the matter of transfer of technology. The developed countries are as reluctant as they have been earlier and we are at the receiving end. We continue to be at the receiving end. The WTO as also the TRIPS are heavily biased against the developing countries and the poorer countries of the world.\textsuperscript{153}

The politician expressed the fear that the Indian pharmaceutical industry would be jeopardised by the *TRIPS Agreement 1994*: 'We are deviating from that 1970 Act which

\textsuperscript{151} Ibid.

\textsuperscript{152} Murasoli Maran, ‘At Doha’ *The Indian Express* (November 25, 2003) at http://www.indianexpress.com/oldStory/35931/.

had tried to provide protection not only to our health care needs but also to our pharmaceutical industry." He then referred to the provisions of compulsory licensing in the context of the South African situation and demanded further deliberations on the law.

The *Patents (Amendment) Act 2002* (India) introduced more than 70 changes to the *Patents Act 1970* (India). The provision dealing with exclusions of patentable subject matter was amended in light of the Article 27 (2) of the *TRIPS Agreement 1994* to cover abstract theories, mathematical or business methods, and computer programs. To address concerns regarding bio-piracy and misappropriation of biological resources, the provisions relating to patent application and examination were also revised. Several amendments were made in Chapter XVI to revise the operation of compulsory licensing, working of patents and revocation. These provisions are separately discussed in Chapter 4. The *Patents (Amendment) Act 2002* (India) also introduced provisions which fulfilled India's obligations under the *Paris Convention for the Protection of Industrial Property of 1883* and *Patent Cooperation Treaty 1970*.

**IV. Patents (Amendment) Act 2005 (India)**

The final deadline for India to comply with the obligations of the *TRIPS Agreement 1994* was January 1, 2005. By this date, India was obliged to extend patent protection to

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155 Section 4 of the *Patents (Amendment) Act 2002* (India) at http://ipindia.nic.in/ipr/patent/patentg.pdf

156 Section 10 and Section 25 of the *Patents (Amendment) Act 2002* (India)

157 Section 3 (b) of the *Patents (Amendment) Act 2002* (India) adding the definition of a convention country and Section 3 (e) defining the international application and Section 3 (k) referring to the *Patent Cooperation Treaty*, signed 19 June 1970 (entered into force 24 January 1978).
pharmaceutical and agrochemical products which were originally excluded from patentability. Given the long history of non-patentability of pharmaceutical products in India and its importance for the Indian drug industry and consumers, it was controversial to amend domestic laws to comply with the TRIPS Agreement 1994. Unlike the earlier two amendments in the patent law, the political situation by that time had substantially changed and the incumbent government faced considerable challenges in the Parliament to enact relevant legislation. In May 2004, Manmohan Singh became Prime Minister of India after the Bharatiya Janata Party lost the elections. The new government of the Indian National Congress-led United Progressive Alliance (UPA) had the backing of several small parties including the Communist Party of India (Marxist).

In a timely attempt to meet the deadline of the TRIPS Agreement 1994, the President of India promulgated the Patents (Amendment) Ordinance 2004 (India) on December 26, 2004. Soon after its promulgations, the Ordinance was severally criticised by different stakeholders and it was lamented that the government had adopted the Patents (Amendment) Bill 2003 (India) without further deliberation. This Bill was tabled by the previous government of the Bharatiya Janata Party and it had lapsed with the dissolution of the Lok Sabha.

On December 29, 2004, the Joint Action Committee Against Amendment of the Indian Patents Act issued the following statement:

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158 Patents (Amendment) Ordinance 2004 (India) at

159 The Joint Action Committee (JAC) was a forum of trade unions, political parties and non-governmental organisations. It was formed to oppose the amendment of the Indian patent law. Participating NGOs included the Research Foundation for Science, Technology and Ecology, the Centre of Indian Trade Unions (CITU), and the Federation of Medical and Sales Representatives' Associations.
The Amendment is ostensibly intended to introduce a full-fledged product patent regime to make our patent legislation compatible with TRIPs. The ultimate undoing of the Patents Act 1970 is thus sought to be accomplished in a non-transparent manner without any deliberations in the Parliament. Such a complex legislation of far reaching importance should have been a subject matter of a thorough, public examination by an Independent Commission. At the minimum, it should have been referred to the deliberative bodies of the Parliament such as a Joint Parliamentary Committee or the relevant Standing Committees of the Parliament for their considered views and recommendations.\textsuperscript{160}

The Committee appealed to all members of Parliament to oppose the proposed Amendment to the Patents Act when the ordinance appeared before the Parliament for approval.

In a fracturing of any political consensus on the topic of patent law reform, the Left Front announced that it would oppose the Ordinance when it was tabled in Parliament, because of a belief that it would exacerbate poverty in India.\textsuperscript{161} The National Working Group on Patent Law also announced its opposition to the Patents (Amendment) Ordinance 2004 (India) and started lobbying to reopen the issue of compulsory licensing and other flexibilities.\textsuperscript{162} Reji K. Joseph explained that: ‘The

\textsuperscript{160} Declaration of Joint Action Committee against Amendment of the Indian Patents Act (December 2D, 2004) at \url{http://www.cptech.org/ip/health/c/india/ngodeclaration12292004.html}


\textsuperscript{162} R.V. Vaidyanatha Ayyar, Public Policymaking in India (India: Pearson Education, 2009) 255.
Recommendations of the Commission became the breeding ground for the protests from various corners when the UPA attempted to introduce the final amendment Bill in December 2004.\(^\text{163}\) The recommendations of this group along with many other proposals provided a strong basis for the revision of the *Patents (Amendment) Ordinance 2004* (India).

Meanwhile, several regional treatment campaigns and international non-governmental organisations also started writing letters to key figures of the Indian government and the Indian National Congress urging them to carefully consider patent law amendments.\(^\text{164}\) The *New York Times* also wrote a damning editorial, observing that:

> India’s government has issued rules that will effectively end the copycat industry for newer drugs. For the world’s poor, this will be a double hit – cutting off the supply of affordable medicines and removing the generic competition that drives down the cost of brand-name drugs. But there is still a chance to fix the flaws in these rules, because they are contained in a decree that must be approved by Parliament. Heavily influenced by multinational and Indian drug makers eager to sell patented medicines to India’s huge middle class, the decree is so tilted toward

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\(^{163}\) Reji K Joseph, ‘Political Economy of India’s Engagement with the WTO: An Analysis in the Context of Amendment of India’s Patents Act (accessed on December 29, 2009) at http://www.ipfw.edu/hri/WTO/Paper%5B1%5D%20-%20reji.pdf

the pharmaceutical industry that it does not even take advantage of rights countries enjoy under the WTO to protect public health.\textsuperscript{165}

Seeking to appease such protestors, the ruling Indian National Congress agreed to consult other Parliamentary parties to improve the provisions of the \textit{Patents (Amendment) Ordinance 2004} (India).

Mr Pranab Mukherjee, the Defence Minister at the time, played a key role in convincing Left parties to adopt a new position on patent law amendments. He persuaded Mr Jyoti Basu, the leader of the Communist Party (Marxist), to support this legislation. Mr Pranab Mukherjee had to struggle with his own party colleagues and pressed his fellow Cabinet Minister, Mr Kamal Nath, Commerce Minister to agree on the compromised text stating that ‘an imperfect legislation is better than no legislation’.\textsuperscript{166} In order to appease its Left Front partners, the government agreed on several amendments to the patent regime. In the final bill, some of the most contentious matters were dropped from the \textit{Patents (Amendment) Bill 2005} (India) and it was decided to refer them to a committee of experts for final resolution. In April 2005, the \textit{Patents (Amendment) Act 2005} (India) was enacted with the support of the Indian National Congress and the Left Front. The Bharatiya Janata Party did not show the reciprocal courtesy to the ruling party and vehemently opposed the Bill which it had initially introduced in the Parliament. It is worthwhile highlighting some of the key themes in the parliamentary debates over patent law.


A. Effects on Domestic Pharmaceutical Industry

There was a strong popular discourse that the TRIPS Agreement 1994 and the new patent regime would adversely affect the growth of the local pharmaceutical industry which had managed to attract many friends within the policymakers.

A strong reflection of these concerns can be seen in the Parliamentary debates when the Patents (Amendment) Act 2005 (India) was tabled for discussion. Shri Uday Singh of the Bharatiya Janata Party stated that:

It seems that the Government is getting unduly influenced by the multinationals and the large Indian companies because by some sheer chance, the Hon. Finance Minister has decided to take away the concessional rate of duty on generic medicine to put it on par with branded medicine. Now, what is going to happen to the thriving generic drug industry in India on which not only we are dependent, I again repeat, many other countries are dependent?167

He surmised that the intent of the legislation was ‘to kill the generic drug industry in India’ in favour of ‘the influence of multinationals’.168

The influential member of Bharatiya Janata Party, Shrimati Maneka Gandhi, commented:

India has benefited from the low cost generic industry to dominate 30 per cent of the low cost drugs in the world. We achieved leadership status by a strong case in

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168 Ibid.
the WTO for flexibilities that protect consumers’ rights against multinationals. We are about to give up these advantages that we gained for the developing world in this Act. We are also putting at risk, the lives of hundreds of millions of people all over the world, not just in our country.\textsuperscript{169}

Many other members of the Lok Sabha and the Rajya Sabha reiterated this argument in their opposition to the Bill.

Rebutting this argument, Shri Kamal Nath, the Minister of Commerce and Industry stated in the Lok Sabha that:

I would like to emphasise, with everything at my command, that in the changing world, in the changing India, it is not for securing the multinationals ... The new reality is beginning to seep in that the Indian scientists are ready to face the challenge of a post-patent era; the Indian companies have, over the past few years, invested heavily in technology and research infrastructure ... We must not undermine the achievements of our own scientists, the scientists coming back from abroad, coming back to India to join our research laboratories.\textsuperscript{170}

It is quite clear from this statement that the Indian government was mainly considering the position of large-scale pharmaceutical firms which had started their own research

\textsuperscript{169} Shrimati Maneka Gandhi, India, \textit{Parliamentary Debates-Combined discussion on the Statutory Resolution regarding disapproval of Patents (Amendment) Ordinance, 2004 (No.7 of 2004) and the Patents (Amendment) Bill, 2005, March 22, 2005 at}\n
http://164.100.47.132/LssNew/psearch/result14.aspx?dbsl=1866

\textsuperscript{170} Shri Kamal Nath, India, \textit{Parliamentary Debates-Combined discussion on the Statutory Resolution regarding disapproval of Patents (Amendment) Ordinance, 2004 (No.7 of 2004) and the Patents (Amendment) Bill, 2005, March 22, 2005 at}\n
http://164.100.47.132/LssNew/psearch/result14.aspx?dbsl=1866
and development initiatives. This line of argument does not explain the implications of new patent regime on medium and small scale generic manufacturers which are contributing enormously in lowering India’s domestic burden of disease.

Further promoting a strong patent regime in India, Shri Kapil Sibalji, the Minister of Science and Technology claimed that India should provide an enabling regulatory framework to attract foreign investment in the neglected areas of medical innovation. He asserted that:

The WTO today in this context is a great opportunity for us to be able to discover new molecules. I will give you an example. Just the other day, the CSIR in collaboration with Lupin discovered a new molecule in tuberculosis called subotern. This new molecule in tuberculosis has not been discovered for 43 years. But CSIR and Lupin discovered it and today after having passed animal trials, we are into human trials. I daresay this is going to be successful and the treatment of tuberculosis is going to be reduced from a long treatment of four to five months to a bare treatment of two months. This is going to help the poor. And who is helping the poor? It is India because we are the hub of the knowledge economy, we are the hub of the intellectual property that is going to be generated in the 21st century.171

This statement also shows a dramatic shift in the pharmaceutical policy of the Government of India. It is now focused on a research-based pharmaceutical industry which may lead to the emergence of a low-volume, high-quality pharmaceutical sector in India.

B. Access to Essential Medicines

The impact of a strong pharmaceutical product patent regime on the availability and affordability of essential medicines is a widely debated and contentious matter. Many members raised this issue during discussions in both Houses of the Parliament and a heated debate was generated in this regard. Members of Opposition parties were concerned that the new regime would result in a price hike and drugs would become inaccessible in India. They also raised the issue of pharmaceutical exports and maintained that a price increase would also affect consumers living in other developing countries. The proponents of the Patents (Amendment) Act 2005 (India) did not agree with these propositions. They insisted that the issue of pricing should not be linked with the Patents (Amendment) Act 2005 (India) as there was a separate regulatory regime governing price allocation. Shri C. Kuppusamy of the Dravida Munnetra Kazhagam Party observed:

An apprehension is created in the minds of the public that once the Amendment Bill is passed, drug prices, especially, life-saving drug prices will go up, and other commodities that are of common use would also go up. The Government should come forward to allay the apprehension. While carrying forward the reforms further like countries like Britain, France, etc. did, India also should take steps to protect the national interests.172

The same apprehensions were shared by other members including Shri C. K. Chandrappan, Shrimati Maneka Gandhi and Shri Uday Singh.

The discussion also covered the issue of affordability in the context of Indian drug exports to other developing countries. Shri Uday Singh noted that:

This Bill is perhaps one of the most important pieces of legislation that this Parliament is considering. I say this because it directly concerns the lives of billions of people and the livelihood of millions of people not only in India but in the lesser developed countries which are dependant on India for medical treatment from where medicines go. To give you an example, 70 per cent of the medicines used for AIDS treatment in the lesser developed countries are medicines made in India. They go from here only for the reason that they are available at prices which are affordable.\textsuperscript{173}

Members also referred to Paragraph 6 of the \textit{Doha Declaration on the TRIPS Agreement and Public Health 2001} to remind India of its obligations toward the provision of affordable drugs to other poor and developing nations.\textsuperscript{174}

In rejoinder, the Minister of Commerce and Industry strongly defended the existing price system in India and mentioned that a new patent regime would not have any adverse implications on the government’s pricing policy.


\textsuperscript{174} Shri Pawan Kumar Bansal (Indian National Congress) and Shrimati Maneka Gandhi specifically referred to the \textit{Doha Declaration on the TRIPS Agreement and Public Health 2001} during their submissions in Lok Sabha.
C. Safeguard Provisions

A considerable time during the Parliamentary discussion was dedicated to issues related to safeguard provisions incorporated in the *Patents (Amendment) Act 2005* (India) – in particular compulsory licences, the lifting of restrictions on parallel importation, pre-grant opposition proceedings, and a patentability threshold.

The most prominent issue which emerged from the debates of the Lok Sabha and the Rajya Sabha was about the scope and operations of compulsory licences under the *Patents Act 1970* (India). Shri Yashwant Sinha, a former Finance Minister in the government of the Bharatiya Janata Party declared that compulsory licensing provisions were only of symbolic, ceremonial importance: ‘I still believe that our provisions are weak, that we need to strengthen them in order to give advantage to our companies.’

Other members also highlighted this point to show their distrust of existing compulsory licensing provisions. Shrimati N. P Durga of the Telugu Desam Party evaluated the proposed compulsory licence provisions in the context of the *Doha Declaration on the TRIPS Agreement and Public Health* 2001, and stated that:

Compulsory licensing ... is helping the domestic enterprises in meeting the ever-increasing demands of the pharmaceutical products at competitive prices ... But the problem is that the procedure is very complex and cumbersome and leaves many loopholes. As a result, the patent-holders will delay or prevent the grant of such licenses. The *Doha Declaration on TRIPS Agreement and Public Health* has recognized the gravity of public health in the developing countries. But, the Ordinance promulgated last December imposes an unnecessary hurdle on many...

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developing countries. Now, the Ordinance requires them to grant compulsory licenses even if the drug is not patented there. This is not required under "waiver" to Article 31(f).\textsuperscript{176}

He called on the Minister to remove these limitations ‘so that India’s generic producers, who produce them for local needs and for exports, will be able to continue their successful supply of low-cost products to the Indian and world markets’.\textsuperscript{177} Such concerns have been supported by the episode of Tarceva and Sutent Compulsory licences which are discussed in Chapter 4. The parliamentary debate did not adequately address problems related to export orientated compulsory licences which hinder the ability of importing countries to get generic drugs from India.

At the time of introducing the \textit{Patents (Amendment) Bill 2005} (India) in the parliament, Mr Kamal Nath claimed that concerns regarding compulsory licences under the \textit{Patents (Amendment) Act 2005} (India) had been addressed: ‘If we were to look at what provisions of compulsory licensing be put where there is the question of prices, where there is the question of public interest, all these issues have been adequately taken care of.’\textsuperscript{178} Given the lack of practical know-how about the issuance of a compulsory licences in India, such confidence would appear to be misplaced.


\textsuperscript{177} Ibid.

The second point raised related to parallel imports. At the moment, pharmaceutical imports are not significant in India because most of the widely used drugs are locally produced. Nevertheless, parallel importation provisions were referred during the debate because of future apprehensions. Shri Pawan Kumar Bansal stated the importance of parallel imports and said that:

Despite the fact that a particular medicine may be patented here by any other company, we have the right to import that patented commodity from anywhere in the world, where it is cheaper, even though it is patented here. Earlier however, this required that the foreign exporter was duly authorised by the patentee. That was the condition earlier ... Now, the law would be, as it has been included here in the Bill before us now, that “no longer do we only need to stick to that condition that the foreign exporter was duly authorised by the patentee to sell and distribute the products.” The position now would be that “the foreign exporter be authorised under the law, thus making the parallel imports easier.” This mechanism, as you know, would help in price control.¹⁷⁹

Apparently under this provision, an Indian pharmaceutical company could set up its manufacturing facility in a least developing country like Nepal to produce and export medicines to India. Given the absence of a patent in Nepal, such company would presumably be ‘duly authorised’ under the laws of Nepal to sell or distribute the

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product. Some commentators suggest that such a broad interpretation of parallel importation provisions may contravene the *TRIPS Agreement 1994*.\(^{180}\)

The third safeguard provision related to pre-grant opposition proceedings. A detailed opposition mechanism was included in the *Patents (Amendment) Act 2005* (India) including pre-grant and post-grant oppositions. The idea of pre-grant opposition was mainly referred to during the Parliamentary debates and it was largely interpreted as an important safeguard provision against frivolous patent applications. Pre-grant opposition was not included in earlier versions of third amendments: *Patents (Amendment) Bill 2003* (India) and the *Patents (Amendment) Ordinance 2004* (India). Many members had raised doubts about the efficacy of pre-grant opposition provisions in the law. Shri Yashwant Sinha asserted that:

> We must have very strong pre-grant opposition provisions and nothing should be done to dilute this because ultimately this is going to stand us in good stead. If there is any weakness in this area, then we are going to be the loser, and I will hasten to add that there is absolutely no TRIPS requirement. TRIPS does not lay down that pre-grant opposition should be modified and should be dealt with in any manner. It is not called for. So, why not let the provisions of the earlier statute stand with regard to pre-grant opposition?\(^{181}\)

At least two members apprehended that a pre-grant opposition mechanism would hinder the functioning of the Patent Office and it would unnecessarily delay the grant of

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patents. Shri Sharad Anantrao Joshi of Swatantra Bharat Paksh Party was critical of the idea of pre-grant opposition, claiming that it would lead to unnecessary delays and compromise the secrecy of the patent system.  

Shri Kharabela Swain of Bharatiya Janata Party also shared some of these concerns and proposed that a time limit should be prescribed for the conclusion of pre-grant proceedings to avoid frivolous objections. Shri Kamal Nath defended the provisions: 'India will be one of the few countries in the world which is going to have a pre-grant and a post-grant opposition.' In practice, several Indian companies and non-governmental organisations have initiated pre-grant opposition proceedings before the Indian Patent Office, with mixed results.

Fourth, the Patents (Amendment) Act 2005 (India) introduced rigorous requirements for the patentability of pharmaceutical and chemical substances. The main apprehension in this regard was the so called phenomenon of evergreening which was frequently

182 Shri Sharad Anantrao Joshi, India, Parliamentary Debates-Debates on Indian Patent (Amendment) Bill 2005 Rajya Sabha, March 23, 2005 at http://164.100.47.5/newdebate/debndx/204/23032005/5to6.htm


referred to by the members of Parliament. Members were concerned that a product patent regime might lead to a situation where trivial patents would restrict the ability of generic manufacturers to launch their legitimate products. Shri Kamal Nath assured the Parliament that the Indian government was fully aware of concerns regarding evergreening and appropriate measures were taken in the law. He concluded that:

In regard to evergreening, I just want to read out section 3(d) which says that a mere discovery of a new property or a new use for a known substance or the mere use of a known process in a new product – these are exceptions, these will not be granted any patent – and substances obtained by a mere ad-mixture resulting only in aggregation of properties of the components thereof or, processes of producing such substances will not be given patents.186

Shrimati Maneka Gandhi lamented that the law had failed to address the problem of evergreening. She said that ‘it is vague about the evergreening effect in which companies extend their patent rights by switching from capsules to tablets, for instance’.187 By contrast, Shri Kharabela Swain once again disagreed with the majority of Lok Sabha members and rejected the notion of any threat associated with

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evergreening. He said that patents should be granted in respect of incremental innovations.188

In addition to the discussion of safeguard measures, there was also some discussion of patent administration, the patent protection of micro-organisms, and TRIPS-Plus standards of patent protection during the Parliamentary debates.

V. Conclusion

The *Patents Act 1970* (India) played a strong role in nurturing the emergence and development of a strong and vibrant pharmaceutical industry in India. This sympathetic policy environment enabled India’s national pharmaceutical firms to expand their operations through reverse-engineering and follow-on research. In response to international trade law, India has made three significant amendments to the *Patents Act 1970* (India). The Indian Parliament played a pivotal role in the development and modernisation of national patent law. In an otherwise polarised political environment, the emergence of bipartisan support for patent law amendments was extraordinary. This political consensus, albeit brief, reflected a range of factors – including India’s desire to play an active role in the global economy; the emergence of a strong knowledge economy in India; and the influence of pro-reform actors on domestic policy-making. The debate in Indian Parliament shows that Indian legislators were clearly well-informed about key concerns related to TRIPS-plus provisions. This could be seen in extensive debates on data exclusivity, compulsory licensing and evergreening of patents. There is clear political commitment at this level to protect India’s industrial and

health interests through safeguard provisions mentioned in new patent law. There was indeed a considerable degree of reluctance to accept TRIPS standards but India, somehow, managed to implement a TRIPS-compliant patent law. Despite this positive note, the political debate in India was somewhat ad hoc and expedient, lacking a strong foundation of policy research.

I would argue that TRIPS-plus patent provisions are not suitable for India because they have the potential to undermine public health and access to essential medicines. In his Report, Anand Grover, the UN Special Rapporteur on the Right to Health, cautioned developing and least developing countries about the negative consequences of TRIPS-plus clauses. He recommended that “developing countries and LDCs should review their laws and policies and consider whether they have made full use of TRIPS flexibilities or included TRIPS-plus measures, and if necessary consider amending their laws and policies to make full use of the flexibilities.” Similar recommendations have also made in other studies.

Furthermore, I would argue that TRIPS-plus patent provisions are not suitable for India, given its stage of economic development. In view of its importance for access to medicines and treatment programs all over the world, it is important to preserve Indian


generic industry as one of the most important and reliable sources of generic drugs. A study published in 2010 shows that Indian companies supply 20% of the global market for generic medicines. In case of antiretroviral drugs, this share increases up to 80% of global purchase volume.\textsuperscript{191} From a public health policy perspective, it is crucial to maintain existing level of drug supplies from India. It will be almost impossible to implement scale-up programs and treatment targets without cost effective Indian generics. India’s political leadership has failed to devise a comprehensive and holistic patent policy, which can cater to the economic and social needs of an emerging economy. Innovation and research culture has its roots in India and several scientific and research institutions are producing valuable knowledge. The question of public sector research was completely ignored during the Parliamentary discourse and the focus of debate is still on the narrowly defined pharmaceutical sector. Earlier changes in patent law were informed from by the expert Justice Ayyangar and Tek Chand Reports. No such study was available this time to suggest suitable amendments in the \textit{Patents Act 1970} (India). As a consequence, Parliament had failed to address certain key issues which were otherwise very important for the future of the Indian drug industry. These include the issues pertaining to biotechnology patents where Indian firms are rapidly gaining important results.

The Indian Parliament could have focused more systematically on the issues of Indian innovation and its role in empowering poor masses in India. This approach can help designing and expanding existing safeguard provisions in Indian patent law which are

\textsuperscript{191} Brenda Waning, Ellen Diedrichsen and Suerie Moon, ‘A lifeline to treatment: the role of Indian generic manufacturers in supplying antiretroviral medicines to developing countries’ (2010) 13:35 \textit{Journal of the International AIDS Society} 1 at

currently limited and narrow. An Indian roadmap to harness the role of the local scientific community through open source and sharing models should serve as guiding principles in this regard. Moreover, I would argue that India should not adopt a TRIPS-Plus regime, because it would undermine multilateral institutions, such as the World Trade Organization and the World Intellectual Property Organization, and fragment international intellectual property. The multilateral intellectual property institutions and norms setting process are already under crisis after the emergence of Anti-Counterfeiting Trade Agreement 2011,\textsuperscript{192} and the Trans-Pacific Partnership Agreement. If this process continues and middle income developing countries like India are also pushed to adopt stricter intellectual property standards through bilateral and plurilateral trade and IP agreements, it would disturb the delicate balance which global IP system has so far achieved. The active role which India has played along with other developing countries at World Intellectual Property Organization and World Trade Organization will be severely affected if India backtracks from its current positions and policies.

\textsuperscript{192} Sara Bannerman, ‘WIPO and the ACTA Threat’ (January 2010) PIJIP Research Paper Series at http://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1004&context=research
Table 4.1 shows that although four Indian firms are among the top ten suppliers by volume, in terms of value only two appeared in the top ten, because of their lower prices. Another source cites the data of Global Fund’s suppliers in terms of brand names and generics. It shows that in 2004, brand name, patented, manufacturers supplied 40.7% of total procurements by volume but their share in expenditure terms was around 53%, whereas, generic manufacturers supplied almost 59.3% of the volume of total drugs with only a 47% share of expenditures. Other international humanitarian agencies like UNICEF and the Clinton Foundation rely heavily on importing affordable drugs from India. Indeed 84% of the ARVs that Médecins Sans Frontières prescribes to its patients worldwide come from Indian generic companies.

There has been much debate as to whether India will be able to continue to be such a dominant supplier of generic medicines, in an era where it must be compliant with the TRIPS Agreement 1994. Several studies consider whether compulsory licensing will be an effective tool to maintain the current level of supplies from Indian generic manufacturers. We can see four different strategies bearing on the relevancy and

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333 Ibid. 56.


335 Gustavo Capdevila, ‘Indian court rejects Novartis’ drug patent suit’ Asia Times online, 8 August 2007, http://www.atimes.com/atimes/South_Asia/1H08Df01.html.

usefulness of compulsory licensing as a means of providing access to medicines. First of all, multinational brand-name pharmaceutical companies represented by Pharmaceutical Research and Manufacturers of America (PhRMA) have favoured a narrow and limited scope for compulsory licensing mechanisms. Accordingly, this industry is largely comfortable with the Waiver Decision 2003 and the way in which limitations and restrictions are imposed on the issuance of compulsory licences. Second, a number of academics and commentators contend that the compulsory licensing arrangements under the Waiver Decision 2003 will have a positive impact on pharmaceutical export mechanisms. Scholars like Frederick Abbott and Jerome H. Reichman belong to this group when they argue that export mechanisms can be boosted through a well-designed implementation strategy. Third, civil society groups such as Médecins Sans Frontières (MSF) and Knowledge Ecology International (KEI) hold critical positions about the negative implications of the Waiver Decision 2003 on export mechanisms. They argue that the complicated and cumbersome procedure envisaged under the Waiver Decision 2003 will inevitably limit the ability of export markets to meet the demands of poor and developing countries. Finally, there is a group of commentators who contend that the Waiver Decision 2003 has a symbolic significance, even though its practical, tangible impact is negligible. Employing the themes of rule complexity and regulatory ritualism, Professor Peter Drahos has highlighted the limitations of the Waiver Decision 2003 to show the futility of outcome.


Chapter 3

The Novartis Case in India:
The Evergreening of the Gleevec Patent

Another important issue is that of inequitable patent laws which can serve as counterproductive hurdles for the use of lifesaving drugs.

Amartya Sen, *Identity and Violence*¹⁹³

I. Introduction

On 17th May 2006, the Swiss pharmaceutical company, Novartis filed two cases in the Chennai High Court, India. Through these two writ petitions Novartis challenged the decision of the Indian Patent Office to reject its patent application for the cancer drug imatinib mesylate (brand name Gleevec). It further challenged the constitutionality of section 3(d) of the *Patents Act 1970 (India)* on the basis of which the Patent Office had rejected the patent application. The appellant also raised the issue that section 3(d) is incompatible with the *Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS Agreement 1994)*. Later, Novartis dropped its first plea and went into an appeal before the Intellectual Property Appellate Board (IPAB).

On 6th August 2007, the Madras High Court ruled against Novartis, holding that section 3(d) is not unconstitutional. The Madras High Court held that it was not the proper forum to decide whether the Indian patent law was *TRIPS Agreement 1994* compliant or not. The High Court also held that section 3(d) was not vague or arbitrary and therefore did not violate the Indian Constitution.

The Madras High Court’s ruling triggered important policy debate about the scope and interpretation of Indian patent law and its possible implications for innovation and health policies. The ruling was also important to the policy debate over access to medicines as patients in many developing countries exclusively relied upon affordable Indian exports of generic medicines and the judgment helped in maintaining the future hopes in this regard. Section 3(d) of the Patent Act 1970 (India) represents India’s unique attempt at striking a balance between innovation and public health, given its status as a technologically proficient developing economy. Although the Madras High Court rightly ruled that section 3(d) was constitutional, its conclusion that it did not have jurisdiction to rule on the TRIPS Agreement 1994 issue deserves a critical review.

On the question of the constitutional validity of Section 3(d), the High Court again adopted a cogent policy by declaring the provision absolutely valid and applicable. The findings of the court on this point are well informed and practical stating that parliament can only provide some broader principles. Nevertheless, it is submitted that terms such as ‘efficacy’, which provides a useful policy lever, need to be construed carefully by the patent office. If pegged too high, it may hurt the innovative strengths of emerging local drug manufacturers and such policy can jeopardise local research and development initiatives.

This chapter primarily deals with the judgment of the Madras High Court. It starts with a brief introduction to the background of Imatinib Mesylate development and Part II elaborates the story of Gleevec, its patents and the role of Novartis in this regard. Part III specifically deals with the contents of the judgment from a patent law perspective and the earlier decision of the Indian Patent Office is also discussed in this part to develop a comprehensive overview of the Novartis patent application and its subsequent rejection. In Part IV, the contents of the judgment are discussed from an international law perspective and this part elaborates issues such as compliance of the TRIPS
Agreement 1994 and the validity of Section 3(d) in view of existing patenting norms. Part V explores the legality of Section 3(d) of the Patent Act 1970 (India) in view of Constitutional provisions. Part VI surveys the responses and reactions which were widely reported after the announcement of the judgment.

II. From Philadelphia Chromosome to Imatinib Mesylate: The Story of Gleevec

Since the identification of leukaemia as a deadly sub-disease of the cancer family, scientists have sought to develop therapeutic solutions.

Peter Nowell and David Hungerford discovered in 1960 that Chronic Myelogenous Leukaemia (CML) patients have a unique chromosome, which was later named as Philadelphia chromosome. CML is generally known as a cancer of bone marrow and the findings of Peter Nowell and David Hungerford establish that in the white blood cells of CML patients, a portion of their chromosome is missing. Dr Janet Rowley, haematologist at the University of Chicago, found in 1973 that the Philadelphia chromosome was a hybrid of two normal chromosomes which have fused together and in the 1980s researchers discovered the fused gene (Bcr-abl). In CML patients the exact chromosomal defect in Philadelphia chromosome is the translocation when parts of two chromosomes, 9 and 22, swap places. The result is that part of the Bcr (breakpoint cluster region) gene from chromosome 22 is fused with part of the abl (abl stands for ‘Abelson’, the name of a leukaemia virus which carries a similar protein) gene on


chromosome 9. In 1990, George Daley created animal models of CML to establish that the Bcr-abl gene was sufficient to cause the disease.

Ciba-Geigy, which later became Novartis, had a cancer research program searching for molecules that inhibited cancer causing tyrosine kinases. Novartis decided to focus on the kinase enzyme and Drs Zimmerman and Buchdunger of Novartis, created and tested 400 molecules to find one that would target this kinase enzyme. It was a difficult exercise to identify one enzyme without disrupting any of the hundreds of other similar enzymes in a healthy cell. After a couple of years of testing, they developed the molecule that would become Gleevec. The most significant development was the findings of Dr Brian Druker and Nicholas Lydon in 1996 when they highlighted one compound in particular and their work enabled Novartis to focus on this compound. Among the different compounds tested, one named ST1571 responded extraordinarily well and paved the way for the development of Gleevec.

197 The Pharmaceutical Research and Manufacturers of America (PhRMA)
http://www.phrma.org/gleevec_2004/
198 Ibid
A. Novartis

In the same year, Ciba-Geigy and Sandoz merged and formed the pharmaceutical giant Novartis.\textsuperscript{201} In 1998, the compound ST1571 went through an extensive human trial phase which revealed its effectiveness whereby all 31 patients in the trial experienced complete remission. Finally, the U.S. Food and Drug Administration (FDA) granted ‘fast track’ designation to the drug and on May 10, 2001, only ten weeks after the company submitted a New Drug Application, the FDA approved Gleevec for the treatment of Philadelphia chromosome-positive CML patients in the blast crisis, accelerated phase or the chronic phase after failure of interferon therapy.\textsuperscript{202}

Gleevec proved to be a blockbuster product for Novartis and the product earned significant profit for the company. In its 2006 Annual Report, Novartis ranked Gleevec among the top selling products of the company which surpassed US$2.5 billion in sales, representing an annual sales growth of more than 17% in local currencies.\textsuperscript{203}

Some commentators doubted the enthusiasm of Novartis in the development of Gleevec. According to Arnold S. Relman and Marcia Angell:

\begin{quote}
[T]here was little corporate enthusiasm for undertaking further clinical work on imatinib. Druker nevertheless persisted, and Novartis finally agreed to support cautious, limited tests of the drug in Druker’s clinic and two other sites … So Novartis’s R&D investment in testing imatinib for the treatment of CML was
\end{quote}

\textsuperscript{201} Information about Ciba-Geigy and Sandoz (1970-1996) at \url{http://www.novartis.com/about-novartis/company-history/2companies.shtml}.

\textsuperscript{202} U.S. Food and Drug Administration, ‘FDA Approves Gleevec for Leukemia Treatment’ (Press Release, May 10, 2001) \url{http://www.fda.gov/bbs/topics/NEWS/2001/NEW00759.html}

made several years after there was already good scientific evidence to suggest that it might be useful.\textsuperscript{204}

Dr John R. Seffrin, then Chief Executive Officer of the American Cancer Society, and President of the International Union Against Cancer, has reminded us about the significant role of public and non-profit sectors in the development of Gleevec. On October 16, 2003 while addressing at the National Press Club, he said: ‘The real story of Gleevec is yet to be told. That is, that Gleevec still wouldn’t be with us today if all three sectors – the private, the public and the non-profit sector – hadn’t each played a key role in bringing Gleevec to market.’\textsuperscript{205}

B. Gleevec Patents

Having developed a large and lucrative portfolio of patents, Novartis considers that it ‘will continue to resist the pressure to soften its position on the need to vigorously protect intellectual property in favour of short-term political gain’.\textsuperscript{206} The company is of the view that weakening intellectual property rights would jeopardise, rather than expand, long-term access to medicines by removing incentives for innovation. After the invention of ‘Phyrimidineamine Derivatives’ in the early 1990s in Novartis labs, patent applications were filed to secure the propriety rights over these compounds which have demonstrated some inhibitive characteristics against CML. Novartis filed a patent

\textsuperscript{204} Arnold S. Relman and Marcia Angell, ‘How the Drug industry Distorts Medicine and Politics: America’s Other Drug Problem’ (December 16, 2002) \textit{The New Republic} 27, 32.


application in Canada on April 1, 1993 which was granted on November 26, 2002.\textsuperscript{207} It also holds a patent for the same compound in the European Union.\textsuperscript{208}

Later, as a result of subsequent research and development, Novartis filed additional patent applications for a 'beta crystalline form of Imatinib Mesylate' in over 50 countries. Novartis claims that by 2006 it had already been granted patents in 35 of them.\textsuperscript{209} This new invention was basically a particular form of methanesulphonic acid addition salt of a particular ‘Pyrimidineamine Derivative’ (‘imatinib Mesylate’) in crystal form. Novartis scientists had invented it in two forms, Alpha and Beta: the ‘Beta form stores better, is less hygroscopic, is easier to process and guarantees a constant quality of the final drug product’.\textsuperscript{210}

In India, in the absence of a product patent regime for pharmaceutical products, Novartis secured Exclusive Marketing Rights (EMR) for Gleevec under Chapter IV A (Exclusive Marketing Rights) of the \textit{Patents Act 1970} brought in by the \textit{Patents (Amendment) Act 1999} (India) with retrospective effect from January 1, 1995. After the promulgation of the \textit{Patents (Amendment) Act, 15 of 2005 (India)}, the Novartis patent application regarding the ‘beta crystalline form of Imatinib Mesylate’ (sold under the brand name Gleevec/Glivec) was scrutinised by the Indian Patent Office. On the 25\textsuperscript{th} January 2006, the Assistant Controller General of Patents and Designs rejected this application in pre-grant opposition proceedings on the grounds that the application

\begin{itemize}
\item \textsuperscript{210} Ibid Paragraph 9 (4).
\end{itemize}
claimed only a new form of a known substance. Novartis then filed the writ petitions in the High Court of Judicature at Madras.

III. Judgment

Novartis filed two separate writ petitions in the High Court of Judicature at Madras. On 6th August 2007, Justice R. Balasubramanian and Justice Prabha Sridevan of a Division Bench of the Madras High Court disposed of both the writ petitions together as the matter involved the same facts and legal questions. Through these writ petitions, Novartis had sought a declaration that Section 3(d) of the Patents Act 1970 (India) as amended by the Patents (Amendment) Act 2005 (India) was unconstitutional. In the first writ petition there was an additional prayer to direct the Controller General of Patents and Designs to allow the petitioner’s patent application No. 1602/NAS/98. However at a later stage, this prayer has been dropped by the petitioner with the approval of the Court.

In this challenge, Novartis questioned the validity of Section 3(d) upon two grounds. The first ground was related to the constitutional validity of the law. Novartis pleaded that Section 3(d) of the Patents Act 1970 (India) was ‘unconstitutional as it is vague, arbitrary and violative of Article 14 of the Indian Constitution’. The second ground was related to the incompatibility of Section 3(d) with the TRIPS Agreement 1994. Justice R. Balasubramanian considered all relevant arguments while delivering the Common Order of the Court. His ruling cut across patent law, international trade law and constitutional law.

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A. Patent Law

On 17th July 1998, Novartis filed an Indian patent application for an invention titled Crystal Modification of A N-Phenyl-2-Pyrimidineamine Derivative, Processes for its Manufacture and its Use. The applicants claimed a Switzerland priority date of 18th July, 1997 and the application was gazetted on 17th July, 1999. Seventeen different claims were made in the complete specification submitted along with the patent application. It is pertinent to note that a relatively lesser number of claims were made in patent applications for Gleevec filed in other jurisdictions. For instance, a Patent Cooperation Treaty (PCT) application (No.PCT/EP1998/004427) has made only thirteen claims.

The invention, as disclosed in the specification, was related to a B-crystal form of methanesulphonic acid salt of 4(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3[4-pyridin-3-yl]pyrimidi-2-ylamino)phenyl]-benzamide (commercially known as imatinib mesylate/brand name Gleevec). The patent specification particularly mentioned that the preparation of the base compound, 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3[4-pyridin-3-yl]pyrimidin-2-ylamino)phenyl-benzamide had already been disclosed in the European Patent publication No. EP-A-056409. This base compound is generally termed as imatinib and its use as an anti-tumour agent is well known. Novartis asserted in the patent application that 'this compound is exemplified in these publications only in


free form (not as a salt). This assertion was primarily made to establish the novelty of the new compound and it later become a major point of controversy during opposition proceedings.

Subsequent to filing the patent application, the Controller General of Patents and Trademarks of India issued the first EMR to Novartis for imatinib mesylate (Gleevec). On 26th September 2005, after the promulgation of *The Amended Act 2005*, the Cancer Patient Aid Association (CPAA) filed a submission in the office of the Patent Controller, Chennai showing its willingness to initiate opposition proceedings under Section 15(1) of the *Patents Act 1970 (India)*. A request for hearing was also made under Rule 55 of the *Patents Rules, 2003 as amended by Patent (Amendment) Rules, 2005*. In response to the aforesaid submission, Novartis reiterated its position maintained in the patent application by rejecting the arguments of CPAA with regard to patentability of imatinib mesylate. The CPAA filed a rejoinder to the statement and reply of the applicant on 12th December, 2005 and the matter went through pre-grant opposition proceedings before the Assistant Controller of Patents and Designs. After hearing the parties and analysing the written submissions and affidavits, the Patent Office refused to proceed with the application of Novartis for the grant of the Gleevec patent. There was doctrinal argument about the novelty and the inventive step of the patent application.

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218 Ibid 1.


B. Lack of Novelty

In its written submissions, the CPAA maintained that the invention, B-crystal form of methanesulphonic acid salt of 4(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3[4-pyridin-3-yl]pyrimidi-2-ylamino)phenyl]-benzamide, was not a new product as it had been published previously. So under Section 25 (1)(b)(i) the Patents Act 1970 (India), the application should be rejected on the ground that ‘the invention so claimed in any claim of the complete specification has been published before the priority date of the claim’. The CPAA also traced the earlier patent applications of Gleevec in Canada and the United States and argued that: ‘[O]n a reading of the specifications for which the patent was granted in Canada and subsequently in the USA, it is clear that the patent was granted not only for the compound in its free state, but also for all its salts’. Novartis, on the contrary, argued that the disclosure made in 1993 in US patent No. 5521184 was different from the one which was claimed in the existing patent application. This invention, according to Novartis, involved two-fold improvements over the prior art as the compound was exemplified in the earlier patent applications only in its free form, not as a salt. In this invention ‘(i) the imatinib free base has been chemically changed into a salt form (ii) a particular crystal form of the salt has been made through human intervention’. Novartis also argued that its 1993 US patent did


222 Ibid.

not carry an example for the preparation of imatinib mesylate and that ‘the claims of the 1993 patent embrace imatinib mesylate’.\textsuperscript{224}

In its rejoinder on 8\textsuperscript{th} December, 2005, the CPAA maintained that despite the statement of the two-step process, the invention was still unpatrientable under Indian law because it was anticipated through the 1993 patent that imatinib mesylate could be obtained with the addition of methanesulphonic acid. Alternatively, if not so, it was ‘an obvious improvement over the free base in the light of the prior art’.\textsuperscript{225} The plea of Novartis that in fact the claims of the 1993 patent embraced imatinib mesylate was rebutted by the CPAA: ‘Even if a prior publication does not expressly disclose in words one or more elements of a patent’s claims, it may nevertheless be anticipating if a person of ordinary skill in the art could have combined the publication’s description of the invention with his/her own knowledge to make the claimed invention.’\textsuperscript{226}

After hearing the parties, Mr V. Rengasmy, Assistant Controller of Patents and Designs, concluded that the CPAA had succeeded in proving that the imatinib mesylate was anticipated by prior publication. First, it was held that methanesulphonic acid was disclosed in the 1993 patent as one of the salt forming group with this disclosure that in the patent specifications the required acid additions salts were obtainable in a customary manner. Second, the ruling found that some of the 1993 patent claims (Claims 6 to 23) categorically mentioned a pharmaceutically acceptable salt of the base compound which by analogy included a beta crystalline form of imatinib. Third, imatinib mesylate was specifically mentioned as a product in a patent term extension certificate for the 1993 patent issued by the US Patent Office.

\textsuperscript{224} Ibid.

\textsuperscript{225} Mr Y.K. Sapru for Cancer Patient Aid Association, ‘Rejoinder to the Statement and Reply of the Applicant, Novartis AG’, 8\textsuperscript{th} December, 2005. Full Text is available on file.

\textsuperscript{226} Ibid.
A PCT application for the same compound was filed on 16th July, 1998 claiming a priority date of 18th July, 1997.\textsuperscript{227} During opposition proceedings, the CPAA raised that Switzerland was not a convention country on 18th July 1997 and it was notified to be a convention country only on 30th November 1998. Hence, Novartis could not claim any priority from its Swiss application. Novartis submitted that priority date was only a facility provided to the applicants to avoid anticipation by publication of the invention between priority date and the filing date. The patent office agreed with the contention of the CPAA.\textsuperscript{228}

The question of prior disclosure and the novelty of imatinib mesylate came under discussion in the \textit{PCT International Preliminary Examination Report} and the novelty of the compound was recognised.\textsuperscript{229} Nevertheless, this reasoning could not persuade the Indian Patent Office and the compound was declared to be a part of the prior art. The issue of novelty and prior disclosure did not come ahead during the High Court proceedings and the judgment as such is silent about this issue.

\textbf{C. Obviousness}

Another issue raised with regard to the Gleevec patent application was related to obviousness. The CPAA submission alleged that the purported invention as disclosed in the patent application was obvious to a person skilled in the art. Thus, the invention did not involve an inventive step within the meaning of Section 2(ja) of the \textit{Patents Act 1970 (India)}. According to the CPAA, the process disclosed in the specifications to

\textsuperscript{227} International Preliminary Examination Report, 8, PCT/EP98/04427 at http://www.wipo.int/patentscope/search/docservicpdf?ptc_id00000009366618

\textsuperscript{228} Order 151205 of Assistant Controller of Patents and Design in the matter of application for patent No. 1602/MAS/98, 25th January, 2006, 5. Text available is available on file.

\textsuperscript{229} Ibid.
obtain a beta crystal form was too simple, being 'merely processing the substance in the alpha form with alcohol in the presence of some water or mixtures at a particular temperature and then initiating crystallisation by adding the beta form as the seed'.

So, the process did not involve any technical improvement as compared to the existing knowledge and any person with ordinary skills in the art could prepare corresponding pharmaceutically acceptable salt benefiting from the information disclosed in the 1993 patent specifications. It was further demonstrated with the support of affidavits and reports from the Indian Institute of Technology and Indian Institute of Chemical Technology that the purported salt was found to steadily exist in the beta crystalline form and it was the most thermodynamically stable form in which imatinib mesylate inherently existed. Novartis was of the opinion that the beta crystalline form was not inherently formed when the 1993 patent specifications were filed and that earlier patent applications only disclosed the free base, not any salt of imatinib. Thus the invention was not obvious to a person skilled in the art.

However, the patent office did not agree with the arguments of Novartis and held that 'the Opponent has reasonably succeeded in establishing this ground of opposition too'. Contrary to the findings of the Indian Patent Office, imatinib mesylate was considered a non-obvious invention in the PCT International Preliminary Examination

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Report. Initially it was acknowledged in the Report that ‘the isolation of a crystalline form of a known salt cannot in itself be regarded as being inventive, since it falls within practice followed by a person skilled in the art’. But, some distinct characteristics of the beta crystalline form as compared to the alpha form were established in the application which was not disclosed in the US Patent application. It was observed that ‘Since the prior art D1 gives no indication of the existence of a particular crystalline salt with superior storage properties at high humidity levels, an inventive step can be acknowledged for the crystalline form of the salt as claimed in claims 1-9, and compositions, uses and synthesis thereof (claims 10-12).

IV. International Law

A considerable portion of the Novartis judgment pertains to the issues which are somehow related to international law. The petitioners challenged the validity of Section 3(d) ‘both on the ground that it violates not only Article 14 of the Constitution of India but also on the ground that it is not in compliance to TRIPS’. The judgment includes elaborate arguments in light of relevant case law and the court finally disposed of the matter against the petitioners by declining its jurisdiction over an issue related to treaty obligations and their domestic enforcement. It is argued here that despite its valid conclusion of declining to afford any remedy to the petitioner, the court could not provide a sound basis for its conclusion of lack of jurisdiction.

The petitioners’ challenge to Section 3(d) on the basis of the *TRIPS Agreement 1994*, was twofold. First, it argued that Section 3(d) was not compliant with the substantial


235 Ibid.

requirements of patentability as laid down in the *TRIPS Agreement 1994* and thus it should be declared invalid. Alternatively, Novartis maintained that if for some reason the court could not invalidate the said provision then at least a declaration should be issued stating the incompliance of Section 3(d) with the *TRIPS Agreement 1994*. Novartis contended that the new language in the *Patents (Amendment) Act 2005 (India)* was contrary to Article 27 of the *TRIPS Agreement 1994*. It was argued that:

The Union of India had in fact not carried out its obligations arising out of “TRIPS” and instead, by amended section making that the discovery of a new form of a known substance, which does not result in the enhancement of the known efficacy of that substance as not patentable, the right to have an invention patented guaranteed under Section 27 of the “TRIPS” is taken away ... Under Article 27 of “TRIPS”, all inventions, subject to paragraph 2 and 3 of that Article, are patentable. Reading Article 27 as a whole, it is argued that the drug invented in the case on hand is patentable.237

The petitioners further argued that Article 27 of the *TRIPS Agreement 1994* had clearly established the patentability criteria and the requirements of Section 3(d) were narrower and beyond the scope of this article ‘which is not at all permissible under the TRIPS Agreement’.238

Finally, the petitioner ‘submitted that where the policy of government and parliament is to implement an International treaty like TRIPS Agreement and where legislation is enacted after its acceptance and ratification, it must be presumed that parliament intends to give effect to the obligations under International law’.239 The petitioner maintained:


239 Ibid.
'Since section 3(d) is in direct violation of TRIPS, it must be declared that it is not in conformity with the obligation taken by India in signing and ratifying the TRIPS Agreement.'240

In response to this assertion, the respondents replied on two different lines. It was first argued that the question of compliance of the TRIPS Agreement 1994 could not be raised before this court and, secondly, the existing Section 3(d) of the Patents Act 1970 (India) was fully compatible with the TRIPS Agreement 1994. In its reply filed by the Cancer Patient Aid Association, India, the respondent maintained that the TRIPS Agreement 1994 could not be the basis of a challenge to statutory law in India:

The TRIPS agreement is not enforceable per se and its compliance or non-compliance cannot be a ground for a constitutional challenge to a domestic law that is the Patents (Amendment) Act 2005 which is validly passed by a competent legislature. It is pertinent to note that India being a dualist nation, TRIPS agreement does not get implemented automatically. It is only through the domestic law that it can be implemented. Therefore this court has no jurisdiction to decide whether the statute violates the TRIPS agreement. In any event the proper forum for the same is the WTO Disputes Panel.241

Other respondents including the Union of India were of the opinion that under the scheme of the TRIPS Agreement 1994, every member state had been given enough room to transform their treaty obligations into national laws keeping in view the needs of their citizens and there was no incompatibility with international law obligations.242

240 Ibid.

241 Affidavit for the Respondents No. 6 in the High Court of Judicature at Madras, Writ Petition No. 24759 of 2006, 2.

Respondents also relied upon some English cases to establish that Indian courts had no jurisdiction to determine the validity of a municipal law on the ground that it was in violation of an international treaty.\(^\text{243}\) In the alternative, the respondents also argued that Section 3(d) was fully compliant with the *TRIPS Agreement 1994*.

Finally, on the issue of jurisdiction, the court agreed with the respondents and declined its jurisdiction by stating:

Therefore we have no difficulty at all that Article 64 of "TRIPS" read with World Trade Organisation's understanding on Rules and Procedures governing the settlement of disputes provides a comprehensive settlement mechanism of any dispute arising under the agreement ... When such a comprehensive dispute settlement mechanism is provided as indicated above and when it cannot be disputed that it is binding on the member States, we see no reason at all as to why the petitioner, which itself is a part of that member State, should not be directed to have the dispute resolved under the dispute settlement mechanism referred to above ... we see no compelling reasons to deviate from such judicial approach when we consider the choice of forum arrived at in International Treaties. Since we have held that this court has no jurisdiction to decide the validity of the amended section, being in violation of Article 27 of "TRIPS", we are not going into the question whether any individual is conferred with an enforceable right under "TRIPS" or not. For the same reason, we also hold that we are not deciding issue No. (b) namely, whether the amended section is compatible to Article 27 of "TRIPS" or not.\(^\text{244}\)


\(^\text{244}\) Ibid. 27-28.
The court agreed not only with the interpretations and the case law cited by the respondents but also based its judgment on the theory of the contractual nature of treaty obligations which thus bind parties to an international covenant. Honourable Justice R. Balasubramanian while writing for the court rejected the relevance of the decision of the House of Lords in *Equal Opportunity Commission & Another v. Secretary of State for Employment*245 which was presented by the petitioners. It was clearly observed that this case involved the scrutiny of local law on the basis of a European Council Directive 75/117 which had already been transformed into national law. Instead, the court relied upon the case of *Salomn v. Commissioner of Customs*) holding that ‘in our opinion, this is the direct judgment on the point’.246

Furthermore, on the basis of the covenant theory of international treaty obligations, the court held that the obligations of the *TRIPS Agreement 1994* were essentially in the nature of a contract and it had evolved its own dispute settlement mechanism which could only be invoked in case of any controversy. After elaborating the relevant clauses regarding the dispute settlement, the court concluded that it had no jurisdiction in the given case and such a matter could only be settled under the dispute settlement mechanism of WTO.247 The court also considered the possibility of issuing a declaration and declined to do so.

**A. Assuming Jurisdiction: Is it that Problematic?**

The jurisdiction of a court in cases such as Novartis is definitely a crucial issue with the possibility of triggering some overwhelming consequences. With regard to the *TRIPS Agreement 1994*...
Agreement 1994, this question has not been raised for the first time in the Novartis case. However, the Novartis court responded to this issue in a unique way by declining its jurisdiction altogether instead of differentiating between the questions of the court’s jurisdiction and the petitioner’s standing. Indeed it refused to deal with the question of standing by surrendering its own jurisdiction without actually looking into trends set out elsewhere in matters pertaining to similar issues.

Most of the courts in other jurisdictions, which were confronted with matters pertaining to the validity of national laws in view of the obligations of the TRIPS Agreement 1994, had clearly assumed their jurisdictions and then disposed of the matters on the basis of respective legal systems and individual merits. Interestingly, none of these courts refused to deal with the matters merely on the ground that such matters could only be raised before the dispute settlement body envisaged under the TRIPS Agreement 1994. Under the rubric of the doctrine of direct effect, these courts sometimes refused to afford any relief to the challenging parties, but in very clear terms there was no attitude of avoidance as we can observe in the Novartis judgment.

The most recent example is the judgment of the European Court of Justice (ECJ) in Merck Genéricos – Produtos Farmacêuticos Ldª v. Merck & Co. Inc., Merck Sharp & Dohme Ldª where on a question referred by a Portuguese court concerning Article 33 of the TRIPS Agreement 2004, the Court declared that ‘national courts may independently decide whether to apply the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) directly in the field of patents’. In this case,

based upon its earlier decisions, the ECJ did not decline its jurisdiction despite the fact that the European Community had not yet exercised its powers in the field of patents or that their exercise was not to date sufficient to lead to the conclusion that the sphere would currently fall within the scope of Community law. This is absolutely in consonance with the ECJ’s earlier decisions in *Parfüms Christian Dior SA v. TUK Consultancy BV* and *Assco Gerüst GmbH and Rob van Dijk v. Wilhelm Layher GmbH & Co. KG and Layher BV.*

In this regard it is also useful to look into the treaty-making provisions of the Indian Constitution which do not put any such bar on Indian courts which the Novartis Court had assumed. Article 51 and Article 253 of the Indian Constitution refers to international law and treaties. Article 51 elaborates one of the directive principles of the state’s underlying responsibility to promote world peace and friendly international relations, and ‘to foster respect for international law and treaty obligations’. Article 253 states that the ‘Parliament has power to make any law for the whole or any part of the territory of India for implementing any treaty, agreement or convention with any other country or countries or any decision made at any international conference, association or other body.’ Traditionally, Article 253 has been interpreted as barring the direct effect of treaties in India. Nonetheless, Indian courts always resorted to Article 51 to illuminate Indian laws and the Constitution, especially in terms of enforcing social and economic rights. For Indian courts, it was not possible to develop a great deal of

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human rights jurisprudence without assuming jurisdiction in cases which they decided on the basis of principles and guidelines enumerated in international treaties. In this way, Indian courts, unlike the Novartis court, had always distinguished between the question of their jurisdiction and the possibility of direct effect.

The Madras High Court reliance on WTO’s dispute settlement system is also questionable as Indian courts traditionally do not recognise any forum established under a treaty which has not been internalised in the form of domestic legislation. In India the WTO Understanding on Rules and Procedures Governing the Settlement of Disputes has not been domesticated and any reference to a forum created under this agreement does not fit in the earlier jurisprudence of the Indian courts on this point.

The reliance of the Novartis court on the argument of the contractual nature of treaty obligations and the WTO dispute settlement procedure is also problematic. The Dispute Settlement Understanding (DSU) of the WTO is the only appropriate forum for dispute settlement inter se states and by no way was it designed to preclude the national courts from ruling on the content of WTO law. The Novartis court was right in determining that it could not strike down a provision of domestic law on the basis of contravention with the treaty obligations but it was fully competent to determine the scope and contents of domestic law on the basis of its inherent jurisdiction.

B. Patentability under Section 3 (d)

Novartis objected to Section 3 of the Patents (Amendment) Act 2005 (India) whereby in Section 3 of the Patents Act 1970 (India), for clause (d), the following has been substituted:

(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery
of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Explanation.—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

Though both the Novartis petition and the judgment are focused on the constitutionality and compatibility of Section 3(d) with regard to Article 14 of the Indian Constitution and Article 27 of TRIPS Agreement 1994, this section is dedicated to analyse the nature and scope of Section 3(d) mainly from a patent law perspective.

For an holistic understanding of Section 3(d) in an appropriate historical context Justice R. Balasubramanian has reproduced following two earlier versions of Section 3(d):

Unamended section 3(d): The mere discovery of any new property or new use of a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Amendment to section 3(d) under Ordinance 7/2004: The mere discovery of any new property or mere new use of a known substance or of the mere use of a known process; machine or apparatus unless such known process results in a new product or employs at least one new reactant.252 (Emphasis in original)

According to Novartis Section 3(d) amendments were proposed to meet the obligations of the *TRIPS Agreement 1994* and in this regard amendment to Section 3(d) under the *Ordinance 2004* was compatible to the *TRIPS Agreement 1994*. However, Novartis counsel maintained: 'without any rhyme or reason, the proposed amendment sought to be introduced by the Ordinance had been completely given up and instead, the offending amended section was brought up'.

Novartis also contended that in its existing form, 'Section 3(d) contradicts to various articles of the *TRIPS Agreement 1994* and the main thrust was with reference to Article 27 of the *TRIPS Agreement 1994*.'

The objection was mainly about the wording of amended Section 3(d) stating: 'which does not result in the enhancement of the known efficacy of that substance' and related explanation to the extent 'unless they differ significantly in properties with regard to efficacy'. Novartis considered that after the introduction of the new amendment the right to have an invention patented under Article 27 of the *TRIPS Agreement 1994* has been taken away. Moreover, the Indian government has failed to comply with its obligations under Article 1 (1) of the *TRIPS Agreement 1994* which mandates every member country to give effect to the provisions of the TRIPS and 'India being a member country, in implementing the various provisions of “TRIPS” brought in the amended section violating their obligations under “TRIPS”'.

The High Court has refrained from deliberating upon the merits of the petitioners’ plea on the incompatibility of the amended Section 3(d) with Article 27 of the *TRIPS Agreement 1994* on account of the lack of jurisdiction. It was held that:

253 Ibid. 9.

254 Ibid.

255 Ibid.
Since we have held that this court has no jurisdiction to decide the validity of the amended section, being in violation of Article 27 of “TRIPS”, we are not going into the question whether any individual is conferred with an enforceable right under “TRIPS” or not. For the same reason, we also hold that we are not deciding issue No. (b) namely, whether the amended section is compatible to Article 27 of “TRIPS” or not.256

Notwithstanding the aforementioned conclusion of the court, it will be pertinent to trace the basis of this controversy in the *TRIPS Agreement 1994* and related patent literature to determine the suitability of amended Section 3(d) with regard to the ‘enhancement of known efficacy’ controversy. Article 27.1 of the *TRIPS Agreement 1994* elaborates the patentable subject matter in terms of patentability requirements. It provides that patents shall be available for any invention, whether products or process, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.257 Article 27.2 provides different grounds on the basis of which member states may exclude certain inventions from patentability.

Novartis claims that the requirements of Section 3(d) as mentioned earlier are beyond the obligations of Article 27 and thus violate the treaty obligations. There is no doubt that subject to Article 27.2, the criteria of patentability enumerated in Article 27.1 is novelty, inventive step and industrial application. However, the *TRIPS Agreement 1994* does not provide definitions of these terms and it is equally silent about the definitions of product and process.

Some commentators consider that it is a leeway available to the member states and the treaty obligations can be transformed into domestic law in numerous ways given the

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256 Ibid. 28.

257 Article 27.1 of the *TRIPS Agreement 1994*.
socio-economic conditions of a country. So, while adhering to its *TRIPS Agreement 1994* obligations a member state can define the patentability criteria in a distinct and unique way because of ‘considerable room to develop their own patent and other intellectual property laws in response to the characteristics of their legal systems and developmental needs’.

In this context Section 3(d) of the *Patent Act 1970* (India) is absolutely compatible with the TRIPS obligations because there is enough flexibility that permits member countries to keep different criteria to assess patentability. Professor Carlos Correa observes specifically about Section 3(d):

> The amendment introduced to the Indian Patent law in 2005 adopted a specific policy with regard to claims regarding salts, esters and other "forms" of existing products. The objective of the Indian provision is clearly to limit the proliferation of patents around existing pharmaceutical products.

This view also gains strength from the Final Report of the *UK Commission on Intellectual Property Rights* when it recommends: ‘Developing countries should aim for strict standards of patentability to avoid granting patents that may have limited value in relation to their health objectives.’

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However, some authors consider that Section 3(d) is ‘the most controversial provision which prohibits patents on derivatives of known substances, unless such derivatives display significant enhanced efficacy’.261

This provision reflects the strong resentment towards evergreening of drugs patents. Justice R. Balasubramanian recognises such policy concerns when he observes:

We have borne in mind the object which the Amending Act wanted to achieve namely, to prevent evergreening; to provide easy access to the citizens of this country to life saving drugs and to discharge their Constitutional obligation of providing good health care to its citizens.262

Under Section 3(d), the key question regarding the exclusion from patentability will be the extent of a claimed derivative’s ‘efficacy’. The first paragraph of Section 3(d) allows the patenting of a derivative which provides an ‘enhancement of the known efficacy’ of a ‘known substance’ but the explanation of the second paragraph lay down another restriction by requiring that the derivatives and the known substance ‘differ significantly in properties with regard to efficacy’. So ‘Section 3(d) thus raises both qualitative and quantitative questions i.e. what kind of data will be required to establish “efficacy” and how great an improvement over the efficacy of the prior art invention will be required to obtain a patent.’263


Precisely this point was raised by Novartis during the arguments that the efficacy of a known substance may be well known but the Patent Controller will exercise uncontrolled discretion without some guidelines in the law itself to understand the expression ‘enhancement of the known efficacy’. Though the Court did not agree with the petitioners’ contention about the invalidity of Section 3(d), for all practical purposes, the patent office and practitioners require at least a functional definition and interpretation of the terms employed in this section. Shamnad Basheer highlights this problem:

Drawing out guidelines for determining “efficacy” is indeed the need of the hour. While the Madras High Court judgment is being celebrated, it does come with certain problems – it wishes away the “efficacy” problem as something to be defined in each specific fact situation ... Unfortunately, apart from a categorical statement that it did not agree, the patent office did not really tell us as to what they thought the term “efficacy” meant and why Novartis alleged invention did not demonstrate enhanced efficacy. Given this background, isn’t it only fair for Novartis for plead that they are clueless as to what the term means.

Obviously a court cannot be expected to provide a definition of such terms and it has approached the issue purely from the constitutional perspective.

One possible difficulty in defining and interpreting the language of Section 3(d) is the lack of any earlier guidance on this point. Indian law is unique in a sense that it has incorporated a broader exclusion from patentability and no jurisprudence is available in patent law to settle such inherent statutory ambiguities. Generally, discussions about

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patentability revolve around the scope and application of novelty and inventive step but the Indian law goes beyond that by providing new restrictions on evergreening. It is pertinent to mention that the language of Section 3(d) is largely derived from the definition contained in the European Union Directive 2004/27/EC, which provides: ‘The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy.’\(^{266}\)

There is the potential for linguistic confusion through the migration of such terms into patent law – guidelines could help resolve any problems.

V. Constitutional Law

In its petition before the Madras High Court, Novartis heavily relied upon the argument that Section 3(d) of the Patent Act 1970 (India) violated Article 14 of the Constitution of India because it was vague, arbitrary and conferred un-canalised powers upon the statutory authority. The litigation raises three distinct questions of constitutional law. The first set of issues is related to the question of contravention of Article 14 of the Constitution which concerns equality before the law. The second set of issues is about the discussions associated with the possibility of granting a declaratory relief under Article 32 of the Constitution of India. The third set of issues is about the right to life and its interpretation and application in this case.

A. Article 14 of the Constitution of India

Article 14 of the Constitution of India states:

14. Equality before law.—The State shall not deny to any person equality before the law or the equal protection of the laws within the territory of India.

The main grounds of the attack to the validity of the Section 3(d) of the Patents Act 1970 (India) were that, it was vague, arbitrary, and confers un-canalised powers on the statutory authority i.e. the patent office which was assigned quasi-judicial functions under the statute. Therefore, it should be struck down under the ‘equality’ clause enshrined in Article 14 of the Constitution. The petitioners submitted overlapping arguments in favour of their position to establish a case of contravention of the basis of the three grounds stated earlier. The petitioner argued that through the amended Section 3(d) under the Patents (Amendment) Act 2005 (India) ‘a further clause was added to the effect that the discovery of a new form of a known substance should result in the enhancement of a known efficacy of that substance and if it does not, then, it is not an invention’. Such a clause, according to the petitioners, was not part of the Patents Ordinance 2004 (India) and it had been added later without due deliberations.

Novartis alleged that in the absence of any guidelines in the Patents (Amendment) Act 2005 (India) regarding the exact interpretation and scope of terms such as ‘efficacy’ and ‘the enhancement of known efficacy’, an unguided discretion was vested with the statutory authority and therefore the amended section was bad in law. Furthermore, the explanation added at the end of Section 3(d) was also attacked on the same ground as it had also limited the scope of patentability. It was submitted that:

In other words, the submission is that, both the amended section as well as the Explanation to the amended section must prescribe in clear terms for the Authority constituted under the Act, the guidelines to decide in what circumstances it can be held that the discovery of a new form of a known

substance had resulted in the enhancement of the known efficacy of that substance and when the derivatives are found to differ significantly in properties with regard to efficacy. Though the expression “efficacy” has a definite meaning, yet, no definite meaning could be attributed to the expression “enhancement of the known efficacy” and “differ significantly in properties with regard to efficacy”. These expressions are ambiguous.268

In response to this contention, respondents submitted that in view of advancement of technology and rapid developments in scientific research, the legislators adopted a general expression and the statutory authority was left free to apply its mind to determine the interpretation of an impugned section in different cases. Therefore it would be unwise to insist upon a statutory interpretation of these terms as having regard to individual inventions; the patent office would determine whether the new form of a known substance had resulted in the enhancement of known efficacy.269

While deciding the matter, the court agreed with the petitioners that the amended Section 3(d) under the Patents (Amendment) Act 2005 (India) was substantially different from the one originally incorporated in the Patents (Amendment) Ordinance 2004 (India) and thus from the Patents Bill 2005 submitted to the parliament. The court also declared that the scope of Section 3(d) was wider and in no way was it limited to pharmaceutical products. However, the exception stated with this section was specifically designed for inventions related to the pharmacology field, namely drugs.270

After a careful examination of relevant facts the and arguments of the parties, the court rejected the plea of the petitioners that amended Section 3(d) was in violation of Article

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268 Ibid. 40.
269 Ibid. 41.
270 Ibid. 44.
14 of the Constitution of India. It was declared that the speeches made during the parliamentary debates and a statement of objectives and reasons associated with legislation was of less significance in the interpretation of a legal provision. The court relied upon an earlier judgment of the Supreme Court of India in *Aswini Kumar v. Arabinda Boss*,271 which held: ‘The Statement of Objects and Reasons appended to the Bill should be ruled out as an aid to the construction of a statute.’272

Therefore, the court rejected the contention of Novartis that the while adopting the amended Section 3(d), the legislator had ignored the spirit behind the introduction of this law contained in the Minister’s statement of objectives.

The court declared that such interpretation could not be construed to invalidate a provision of law which was duly approved by the legislator. Many cases were cited in this regard to reject the Novartis stance on this issue.273 It was then concluded that ‘it is not possible to sustain the arguments advanced by the learned senior counsels that having shown section 3(d) in a particular form in Ordinance 7/2004 and bringing it in a totally different form in Amending Act 15/2005, the amending section ex-facie stands in violation of Article 14 of the Constitution of India’.274

The court went further with the issue of interpretation and scope of the terms ‘efficacy’ and ‘the enhancement of known efficacy’, as it was a major argument of Novartis. The Madras High Court resolved this matter in terms of therapeutic efficacy by referring to the simple meanings of terms in different medical dictionaries. After determining the

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statutory scope of an ‘explanation’ in view of the established case law, the court declared that scientifically it was possible to show with certainty the properties of a substance. The court endorsed the opinion of the Additional Solicitor General, India: ‘The writ petitioner is not a novice to the pharmacology field but it, being pharmaceutical giant in the whole of the world, cannot plead that they do not know what is meant by enhancement of a known efficacy and they cannot show that the derivatives differ significantly in properties with regard to efficacy.’

The court also scrutinised the argument of Novartis that the Parliament should have provided and disputed terms in Section 3(d) in the light of previous case law and statutory interpretations. In view of Benilal v. State of Maharashtra and the Registrar of Co-operative Societies v. K.Kunjabmu, parliament could not foresee things that may arise in the future and ‘parliament expresses its object and purpose in general terms when enacting Statute’. Thus, the court concluded that the petitioners could not make a case under Article 14 of the Constitution:

It is not shown by the learned senior counsels appearing for the petitioners before us that in the exercise of the discretionary power by the Patent controller, any of the petitioner’s fundamental rights are violated namely, to carry on the trade or the petitioner stand singularly discriminated.

Finally on the issue of invalidity on the basis of Article 14 of the Constitution, the court differentiated the way in which both economic and social legislations could be

275 Ibid. 59.
278 Judgment of the High Court of Judicature at Madras in Novartis AG v Union of India (2006), 60.
279 Ibid. 73.
construed. In light of *R.K. Garg v. Union of India*\(^{280}\) the rule was highlighted that the laws relating to economic activities could be viewed with greater latitude than laws about civil rights such as freedom of speech. The *Patents Act 1970 (India)* could only be construed in this context as it had been amended over the periods keeping in view the economic conditions of the country. Therefore from the very beginning, the Parliament was aware about the change in the economic conditions of the country, which made them amend the earlier laws to suit the prevailing economic conditions. It was held that the petitioners failed to demonstrate any legal ground relating to equality before the law to invalidate the amended section.\(^{281}\)

**B. Declaratory Relief under Article 226**

Another dimension of the Constitutional debate was the possibility of issuing a declaration in this case which was filed under Article 226 of the Indian Constitution. Novartis presented a case that if the court could not strike down Section 3(d) of the *Patents Act 1970 (India)* on the basis of contravention of the *TRIPS Agreement 1994* then at least, as an alternative remedy, a declaratory relief could be pronounced to the effect that the impugned Section was inconsistent with the obligations of the agreement. The Petitioners stated that Section 3(d) of the *Patents Act 1970 (India)* as amended by the *Patents (Amendment) Act* (India), was invalid, illegal and unconstitutional on the grounds of contravention of Article 14 of the Constitution of India and the petitioners were entitled to a declaration.

The court addressed this issue mainly from a Constitutional perspective and it declared that the scope of declaratory relief in proceedings under Article 226 of the Constitution of India was limited to the situations where such relief could actually provide real


\(^{281}\) Judgment of the High Court of Judicature at Madras in *Novartis AG v Union of India* (2006), 82.
benefit to a party. Thus, in other cases where such relief has a mere notional value, the court should abstain from exercising its Constitutional jurisdiction.\(^{282}\) The Court established through the case law that the scope of declaration under Article 226 was quite limited; however, a court exercising its jurisdiction under the provisions of the Constitution could rely upon Article 32 to afford such a relief.\(^{283}\)

Then the High Court analysed the case law under Article 32 to determine whether a declaration could be issued on the Novartis application and noted that the Supreme Court of India had held that it would not hesitate to grant a declaratory relief under Article 32 of the Constitution of India where fundamental rights had been violated. After elaborating this standard, the court held that the amended Section 3(d) did not totally take away the right of the petitioner to carry out the business and trade in India and thus a case for declaration could not be established. Furthermore, petitioners were not satisfied with the amendments in a statute but ‘it is a settled position in law that nobody can compel the Parliament to enact a law’.\(^{284}\) Based upon this settled point, the court questioned the usefulness and utility of such a declaration even if the court could consider declaring that the amended provision was not in the discharge of India’s obligations under Article 27 of the TRIPS Agreement 1994. Thus, in view of *Katakis v. Union of India*\(^{285}\), a declaration could not be given where it would serve no useful purpose to the petitioner.

Some experts, however, view it differently. If a court is exercising discretionary powers under writ jurisdiction then it should keep in view the treaty obligations and make orders accordingly. In the words of Justice R. K. Abichandani: ‘While the role of

\(^{282}\) Ibid. 35.

\(^{283}\) Ibid. 30.

\(^{284}\) Ibid. 34.

\(^{285}\) *Katakis v Union of India* Writ Petition No. 54/68 of 28-10-1968 (Unreported)
judiciary is confined to the four corners of the statutory provisions governing the intellectual property rights, its discretionary powers enable it to legitimately take into account the ramifications that its discretionary orders would have in the context of the wider horizons of the intellectual property rights.\textsuperscript{286}

\textbf{C. Right to Health under Article 21}

The human rights based approach adopted in and around the Gleevec patent litigation had intensified the importance of the case throughout the world. Novartis claimed that its intellectual property right had been abridged and the case was filed to protect its strategic assets. The patient groups argued that an attempt to get a patent on imatinib would threaten their right to health by narrowing down the options to access affordable medicines. The submissions of one respondent, the Cancer Patients Aid Association, were quite conspicuous in this regard and they heavily relied upon the related provisions of the Indian Constitution and other international instruments.

In its written reply to the Novartis petition, the Cancer Patients Aid Association maintained that India was bound by a Constitutional duty to comply with the positive obligations of the right to health of its citizens including those affected by Chronic Myelogenous Leukemia (CML). In this regard reference was made to the right to life guaranteed under Article 21\textsuperscript{287} of the Constitution of India. It was also submitted that the non-availability and non-affordability of any form of Imatinib Mesylate to CML


\textsuperscript{287} Article 21. Protection of life and personal liberty.—No person shall be deprived of his life or personal liberty except according to procedure established by law.
patients would also violate the rights of the CML patients under Articles 14 and 21 of the Constitution.  

It is worthwhile mentioning that the Indian Constitution does not recognise the right to health as a fundamental right per se. However, the Supreme Court of India in *Vincent Panikurlangara v. Union of India*\(^{289}\) recognised the enforceability of the right to health within the scope of Article 21 of the Indian Constitution. Later, the Supreme Court through an expansive interpretation of Article 21 (right to life) in its landmark judgment of *Paschim Banag Khet Samity v. State of West Bengal*, declared that the right to life included the right to health and the right to emergency medical care.\(^{290}\)

In addition to their reliance upon the Constitutional provisions, the Cancer Patients Aid Association also referred to various international instruments to highlight India’s commitments and obligations to protect the health of its citizen’s by adopting favourable administrative and legislative measures. In this regard, Article 3 of the *Universal Declaration of Human Rights* states: ‘Everyone has the right to life, liberty and security of person.’ Article 25 (1) of the *Universal Declaration of Human Rights*, Article 6 of the *International Covenant in Civil and Political Rights (ICCPR)* to which India is a party and Article 12.1 of the *International Covenant on Economic, Social and Cultural Rights, 1976* (ICESCR) were specifically mentioned to establish India’s obligations in this regard. In *Vishakha v. State of Rajasthan*, the Supreme Court also declared that Article 21 of the Constitution of India had to be interpreted in the light of international instruments.\(^{291}\) Respondents also referred to the poverty profile of India

\(^{288}\) Affidavit for the Respondents No. 6 in the High Court of Judicature at Madras, Writ Petition No. 24759 of 2006, 12.

\(^{289}\) *Vincent Panikurlangara v Union of India* (1987 (2) SCC 165.


and the need to devise an intellectual property policy to stimulate the research and development in the best interests of poor and marginalised groups who are badly in need of affordable quality medicines.292

The judgment of the Madras High Court mainly deals with the legal and technical aspects of the dispute. However, the court could not fully avoid the appeal of such analysis and it had sporadically reflected upon those arguments by upholding the use of policy style reasoning to validate the contentious provision of a law. The court observed that:

Lengthy arguments have been advanced ... that India, being a welfare and a developing country, which is pre-dominantly occupied by people below poverty line, has a constitutional duty to provide good health care to its citizens by giving them easy access to life saving drugs. In so doing, the Union of India would be right, it is argued, to take into account the various factual aspects prevailing in this big country and prevent evergreening by allowing generic medicine to be available in the market. As rightly contended by the learned Additional Solicitor General of India, the Parliamentary debates show that welfare of the people of the country was in the mind of the Parliamentarians when Ordinance 7/2004 was in the House.293

Finally, concluding in its own words, the court stated that: 'We have borne in mind the object which the Amending Act wanted to achieve namely, to prevent evergreening; to


293 Judgment of the High Court of Judicature at Madras in Novartis AG v Union of India (2006), 70.
provide easy access to the citizens of this country to life saving drugs and to discharge their Constitutional obligation of providing good health care to its citizens.294

The statement is clear to the extent that a policy-style reasoning can be used to construe the scope and limitation of a law and public interest can play a vital role in this regard.

D. The Right to Health versus the Right to Property

It is pertinent to note that the petitioners did not argue along the same lines by raising the plea of right to property as compared to the respondents’ reliance on right to health. The reason perhaps is the fact that the Indian Constitution does not recognise the right to property as a fundamental right and Novartis could not rely upon the counter argument of fundamental right to property which it had raised in an earlier case in South Africa. On 18 February 1998, forty-two pharmaceutical companies including Novartis South Africa (proprietary) Limited brought an action before the High Court of South Africa against the Government of South Africa to challenge the constitutionality of some of the provisions embodied in the Medicines Amendment Act 90 of 1997.295 One of the grounds of this challenge was the violation of the right to property which was guaranteed as a fundamental right in the Constitution of South Africa which was adopted on 8 May 1996, and amended on 11 October 1996.

It was alleged that Section 15C of the Medicines Amendment Act 1997 authorised the Minister of Health, in conflict with Section 25 of the Constitution, to deprive owners of intellectual property in respect of pharmaceutical products and alternatively to expropriate such property without any provision for compensation to be paid in respect

294 Ibid. 80.

thereof. In response to this plea, South African governments relied upon the fundamental right to health to justify its action under the impugned legislation. As the case was finally settled out of the court, a determination on these competing interests could not be made.296

As compared to the South African situation, until 1978, the right to acquire, hold and dispose property was recognised as a fundamental right under the Indian Constitution by virtue of Article 19(1) (f). Under Article 31 of the Constitution this right could be deprived subject to various provisions of applicable law and the payment of adequate compensation. As part of its agenda of land reforms, the Indian Government sought to limit the jurisdiction of the courts in the cases of compulsory acquisition of property.297 Nevertheless, the Indian judiciary continued to interpret the right broadly.298 In Golak Nath v. State of Punjab, the Supreme Court held that fundamental rights including the right to property were part of an unamendable core of the Constitution.299 Subsequently the Congress was able to reform the area.300 Finally, by virtue of the Forty Fourth Amendment Act 1978, Article 19 (1) (f) and Article 31 were deleted from the

Constitution. Article 300-A provides the weaker, unenforceable right: ‘No person shall be deprived of his property save by authority of law.’

In this context, the reluctance of petitioners to address the respondents’ right to health argument through a counter plea of the right to property is fully understandable. Novartis mainly relied upon the argument of violation of its fundamental rights under Article 14 of the Constitution of India but the court rejected this plea stating that petitioners could not make a case under Article 14.

VI. Responses

The Novartis case has become a cause célèbre in the recent policy debates about the global harmonisation of patent regimes. The importance of the decision is evident from the immediate responses and comments to the announcement of the High Court’s verdict.

A. Government Responses

A day after the Madras High Court decision, Indian Commerce and Industry Minister Kamal Nath said that India’s patent laws were in conformity with the intellectual property rules laid down by the World Trade Organisation (WTO). Minister Nath told the press that: ‘Our patent laws are WTO compliant’ and it is ‘only one company that has raised its voice’. In April 2007, Indian Health Minister, Anbumani Ramadoss,

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urged Novartis to step back saying India had not used compulsory licensing yet and ‘shouldn’t be pushed towards that’.303

By contrast, the Swiss government announced that it would not pursue the allegation by Novartis that Indian patent law is incompatible with the TRIPS Agreement 1994 at the dispute settlement board of the World Trade Organisation (WTO). Doris Leuthard, Federal Councillor, Department of Economic Affairs of the Swiss Confederation said: ‘We accept any case settled in India. It is normal litigation, in which one party happens to be a company and another is a country.’304 It is worthwhile mentioning that Leuthard was in Delhi to sign a memorandum on cooperation in international property rights with India.305

It is important to note that the United States Trade Representative (USTR) and the European Union (EU) Trade Commissioner have not shown any response to the Novartis judgment. Traditionally, the USTR has always shown a great concern about the IP norms and enforcement in India and according to USTR 2007 Special 301 Report India will remain on the Priority Watch List in 2007. The Report highlights the concerns of the US government about inadequate IPR protection and enforcement in India.306 Likewise the EU Trade Commissioner has not commented on the Madras High Court judgment. In early 2007, at the height of the Gleevec dispute, Novartis was actively

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306 United States Trade Representative, 2007 Special 301 Report, (2007) [26].
lobbying the EU Parliament and urging its 785 members not to sign a written declaration opposing its stance on India’s 2005 patent law.\textsuperscript{307} Prior to that five Members of the European Parliament (MEPs) representing four parties issued a ‘declaration’ asking Novartis to drop the case and the European Commission and Council to take a position on it.\textsuperscript{308}

\textbf{B. Non-Governmental Organisations}

During the Novartis trial, several Non-Governmental Organizations (NGOs), working in the areas of humanitarian aid and public health, launched specific campaigns to support the action of the Indian Patent Office on Novartis patent application. On 7\textsuperscript{th} August 2007, four NGOs issued a joint statement welcoming the decision. The Cancer Patients Aid Association (CPAA), the Lawyers Collective HIV/AIDS Unit, the Delhi Network for Positive People (DNP+) and international medical humanitarian organisation Médecins Sans Frontières (MSF) said in a joint statement: ‘The landmark decision by the Madras High Court upholding India’s Patents Act in the face of the challenge by Swiss pharmaceutical company Novartis is a major victory for patients’ access to affordable medicines in developing countries.’\textsuperscript{309} In their joint statement these organisations hoped that India will continue to be the ‘pharmacy of the developing

\begin{footnotesize}
\begin{itemize}
\item Ed Silverman, ‘Novartis Woos EU Politicians’, \textit{Pharmalot}, March 21\textsuperscript{st} 2007
  

\item Tove Gerhardsen, ‘Opposition Gains Support Against Novartis Patent Lawsuit In India’, \textit{Intellectual Property Watch}, 15 February 2007,


\item NGO Statement on Patent Ruling: Joint Statement by CPAA, MSF, DNP+ and Lawyers Collective on Novartis Judgment the Cancer Patients Aid Association (CPAA), the Lawyers Collective HIV/AIDS Unit, the Delhi Network for Positive People (DNP+) and Médecins Sans Frontières,

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world' given the fact that developing countries and international agencies like UNICEF and the Clinton Foundation rely heavily on importing affordable drugs from India.310

Another alliance of international NGOs termed the decision an important victory for global public health and hoped that the decision would protect India’s special role as the world’s leading provider of affordable medicines to the poor. In a joint statement, CARE International and Oxfam International, and the church-based advocacy network, the Ecumenical Advocacy Alliance declared: ‘This ruling is a lifeline for the millions of people who cannot afford brand-name drugs, and ensures that essential medicines from India will reach those who rely on them.’311

Immediately after the challenge of the Indian Patent Office decision by the Novartis, MFS launched a campaign for the withdrawal of the case. The campaign was run with the help of several MSF partner non-governmental organisations, and massive lobbying efforts were made in the US, EU and Canada to solicit support for the Indian patent law. On August 6th 2007, a Press Release by the MSF, declared the Madras High Court decision a landmark judgment and a major victory for patients’ access to affordable medicines in developing countries. Dr Tido von Schoen-Angerer, Director of the MSF Campaign for Access to Essential Medicines commented: ‘This is a huge relief for millions of patients and doctors in developing countries who depend on affordable medicines from India.’312 In its Press Release MSF also reminded about the petition


312 Médecins Sans Frontières (MSF), ‘Indian Court Ruling in Novartis Case Protects India as the
‘Pharmacy of the Developing World’ (Press Release August 6, 2007) at http://www.msfaccess.org/about-
signed by over 420,000 people worldwide urging Novartis to drop the case because of the devastating impact Novartis' actions could have on access to essential medicines.

C. Response of Industry

Subsequent to the judgment issued by the Madras High Court, Novartis dissented that the decision will have long-term negative consequences for research and development into better medicines for patients in India and abroad. Ranjit Shahani, Vice-Chairman and Managing Director, Novartis India Limited expressed his disagreement with the ruling: ‘Our actions advanced this essential debate in India; now local and international leaders in both industry and academia recognize the inadequacies of Section 3(d) and are raising serious concerns about the deficiencies of the Indian patent system.’ He added: ‘Because India does not have strong intellectual property law, no company will launch their latest patent product as a result of this judgment.’ He was of the opinion that in the absence of a strong IP regime foreign companies will prefer to invest in China and he called on the WTO and the Indo-American Chamber of Commerce to push for stronger intellectual property laws.

Carrie Scott, a spokeswoman for Novartis International AG, said: ‘We disagree with this decision, and are considering our options.’ The Novartis spokesman further said

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313 Novartis Media Relations, ‘Novartis concerned Indian court ruling will discourage investments in innovation needed to bring better medicines to patients’ (Press Release 06-08-2207).
http://cws.huginonline.com/N/134323/PR/200708/1144199_5_2.html.

314 Sarah Hiddleston, ‘The Madras High Court rejects pharma major Novartis’ petition against a provision of the Indian patent law’, Frontline, 24(16), August 11-24, 2007,


316 http://corporate.lexisnexis.com/news/corporate-counsel,intellectual-
that the Gleevec patent has been granted in nearly 40 countries including China, Russia, Taiwan and Novartis firmly believe the same should be the case in India.

The Indian Pharmaceutical Alliance, a group of generic companies, has been relieved by the verdict. D.G. Shah, secretary-general of the Alliance said: ‘The court’s decision is a sigh of relief from expensive and lengthy litigation in the future, and allows companies to continue to market not only imatinib mesylate (Gleevec) but also other similar molecules for which patents are claimed for trivial changes in India.’ Yusuf Hamied, chairman of the Indian pharmaceutical company Cipla, also described it as a positive ruling. In a subsequent statement, the U.S. - India Business Council (USIBC) hoped that the Indian High Court’s decision in the Novartis case will encourage responsible debate and bring about changes in India’s laws to ensure that medical innovation is encouraged.

D. Editorials and Columns

Several newspaper editorials and columns devoted considerable attention to the Novartis decision and analysts have considered the future implications of the judgment. In a leading article contributed to *The Hindu*, an Indian daily, Feroz Ali suggests that

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the decision should be understood in an overall context by knowing what it permits and what it prohibits. He considers that section 3(d) is a trendsetter provision and nowhere in the world can such a provision be found in the patent legislation.\textsuperscript{320} It seems an overstatement as developing countries are increasingly following model patent laws developed by different NGOs which contain provisions similar to the Indian patent law. Feroz Ali further writes: ‘What section 3(d) actually does is to allow genuine improvements and at the same time bar frivolous “tweakings” which are passed under the garb of incremental innovation.’\textsuperscript{321}

A commentator in \textit{The Economic Times} criticised that some NGOs had given misleading statements after the decision and an impression has been given that the weakening intellectual property rights (IPRs) would magically give the poor the best drugs available. The authors noted: ‘This “patients not patents” campaign has a simplistic appeal but it undermines growth and it distracts attention from the real causes of ill health, delaying difficult reform where it is most needed.’\textsuperscript{322} The author argues that the patent debate had diverted attention from the barriers to access to healthcare such as health infrastructure, doctors and nurses and the patients are suffering from the current fixation with patents and prices.


\textsuperscript{321} Ibid.

The New York Times approached the decision with a caption: 'Setback for Novartis in India over Drug Patent.' It has noted that now Indian companies will be free to manufacture cheaper generic versions of patented medicines.

An editorial in The Wall Street Journal Asia criticised the patent policy of the Indian government which allowed the incorporation of some last minute loopholes in the patent law in 2005, which later provided the basis for the rejection of the Novartis patent application. The editorial noted that Indian patients and the drug manufacturers will be the losers in the wake of the High Court judgment. It further stated that: 'There’s a good reason why major pharmaceutical companies have set up shop in Singapore and China rather than on the Subcontinent.'

Praful Bidwai writing for the Inter Press Service revealed that, despite the Court’s verdict, the Indian government was planning to amend the patent law to encourage incremental innovation by pharmaceutical drug companies. In an article for The Economic Times Sanjeev Choudhary also confirmed this report when he stated: 'We are looking for ways to award patents for discovery of a new form of a known substance which results in the enhancement of the known efficacy of that substance.'

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326 Sanjeev Choudhary, ‘Novartis to divert India investment after patent case The Economic Times-India’, The Economic Times, August 9, 2007.
VII. Conclusion

The judgment of the Madras High Court not only establishes the validity of Section 3(d) of the *Patent Act 1970* (India) but also sets the tone of judicial response to the question of interpretation of patentability criteria in India. The case has been an influential precedent. The Kolkata patent office has rejected Eli Lilly’s patent application for Forteo, an osteoporosis drug after hearings on a pre-grant opposition filed by the domestic drug manufacturer USV Ltd. The application was rejected on the grounds of prior knowledge, incremental innovation and the failure to establish enhancement of known efficacy.\(^3\) Abbott Laboratories also faced opposition proceedings on the same grounds for its application to patent Aluvia, a ‘heat stable’ form of an antiretroviral drug, consisting of Lopinavir and Ritonavir.\(^3\) The High Court has appropriately suggested that the meaning of the terms ‘efficacy’ and the ‘enhancement of known efficacy’ could be judged in light of the therapeutic effect of the new form. So, the burden of proof is on the applicant to show the enhanced efficacy. This may help in reducing the possibility of evergreening but the patent office should develop some guidelines to sustain its practices in future by setting aside the possibilities of any misuse of powers under the relevant clauses.

On the issue of international law compliance and the jurisdiction of national courts, the judgment highlights the need to adopt a proactive engagement strategy to interpret the law cohesively in the light of treaty obligations and national policy objectives. The *TRIPS Agreement 1994* assumes a critical role in the national courts for the enforcement of obligations under the agreement, and the courts should respond to this duty by


devising appropriate interpretations. Nonetheless, the judgment will assist in maintaining the current flow of Indian drugs exports to poor patients in many developing countries across the world.
Chapter 4

The Pfizer-Natco Controversy:
Indian Patent Law and Compulsory Export Licences

Injurious Commissions also include severely restrictive – and inefficient – trade barriers that curb exports from poorer countries.

Amartya Sen, *Identity and Violence*329

I. Introduction

A 2005 publication of UNAIDS, *AIDS in Africa: Three Scenarios to 2025*, contains several moving stories about HIV/AIDS in Africa, describing how the AIDS epidemic in Africa could evolve over the next 20 years.330 The scenarios set out to answer one central question: over the next 20 years, what factors will drive Africa’s and the world’s responses to the AIDS epidemic, and what kind of future will there be for the next generation? Amongst the various aspects of the problem, access to and uptake of AIDS treatment is discussed and highlighted throughout the document. The publication highlights how crucial Indian pharmaceutical exports are for the treatment of the HIV/AIDS epidemic in Africa.

African nations and many other developing countries require access to essential medicines to address public health concerns. The creation of a safe, secure and reliable access to an essential medicines regime depends upon a number of factors ranging from mobilisation of resources to administration of drugs to those who badly need them in extreme poverty situations. Factors such as resources prioritisation, adequate


procurement policies, supporting infrastructure and trained personnel are definitely very crucial for any successful essential drugs program. However, the most critical factor is the very availability of the medicines which could then be provided to those who need them. The most crucial and the daunting barrier increasingly faced in this regard is the accessibility to safe and affordable medicines to keep up the life expectancy trajectory of millions of poor patients around the world.

According to available research, Indian generic pharmaceutical companies provide a major portion of pharmaceutical products which are procured by various international and regional organisations for their treatment projects related to HIV/AIDS, malaria and tuberculosis. The following table shows the list of top ten suppliers of Antiretroviral (ARV) drugs under the Global Fund’s procurement program.

**Table 4.1: Top Ten Suppliers of ARVs under Global Fund in Terms of Consignments (June 2003-Jan 2006)**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Total No. of Consignments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cipla Ltd.</td>
<td>342</td>
</tr>
<tr>
<td>Aspen Pharmacare</td>
<td>221</td>
</tr>
<tr>
<td>Bristol Myers Squibb</td>
<td>158</td>
</tr>
<tr>
<td>GlaxoSmithKline Ltd.</td>
<td>144</td>
</tr>
<tr>
<td>Abbott Laboratories</td>
<td>88</td>
</tr>
<tr>
<td>Merck</td>
<td>73</td>
</tr>
<tr>
<td>Ranbaxy Laboratories</td>
<td>45</td>
</tr>
<tr>
<td>Hetro Drugs Ltd.</td>
<td>35</td>
</tr>
<tr>
<td>Roche</td>
<td>32</td>
</tr>
<tr>
<td>Boehringer Ingelheim</td>
<td>25</td>
</tr>
</tbody>
</table>

Source: Global Fund as cited by Biswajit Dhar

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332 Biswajit Dhar and K.K. Gopakumar, ‘Post-2005 TRIPS scenario in patent protection in the pharmaceutical sector: The case of generic pharmaceutical industry in India’ (2006), UNCTAD, IDRC and ICTSD, 57 at http://www.measwatch.org/autopage/file/MonMarch2009-14-25-16-
This chapter contends that the compulsory licensing mechanism for exports under the *Waiver Decision 2003* lacks efficacy. It argues that the Indian compulsory licensing regime fails to facilitate affordable drug supply to other developing countries, because of the rigidity and complexity of treaty rules; economic considerations; technological constraints and capacity; and a fickle lack of political commitment. The main hypothesis extended is that without a viable, affordable and continuous generic supply from India, the success of *Doha Declaration 2001* would be substantially compromised.

Part II of this chapter deals with the key provisions in the *TRIPS Agreement 1994* dealing with the exports of pharmaceutical drugs. Part III considers the *Doha Declaration 2001* and the subsequent *Waiver Decision 2003*. Part IV considers the various species of compulsory licensing under Indian patent law. Part V considers the first Indian compulsory licensing instance under the new law and the Natco’s application for the grant of compulsory licences of Tarceva and Sutent.

**II. The TRIPS Agreement 1994 and Pharmaceutical Exports**

Before the adoption of the *TRIPS Agreement 1994*, developing countries were largely free to determine the scope, term and availability of patent protection as a part of their overall industrial and public health policy objectives. Although many developing countries were members of the *Paris Convention for the Protection of Industrial Property of 1883 (Paris Convention 1883)*, they retained the flexibility to legislate on domestic pharmaceutical production and access to essential medicines. In terms of substantive rule-making, patentable subject matter, local usage and enforcement measures, the *Paris Convention 1883* leaves considerable space for Member States to
devise and implement their own patent systems. Indeed, it even allows Member States to deny protection for certain subject matters such as pharmaceutical products.

However, under the *TRIPS Agreement 1994*, all Member States are now required to comply with the minimum standards set out in the treaty. The obligations of the *TRIPS Agreement 1994* include the extension of patent protection to all qualifying inventions without the discrimination of any field of technology and origin of subject matter.\(^{339}\)

Thus the developing countries were obligated to extend patent protection to pharmaceutical products pursuant to the requirements of the *TRIPS Agreement 1994*. Since the expiry of the limited transition period in 2005, the situation has radically changed in developing countries and they have introduced new laws and governing regulations dealing with the patentability of medicines and related components. In 1994, India decided to take advantage of the transitional period allowed under the *TRIPS Agreement 1994* for developing countries, which ultimately ended in 2005.

The *TRIPS Agreement 1994* recognises the right of member countries to issue compulsory licences subject to procedural requirements laid down in Article 31. However, the option of invoking Article 31 flexibilities to meet public health objectives had no real meaning for many developing and least developing countries because they lacked any local pharmaceutical manufacturing capabilities. The problem is directly linked with the language of Article 31(f) of the *TRIPS Agreement 1994* which, after initially allowing the grant of a compulsory licence, restricts the operation of this option by stating:

\[(f) \text{ any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;}\]

\(^{339}\) Article 27.1 of the *Agreement on Trade Related Aspects of Intellectual Property Rights* (The TRIPS Agreement 1994) at [http://www.wto.org/english/tratop_e/trips_e/t_agm4_e.htm#Footnote13](http://www.wto.org/english/tratop_e/trips_e/t_agm4_e.htm#Footnote13).
However, in practice, many developing and least developing countries lacked sufficient manufacturing capacity for the production of highly advanced and technologically sophisticated medicines to address public health epidemics. They did not have even a possibility of getting cheaper medicines from India, China or Brazil under a compulsory licence because any such production in these countries was supposed to be predominantly for the supply of the local market and only a fraction of total produce was allowed to be exported to the countries which mainly needed these drugs.

The WTO Ministerial Conference adopted the *Doha Declaration 2001*\(^{340}\) in November 2001. This was the product of an extensive lobbying effort of international humanitarian organisations, NGOs and the governments of developing and least developing countries. The *Doha Declaration 2001* reaffirmed the flexibilities built into the *TRIPS Agreement 1994*, including the right of Member States to issue compulsory licences on public interest grounds.\(^{341}\) The Declaration then specifically addressed the problem of Member States lacking the capacity to manufacture cheaper generic substitutes and which are otherwise not capable of exploiting the flexibilities under the existing Article 3(f) requirement. Paragraph 6 of the *Doha Declaration 2001* mandated the relevant WTO body to work out a suitable solution, keeping in view the limitations of such countries with an aim to ensure access to essential medicines.\(^{342}\)

After almost two years of extensive discussions at WTO a solution, initially embodied in the form of a Waiver, was reached on 30 August 2003 (*Waiver Decision 2003*).\(^{343}\)


\(^{341}\) Ibid. Paragraph 5(b).

\(^{342}\) Ibid. Paragraph 6.

the light of various proposals and discussions, it was decided that this Waiver Decision 2003 would be rendered as permanent in the form of an amendment to the TRIPS Agreement 1994 as Article 31bis.\(^{344}\) The ratification of the proposed amendment is still pending while Member States consider their options. Meanwhile the waiver reached on 30 August 2003 is effective and would continue to operate. The Waiver Decision 2003 and the Protocol amending the TRIPS Agreement 1994 are summarised in the following section along with a brief analysis of some provisions.

III. The Waiver Decision and Proposed Article 31bis

In 2001, paragraph 6 of the Doha Declaration 2001 recognised that the countries with limited or virtually no manufacturing capacity in the pharmaceutical sector had difficulties in invoking the compulsory licensing mechanism set out in Article 31 of the TRIPS Agreement 1994. Subsequently based upon the mandate of the Doha Declaration 2001, the WTO General Council’s Waiver Decision 2003 paved the way to allow countries with sufficient manufacturing capacity to make and export pharmaceutical products to countries which require such medicines for public health needs. This objective is achieved through a mechanism whereby restriction of Article 31(f) is waived for the exporting countries (by relaxing the requirement of manufacturing predominantly to the supply of domestic market), and restriction of Article 31(h)\(^{345}\) is waived for importing countries. Proposed Article 31bis essentially reflects the terms of the Waiver Decision 2003 by establishing the waiver of certain obligations of the TRIPS Agreement 1994 as mentioned earlier.


\[^{345}\]Remuneration requirement is explicitly waived. This aspect is discussed further hereafter.
A. Scope and Coverage of Diseases

Paragraph 1 of the *Waiver Decision 2003* defines ‘pharmaceutical product’ broadly without limiting application of the solution to certain specific diseases. It reads:

(a) “pharmaceutical product” means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included.346

The definition is sufficiently broad as active pharmaceutical ingredients (APIs) and diagnostic kits are expressly covered. The definition is also sufficiently broad to cover vaccines because vaccines are ‘products of the pharmaceutical sector’.

The negotiations prior to the adoption of *Waiver Decision 2003* were quite extensive with regard to the scope and coverage of diseases to be covered under the proposed mechanism. The United States proposed to restrict the candidate list of diseases to HIV-AIDS, malaria, tuberculosis and a relatively small group of infectious diseases. The US proposal also sought to limit the countries that would benefit from the solution and considered it to be the Ministers’ intention at Doha.347 At some later stage of negotiations, the EC had demonstrated a relatively more flexible approach and suggested that the solution be confined to grave public health problems and a potential

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role of WHO was also mentioned to identify such grave situations.\(^\text{348}\) On 28 January 2003, India together with several developing countries submitted that they would not accept the USA and EC proposals as they would narrow down the scope of paragraph 1 of the Doha Declaration.\(^\text{349}\)

India’s position prevailed. Paragraph 1 of the *Doha Declaration 2001* does not mention any limitation on the application of the Declaration to certain specific diseases or medicines and the position of developing countries was finally reflected in the *Waiver Decision 2003*. The proposed Article 31bis mirrors this stance.

**B. Notification Requirement and Eligible Countries**

Both the *Waiver Decision 2003* and the proposed Article 31bis contemplate two important notification requirements. The first is a general notification of intent which is required from all importing member countries that use the system, other than least developing countries.\(^\text{350}\) The group of members belonging to least developing countries are thus free to invoke the mechanism without any notification of intent. The second notification requirement is with regard to exporting member countries when they consider exporting pharmaceutical products manufactured under compulsory licensing system. The mechanism also provides that any Member State may notify the *TRIPS Council* that it does not intend to use the system as an importing country or that it only intends to use it in a limited way. Almost all OECD countries have practically opted out by notifying their intention not to use the system or to use it in a limited way.\(^\text{351}\)

\(^{348}\) Ibid.

\(^{349}\) Ibid. 3


\(^{351}\) Ibid. Footnote 3 to Paragraph 1(b).
number of Member States (Hong Kong, China, Israel, Kuwait, Macao Chian, Mexico, Qatar, Singapore, Chinese Taipei, Turkey and the United Arab Emirates) notified their intention to use the system only in cases of national emergency or other circumstances of extreme urgency.\textsuperscript{352} By analogy, one can construe that other non-notifying Member States may then use the system liberally in situations other than national emergency or circumstances of extreme urgency.

On 19 July 2007, Rwanda became the first WTO Member State which notified its intention to use the system to import some 260,000 packs of TriAvir, a fixed-dose combination product of Zidovudine, Lamivudine and Nevirapine, from a Canadian pharmaceutical firm Apotex, Inc.\textsuperscript{353} It is pertinent to note that Rwanda had no obligation to notify as such being a designated least developing country and it was eligible to use the system without following any procedural formalities. However, a notification requirement is imposed upon the potential exporting WTO Member States pursuant to paragraph 2(c) of the \textit{Waiver Decision 2003}. In response to the request of Rwanda, the Canadian Government notified the TRIPS Council of the terms of the export licence it had issued in this regard.\textsuperscript{354} Some commentators have criticised the elaborate and lengthy procedural notification procedure in the Canadian regime.


C. Determination of Manufacturing Capacity

According to Article 31bis least developing countries are automatically eligible to import medicines under the system envisaged in this regard. In addition to this, any country making a determination that it has insufficient or no manufacturing capacity of a particular pharmaceutical product, can also become an eligible importing state.\textsuperscript{355} This Article further provides that the determination of manufacturing capacity in this regard by the importing country excludes the production facilities which are owned or controlled by the patent holders. It states:

Where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply.\textsuperscript{356}

The language of the Article 31bis about the definition of pharmaceutical product and determination of manufacturing capacity would be helpful for a developing country that wants to use this system merely to import pharmaceutical products to manufacture medicines locally for justified public health needs.


\textsuperscript{356} Ibid. Appendix to Annexure.
D. Licensing Scheme

Both the Waiver Decision 2003 and proposed Article 31bis detail the procedural and substantive requirements that deal with the issuance of compulsory licences by importing and exporting countries.

As an importing country, members from least developing countries are entitled to use the system without meeting any notification requirement. Thus, these countries can use the system without issuing domestic compulsory licences which is otherwise required under the scheme. Likewise, any other Member State, where the desired medicine is not patented, can also use the system without issuing a compulsory licence. In all other cases, countries which are willing to use this system must issue a compulsory licence prior to importation and it must notify the TRIPS Council of such intention.357 The conditions which are generally set out in Article 31 of the TRIPS Agreement 1994 should be complied with while the countries consider the option of issuing compulsory licence. So the solution evolved through the Waiver Decision 2003 and the proposed Article 31bis should be construed and applied in conjunction with other substantive requirements of the TRIPS Agreement 1994 unless specifically waived. The issuance of a compulsory licence itself entails several procedural and administrative complications within the overall scheme of the TRIPS Agreement 1994 and it has yet to be seen how developing countries will overcome those legal and administrative barriers to implement the Waiver Decision 2003 in an effective and efficient way. However, Article 31 does not attempt to limit in any way the grounds upon which compulsory licences may be issued and its procedural requirements can be incorporated in domestic legislation in a way which would supplement the flexibilities designed under Article 31bis.

357 Ibid. Paragraph 2(a) (iii).
Article 31bis also suggests some disclosure obligations on importing country in terms of identification of product(s) and expected quantities to be imported. This should be notified to the TRIPS Council.358 This aspect has been specifically criticised by some commentators for being too restrictive and inhibitive as an exact determination of expected quantity can be unviable both practically and economically. Furthermore, no model exists to satisfy such procedural requirements and it may put the willing Member States in an unending exercise of monitoring and evaluation.359 Some commentators do not consider it a critical obstacle and suggest that the proposed Article 31bis does not demand a particular fixed formula, and there are various possibilities for complying with this obligation in efficient and innovative ways.360 In order to facilitate the usage of complex notification and determination procedure, a World Bank study in 2005 developed some model forms which Rwanda had used in 2007 to notify the WTO about its intention of using Waiver Decision 2003.361

The proposed Article 31bis and the Waiver Decision 2003 would also regulate the conditions for issuing a compulsory licence for exporting Member States.362

358 Ibid. Paragraph 2(a) (1).
authorised manufacturer from the exporting country can only manufacture and export the required quantities which the importing country has notified earlier.\textsuperscript{363} On the insistence of developed countries, the so called safeguards against diversion are also enumerated in this regard which requires that the product should be clearly identified as having been produced under this system. This may involve special packaging, labelling, special shaping or colouring provided that the distinctions are feasible and do not significantly affect price.\textsuperscript{364} Further conditions are put on the licensees to post destination and identification information on a website.\textsuperscript{365}

Non-governmental organisations, international humanitarian organisations and academics have criticised the bureaucratic approach of the \textit{Waiver Decision 2003} and the Article 31\textit{bis}.\textsuperscript{366} A 2006 report of \textit{Médecins Sans Frontières} (MSF) notes:

Prolonged prior negotiations severely limit the ability to use the August 30th Decision and act as a disincentive to manufacturers to participate in the process ... Anti-diversion measures that generic companies must comply with are onerous and are further disincentives to their participation in the process.\textsuperscript{367}

\textsuperscript{363} Ibid. Paragraph 2(b) (i).
\textsuperscript{364} Ibid. Paragraph 2(b) (ii).
\textsuperscript{365} Ibid. Paragraph 2(b) (iii).

\textsuperscript{367} \textit{Médecins Sans Frontières} (MSF), \textit{Neither Expeditious, Nor A Solution: The WTO August 30th Decision Is Unworkable: An illustration through Canada’s Jean Chrétien Pledge to Africa}, Prepared for
Highlighting the need for a viable and robust supply of pharmaceutical drugs, the report also considered the challenging task of manufacturing and supplying under compulsory licensing arrangement. In this regard, the MSF report complains that ‘the Decision flies in the face of the practical reality of managing a health programme, where flexibility and rapidity of response to ever-changing circumstances are vital’. Some commentators have suggested that procurements strategies can incentivise the potential supplier and such policies can be used to overcome the problem of limited demand.

**E. Remuneration and Non-Authorised Importation**

Article 31bis provides that adequate remuneration need only be paid in the country of export by taking into account the economic circumstances of the importing country. The system requires the importing countries to take reasonable and proportionate measures to prevent diversion or re-exportation of medicines supplied under this arrangement. The proposed Article 31bis obligates Member States to enable patent holders to protect themselves against unauthorised importation of pharmaceutical products manufactured under the system, but no additional legislative or administrative measures are required in this regard.

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368 Ibid. 4.


371 Ibid. Paragraph 3.

F. **Regional Arrangements**

As the group of least developing countries from Africa was quite instrumental behind the development and adoption of the *Doha Declaration 2001* because of limited drugs manufacturing capacity within the region, the final solution addresses the need of such countries in a somewhat specialised and preferential way. The proposed Article 31bis contains a special provision for Member States that belong to regional trade agreements of which at least half the members are currently least developing countries.\(^{373}\) For such a regional group, a relaxation is designed with regard to re-exportation to a member country once the product is manufactured and exported to one country under the compulsory licence. However, importing countries have not been discharged from the obligation of issuing separate compulsory licences where otherwise applicable.\(^{374}\)

G. **Implementation and Ratification**

The *Waiver Decision 2003* was adopted after much deliberation and difficult negotiations and it was hoped that it would open a window of opportunities for least developing countries to boost their public health coverage programs. With the finalisation of the Protocol of Amendment in the form of Article 31bis, commentators were keen to look at the practical aspects of the new system as there were a number of concerns regarding the cumbersome nature of the proposed solution. To date, thirty-one countries including *European Communities* have notified their acceptance of the proposed amendment of the *TRIPS Agreement 1994*.\(^{375}\)

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\(^{373}\) Ibid. Paragraph 3.

\(^{374}\) Ibid.

\(^{375}\) These countries include United States (17 December 2005), Switzerland (13 September 2006), El Salvador (19 September 2006), Rep. of Korea (24 January 2007), Norway (5 February 2007), India (26 March 2007), Philippines (30 March 2007), Israel (10 August 2007), Japan (31 August 2007), Australia
However, the export scheme was not used until July 2007 when one least developing country, Rwanda, notified its intention to benefit from the scheme set out initially in the *Waiver Decision 2003.*

The proposed Article 31*bis* would be rendered permanent in the form of an amendment to the *TRIPS Agreement 1994* once it is ratified by two-thirds of WTO members. By the December 2007 deadline, only 13 of 151 WTO countries had ratified it. The WTO pushed back the ratification deadline to December 2009 and in the meanwhile, the 2003 waiver remains in effect. With thirty-one countries accepting the proposed amendment in September 2010, it is anticipated that the Article 31*bis* would not be included into the *TRIPS Agreement 1994* in the wake of growing criticism and opposition of civil society organisation, and the situation may continue to be governed under the *Waiver Decision 2003.* Moreover, there is some confusion about the status of the acceptance notification of the European Communities and individual community members have yet to notify their intentions.


Most of the non-governmental organisations, humanitarian agencies and independent experts consider the system is defective in its design and modalities and it is extremely difficult for potential Member States to invoke it to meet their public health needs. They maintain that conditions associated with the issuance of licences, notification requirements, the so-called safeguard clause and anti-diversion measures have unnecessarily over-burdened the system and it is very hard for least developing countries to overcome these barriers. James Love of the Consumer Project on Technology wrote about the *Waiver Decision 2003*: ‘The new agreement has very modest benefits, and it has very substantial costs, risks and uncertainties.’

This view is further augmented by the European Generic Medicine Association (EGA) declaring that WTO compulsory licensing system is unworkable and will not improve access to medicine. Mr Greg Perry, Director General of the EGA expressed his views recently at the WTO Public Forum 2008 and said: ‘The WTO’s 2003 August 30 Decision concerning compulsory licenses is complicated, unworkable and unable to deliver any significant improvement in access to medicines.’

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13(2) *Journal of International Economic Law* 459-473.


However, Frederick Abbott and Jerome Reichman construe the terms of the new system in a positive way suggesting that a better trade-off deal was practically not possible given the political and structural environment of trade negotiations at that time. They consider that most of the procedural requirements set out in the new system can be intelligently managed within national laws and willing Member States can overcome potential problems through pooled procurement strategies and innovative decision-making.382

However, in the light of theoretical analysis and the two cases (Rwanda and India), it is hard to construe the Waiver Decision 2003 as a positive measure which can solve the problem of access to medicine. The decision is cumbersome and rigid and beyond its textual constraints, it also restricts the economic incentive which is essential to maintaining a manufacturing base.

IV. Indian Compulsory Licensing Regime

After the series of sporadic amendments, India finally brought its patent law into conformance with the TRIPS Agreement 1994 through the Patents (Amendment) Act 2005 (India). It is important to see that India has incorporated the spirit of the Waiver Decision 2003 in its domestic law to facilitate the smooth flow of generics export to other countries. The Waiver Decision 2003 is merely an international instrument and its real potential will be demonstrated once put into operation under domestic laws and regulations. Through the Patents (Amendment) Act 2005 (India), India has supposedly provided some robust and strong compulsory licensing avenues which yet need to be tested practically to judge its effectiveness.

The principal provisions dealing with compulsory licensing consist of Section 84, Section 92 and Section 92A of the *Patents Act 1970 (India)*. In addition to this, Section 11A also provides a mechanism for automatic compulsory licensing in certain cases. Here, I am focusing on the compulsory licensing provision relevant to pharmaceutical exports.

**A. Section 92A: Doha Style Compulsory Licence**

The *Patents (Amendment) Act 2005 (India)* introduces a third compulsory licensing avenue which reflects the WTO *Waiver Decision 2003* in domestic law. Section 92A provides for compulsory licences to enable exports of pharmaceutical products to those countries with no manufacturing capacity of their own. It states that:

Compulsory licence shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory licence has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India. The Controller shall, on receipt of an application in the prescribed manner, grant a compulsory licence solely for manufacture and export of the concerned pharmaceutical product to such country under such terms and conditions as may be specified and published by him.\(^{383}\)

This Section also defines the term ‘pharmaceutical product’ in line with the language of the *Waiver Decision 2003* and the proposed Article 31bis and includes ‘any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address public health problems and shall be inclusive of ingredients

\(^{383}\) Section 92A(1) and (2) of the *Patents Act 1970 (India).*
necessary for their manufacture and diagnostic kits required for their use. An application for the grant of a compulsory licence under this Section can be filed at any time after a patent has been issued.

Section 92A provides a relatively flexible and fast track Doha style licensing mechanism in view of the Waiver Decision 2003 and the adoption of subsequent national laws in many Member States such as Canada, China, Norway and the European Union. It necessarily reflects the spirit of the Waiver Decision 2003 and employs a less restrictive language and procedural requirements to issue a compulsory licence. For instance, Indian law does not explicitly require as a pre-condition that an importing country should have issued a licence before Indian law comes into action, and it merely puts the condition of a notification or otherwise to allow exportation of patented medicines. This provision was first introduced through the Patents Ordinance 2004 (India) and at that time it required that the exporter obtain a compulsory licence from the importing country as well. However, this requirement was later dropped to accommodate situations where no such patent exists in the importing country and a notification would suffice in such cases.

The Section is completely silent about the requirements of specifying the amount of pharmaceutical products that will be manufactured under compulsory licence which is an important procedural aspect of the Waiver Decision 2003. Likewise, no requirements are mentioned with regard to separate packaging, colouring or shape. It is important to note that no such guidelines are currently under consideration when the Indian Patent

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384 Ibid. Explanation.

385 Ibid. No post grant waiting period is maintained under this Section unlike Section 84 of the Act.

Office is finalising its *Manual of Patent Practice and Procedure*. This particular Section was scrutinised recently when the Indian generic manufacturer Natco applied for a compulsory licence for Roche's patented medicine, Tarceva, for export to Nepal.

B. Section 11A: Automatic Compulsory Licences

India was among those developing countries which opted to enjoy the full transition period allowed under the *TRIPS Agreement 1994*. Thus until 2005, India was not granting product patents for pharmaceutical and agro-chemical products and, in lieu, it had established a mailbox mechanism to determine priority matters in the post-2000 scenario. By virtue of this mailbox facility, applications would be judged for 'novelty' on the basis of the filing date and not with reference to 2005, the year in which product patents were first incorporated into the patent regime. The *Patents (Amendment) Act 2005 (India)* provides that where a patent is granted to any of those mailbox applications, an automatic compulsory licence would issue to those generic companies that made a 'significant investment' and were 'producing and marketing' a drug covered by the mailbox application prior to 2005. Such licence is subject to the payment of a reasonable royalty.

There has been much discussion about the Indian compulsory licensing regime and a range of positions can be identified in this regard. First, the Pharmaceutical Research and Manufacturer of America (PhRMA) in its 2008 submission to USTR termed the Indian compulsory licensing provisions as one of the most damaging provisions of the Indian Patent Law. Second, some commentators consider that the Indian export

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388 Section 11A Proviso of *Patents Act 1970 (India)*.

389 Pharmaceutical Research and Manufacturer of America, 'Special 301 Submission 2008', February 11,
oriented compulsory licensing regime is the broadest in scope when compared with other jurisdictions and thus ‘widespread use of the Section 92A avenue for compulsory licensing to export patented medicines appears likely’.390

However, I would argue here that the Indian compulsory licensing provisions under Section 92A should be understood and analysed both in a legal and factual context. A study undertaken for WHO shows that very few Indian pharmaceutical companies think that the Indian patent law provides an economically lucrative option for them to retain their export sales. Of the 103 firms, only 25 firms thought it was an economically lucrative option, whereas 78 firms did not think so. It is important to note that out of 25 firms which responded positively, only 6 firms have a strong technological base to meet export market demand on a sustainable basis.391

V. Tarceva and Sutent Compulsory Licences

The Indian compulsory regime has been tested by two separate compulsory licence applications for anti-cancer medicines involving Tarceva and Sutent.


A. Erlotinib hydrochloride (Tarceva)

Erlotinib which is marketed by Genentech, OSI Pharmaceuticals and Roche in different parts of the world under the brand name Tarceva, is prescribed for the treatment of non-small cell lung cancer and pancreatic cancer. It is basically a small molecule human epidemic growth factor type 1/epidermal growth factor receptor inhibitor which was approved in November 2004 by the U.S. Food and Drug Administration (FDA). The drug is primarily developed by OSI Pharmaceuticals and later business and marketing partnerships were developed with Genentech and Roche. Now OSI Pharmaceuticals and Genentech are marketing the Tarceva brand in the United States, and elsewhere it is marketed by Roche. After its marketing approval in 2004, Tarceva did quite well in the global oncology market by generating substantial revenue for marketing companies.

In its Business Report 2007, the Roche Group declared Tarceva among its top selling pharmaceutical products with sales of 1,062 million Swiss Francs. The Report indicates a 31% annual increase in sales. Genentech markets this drug jointly with OSI Pharmaceutical and in 2007 it reported US $417 million sales with a steady annual growth since 2006. For OSI Pharmaceuticals, Tarceva stands as the single most important drugs for business and revenue purposes. In 2007, it reported revenues of $340 million (up 41% on the prior year) and it was observed:

The business continues to be anchored around our flagship anti-cancer therapy Tarceva® which, just three years after the November 2004 approval in non-small

392 U.S. Food and Drug Administration Consumer Information at http://www.fda.gov/cder/consumerinfo/druginfo/Tarceva.HTM.


cell lung cancer (NSCLC), exited the year with fourth quarter global sales of $250 million – an annualized run-rate of $1 billion, the recognized industry-wide metric of a blockbuster.395

B. Tarceva Patents

OSI Pharmaceuticals and Roche secured the patents of erlotinib (the active pharmaceutical ingredient of Tarceva) in the United States, Europe, Japan, and number of other countries. Indeed, Roche claimed in India that patents related to Tarceva had already been filed in more than 80 countries and in almost 50 countries it was granted.396 In the United States, the Orange Book data shows two patents related to Tarceva which would respectively expire on March 30, 2015 (Patent No. 5747498) and November 9, 2020 (Patent No 6900221).397 In addition to this, OSI Pharmaceuticals was granted patent term extension certificates which extend the United States patent to November 2018 and a corresponding patent in Europe to March 2020.398 Further patenting activity is expected around Tarceva given its emerging importance and ongoing research regarding the possibility of future use of the same molecule for pipeline products. OSI Pharmaceuticals states in this regard:


397 Approved Drug Products with Therapeutic Equivalence Evaluations in Electronic Orange Book at http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=021743&Product_No=001&table1=OB_Rx

We are also currently pursuing U.S. and international patents for new inventions concerning various other formulations of erlotinib and related intermediate chemicals and processes in an effort to enhance our intellectual property rights in this compound. We have obtained a patent covering a key polymorphic form of Tarceva in the United States, which expires in 2020. We are also currently seeking patent protection for additional methods of use for Tarceva, including the use of Tarceva in combination with other compounds.\(^{399}\)

In India, Pfizer Inc. USA and OSI Pharmaceuticals jointly filed an Tarceva patent application on 30\(^{th}\) March 1995. The invention claimed in the patent application was related to ‘Quinazoline Derivatives Compounds and Composition thereof’ with initially 27 claims.\(^{400}\) It is worthwhile mentioning that the corresponding US patents showed a broader claim strategy where 79 claims were made under United States Patent No. 6,900,221.\(^{401}\) The other US patent related to Tarceva contains 32 claims.\(^{402}\) However, realising the very broad scope of claims made in Patent No. 5,747,498 which may  

\(^{399}\) Ibid.


\(^{401}\) Norris, Timothy et al (2005), ‘Stable polymorph on N-(3-ethynylphenyl)-6, 7-bis (2methoxyethoxy)-4-quinazolinamine hydrochloride, methods of production, and pharmaceutical uses thereof’, US Patent No: 6,900,221 at http://patft.uspto.gov/netacgi/nph-

Parser?Sect1=PTO1& Sect2=HITOFF& d=PALL&p=1&u=%2Fnetahtml%2FPTO%2Fsrchnum.htm&r=1 &f=G&l=50&s1=6,900,221.PN.&OS=PN/6,900,221&RS=PN/6,900,221


Parser?Sect1=PTO1& Sect2=HITOFF& d=PALL&p=1&u=%2Fnetahtml%2FPTO%2Fsrchnum.htm&r=1 &f=G&l=50&s1=5747498.PN.&OS=PN/5747498&RS=PN/5747498
become ultimately susceptible to challenge under Paragraph IV procedure of the *Drug Price Competition and Patent Term Restoration Act* (Hatch-Waxman Act), OSI Pharmaceuticals filed an application in February 2008 to the *United States Patent and Trademark Office* to correct certain claims by deleting surplus compounds from the claims.\(^{403}\)

The Indian Patent Office had already raised these objections with regard to the Tarceva patent application and on 22 January, 2006, eleven preliminary objections were raised in the First Examination Report of the Indian Patent Office including the lack of novelty and the inventive step.\(^{404}\) These objections were later removed and finally the applicants managed to secure a patent on the following two claims:

1. A novel \([6,7\text{-bis}(2\text{-methoxyethoxy})\text{quinazolin-4-yl}](3\text{-ethynylphenyl})\) amine hydrochloride compound of the formula A, and
2. A process for preparing the compound as claimed in claim 1.\(^{405}\)

### C. Pre-Grant Opposition by Natco Pharma

After the case was put for the final grant of patent, Natco Pharma Ltd., a local generic manufacturer, filed an opposition to the grant of patent on 10\(^{\text{th}}\) April 2007. This application was made under Section 25(1) of the *Patents Act 1970 (India)* which deals with pre-grant opposition proceedings. The grounds on which pre-grant opposition may

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\(^{405}\) Ibid. 13.
be based include virtually all patentability criteria including anticipation, lack of inventive step and non-invention. In its opposition petition, Natco Pharma mainly raised concerns about whether the application was non-obvious, and whether there had been sufficient disclosure of the invention in the specifications.

In view of these objections, the Indian Patent Office examined the question of the novelty and inventive step again in the light of prior art citation EP 0566226, published on 20.10.93 and EP 0520722 published on 30.12.92. In the end, it decided that none of the citations were specific for the claims made under the patent application. The opponent maintained that the claimed invention was an obvious derivative derived from 4-Anilinoquinazoline nucleus and ‘the combination of simple functional groups like alkoxy, alkyl, alkynyl, halo to already known basic nucleus or compound is obvious to a person of ordinary skill in the art’. Applicants also survived the attack on their claims on the basis of Section 3(d) of the Patents Act 1970 (India) by showing the data regarding survival rate increase by the use of drug. The Patent Office decided in favour of applicants and the patent was granted accordingly against two claims agreed during the proceedings.

During the hearings, the parties could not agree on the nature of opposition proceedings with Natco considering it as a pre-grant opposition under Section 25(1) and OSI Pharmaceuticals and others as a post-grant opposition under Section 25(2). This confusion basically arose because of an earlier decision by the Patent Office on its own

406 Section 25 (1) a-k of the Patents Act 1970 (India).


408 Ibid. 19.
objections and the subsequent order for the grant of patent which was delayed due to internal processes. This distinction is important from the point of view of the possibility of filing a post-grant opposition, though Natco could not succeed in its pre-grant opposition. On this point, the Patent Office decided that the proceeding was a pre-grant opposition. The success in pre-grant opposition was an important victory for OSI Pharmaceuticals and other parties and its Annual Report 2007 states: ‘A patent corresponding to the U.S. composition of matter patent for Tarceva was granted in February 2007 in India and we, along with our collaborator Roche, successfully opposed a pre-grant opposition by Natco Pharma, Ltd. of Mumbai, India in July 2007.’

D. Sunitinib Malate (Sutent)

Sunitinib Malate is prescribed for the treatment of renal cell carcinoma, a type of kidney cancer. It is manufactured and marketed by Pfizer under the brand name Sutent and also used for the treatment of gastrointestinal stromal tumour (GIST). GIST is a cancer of the stomach and bowels which is caused by the uncontrolled growth of cells in the wall of the stomach or bowel. Sutent was the first medicine approved by the U.S. Food and Drug Administration (FDA) simultaneously for two indications. While approving the drug in January 2006, Steven Galson, Director of FDA’s Center for Drug Evaluation and Research, observed: ‘Today’s approval is a major step forward in making breakthrough treatments available for patients with rare and difficult to treat forms of cancer.’

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409 Ibid. 26.


411 U.S Food and Drug Administration, ‘FDA Approves New Treatment for Gastrointestinal and Kidney..."
In Pfizer’s product portfolio, Sutent is still categorised as one of the new medicines which is performing very well with an increase of 166% in sales revenue during 2006.\(^{412}\) Sutent’s sales revenue increased to US$581 million in 2006 and that was mainly because of its widespread and speedy marketing approval in Europe and many Asian countries.

**E. Sutent Patents**

In the United States, three patents were granted for Sutent which would expire on February 15, 2021 (Patent No. 6573293 and Patent No. 7125905) and December 22, 2020 (Patent No. 7211600). In addition to this, a New Chemical Entity (NCE) exclusivity protection is also applicable until January 26, 2011.\(^{413}\) A PCT application (Application No. PCT/US1999/012069) was also filed in 1999 and the patents were granted in several designated countries between 2001 and 2005.\(^{414}\) The parallel Indian patent application was filed on August 9, 2002 under the title of Pyrrole Substituted 2-Indolinone Protein Kinase Inhibitors and a patent was granted on August 31, 2007.\(^{415}\) This patent (Patent No. 209251) was granted jointly to Sugen Inc. and Pharmacia & Upjohn Company. Sugen was a small California based biotechnology company which

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\(^{413}\) Approved Drug Products with Therapeutic Equivalence Evaluations in Electronic Orange Book at [http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=021938&Product_No=00&table1=OB_Rx](http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=021938&Product_No=00&table1=OB_Rx)


\(^{415}\) Government of India, Controller General of Patents Designs and Trademarks at [https://124.124.220.66/patentgrantedsearch/(S(k3gh1m55vis3y1rkuxtctx55))/GrantedSearch.aspx](https://124.124.220.66/patentgrantedsearch/(S(k3gh1m55vis3y1rkuxtctx55))/GrantedSearch.aspx)
was acquired by Pharmacia & Upjohn Company in the late 1990s and subsequently Pharmacia & Upjohn Company was acquired by Pfizer in 2003. However, Pfizer kept using these distinct business identities as a business strategy.\textsuperscript{416}

Patent protection is central in Pfizer’s business strategy and one of its foremost business strategies is to refocus and optimise its patent protected portfolio.\textsuperscript{417} In its Annual Review of 2007, Pfizer declared: ‘We are refocusing and optimizing our patent-protected portfolio to speed up the flow of new products, invest more in areas of strength, and deliver greater value to customers and patients.’\textsuperscript{418} In this context, an attempt to secure compulsory licences for these two drugs was really seen as an offensive move by the patent owners and both applications were fiercely contested in the patent office.

\textbf{F. Natco’s Compulsory Licence Application}

Notwithstanding the unsuccessful attempt to block the Tarceva patent through a pre-grant opposition procedure, Natco Pharma Ltd. applied for compulsory licences under Section 92A of the \textit{Patents Act 1970 (India)}. As mentioned earlier in this chapter, Section 92A provides the avenue for the grant of a Doha style compulsory licence solely for export purpose. In early January 2008, Latha Jishnu of the \textit{Business Standard} reported that:

\begin{quote}
[T]he first application for a compulsory licence filed in India, has put a key provision of the Indian Patents (Amendment) Act, 2005 under the scanner. The
\end{quote}

\textsuperscript{416} Pfizer \textit{Annual Review} 2007, 14,

\textsuperscript{417} Ibid. 4.

\textsuperscript{418} Ibid. 12.
application has been filed by Natco Pharma of Hyderabad for Roche’s erlotinib (brand name Tarceva), which is used in the treatment of lung cancer.\textsuperscript{419}

In its application to the Patent Office for the grant of a compulsory licence under Section 92A, Natco asked for permission to manufacture 30,000 tablets of Tarceva for export to Nepal against a fixed royalty of 5%. Later, it was also reported that Natco applied for a compulsory licence of Sutent against the same terms and conditions.\textsuperscript{420}

\textbf{G. Nepal: Public Health Profile and Access to Medicines}

Nepal is a least developing country in South Asia having boundaries with China in the north and India in the south. With a population of 27,641,000 its gross national income per capita is US$1,010.\textsuperscript{421} The share of annual health expenditure as a percentage of the national budget was 5.1\% in 2001-03. Nepal’s rank in terms of the UNDP Human Development Index (HDI) is 142 among 177 countries.\textsuperscript{422}

There have been a number of estimates of cancer incidence in Nepal. Some estimates show that the incidence of cancer is approximately 120 per 100,000 head of population, and it is assumed that there are 35,000 to 40,000 cancer sufferers in the country.\textsuperscript{423} The incidence of cancer is thought to be rising every year. The hospital based statistics

\begin{footnotesize}
\begin{itemize}
  \item \textsuperscript{421} World Health Organization Country Statistics at http://www.who.int/countries/npl/en/
  \item \textsuperscript{423} Sunil Kumar Joshi, ‘Occupational Cancer in Nepal – An Update’ (2003) 1(2) Kathmandu University Medical Journal 144-151, 144 at http://member.wnso.org/drsunilkj/Occupationalcancer.pdf
\end{itemize}
\end{footnotesize}
showed that there were 23% cases with malignancies in 1993 compared to 19% in 1989. The five most common malignant diseases in Nepal are bronchial cancer, breast cancer, cervical and ovarian cancer, stomach and colorectal cancer and leukaemia. The Nepal pharmaceutical industry is largely dependent upon the Indian market and most of local manufacturers are importing their raw materials from India and China (see Table 4.2)

### Table 4.2: Top 15 Suppliers to Nepal

<table>
<thead>
<tr>
<th>Rank</th>
<th>Company</th>
<th>Origin</th>
<th>Value (in crore)</th>
<th>Market Share (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Nepal Pharma</td>
<td>Nepal</td>
<td>13.2</td>
<td>3.85</td>
</tr>
<tr>
<td>2</td>
<td>Lomus Pharma</td>
<td>Nepal</td>
<td>11.8</td>
<td>3.47</td>
</tr>
<tr>
<td>3</td>
<td>Aristo</td>
<td>Indian</td>
<td>11.4</td>
<td>3.31</td>
</tr>
<tr>
<td>4</td>
<td>Deurali Janata</td>
<td>Nepal</td>
<td>10.7</td>
<td>3.08</td>
</tr>
<tr>
<td>5</td>
<td>Knoll Pharma</td>
<td>MNC</td>
<td>9.6</td>
<td>2.78</td>
</tr>
<tr>
<td>6</td>
<td>Dabur</td>
<td>Indian</td>
<td>9.1</td>
<td>2.65</td>
</tr>
<tr>
<td>7</td>
<td>Lupin</td>
<td>Indian</td>
<td>8.7</td>
<td>2.50</td>
</tr>
<tr>
<td>8</td>
<td>National Health Care</td>
<td>Nepal</td>
<td>8.6</td>
<td>2.50</td>
</tr>
<tr>
<td>9</td>
<td>Hoechst</td>
<td>MNC</td>
<td>8.1</td>
<td>2.35</td>
</tr>
<tr>
<td>10</td>
<td>Alkem</td>
<td>Indian</td>
<td>7.8</td>
<td>2.27</td>
</tr>
<tr>
<td>11</td>
<td>Ranbaxy</td>
<td>Indian</td>
<td>7.4</td>
<td>2.14</td>
</tr>
<tr>
<td>12</td>
<td>Cadila Pharma</td>
<td>Indian</td>
<td>6.3</td>
<td>1.84</td>
</tr>
<tr>
<td>13</td>
<td>Cadila Health Care</td>
<td>Indian</td>
<td>6.3</td>
<td>1.83</td>
</tr>
<tr>
<td>14</td>
<td>E Merck</td>
<td>MNC</td>
<td>6.0</td>
<td>1.75</td>
</tr>
<tr>
<td>15</td>
<td>Novartis</td>
<td>MNC</td>
<td>5.6</td>
<td>1.64</td>
</tr>
</tbody>
</table>

Source: Dr R. K. Srivastava

Nepal joined the WTO on April 23, 2004 and it is regarded as at least a developing country for implementation and enforcement of various treaty related obligations including the *TRIPS Agreement 1994*. Historically, Nepal had domestic intellectual property laws but it had to amend those laws in the light of obligations of the *TRIPS Agreement 1994*.

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424 Ibid.


426 World Trade Organization, ‘Member Information: Nepal and WTO’ (accessed on September 13, 2010) at http://www.wto.org/english/thewto_e/countries_e/nepal_e.htm
Agreement 1994 by January 1, 2006.\textsuperscript{427} This is of course subject to the \textit{Doha Declaration}'s extended deadline for least developing countries to apply provisions on pharmaceutical patents until 1 January 2016.\textsuperscript{428}

As a least developing country, Nepal has as yet no obligation to protect pharmaceutical products under patent law. According to the \textit{Patent, Design and Trademark Act 1965 (Nepal)}, a patent is defined as ‘any useful invention relating to a new method or process of manufacture, operation or publicity of any material or a combination of materials, or that made on the basis of a new theory or formula’.\textsuperscript{429} A patent is valid only for 15 years after registration.\textsuperscript{430} There has been a little patenting activity in Nepal and only 49 Patents were registered until 2002.\textsuperscript{431}

Natco's compulsory licensing applications have generated substantial debate in India and elsewhere but surprisingly there is complete silence from Nepal. Though these compulsory licenses were intended to be used for export to Nepal but we can see virtually no debate in Nepal about this issue. With the status of a least developing country, Nepal has no obligation to respond to this situation with a domestic compulsory license and its mere notification should suffice in the given circumstances. In fact, there is no compulsory licensing related provision in the \textit{Patent, Design and Trademark Act 1965 (Nepal)}.

\textsuperscript{427} World Trade Organization, ‘WTO Ministerial Conference Approves Nepal’s Membership’ (accessed on September 13, 2010) at http://www.wto.org/english/news_e/pres03_e/pr356_e.htm

\textsuperscript{428} World Trade Organization, ‘The Doha Declaration Explained’ (accessed on September 13, 2010) at http://www.wto.int/english/tratop_e/dda_e/dohaexplained_e.htm

\textsuperscript{429} Section 2(a) of the Patent, Design and Trade Mark Act, 1965 at http://www.vakilno1.com/saarclaw/nepal/patentandtrademarkact/chapter1.htm


Trademark Act 1965 (Nepal). However, for a successful outcome of Natco’s application in India, at least two factors are important in Nepal. First, Nepal should determine and establish its public health need with regard to products which Natco is attempting to manufacture under compulsory license. Second, Nepal should notify the WTO about its intention to invoke the Waiver Decision 2003, much like Rwanda.

Natco’s attempt looks half-hearted and apparently it rushed to the patent office without adequate preparation. These points were justifiably highlighted by the patentees before the patent office and played a decisive role in the final outcome. The matter is further discussed in subsequent sections. Pfizer’s presence in Nepal and its pricing policy there is another aspect of this debate which is not discussed by the commentators. Aiming clearly to counter Natco’s compulsory licensing application, Pfizer announced the launch of a free Sutent access program in Nepal. The decision was first revealed in April 2008, much later than the filing of the compulsory licensing applications in India.

H. Procedural Requirements

In contrast to the Doha Declaration 2001 and the Waiver Decision 2003, Section 92A adopts a straightforward and relatively fast track mechanism to issue a compulsory licence for export purposes. This provision does not stipulate the requirement of issuance of two back-to-back compulsory licences in importing and exporting countries along with separate notification obligations. In fact, the provision is silent about the royalty payment and no formula is referred for its calculation. However, the Patent

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(Note that ‘The move may upset Indian generic drug maker Natco Pharma Ltd’s efforts to secure a compulsory licence for exporting copy-cat versions of the drug’.)
Controller is authorised under the relevant provision to determine the terms and conditions of such licence.

Despite the gaps in Section 92A, it is important to note that the whole scheme is designed to meet the obligations of the *Doha Declaration 2001* and any interpretation of this section should be construed against this background. In light of the *Doha Declaration 2001* and related provisions of Indian law, Natco’s application can be analysed in the following way.

According to the *Doha Declaration 2001*, an importing country is obliged to notify the *Council for TRIPS* about the name and expected quantity of the drug which it intends to import under the scheme. The Declaration further requires that the member state must establish beforehand that it has virtually no, or a very limited, manufacturing capacity with regard to the drug which it wants to import and it should issue a compulsory licence if the product is patented in that importing country. In this case, Nepal is a least developing country and it does not need to establish its insufficient manufacturing capacity pursuant to the *Doha Declaration 2001*. Given that Nepal has no product patent regime, issuing a compulsory licence has no relevance. However, general notification of intent to the *Council for TRIPS* is required which Nepal has not made. In the very first Doha-style compulsory licensing case, Rwanda had notified its intention to use the mechanism of the *Doha Declaration 2001*.433

It is unclear how the Indian Patent Office will operate in the absence of such a notification to the *Council for TRIPS*. Nepal has only reportedly issued an import letter in favour of Natco. The contents of this letter which was issued from the Nepalese

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Ministry of Health are not yet known so its adequacy in terms of satisfying the procedural requirement of *Doha Declaration 2001* is yet to be established. This point was precisely raised by the patentees during a hearing before the Patent Office and an objection was raised as following:

Counsel for patentees further argued that the “notice” by the Nepal government that Natco was relying upon was insufficient to amount to a formal notification of an intent to import drugs produced under a compulsory licence. He alleged that Natco, in its application for a compulsory licence, had merely submitted a letter from the Nepal government recommending that one consignment of erlotinib be approved for import from India during the period 2006-2007. He argued that this was insufficient to demonstrate Nepal’s intent to utilise the 30 August mechanism to import drugs produced under a compulsory licence. In contrast, he pointed to the formal notification provided to the WTO by Rwanda of its intent to utilise the paragraph 6 implementation.434

Setting aside the procedures of the *Doha Declaration 2001* for a moment, Natco can argue that Indian law does not prescribe the requirement of notification to the *Council for TRIPS* and any document establishing the intent of the importing country should be considered satisfactory.

Indeed, a bare reading of Section 92A supports this assertion as it states:

Compulsory licence shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing

capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory licence has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India.\textsuperscript{435} (emphasis added)

Once the importing member country fulfils the requirement, then the exporting country can issue a compulsory licence under its domestic law. In this case Natco has applied to the Patent Office after securing a letter from Nepal stating its intent, the name of the product, required quantities and a royalty offer. This licence is necessary in India given the existence of a valid patent by OSI Pharmaceuticals and Pfizer.

In the absence of any notification from Nepal, it is difficult to determine the prevalence of a public health problem and its nature. Paragraph 1 of the \textit{Doha Declaration 2001} clearly spells out the intent by linking it with public health problems. It is not necessary for Nepal to show a national emergency before importing drugs from India under the Indian compulsory licence but such an action should definitely be related to a public health problem. The relevance of an anti-cancer drug contrary to an HIV/AIDS treatment may become a contentious point as we have already seen this line of argument the case of Thailand.\textsuperscript{436}

\textsuperscript{435} Section 92A(1) and (2) of the \textit{Patents Act 1970 (India)}.

I. The Right to a Hearing

In response to Natco’s application, Pfizer approached the Patent Office to contest the matter both on its merits and on procedural grounds. Indeed, the Patent Office itself identified some lacunas in Natco’s application and those were communicated to the applicant. Natco responded to those points and maintained that patentees had no right to be heard in this case. On the questions of maintainability of this application and the patentees right to become a party, two hearings were held and finally the Patent Office resolved this matter to the extent of a hearing right in favour of patentees.

It is pertinent to note that Section 92A of the Patents Act 1970 (India) is silent on the question of a patent holder’s right to a hearing and relevant rules along with draft Manual of Patent Practice and Procedure are equally unhelpful in this regard. Natco interprets it as a fast track compulsory licensing avenue unlike other provisions and asserts that a hearing right would unnecessarily delay the licence issuance process. Patent holders believe that their right to a hearing is inherent and based upon natural justice and several provisions of patent law. This question arose in discussion during the first two hearings when deliberations on the merit of the application were set aside for a while and parties argued their position on this preliminary hiccup. The parties raised several crucial points in their submissions.

To resolve this matter and decide about the stay petition of Natco, the Delhi Patent Office held a hearing on March 19, 2008. This hearing was attended by the parties and representatives of the Lawyers Collective, the HIV/AIDS Unit and the MSF Access Campaign. The latter two parties attended the proceedings as observers and the counsel of patentees raised objections about their presence asserting the proceedings as a private
hearing. However, it was finally resolved that the observers could attend the proceedings with the objection of patentees placed on the record.437

In favour of their position, patentees relied both on statutory and common law grounds to establish the right to hearing before a compulsory licence was issued. The Patentee argued that under the notion of ‘natural justice’ and ‘due process’, a hearing opportunity was fundamental before any decision adverse to their right was considered. Further reliance was made on Section 80 of the Patents Act 1970 (India) and Rule 129 of the Patents Rules 2003 (India). A joint reading of Section 80 and Rule 129 suggest that the Patent Controller is required to grant a patent applicant, or any party to a proceeding, a hearing before exercising any discretionary power adversely. Thus, it was argued, the patentees had a right to be heard before the grant of compulsory licence.438 Pfizer also relied upon a number of Indian cases to establish its position on the right to be heard and in this regard reliance was made on audi alterum partum.439 The same principle was upheld in several other cases such as Union of India v. T.R. Verma440, Basudeo Tiway v. Sido Kanhu Uni441 and Udit Narayan Singh v. Additional Member Board of Revenue.442

In response to such assertions, the applicant (Natco) maintained that Section 92A was clear in its language and intention and such hearing was deliberately avoided at the time of amendments in the law. Section 92A was a clear response to the mandate of the Doha

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438 Ibid.

439 Maneka Gandhi v Union of India (1978) 1 SCC 248.


442 Udit Narayan Singh v Additional Member Board of Revenue AIR 1963 SC 786.
Declaration 2001 and the legislature intentionally adopted a fast track and efficient mechanism to meet the public health challenges in importing countries. Thus, a clear distinction was made between the general compulsory licensing provisions (Sections 84-92) and this provision (Section 92A). Domestic compulsory licensing provisions clearly provide a hearing opportunity and Section 92A is deliberately silent on this point to expedite the procedure. Natco insisted that Section 92A could be construed in the light of the Doha Declaration 2001 which prompted the need for rapid response in the case of a public health crisis. Natco maintained that:

On analysis of the section 92 (A) of the Indian Patents Act, it is clear that law specifically excludes any interference or intervention or even participation by the patentee. Therefore, the question of contesting the grant of license does not arise. The entire mechanism is a departure from the usual procedure of grant of compulsory license and is aimed at giving effect to and fulfilling the objectives of said Doha Declaration which emphasizes on the rapid response to the urgent needs of the least developed countries or developing countries for immediate access to patented medicines.443

Natco also referred to the relevant Canadian legislation (Section 21.14) where no such right was incorporated in the law before the issuance of a compulsory licence.444 In response to the patentees’ position that certain matters could only be determined with the assistance of patentees, Natco relied on the joint publication of WHO/UNDP which could be used to work out adequate remuneration in such circumstances without the

444 Ibid.
involvement of the patentees. It further argued that the common law doctrine of natural justice could not be applied in an absolute manner and it had always been regulated under different situations and in view of the unambiguous language of Section 92A, general rules could not be attracted.

The Patent Office finally resolved the matter of the hearing controversy on July 4, 2008. In his decision, Hrdev Karar, Assistant Controller of Patents and Design, dismissed the interlocutory petition of Natco and allowed the patentees to become parties to proceedings before the Patent Office in the matter under Section 92A. The Patent Office decision is important in view of future applications of Section 92A and it would eventually pave a way towards elaborate and lengthy proceedings before the grant of a compulsory license.

The decision is mainly about the patentee’s right to participate in proceedings held under Section 92A and several other points were also discussed by the Assistant Controller regarding the maintainability of Natco’s application. For instance, it is noticed that Natco could not substantiate its application for the grant of a compulsory licence by producing a notification from the Government of Nepal. The letter which Natco had attached along with its original application was declared insufficient in the light of legislative requirement. Natco did not submit proof to suggest that there was a public health emergency in Nepal due to the lack of availability of the drug. The Assistant Patent Controller, therefore, stated in his order that one of the reasons for the ‘hearing’ was to ensure that the provisions of 92 (A) were not ‘abused’.

The participation of patentees and their hearing right are recognised in the decision in purview of Section 92A and the applicant's submission on this point was turned down. Agreeing with the patentees' arguments on this point, the Assistant Controller of Patents and Design said:

> It may be observed that the requirements as mentioned in section 92A and rules made thereunder impliedly demands the presence of the patentee, therefore the doctrine "necessary implication or the maxim expression 'unius est exclusio alterius' need not to be applied. The principle audi alteration partem would be more beneficial for proper administration of justice. Therefore, the patentee is required to be invited to the hearing in respect of proceedings of section 92(A)."446

The hearing controversy is now resolved by this decision and the remaining matter is to be decided on its merits. This initial controversy raised important procedural questions which have the potential to stall a compulsory licence application for a considerable time. An unrestricted and full-fledged hearing right may hamper the development of a standard working procedure which can be later employed by other generic companies to apply for compulsory licences under Section 92A. This first case is highly important not only for Indian manufacturers but also for the rest of the developing world as the placement of a quick and efficient mechanism in India would help them activate their domestic regulations to important cheaper drugs from generic resources. Obviously any unnecessary delay or cumbersome procedure should be considered against the legislative intent and procedural requirements under Section 92A.

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446 Ibid. 13.
After this decision, it was expected that the matter would shift to normal proceedings and the patent office would decide about the grant of compulsory licence after hearing both parties. Though the decision was disappointing for Natco it was expected that Natco would strongly push its case on the merits for the grant of a compulsory licence. However, in September 2008, Natco requested the Controller of Patents to withdraw its applications for compulsory licenses for export of the generic anti-cancer drugs Sutent and Tarceva.

Apparently it was an unexpected move although some commentators noted that it was anticipated after Patent Office’s decisions on Natco’s interlocutory petition. Shamnad Basheer observed that:

[P]atent office was concerned that the Doha CL process ought not to be abused by generic manufacturers that wished to make a quick buck. Therefore, the best way to ensure this was to hear the other side as well … Natco’s decision to withdraw its application may have stemmed from a fear that it would lose on merits.

The outcome is indeed disappointing for a variety of reasons. First, this case was a good chance for Indian generic companies to test the application of export oriented compulsory licences. Second, the decision of the Patent Office was unreasonable in that it had indeed determined the outcome of Natco’s application beforehand. The decision expressed serious doubts about the maintainability of a compulsory licensing

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application at a stage when there was controversy about the hearing matter. Natco had also apparently rushed into this matter without completing its homework in Nepal, and it could not substantiate its case for the grant of compulsory licence on public health grounds.

VI. Conclusion

In conclusion, one possible way of maintaining Indian exports at their current level is through the strategic use of compulsory licensing provisions which are incorporated in Indian law. I have analysed this potential in the light of early compulsory licensing instances. Natco’s application for a compulsory licence highlights the ambiguities in the law and procedure. Contrary to the general assumptions, the system did not work efficiently in this first case for a variety of reasons which could be attributed to the Patent Office, patent law, the applicant and patent holders. However, the main reasons were procedural ambiguities and the lack of appropriate homework by the applicant.

I have argued that both the international framework (WTO Waiver Decision 2003) and the domestic rules (Indian compulsory licensing provisions) will not help in achieving the objectives of the Doha Declaration 2001. Four main reasons are cited here to support this position. First, the complexity of rules is a vital constraint and it operates both on the levels of treaty law and domestic regulation. Second, pharmaceutical firms view the export potential in terms of market size and the profits involved in such supply. Because of the complexity of rules, and fragmented markets, the firms may be less inclined to engage in export oriented production if their commercial expectations are largely unmet. Third, the chances of supplies being available becomes more unlikely especially if the firms have to make specific technological investments to produce the drugs required for a limited time in a restricted territory. Such technological investment is essential to the manufacture of new drugs which are constantly in demand in most of
the African countries. Fourth, the Indian government lacks the political will or enthusiasm to engage in the wide scale use of Section 92A. The Indian government has a vested interest in integrating into the global economy and trading network.

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If a patent granted on mail box application the subject to some conditions.

Notification by central Government. Availability of compulsory licence.

Form 17 with Rs. 1500- (Natural Person)/Rs. 6000- others

Immediate grant of Compulsory licence under Section 92(3) in the circumstances of National Emergency or extreme urgency or public non-commercial use including public health crises relating AIDS HIV tuberculosis, malaria or epidemics

Section 92(1) opposition for the settlement of terms & conditions

Prima Facie case made out under section 87

Refusal after hearing within one month if no Prima Facie case

Advertisement of the application and applicant to serve copies to the patentee

Opposition by the patentee, if desired with in two months from the date of publication

Automatic Compulsory Licence

Grant Compulsory Licence

Figure 4.1 Four Modes of Compulsory Licensing under the Patents Act 1970 (India) as amended at 2005
Chapter 5
Patent Enforcement, Border Measures and Access to Essential Medicines

I. Introduction

On 30th April 2009, the United States Trade Representative (USTR) released its 2009 Special 301 Report. Professor Michael Geist has observed of the process:

[The USTR’s] Special 301 report has become a staple on the spring calendar. Toward the end of each April, the USTR issues the annual report card on intellectual property protection around the world. The report, which typically identifies 30 to 40 countries that the U.S. has targeted for legal reform, is at times reminiscent of the classic movie Casablanca, as the USTR rounds up the usual suspects and is shocked to find that their legal rules do not match those adopted in the U.S.

The Canadian Professor observes that ‘the USTR report should be seen for what it is: a biased analysis of foreign law supported by a well-orchestrated lobby effort’.

The 2009 Special 301 Report cast aspersions upon the poor state of intellectual property protection and enforcement in India. Along with China, Russia and several other countries, India is placed on the Priority Watch List. The report characterises at least

450 Office of the United States Trade Representative, ‘2009 Special 301 Report’, 30 April 2009 at http://www.ustr.gov/sites/default/files/Full%20Version%20of%20the%202009%20SPECIAL%20301%20REPORT.pdf


452 Ibid.
nine Indian destinations as notorious markets where massive infringement activities take place. It is observed that:

The United States also encourages India to improve its IPR enforcement system … Piracy and counterfeiting, including of pharmaceuticals, remain a serious problem in India.453

The USTR 2009 Special 301 Report has a different vision of enforcement and it aims at achieving the maximum level of intellectual property protection through effective and robust enforcement policies.

In a rejoinder to the 2009 Special 301 Report, Consumers International (CI), an umbrella body of more than 220 consumer organisations from 115 countries, issued its first Intellectual Property Watch List.454 The list contains a survey of 16 countries and concludes that Indian consumers benefit the most from national intellectual property laws. South Korea stands second in the list of best rated countries and the United Kingdom is the top worst-rated country. The assessment criteria which is used in the list to determine the best intellectual property practices revolves around the themes of safeguard measures and flexibilities which consumers can use while dealing with protected subject matters. Three main themes are identified which help in determining the status of different countries. These include freedom to access and use, freedom to share and transfer and administration and enforcement policies. One of the interesting findings of the report is about the United States. It observes that the United States

453 Ibid. 18-19.

applies a double standard, with ‘far more flexibility for U.S. consumers than for people in the countries they criticize’. 455

A focus on enforcement issues had typically dominated the debates throughout the negotiation history of the *TRIPS Agreement 1994*. The lack of effective enforcement norms was one of the main concerns of industrially advanced countries during the Uruguay Round of Trade Negotiations (1986-1994) which ultimately culminated in the form of the *TRIPS Agreement 1994*. 456

*The TRIPS Agreement 1994* is the first international agreement which contains specific enforcement norms which are binding upon its member states. 457 Despite successful adoption of the *TRIPS Agreement 1994*, the offensive launched by the developed countries to achieve the highest standards of enforcement is still continuing.

However, these efforts are now pushed through a range of multilateral and bilateral forums and a clear trend of forum shifting can be observed in this regard. The enforcement agenda is no more on a priority agenda list of developed countries in the World Trade Organization and these issues are diverted to new forums. 458 In October 2007, the United States Trade Representative made an announcement about the negotiations, which has led to the *Anti-Counterfeiting Trade Agreement 2011* (ACTA).

In addition to United States, Canada, the European Union, Japan, Korea, Mexico, New

455 Ibid. 1.


http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds362_e.htm

Zealand, and Switzerland initially agreed to participate in ACTA negotiations. In October 2010, the text of the agreement was published. The enforcement agenda is also pushed through the World Customs Organization (WCO) which has developed and promoted the adoption of *Provisional Standards Employed by Customs for Uniform Rights Enforcements* (SECURE). These standards include several provisions which go beyond the obligations of the *TRIPS Agreement 1994* and commentators have expressed their concerns about the organisational mandate of World Customs Organization to engage in these activities.

The enforcement of intellectual property rights is also high on the agenda of the Organization for Economic Cooperation and Development (OECD), The Group of Eight (G8), the World Intellectual Property Organization (WIPO) and the World Health Organization (WHO).

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463 Organization for Economic Cooperation and Development, ‘OECD Project on Counterfeiting and Piracy’ (accessed on 8 July 2009) at http://www.oecd.org/document/50/0,3343,en_2649_34173_39542514_1_1_1_1,00.html

In 2006, the WHO supported the establishment of the International Medical Products Anti-Counterfeiting Taskforce (IMPACT), and provided secretarial support. The IMPACT has developed *Principles and Elements of National Legislation against Counterfeiting Medical Products*. These principles are promoted as a model law and there are many enforcement-related provisions which are dubbed as anti-counterfeiting measures. Developing countries have shown their strong concerns both about the processes and agenda of IMPACT.

In addition to these developments, a large number of bilateral free trade agreements were negotiated by the United States and the European Union which provide TRIPS plus enforcement standards and effectively reduce the ability of their trading partners to rely upon the flexibilities of the *TRIPS Agreement 1994*.

This escalation of enforcement measures is disturbing for the developing world. Most of the developing countries are still coping with the higher standards of the *TRIPS Agreement 1994* and finding it difficult to achieve the right balance between intellectual property enforcement and other policy considerations. A recent study by Professor Carsten Fink shows that the so-called economic benefits of intellectual property enforcement are quite ambiguous for developing countries. On the contrary, the costs associated with enforcement measures are considerably high. He concludes that: ‘If


weak IPRs enforcement in developing countries reflects fundamental institutional deficiencies, it is not clear how far obligations in trade agreements or technical assistance activities can at all remedy such deficiencies.467

Realising the limitations of economic benefits which a country can get from strong intellectual property enforcement, there is a need to rethink the intellectual property led model of development promoted by the United States. While approving the importance of market forces and the need for adequate patent rights (as rules of operation), Professor Amartya Sen warns about the negative impact of patents on poor patients. He states that:

While it is certainly important not to create economic conditions such that the innovative research of pharmaceuticals dries out, there are, in fact, plenty of intelligent compromise arrangements ... that can provide good incentives for research while allowing the poor of the world to buy these vitally important drugs. It must be remembered that the non-buying of drugs by the poor which they cannot afford to buy can hardly add anything to the incentives of the drug producers; the issue is to combine efficiency-based considerations with demands of equity, in an intelligent and humane way, with an adequate understanding of demands of global efficiency as well as justice.468

This chapter addresses the question, how can countries like India adopt enforcement measures which are consistent with its international obligations and reduce the welfare loss to society at the same time? Focusing upon the Tarceva case, Part II of the chapter explores the changing dynamics of patent litigation and enforcement in India, which offers new risks and opportunities both for Indian consumers and pharmaceutical

467 Ibid. xvi.

manufacturers. Part III considers the challenges which India may face at international forums in the form of new and strict enforcement measures. The recent controversy of seizure of Indian generics is discussed in this part in the light of European Union laws and the TRIPS Agreement 1994. The chapter concludes that India needs to develop a coherent policy on patent enforcement, both domestically, and in international diplomatic negotiations. India should, however, be mindful of the fact that any TRIPS plus approach through bilateral trade negotiations would prejudice its interests in the pharmaceutical sector.

II. Domestic Enforcement of Patent Rights: Injunctive Relief in Indian Courts

Since receiving marketing approval in October 2007 from the Indian Government, Cipla Limited – the second largest generic manufacturer in India – has been manufacturing the pharmaceutical drug, Erlocip. F. Hoffmann-La Roche Ltd. (Roche) filed a case in the Delhi High Court to stop Cipla from manufacturing this drug and an interim application was also filed for the grant of a temporary injunction against Cipla. The matter is still pending before the Delhi High Court on its merits but on the question of interim relief and injunction, Justice S. Ravindra Bhat rendered his judgment on 19 March 2008 whereby an interim injunction was refused subject to certain conditions.

This decision of the High Court of Delhi is important in view of earlier patent jurisprudence in India on the question of granting an ad-interim injunction and the overall context of generic companies’ strategies to manufacture cheaper versions of patented drugs by using the flexibilities of Indian patent law. It can be anticipated that injunctive relief issues will play an important role in future patent litigation in India and the development of case law in this regard is quite crucial from an enforcement
perspective. The judgment of the High Court of Delhi in *F. Hoffmann-La Roche Ltd v. Cipla*⁴⁶⁹ is discussed in this section of the chapter.

The suit was jointly filed by Roche, Pfizer and OSI Pharmaceuticals where the latter two were patent holders and Roche was the partner under a *Development Collaboration and Licensing Agreement*. The drug, Tarceva, was also registered with the *Directorate General of Health Services* in the name of Roche. Roche was responsible for importing and marketing this drug in India and it was not as such manufactured in India by the rights holders.⁴⁷⁰ Though the judgment is mainly about the grant of an ad-interim injunction in patent infringement cases, it elaborates on certain other key matters related to patentability criteria, rules governing injunctions and the relevance of public health in matters pertaining to pharmaceutical patents.

**A. Validity of Patent**

In accord with standard practice in patent infringement suits, Cipla, in its written statement, has challenged the validity of the patent granted by the Patent Office.⁴⁷¹ Through its counter claim, Cipla raised the objections related to novelty, inventive step and proper disclosure. The plaintiffs vehemently opposed this move by seeking permanent injunction restraining infringement of their patent rights to the drug Tarceva. In addition, an application was filed seeking an ad-interim injunction, restraining the defendant from manufacturing, offering for sale, selling and exporting the drug Tarceva. This application was dismissed by the High Court of Delhi.


⁴⁷⁰ Ibid. Paragraph 3.

In their written submission and oral arguments, the plaintiffs heavily relied on the presumption of validity of their patent in view of its grant by the Patent Office after due process.\textsuperscript{472} The patent application was filed in 1995 with 27 claims but later on 25 of them were dropped and the patent was granted only on 2 claims. The whole process took a considerable time and close scrutiny, and the plaintiffs could secure a patent only after satisfying all requirements enumerated in law. Furthermore, the plaintiffs' patent also survived a pre-grant opposition filed by Natco Pharma and in its final order, the Patent Office rejected all the objections raised by the opposing party. To defend the validity of their patent, the plaintiffs submitted that the current objections raised by Cipla in their written statement about the validity of the patent were substantially similar to those which the Patent Office had heard and rejected during opposition proceedings.

Cipla attacked the notion of presumption of validity of the patent by citing a number of Indian cases to demonstrate that the plaintiffs' patent was new and such presumption could not be attracted at least before the expiry of six years after the grant of patent. Reliance was placed on \textit{Franz Zaver Humer v. New Yash Engineers}\textsuperscript{473} and other cases to establish the different treatment of new and old patents during infringement proceedings. Cipla also raised number of objections regarding the validity of the plaintiffs' patent. It was alleged that the patent was liable to be revoked because it was a quinazolin derivative; a mere improvement from the existing prior art which would be obvious for a person skilled in the art. It was submitted that: 'The patented compound of the Plaintiffs is a quinazolin derivative used for the treatment of cancer therefore, a

\textsuperscript{472} Ibid.

\textsuperscript{473} \textit{Franz Zaver Humer v New Yash Engineers} AIR 1997 Delhi 79.
derivative of a known compound and hence not patentable under Section 3 (d) of the Act. 474

Cipla also mentioned at least three European patents dated 1993 which disclosed quinazolin derivatives. One of these patents disclosed exactly the same chemical structure which the plaintiffs claimed except for one substitution, which was again claimed to be obvious. So in the absence of an established enhancement of efficacy pursuant to Section 3(d), a patent could not be granted and the plaintiffs failed to demonstrate this. It was also alleged that Tarceva was just a derivative of Gefitinib from Astra Zeneca for which a patent was refused in India, on the ground that the said product was already in prior use and was in the public domain. Thus, the defendant submitted that the Patent Office erred in granting a patent for Tarceva. It alleged that the plaintiffs’ attempt to protect Tarceva was not less than indulging in evergreening. Relying on the ruling of the Madras High Court in Novartis v. Union of India, where the Court extensively relied on legislative debates in this regard 475, the defendant argued that evergreening was clearly considered contrary to public policy and the statutory language employed in Section 3(d) of the Patents Act 1970 (India) was evident on this point.

In their response to the defendant’s arguments, the plaintiffs questioned the very notion of new and old patents and asserted that there was no statutory basis for such distinction. Instead, they maintained that the new patent regime in India put in place a multilayered scrutiny mechanism before the grant of a patent in terms of internal examination, pre-grant opposition, post-grant opposition and the possibility of


475 Ibid. Paragraph 11.
revocation. So the old case law could not survive in this context. It was further argued that the objections raised about anticipation of invention, prior art and efficacy within the meaning of Section 3(d) had already been considered by the Patent Office during pre-grant opposition and the patent was granted after that. On the issue of the chemical structure familiarity, the plaintiffs asserted that sometimes a minute relocation or substitution in positions could add an extraordinary inventive step and such examples were not unknown in pharmaceutical sciences. They also rejected the plea that Tarceva was merely a quinazolin derivative and claimed a substantial enhancement of efficacy over the existing products.476

In the judgment, Justice Bhat refrained from going into the merits of opposing arguments about the patentability issue and kept his analysis limited to a decision on the interim application.477 He considered the standards of novelty and inventive step in judging prima facie validity of patents; as well as the principles guiding the grant of a temporary injunction.

Justice Bhat cited the decision of the United Kingdom Court of Appeal case in Windsurfing International v. Tabur Marine478 (GB) Ltd. to elaborate the steps to be taken into account while determining patentability as follows:

1. Identifying the inventive concept embodied in the patent;

2. Imputing to a normally skilled but unimaginative addressee what was common general knowledge in the art at the priority date;

476 Ibid. Paragraph 24-25.

477 F. Hoffmann-La Roche Ltd v Cipla (I.A 642/2008 IN CS (OS) 89/2008) dated March 19 2008, paragraph 73, Full text is available at:
http://courtnic.nic.in/dhcorder/dhcqrydisp_j.asp?pn=1031&yr=2008

3. Identifying the differences if any between the matter cited and the alleged invention; and

4. Deciding whether those differences, viewed without any knowledge of the alleged invention, constituted steps that would have been obvious to the skilled man or whether they required any degree of invention.\textsuperscript{479}

He then cited the United States Supreme Court in \textit{Graham v. John Deere Co. of Kansas City}\textsuperscript{480} to state the requirement of non-obviousness.

Justice Bhat declared that the Patent Office erred in its findings in the pre-grant opposition because it conflated anticipation with obviousness. On this point, he again relied on a recent United States case, \textit{KSR International Co v. Teleflex}\textsuperscript{481}, to reject the application of tightly formulistic teaching, suggestion, and motivation (TSM) test. He states that:

A hint of this TSM method appears to have crept in the examination of the plaintiff's claim, in the Controller's order, particularly at page 22, where he appears to have proceeded to rule out any motivational factors to the persons skilled in the art – by looking into the prior art for finding out or predicting the improvement in the properties of the quinazolin derivative compound. The

\textsuperscript{479} \textit{F. Hoffmann-La Roche Ltd v Cipla} (I.A 642/2008 IN CS (OS) 89/2008) dated March 19 2008, paragraph 73, Full text is available at:


\textsuperscript{480} \textit{Graham et al. v John Deere Co. of Kansas City et al} 383 U.S. 1 (1966) at


\textsuperscript{481} \textit{KSR International Co v. Teleflex} 550 US 1,(2007) at

http://www.supremecourts.gov/opinions/06pdf/04-1350.pdf
plaintiff too appears to be emphasizing this since its argument is that the prior art does not contain description of a similar compound.482

Finally on this point, the court rejected the plea of plaintiffs that the product of the defendant was inferior in quality because the product was clearly approved for a marketing purpose by the relevant authorities. Without prejudice to the rights of the plaintiffs, it was stated that:

The court should refrain from conducting a mini trial as to the strength of the parties, at the interlocutory stage. All that can therefore said is that the plaintiff’s case though arguable and though disclosing prima facie merit, has to answer a credible challenge to the patent, raised by the defendant.483

B. Injunctive Relief in Patent Infringement Cases

The main issue raised and discussed in the judgment was related to the grant of injunctive relief in patent infringement cases. In his analysis and findings, Justice Bhat did not confine himself to the particular issue of interlocutory injunction and considered the questions of remedies, more broadly. Displaying a cosmopolitan frame of reference, the judge referred to a range of Indian, British, and North American precedents on the question of injunctions.

In support of their application for an ad-interim injunctive relief, the plaintiffs again relied on the presumption of validity of their patent and asserted that a duly granted patent could attract an equitable relief which would otherwise cause an irreparable harm

482 F. Hoffmann-La Roche Ltd v Cipla (I.A 642/2008 IN CS (OS) 89/2008) dated March 19 2008, paragraph 76, Full text is available at:

483 Ibid. Paragraph 78.
to the patentees. It was submitted that ‘it would not be appropriate that the remedy of injunction prescribed under section 108 of the Act is denied to the Plaintiff merely because the Defendant has raised a defense of invalidity of the patent’.484

On the contrary, the defendant argued against the granting of such relief in the light of several cases before the Indian courts. The defendant maintained that, as the patent was new, it had no presumption of validity and in such case, a refraining order from the court could be disastrous for the defendant. The defendant also adverted to the non-working of patents in India and suggested that working of a patent was an essential prerequisite for the grant of preliminary injunctive relief. The plaintiffs had failed to manufacture this drug in India and their imported drugs were not within the reach of poor patients. Any injunction in this situation would be against the interests of the public at large.485

The judgment on this point is quite coherent and lucid and a detailed analysis of relevant case law has been done. Interestingly both the parties cited the celebrated triple-test enunciated in the English case of American Cyanamid Co. v. Ethicon Ltd.486 First, under the American Cyanamid test, the court has to consider whether there is a serious question to be tried. Second, the court has to see whether damages would be an adequate remedy for a party injured by the court’s grant of, or its failure to grant, an injunction. Third, if damages cannot be an adequate remedy, the court has to determine where the balance of convenience lies.

484 Ibid. Paragraph 16.
485 Ibid. Paragraph 13 and 14.
Against the backdrop of this standard, Justice Bhat analysed the prevailing jurisprudence in India on this point. In *Ramdev Food Products Ltd v. Arvindbhai Rambhai Patel and Others*\(^{487}\), the Supreme Court had approved the *American Cyanamid* approach in the context of a trademark case. The earlier jurisprudence of Indian courts is consistent in that where the patent is of recent origin and its validity has not been tested, the courts should not grant injunctions where infringement is alleged; it has also been held that if the defendant alleges that the patent cannot be sustained, the injunction should be refused. This is upheld in several cases including, but not limited to, *Manicka Thevar v. Star Ploro Works*\(^{488}\), *Ram Narain v. Ambassador Industries*\(^{489}\), *Surendra Lal Mahendra v. Jain Galzers*\(^{490}\), *National Research and Development Corporation of India v. Delhi Cloth General Mills*\(^{491}\) and *Standipack Pvt. Ltd. and Ors. v. Oswal Trading Co. Ltd. and Ors.*\(^{492}\).

In another recent case of *Bilcare v. Amartara Pvt. Ltd*\(^{493}\), the High Court of Delhi reaffirmed that the mere grant of patent did not guarantee its validity and if a counterclaim of invalidity was filed then no validity presumption could be attached to such patent\(^{494}\). Justice Bhat then discussed the relevance of *eBay v. MercExchange* and summarised the issue of interlocutory injunction as following:


\(^{488}\) *Manicka Thevar v. Star Ploro Works* 1965 Mad 327, paragraph 5.


\(^{491}\) *National Research and Development Corporation of India v. Delhi Cloth General Mills* AIR 1980 Del 132.

\(^{492}\) *Standipack Pvt. Ltd. and Ors. v. Oswal Trading Co. Ltd. and Ors* AIR 2000 Del 23.

\(^{493}\) *Bilcare v Amartara Pvt. Ltd* 2007 (34) PTC 419 (Del).

\(^{494}\) For an overview of *Bilcare* and its comparison with *KSR*: Joshua D. Sarnoff 'Bilcare, KSR,'
(i) In patent infringement actions, the courts should follow the approach indicated in *American Cyanamid*, by applying all factors;

(ii) The courts should follow a rule of caution, and not always presume that patents are valid, especially if the defendant challenges it;

(iii) The standard applicable for a defendant challenging the patent is whether it is a genuine one, as opposed to a vexatious defense. Only in the case of the former will the court hold that the defendant has an arguable case.495

After elaborating the applicable standard, the Court considered its application in the existing case and decided to resolve this matter on the question of the balance of convenience. The plaintiffs had made out an arguable case and, at the same time, the defendant’s challenge was genuine.

After considering a range of factors under the *American Cyanamid* approach, the Court ultimately declined to issue an ad-interim injunction. Justice Bhat established that on account of public interest in access to life saving drugs, the balance of convenience clearly tilted in favour of the defendant and subject to certain conditions (furnishing undertaking to pay damages, if awarded finally and maintenance of proper account), the defendant could continue manufacturing its drug until the final disposition of this matter on merits.

Regardless of the merits of this case, the Court’s reliance on recent United States case law is an interesting dimension of this debate. Justice Bhat referred to the Supreme


495 F. Hoffmann-La Roche Ltd v Cipla (I.A 642/2008 IN CS (OS) 89/2008) dated March 19 2008, paragraph 65, Full text is available at:

http://courtnic.nic.in/dhcorder/dhcqrydisp_j.asp?pn=1031&yr=2008
Court of the United States decision in *eBay v. MercExchange*\(^{496}\) to suggest that there is a traditional four factors test for issuance of an injunction. This is an important departure from the prevailing Indian jurisprudence on this point and its consequences. Traditionally Indian courts referred to English cases in corporate and commercial matters because of a shared heritage of legislation and case law. While discussing the application of *eBay*, Justice Bhat commented that plaintiffs failed to raise the issue of irreparable hardship which was otherwise an important factor. It is interesting to note that since the *eBay* case, many courts in the United States have given conflicting opinions on the point of survival of the irreparable harm doctrine in the *eBay* judgment. The post *eBay* cases which no longer consider the presumption of irreparable harm include *z4 Technologies, Inc. v. Microsoft Corporation*\(^{497}\), *Paice L.L.C. v. Toyota Motor Corporation*\(^{498}\), *Voda v. Cordis Corp*\(^{499}\), *Torspo Hockey International, Inc. v. Kor Hockey Ltd.*\(^{500}\)

It would appear that Justice Bhat has considered the implications of *American Cyanamid* and *eBay* together on this point but ignored the post eBay developments in


American courts which are struggling to apply eBay findings in different fields of technologies.

C. Public Health and Access to Drugs Considerations

Finally, the court considered the question of the balance of convenience and irreparable hardship in the context of Article 21 of the Constitution and public interest in access to life saving drugs. Cipla heavily relied on this argument in its submissions and stated the huge price difference between the two products time and again during the proceedings. It submitted that:

[I]t is in the interest of the patients that no injunction should be granted. The plaintiffs’ capsule costs Rs.4,800/- per tablet and the equivalent tablet of the defendant costs Rs.1,600/- . Thus, a month’s dosage for a patient undergoing treatment for cancer is Rs.1.4 lakh whereas the equivalent cost of the defendant would be Rs.46,000/-. It is alleged that in the area of life saving drugs, it is in the public interest of the general public and patients suffering from diseases like cancer that medicines are made available at cheap and affordable prices so long.501

Though the plaintiffs tried to rebut this argument by showing that import duty was part of their calculated price, Cipla maintained that its product was also subject to excise duties.

Weighing up the factors of the balance of convenience, irreparable hardship, public interest and Article 21 of the Constitution, the court held

Thus, unlike in cases involving infringement of other products, the Courts have to tread with care when pharmaceutical products and more specifically life saving

drugs are involved. In such cases, the balancing would have to factor in imponderables such as the likelihood of injury to unknown parties and the potentialities of risk of denial of remedies ... Another way of viewing it is that if the injunction in the case of a life saving drug were to be granted, the Court would in effect be stifling Article 21 so far as those would have or could have access to Erlotcip are concerned.502

To support this assertion, reliance was made on a United States case of Roussel Uclaf v. G.D. Searle and Company Ltd.503 to establish the differential treatment of life saving drugs.

In its final deliberation on the issue of injunctive relief, the court also considered the public interest in protecting the property rights in the patent but while comparing the competing public interests, Justice Bhat observed that:

The National Cancer Registry Report released by the Indian Medical Council in 2007 states that every hour 50 persons are diagnosed of cancer in the country. The same report states that 24% of all cancer incidents, are in relation to lung cancer. The figures of those suffering from the ailment that Tarceva and Erlocip seek to alleviate therefore, are significant. There is no empirical material, or statistical method by which the Court can deduce the numbers of such patients who would be using the plaintiff’s product if injunction is refused; on the other hand, it is plain that a large number of them would be deprived of access to a life saving drug if injunction is granted. Therefore, this Court is of the opinion that as between the two competing public interests, that is, the public interest in granting an injunction to affirm a patent during the pendency of an infringement action, as

502 Ibid. Paragraph 85.
opposed to the public interest in access for the people to a life saving drug, the balance has to be tilted in favour of the latter.\textsuperscript{504}

According to Justice Bhat, an applicant must show that there is an inventive step and that any new form listed in the explanation to Section 3(d) shows a significant enhancement of efficacy over known forms. So, ‘the test of patentability has become more precise and specific’.\textsuperscript{505}

The importance of this decision is obvious in the light of new jurisprudence which it has created in the Indian judicial milieu. Some courts had adopted a cautious approach towards the grant of injunctive relief in patent infringement cases by avoiding a direct and immediate presumption of validity in favour of the patentee. This decision adds an important dimension of public policy as a part of an equitable formula which should be used in such cases.

A clear and unambiguous statement concerning people’s right to health and access to medicine is an important development and in conjunction with the flexibilities of patent law, it can really work well in favour of generic manufacturers. It is not clear how this decision would be interpreted in the larger perspective of the Patent Office’s practice, but its relevance for the pharmaceutical sector is direct, precise and clear-cut.

**III. Detention of Transit Drugs: EU-India Dispute**

On December 4, 2008, Netherlands custom authorities detained a shipment of generic medicine which was destined for Brazil. The medicine, losartan potassium, was manufactured in India by Dr Reddy’s Laboratories.\textsuperscript{506} The Laboratories had exported

\textsuperscript{504} Ibid. Paragraph 86.

\textsuperscript{505} Ibid. Paragraph 57.

around 500 kilograms of losartan to Brazil under the instruction of EMS, a Brazilian importer. The shipment was en route when it was detained in the Netherlands on the suspicion of infringing patent rights.

Losartan potassium is an anti-hypertensive used in treating arterial hypertension and in most of the regulated markets around the world it is marketed under the brand names of Cozaar and Hyzaar. Both of these drugs are manufactured and marketed by Merck & Co. Inc., one of the largest pharmaceutical companies in the world. Losartan potassium was first approved by the United States Food and Drug Administration in 1995 followed by further approvals of additional dosages and new indication in 1998 and 2005.\textsuperscript{507} Merck & Co. Inc. had secured three patents in the United States for different formulations of Cozaar and Hyzaar and it was also granted additional paediatric exclusivity.\textsuperscript{508} The earliest patent expiry was on August 9, 2009 while the last patent would expire on May 4, 2014.

\textsuperscript{507} United States Food and Drug Administration, ‘Electronic Orange Book Home Page’ (accessed on July 1, 2009) at http://www.accessdata.fda.gov/scripts/cder/ob/docs/tempai.cfm


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&f=G&l=50&s1=5210079.PN.&OS=PN/5210079&RS=PN/5210079 and Carini, David J et al (1997),
According to the data of the World Intellectual Property Organization, at least 52 patents are listed with losartan as a key ingredient. These patents which were filed under the arrangements of the *Patent Cooperation Treaty 1970* (PCT) include a patent which was published on June 29, 1995. This patent application was jointly filed by the Merck and Co. Inc. and E. I. du Pont de Nemours and Company (DuPont). DuPont holds the patent rights of losartan potassium in most of the European markets and it has played a major role in the detention of Dr Reddy’s consignment to Brazil. It is important to note that losartan is not patented both in Brazil and India and it was detained in the Netherlands where a valid patent exists. On December 24, 2009, Dr Reddy’s Laboratories was notified about the confiscation of its shipment at Amsterdam Schiphol Airport. This notification from the lawyers of patent holders and its licensee categorically demanded the destruction of infringing goods. They also solicited a waiver from the shipper, Dr Reddy’s Laboratories, to the effect of surrendering its consignment. The consignment was held by The Netherlands custom authorities for

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36 days and it was finally released and returned to Dr Reddy’s Laboratories in India after an agreement was reached between the parties.511

The detention of the generic version of losartan potassium triggered a controversy among the European Union, India and Brazil. The detention and threat of destruction was largely seen as a barrier to trade in legitimate generic medicines which play a vital role in access to the medicine program in many countries. Both India and Brazil strongly reacted against the action of the Dutch authorities and termed it against the spirit of the Doha Declaration on the TRIPS Agreement and Public Health 2001 (the ‘Doha Declaration’). It was later on revealed that this detention was not an isolated incident. Such confiscations of shipments of generic medicines were frequently made at different European airports and the most of the detentions were carried out by the Dutch authorities. Initially it was reported that at least four separate instances of detention had occurred during the past few months involving different destinations. However the figure increased markedly when Dutch authorities released some details on an access to information request of Health Action International512, a consumer group working in the areas of drug policy and access to medicines. According to this information, Dutch authorities conducted 17 seizures in the year 2008. Sixteen consignments originated from India and one from China. These shipments were destined for Brazil, Colombia, Ecuador, Mexico, Nigeria, Peru, Portugal and Spain. These medicines were for the


treatment of diseases such as cardiological ailments, AIDS, dementia and schizophrenia. Fifteen of the 17 consignments were destined to developing countries.513

The issue of the confiscation of losartan potassium came into the limelight immediately after the detention. India and Brazil along with several other developing countries challenged the validity of such actions under the TRIPS Agreement 1994. In the WTO General Council Meeting on the 3rd February 2009, the Indian representative vehemently rejected the action of Dutch authorities and stated that:

In addition to going against the spirit of a rule based trading system and impeding free trade, such acts represent a distorted use of the international IP system and circumscribe TRIPS flexibilities … The WTO rule based system provides for freedom of transit by the most economical and convenient routes and without unnecessary delays and restrictions. The act of seizure by the Dutch authorities is therefore, a denial of the rule based system which we seek to build and strengthen in the WTO. The concept of “territoriality" is a key stone in the edifice of the TRIPS Agreement. There are no indications that the drug consignment was meant for the markets of the EC. Seizure, and initiating procedures for destruction of such consignments, violates this key principle. Members have always strived for a balance between public health concerns and protection and enforcement of IPRs … It is ironical that while on one hand WTO has taken steps to promote access to affordable medicines and remove obstacles to proper use of TRIPS flexibilities,

on the other hand some Members seek to negate the same by seizing drug consignments in transit.\textsuperscript{514}

The Indian representative further highlighted the adverse implications of the detention of generic medicines upon public health objectives.

Similar concerns were raised by the Brazilian representative, who stated that the trade in generic medicines was perfectly legal from the intellectual property point of view. The representative complained that the European regulation was against the spirit of free trade, because it empowered customs authorities to interfere with the transit of generic medicines. In its view, generic medicines should not be confused with counterfeit or pirated goods. Generic medicines were not sub-standard or illegal. It was further stated that:

The measure taken by the Dutch authorities clearly violates the freedom of transit, which is a right enshrined in GATT Article V. Only very exceptional circumstances warrant restrictions on that freedom. Brazil is not aware of any such circumstance in this concrete case. The decision to impede the transit of a cargo of generic medicines – which was not headed for the Dutch market – is unacceptable and sets a dangerous precedent. Worse still, there are indications that this is not an isolated case ... Under TRIPS, the medicines seized are generic under the law of the market in which they were meant to be commercialized. In this case, they are generic as regards Brazilian law, and Indian law, as we

understand it. Whether or not the medicines were generic under the law of the country of transit is an irrelevant question.\textsuperscript{515}

The Brazilian representative concluded, indignantly: ‘What is not irrelevant is the decision taken by Dutch Customs authorities to block the transit and thus impede the access of Brazilian hypertension patients to safe and price-competitive generic medicines.’\textsuperscript{516} The diplomat lamented: ‘In Brazil and in other countries, hypertension is a common but serious disease, often leading to death.’\textsuperscript{517}

However, EU Ambassador Eckart Guth did not agree with these contentions and maintained that the Dutch seizure ‘is allowed by TRIPS and is based on provisions in EU customs law that allow customs to temporarily detain any goods if they suspect that these goods infringe an intellectual property right’.\textsuperscript{518} He also said that the goods were never seized and were merely detained under the law and ultimately returned to the owner. He also tried to underplay the significance of detention by stating that:

In the present case, it appears that, following a request by a company which has patent rights over the medicine in question in the Netherlands, the Dutch authorities temporarily detained (which does not mean seize, confiscate or destroy) a small shipment of drugs worth 55,000 euros in a Dutch airport, in order to control it. This action is allowed by TRIPS and is based on provisions in EU

\textsuperscript{515} World Trade Organization General Council Meeting, ‘Intervention by Brazil’ (February 3, 2009) at http://www.ip-watch.org/files/RemediosIntervencao-do-Brasil-Conselho%20Geral-03%2002%202009.doc

\textsuperscript{516} Ibid.

\textsuperscript{517} Ibid.

\textsuperscript{518} Ibid.
customs law that allow customs to temporarily detain any goods if they suspect that these goods infringe an intellectual property right.\textsuperscript{519}

Some of these factual assertions were later on rebutted by evidence presented by Dr Reddy’s Laboratories. Other developing countries have also raised their concerns on generic seizure in support of positions of Brazil and India. They include Argentina, Bolivia, Burkina Faso, China, Costa Rica, Cuba, Ecuador, Egypt, Indonesia, Israel, Nigeria, Pakistan, Paraguay, Peru, South Africa, Thailand and Venezuela.\textsuperscript{520}

\textbf{A. Generics Detention and Access to Medicines}

Indian pharmaceutical exports are crucial for global access to medicine initiatives as India alone exports generics of worth US$3.1 billion in the form of active pharmaceutical ingredients and finished products. Currently Indian generic manufacturers are exporting their products to more than 150 countries worldwide. Dr Reddy’s Laboratories is the largest pharmaceutical company in India with a market share of 10%. In the year 2006-07, the company has witnessed a strong growth of 138% in its export business.\textsuperscript{521} Thus, any attempt to restrict pharmaceutical exports from India may affect access to medicines in many developing and least developing countries. This


realisation has prompted the strong reaction by the group of developing countries who raised their concerns in the WTO General Council Meeting on the 3rd to 4th February 2009. Furthermore, the attempt to block the export of generics from India is not a rare incident. The pattern shows that it is gradually becoming a systemic problem where pharmaceutical trade between developing countries is deliberately targeted.

Given the public health implications of generic drug seizure during transit, seventeen non-governmental organizations sent a letter to the Director General of World Health Origination (WHO) asking to break its silence on the issue of the Dutch seizure of generic medicines. The letter states that the detention of generic medicines by the Dutch authority is in conflict with the resolution of the World Health Assembly which states that ‘international negotiations on issues related to intellectual property rights and health should be coherent in their approaches to the promotion of public health’. The letter refers to specific examples of the seizure of generics by the Dutch authorities and considers it a larger problem of the enforcement strategy of the European Union. It also anticipates that the practice of detention poses great risks for WHO, UNITAID and the Global Funds which are engaged in the supply and shipment of drugs.

The fears raised in the letter were realised on February 27, 2009 when a UNITAID funded consignment of 49 kilograms of abacavir sulfate tablets was detained by the Dutch authorities claiming that it contained counterfeited goods. The drug was manufactured in India and it was destined for Nigeria as a UNITAID funded shipment. UNITAID immediately responded to the situation issuing its statement declaring that:

522 BUKO Pharma-Kampagne et.al ‘Re: Seizures of Medicines as Goods in Transit to Developing Countries’ (February 18, 2009) at http://www.keionline.org/misc-docs/seizures/WHO_seizures_18feb.pdf
The tablets are NOT counterfeit nor does this shipment infringe other form of intellectual property to our knowledge. They are medicines used in second-line treatment of HIV/AIDS manufactured by Indian company Aurobindo. These medicines have been prequalified by the World Health Organization and have received tentative approval by the United States Food and Drug Administration. UNITAID is gravely concerned for the patients who are waiting for these urgently needed medicines, which were destined for a programme implemented by the William J. Clinton Foundation on behalf of UNITAID in Nigeria. Interruption in HIV therapy is extremely dangerous and can cause resistance to the medicines. We therefore strongly urge the Dutch government to release the medicines so that they can reach patients as soon as possible. UNITAID is worried more generally about the trend that seems to have taken hold in recent months where generic medicines are stopped or confiscated while transiting through the Netherlands. Generic medicines are not counterfeit medicines. The Aurobindo abacavir tablets are legitimate products and there is no reason to raise concerns related to counterfeiting. 524

This shipment was later released on March 17, 2009 but this incident again established the existence of systemic problems both in law and practice of the European Union’s border control measures.

In March 2009, WHO issued a statement, observing that ‘recent events related to the handling of medicines in transit and the potential consequences for the supply of

medicines in developing countries are of major concern to the organization'. However, this brief statement indeed failed to address the concerns which were raised in the letter addressed to the Director General of World Health Organization. After the detention of the UNITAID consignment, it is clear that the problem is not just confined to a few confiscations and it indeed requires a strong institutional response from the international health regulatory body.

Contrary to WHO’s response, the matter was thoroughly discussed in the forum of the World Trade Organization (WTO). The non-governmental organisations that sent the letter to the World Health Organization also sent a letter to Pascal Lamy, Director General of WTO, stating their concerns about the border control measures of the European Union. It was requested in the letter that the Director General, according to Article 5 of the WTO Understanding on Rules and Procedures Governing the Settlement of Disputes, should take an ex-officio action to explore the risks associated with the European Union’s Custom’s rules. Pascal Lamy responded to this letter on March 4, 2009 and recognised the importance and relevance of this issue. He mentioned that the matter was thoroughly discussed both at the WTO General Council Meeting on February 3, 2009 and at the TRIPS Council Meeting on March 3, 2009. However, he did not agree with the proposition that the Director General should intervene in the matter. He said that parties would resolve this matter bilaterally as they had indicated in the discussion.

526 BUKO Pharma-Kampagne et.al ‘Re: Seizures of Medicines as Goods in Transit to Developing Countries’ (February 18, 2009) at http://www.keionline.org/misc-docs/seizures/WTO_seizures_18feb.pdf
However, the resolve to settle this matter bilaterally could not work as another Indian shipment of generic medicine was detained in Frankfurt, Germany on May 5, 2009. This time the drug, amoxicillin, was destined for the Republic of Vanuatu in the Pacific and its 3,047,000 tablets (250 mg), equivalent to 76,000 courses of treatment, were confiscated on the ground that the brand name of GlaxoSmithKline (GSK), Amoxil, had been infringed. This incident again created an uproar. India raised this issue at the World Trade Organization Council on Trade-Related Aspects of Intellectual Property Rights (The TRIPS Council). This time the Indian representative directly attacked the relevant regulation of the European Customs’ regulation and stated that:

Since seizures have been recurring at different ports and on different grounds, it is therefore clear that rather than just being a problem of implementing a law by Dutch Customs authorities, it is the EC regulation 1383/2003 itself that is problematic and can be misused, and has been misused, to create barriers to legitimate trade. We, once again, call upon the EC to urgently review the Regulation and the actions of the national authorities based on the Regulation, and bring them in conformity with the letter and spirit of the TRIPS Agreement, the rules based WTO system and the DMD on Public Health … India attaches the highest importance to protection and enforcement of IPRs in accordance with the TRIPS Agreement. However, we do not see the Agreement as divorced from the Objectives and Principles set out in Art 7 and 8 of the Agreement. Enforcement of IPRs in disregard of these Objectives and Principles and efforts to enshrine new, maximalist TRIPS plus enforcement provisions in other multilateral forums will

seriously undermine the delicate balance in the TRIPS Agreement and raise systemic issues, particularly for developing countries.529

The statement clearly shows that the matter of contention in this issue is the European Union regulation which empowers the detention of generic medicines in transit. India considers that such measures are clearly built against the spirit of the TRIPS Agreement 1994 and should be withdrawn by the European Union. By contrast, the European Union maintains that its relevant regulations are consistent with its obligations under the international law and that its member states can exercise detention powers on transit goods. It is worth considering the legality of these measures in the light of the TRIPS Agreement 1994 and the jurisprudence of European Court of Justice.

B. EC Border Measures Against Transit Generic Drugs

The detention of generic medicines in transit through the European Union is based on the Council of the European Union Regulation No. (EC) 1383/2003 of 22 July 2003 (European Union).530 This regulation empowers the national Customs authorities to take action against goods suspected of infringing certain intellectual property rights and a community-wide uniform procedure is devised in this regard. It was not the first time that such measures were introduced in the European Union.531 This regulation was


531 Earlier in 1994, the Council of European Union had adopted its first regulation on the border measures concerning pirated and counterfeited goods Council Regulation (EC) No 3295/94 of 22 December 1994
subsequently replaced with a more comprehensive regime which provides Customs’ seizure of goods infringing intellectual property rights such as trademarks, copyrights, patents, geographical indications, designs, plant variety rights, and supplementary protection certificates.\textsuperscript{532} Rights-holders, exclusive licensees and their representatives are entitled to invoke the processes of confiscation. In addition, Customs authorities may ex officio suspend the release of the goods even before a formal request is made by the right-holder.\textsuperscript{533}

Customs authorities are entrusted with extensive powers to suspend and detain the goods in transit which are not primarily destined for any member state of the European Union. These powers are even applicable when goods are bound for Customs free zones.\textsuperscript{534} These powers were used by the Dutch and German Customs authorities when consignments of generic drugs were detained. It is pertinent to note that over the last few years, the scope and implementation of practices related to these regulations have gradually evolved in the European Union. Relying upon the considerable body of European case law on the detention of goods in transit, I will argue that the detention of generic medicines was unjustified under the jurisprudence of the European Court of Justice.

\footnotesize{


\textsuperscript{533} Ibid. Article 4.

\textsuperscript{534} Ibid. See Article 1 for subject matter and scope.
}
In *Commission v. France*[^335], a case was filed by the European Commission alleging an infringement action against France on the basis that a domestic law enabled French Custom authorities to intervene when a product was transported through France which could infringe a design right in France. This was notwithstanding the fact that no such right was infringed both in the country of origin and the country of destination. The ECJ held that the French Republic had violated Article 28 (formerly Article 30) of the EC Treaty by providing a right for the Customs authorities to retain goods in transit via France which had been legally manufactured in Spain and were destined for another member state where they could equally be legally offered for sale. The court rejected the plea that those goods would infringe a right-holder’s design rights under French law and declared that it was immaterial in the facts of the case.

In the second case, in *Administration des douanes v. Rioglass SA*, the issue was regarding a shipment from a member state (Spain) to a non-member state (Poland—was not a part of EU at that time) through another member state (France). The goods were seized by the French Customs authorities for infringement of domestic trademarks and the case was referred to the European Court of Justice with the following question:

> Is Article 30 of the Treaty, now Article 28 EC, to be interpreted as meaning that it precludes the implementation ... of procedures for detention by the customs authorities of goods lawfully manufactured in a Member State of the European Community which are intended, following their transit through French territory, to be placed on the market in a non-member country, in the present case, Poland?[^336]

[^335]: *Commission v France* Case C-23/99 (26 September 2000)

[^336]: *Administration des douanes et droits indirects v Rioglass SA, Transremar SL* Case C-115/02 (23 October 2003).
The court held that: ‘a measure of detention under customs control, such as that in issue in the main proceedings, cannot be justified on the ground of protection of industrial and commercial property within the meaning of Article 30 EC’. 537

The final case which is important for our analysis here is Montex v. Diesel which was decided in 2006. The European Court of Justice held that trademark ownership in the country of transit did not allow any interference with the transit procedure unless the ‘goods are subject to the act of a third party while they are placed under the external transit procedure which necessarily entails their being put on the market in the Member State of transit’. 538 The court also clarified that the risk of diversion to the transit market must be established and the risk that ‘they could theoretically be marketed fraudulently’539 is insufficient to support the trademark owner’s application under the border control regulations. Therefore, ‘every external transit of goods bearing the (protected) sign540 should not be automatically considered as a relevant infringement under the border control regulation. The burden of proof that there is a sufficient risk of fraudulent diversion to the transit market lies on the part of the right-holder, ‘by establishing either the existence of a release for free circulation in a Member State in which the (right) is protected, or of another act necessarily entailing their being put on the market in such a Member State’. 541 The court concluded ‘that Article 5(1) and (3) of Directive 89/104 is to be interpreted as meaning that the proprietor of a trade mark can prohibit the transit through a Member State in which that mark is protected (the Federal 537 Administration des douanes et droits indirects v Riqglass SA, Transremar SL Case C-115/02 (23 October 2003).

538 Ibid. Paragraph 23.

539 Ibid. Paragraph 24.

540 Ibid. Paragraph 25.

Republic of Germany in the present case) of goods bearing the trade mark and placed 
under the external transit procedure, whose destination is another Member State where 
the mark is not so protected (Ireland in the present case), only if those goods are subject 
to the act of a third party while they are placed under the external transit procedure 
which necessarily entails their being put on the market in that Member State of 
transit". 542

The outcome of the case is very clear that transit goods do not constitute infringement 
when there is no risk of diversion and the Customs authorities’ powers to detain such 
goods are extremely limited.

The losartan potassium case, and the legality of Customs authorities’ detention, can be 
evaluated in light of such precedents. As mentioned earlier, the medicine is not patented 
in either India or Brazil. A review of the case law suggests that the powers of Customs 
authorities are limited and exceptional regarding the detention of transit goods. The first 
two cases suggest that the detention of transit goods on the basis of border regulations 
cannot be even justified when goods are destined for internal markets. Subsequent cases 
provide the criteria suggesting when border regulations can be used to detain goods 
which are destined for non-member states. The only valid reason for the intervention of 
Customs authorities is the risk of diversion and even that risk is required to be fully 
established by the right-holder. In the losartan potassium case, no evidence was 
provided which could reveal the apprehension of diversion to the European market. In 
the absence of any evidence, the detention of the shipment is an act of transgression 
against the powers provided by the European Union directive, and the case law of the 
European Court of Justice.

542 Ibid.
Although the cases mentioned earlier mainly deal with trademark and design infringements, they can be fully contextualized in the cases of patent infringements. The European Court of Justice has adopted specific subject matter approach in this regard to determine whether an act of importation, direct or transit, would affect the entitlements of the right-holder or not. A survey of European Union border control measures and its analysis in the light of the jurisprudence of the European Court of Justice clearly establishes that the seizure of generic drugs by the Dutch and German authorities does not fit within the framework of the Community’s legal and regulatory framework. Though the European Union’s border control regulation provides for the right of detention of goods in transit in case of infringement of intellectual property rights, these provisions were very narrowly interpreted by the highest court of the European Union. Customs authorities are repeatedly informed to refrain from such seizure unless there are valid apprehensions of diversion in the Community’s internal market. Such apprehensions have never been communicated with regard to consignments of generic medicines, and their seizure therefore lacks any valid legal ground.

C. EC Border Control Measures and TRIPS Agreement 1994

Regulation No. (EC) 1383/2003 of 22 July 2003 (European Union) can also be analysed from the perspective of international trade law to determine the validity of detention actions by the Customs authorities. The TRIPS Agreement 1994 provides a comprehensive framework of intellectual property norms and related enforcement measures. In its statement at the World Trade Organization Council on Trade-Related Aspects of Intellectual Property Rights (The TRIPS Council) on June 2009, India categorically stated that the European Union’s border control law was against the spirit of the TRIPS Agreement 1994. It was stated that:
EC has sought to justify the action of customs authorities to control goods in transit suspected of infringing IPRs as a means to stop "traffic of potentially dangerous products, such as fake medicines, even when the shipments were destined for any country". ... We wish to remind the EC that the concept of "territoriality" is a key stone in the edifice of the TRIPS Agreement and a widely understood and accepted principle. In our view, sovereign functions of the country of destination should be exercised by the country itself and other countries may assist in enforcement of their law, if requested. The seizures run counter to the spirit of the TRIPS Agreement and the resolution 2002/31 of the Commission on Human Rights on the right to enjoy the highest standards of physical and mental health ... It is ironical that while on the one hand WTO has taken steps to promote access to affordable medicines and remove obstacles to proper use of TRIPS flexibilities, on the other hand some Members seek to negate the same by seizing drug consignments in transit and creating barriers to legitimate trade.543


Part III of the TRIPS Agreement 1994 specifically deals with the enforcement of intellectual property rights. It is pertinent to note that the TRIPS Agreement 1994 is the first multilateral agreement which contains detailed enforcement provisions ranging from border measures to infringement remedies. Additionally, Part III contains provisions on provisional measures, administrative proceedings and criminal sanctions

for certain severe infringement matters. For the purpose of the issue currently under discussion, Section 4 of Part III is directly relevant which deals with special requirements related to border measures. The general obligation regarding certain subject matters of intellectual property rights is stated as follows:

Members shall, in conformity with the provisions set out below, adopt procedures to enable a right holder, who has valid grounds for suspecting that the importation of counterfeit trademark or pirated copyright goods may take place, to lodge an application in writing with competent authorities, administrative or judicial, for the suspension by the customs authorities of the release into free circulation of such goods.

With regards to other forms of intellectual property rights such as patents, Article 51 of the TRIPS Agreement 1994 permits member states to extend border measures to such an area provided that the requirements of Section 4 are adequately met. This is what the European Union has precisely done in its Regulation No. (EC) 1383/2003 of 22 July 2003 (European Union) which provides the application of border measures in the case of almost all forms of intellectual property rights. These obligations would therefore be non-compliant with the Treaty obligations.

Article 52 of the TRIPS Agreement 1994 obliges member states to require from the right-holder adequate evidence to the satisfaction of competent authorities under the law of the country of importation, and establish that there is a prima facie infringement case of relevant intellectual property rights. Thus, in the case of Regulation No. (EC) 1383/2003 of 22 July 2003 (European Union), it should be an obligation on the part of

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544 Agreement on Trade Related Aspects of Intellectual Property Rights (The TRIPS Agreement 1994) at http://www.wto.org/english/tratop_e/trips_e/t_agm4_e.htm#Footnote13

545 Ibid. Article 51, First Paragraph.
the right-holder to demonstrate a prima facie case of infringement based upon the law of the country of importation. In the context of the losartan potassium case, the crucial question is about the identification of the country of importation. There are two possible interpretations. First, the country of importation is Brazil as the shipment was destined for it and Brazilian law should be applied to determine the issue of infringement. However, an alternative interpretation may suggest that the country of importation in this case is the country of transit i.e. the Netherlands, and the patent holder should establish a prima facie case on the basis of Dutch law. There is nothing in the TRIPS Agreement 1994 and the jurisprudence of the WTO Dispute Settlement Body which can directly help us in this regard. The Oxford English Dictionary defines importation as ‘the bringing in of goods or merchandise from a foreign country’.546 This literal meaning is perhaps not very useful in the context of the current dispute.

There are additional problems of compliance in the Regulation No. (EC) 1383/2003 of 22 July 2003 (European Union). Article 53 (1) of the TRIPS Agreement 1994 provides that the relevant authorities shall have powers to demand security from the right-holder when acting on his request. This is an important safeguard which helps the defendant. However, the European Union’s border regulation fails to incorporate this mandatory requirement of the TRIPS Agreement 1994 and merely requires a written undertaking from the right-holder.547 Likewise Article 59 of the TRIPS Agreement 1994 requires that


the destruction of infringing goods must be in accordance with the details mentioned in Article 46 of TRIPS Agreement 1994. Thus, before any destruction is mandated, a positive finding should be established based upon the evidence before the judicial authorities. The border control regulation of the European Union once again fails on this account and a direct and simplified destruction procedure is provided in Regulation No. (EC) 1383/2003 of 22 July 2003 (European Union). Based upon this provision, Dr Reddy’s Laboratories had been served a notice by the lawyers of the patent holder to extend consent for the destruction of generic drugs.

Beyond the substantive provisions of the TRIPS Agreement 1994, there are additional arguments which suggest that several aspects of the Regulation No. (EC) 1383/2003 of 22 July 2003 (European Union) do not comply with the letter and spirit of the TRIPS Agreement 1994. The seizure of generic medicine in transit is apparently against the objectives of the Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration 2001) as it was stated in the Declaration that WTO members:

[A]gree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.

Any attempt to apply border measures in a way which discourages the supply of generic medicines to the developing countries clearly violates the spirit of the Doha Declaration.

548 Ibid. Article 11.

549 Doha Declaration on the TRIPS Agreement and Public Health, WTO Doc WT/MIN(01)/DEC/2 (14 November 2001) at http://www.wto.org/english/tratop_e/minist_e/min01_e/mindecl_trips_e.htm
on the TRIPS Agreement and Public Health (Doha Declaration 2001). India has assumed a correct position at different multilateral forums to agitate for the detention of its generic exports and in this regard it can rely upon the existing legal and regulatory framework. There are apparently good prospects for India to contest this matter in the World Trade Organization on the basis of the TRIPS Agreement 1994 and the relevant jurisprudence of the European Court of Justice.

IV. Conclusion

The enforcement of intellectual property rights is prominent on the agenda of industrialised countries and a strong push for the adoption of higher enforcement norms is evident from different multilateral and bilateral initiatives. Developing countries such as India have a range of policy options to address intellectual property enforcement within the framework of the TRIPS Agreement 1994. The crucial aspect is the implementation and practical utilisation of the safeguards which are permitted under the existing laws. Most of the enforcement issues are domestic policy matters and countries can adopt innovative measures to ensure that intellectual property enforcement should not affect public access to essential medicines. The Tarceva case discussed in this chapter demonstrates how the legal system can be equipped with the public policy objectives within the limits of country’s international obligations. The matter of remedies and injunctive relief largely depends upon the factual matrix of a case and courts should be empowered to interpret the law in the best public interest.

The position of India has been reinforced by emerging trends in other forums. Article 45 of the World Intellectual Property Organization Development Agenda has emphasised the need ‘to approach intellectual property enforcement in the context of broader societal interests and especially development-oriented concerns, with a view that ‘the protection and enforcement of intellectual property rights should contribute to the
promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations', in accordance with Article 7 of the TRIPS Agreement'. Such a statement would allow nation states considerable flexibility in devising enforcement regimes, which are appropriate to a nation’s level of development. Cross-border intellectual property enforcement, however, offers complex challenges as many countries have adopted laws and regulations which go beyond the standards of the TRIPS Agreement 1994.

It is also important to note that consistency in Indian policy is an important pre-requisite for resisting the onslaught of a new enforcement offensive. India is currently negotiating a Free Trade Agreement (FTA) with the European Union. Article 2 (1) of the draft FTA indicates that ‘this chapter shall complement and further specify the rights and obligations between the Parties beyond those under the TRIPS Agreement and other international treaties in the field of intellectual property to which they are parties’. The European Union has proposed many TRIPS-plus provisions in the draft text which is still under negotiations between the two countries. On the issue of enforcement and border measures, Professor Carlos Correa insightfully observes that Customs authorities lack the technical capacity to determine complex matters such as the scope of patent claims, and infringement:

The proposed expansion of border measures much beyond what is required under the TRIPS Agreement would make such measures applicable not only to the

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551 Ibid.
importation but also to the exportation of goods and to goods in transit. The seizure by European custom authorities of generic medicines in transit through European territory illustrates about the possible implications on legitimate trade of the broad application of border measures. This case not only shows the problems posed by the application of IPRs to goods merely in transit (which may constitute a violation of article V of GATT) but also the inadequateness of applying, as proposed by the EU, border measures to patent infringements.552

Though these proposals have not yet been endorsed by India, it is expected that substantial amendments will be forwarded by the Indian government in this regard although a cautious approach should be advocated at the very outset.

Chapter 6
Equitable Licensing and Publicly Funded Research

I. Introduction

On the 24th June 1994, the antiretroviral drug stavudine – which has the brand name Zerit – was approved by the U.S. Food and Drug Administration (FDA). Despite the fact that the drug was highly useful, and recommended for HIV/AIDS patients in South Africa, Yale University only agreed that stavudine would not be patented in South Africa, after extensive lobbying and public controversy.

The story of the development of stavudine dates back to 1964 when Dr Jerome Horwitz of the Michigan Cancer Foundation synthesised a group of compounds called dideoxythymidines which included AZT, ddc, ddl and d4T. Though these compounds could not be successfully tested for the treatment of cancer, their discovery laid the foundation for HIV/AIDS treatment. In the late 1980s, Dr Tai-Shun Lin and Dr William Prusoff of Yale University developed the drug stavudine, based upon the d4T compound and this drug was licensed to Bristol-Myers Squibb (BMS). This research was jointly funded by the NIH and Bristol-Myers Squibb secured an exclusive license for the product on January 12, 1988. Yale University secured an initial patent in 1990.

553 Susa Coffey, ‘Stavudine (Zerit)’, (October 31, 2006) HIVInSite at http://www.hivinsite.org/InSite?page=ar-01-04


555 Ibid. 192.

556 Yale University, ‘Yale Innovators: Faculty Innovators’ (accessed on June 28, 2009) at http://innovators.yale.edu/faculty-prusoff.asp

557 Ashley J. Stevens, ‘Valuation and Licensing in Global Health’ in Anatole Krattiger et al (eds),
Acquiring rights to file further patents under a licensing agreement, Bristol-Myers Squibb elected to file patents of stavudine in a number of countries including South Africa, Mexico and Egypt.

In 2000, Toby Kasper, a volunteer working with the Médecins Sans Frontières (MSF) started compiling a list of essential medicines needed for the treatment of HIV/AIDS patients in South Africa. Given the exorbitant prices of drugs such as stavudine, MSF started campaigning for the availability of generic versions of antiretroviral drugs. In 2001, the Indian drug manufacturer Cipla, offered to supply generic versions of several antiretroviral drugs including stavudine at a considerably lower price but its request to receive a voluntary manufacturing license was rejected by the patent holders.558

In Yale University a first year law student, Amy Kapczynski, led a campaign for the inventor and initial patent holder of stavudine, Yale University, to play its role in allowing generic competition in South Africa. MSF also wrote to Yale University asking if it:

would consider the importation of generic versions of stavudine for use in providing treatment free of charge to people with HIV/AIDS unable to afford treatment an infringement of your intellectual property rights ... issue a voluntary license to allow the importation and use of generic stavudine in South Africa.559


Volume 1 (Oxford: Centre for the Management of Intellectual Property in Health Research and Development, Oxford Centre for Innovation, 2007), 93 at


558 Ibid.

559 Letter from Eric Goemaere, Representative of Médecins Sans Frontières-South Africa, to Jon Soderstrom, Managing Director, Office of Cooperative Research, Yale University (Mar. 9, 2001).
After Yale University responded negatively to this request, Amy Kapczynski and her colleagues mobilised the students and faculty by gathering more than 600 signatures asking for a decisive university action. After massive media attention and public comments, Bristol-Myers Squibb finally announced on the 14th March 2001 that it would not enforce its stavudine patent in South Africa. Bristol-Myers Squibb further announced the reduction of the price of its treatment in South Africa and eventually signed a non-suit agreement with Aspen Pharmaceuticals, South Africa’s generic manufacturer.560

The Zerit (stavudine) controversy highlighted the largely neglected problem of university patenting and related practices in the United States. Initial research and development in the pharmaceutical sector is quite often conducted with the funding and support of public sector grants.561 These research outputs are then licensed to private companies which develop them further before a commercial product is launched. In the life cycle of invention, the role of public sector entities such as universities, hospitals, and research institutes is very crucial. Like stavudine, several drugs were initially developed – wholly or partially – with public sector funding, but ended up in private ownership by commercial pharmaceutical or biotechnology companies.562 Many studies


have been recently conducted examining the role of universities amidst the global crisis of access to medicines.

The dispute over Zerit (stavudine) is not the only case where publicly funded research has been the subject of larger political debate. Commentators have cited several other examples where crucial medicines and other health technologies were developed with public sector funding but subsequently transferred to private companies through exclusive licenses. The use of licenses for technology transfer and commercialisation of academic research is a widely recognised and popular phenomenon. However, the terms of licenses are critical to determine the scope of exclusivity and products' accessibility. The licensing regime developed in the United States after the enactment of the *University and Small Business Patent Procedures Act* (the 'Bayh-Dole Act) 1980 (US) has led to a range of problems. In the pharmaceutical sector, exclusive licenses concluded between academic and research institutions and drug companies created access barriers beyond the shores of the United States. After securing licences from universities in United States, drug companies secured patents in many developing countries for medicines which were badly needed there.

Against this backdrop, the role of academic patents and licences of publicly funded research has come under scrutiny and questions have been raised about the ramifications of universities' licensing policies. Commentators have raised some basic questions about the nature of academic research and its direction. This debate is informed by

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565 Amy Kapczynski et al, 'Addressing Global Health Inequities: An Open Licensing Approach for
some key themes which are used to reflect upon the limitations of the existing licensing regime. These themes revolve around the concepts of ‘public goods’, the ‘commons’ and ‘social production’ and they help in shaping the alternative ideas of licensing best practices and appropriate models. It is presumed that effective intellectual property management through publicly-minded licensing can help in addressing the problem of access to medicines. Licensing tools can be innovatively reshaped in the form of socially responsible licences, equitable access licences, patent pools and a wide array of open source techniques. I have explored these themes in this chapter with the aim to see how existing licensing practices can be transformed to achieve the objective of equitable access.

Professor Amartya Sen’s conception of poverty and capability deprivation helps us in contextualising the constraints of conveying the benefits of publicly funded research to poor patients. He argues that poverty and capability deprivation may lead to social exclusion. In the case of health care, he writes that:

The exclusion of large sections of the population from public health services provided by the State has been a matter of considerable discussion in recent years, since it is an extensive problem in many Asian countries. To this some authors have proposed adding the international exclusion involved in the unavailability of modern health care in the poorer regions, often because of high medicinal cost (for example, for the medical care of AIDS patients). 566

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The intellectual property policies of research organisations and universities play an important role in widening the gap of social exclusion. Equitable licensing schemes can provide a satisfactory solution to this problem to reduce the incidence of social exclusion.

Part II of this chapter deals with academic innovations and open licensing strategies. After explaining the current licensing practices of academic institutions, I have explored alternative approaches which are mainly focused on adopting carefully crafted safeguard measures. The proposed Indian law dealing with patents on publicly funded research is also discussed in this part. Part III specifically deals with the Open source drug discovery model. Various theoretical perspectives and practical nuances of open source are discussed in this section before exploring the prospects for this model for India. Part IV considers the patent pools proposal and the initiatives of UNITAID and GlaxoSmithKline are analysed to determine their relevance in the Indian context.

After surveying various licensing regimes and the experience of academic licences in the United States, it is concluded here that the access to medicines problem in developing countries can be partially dealt with through public minded licensing practices. Universities and academic institutions can proactively perform their role through innovative means and the existing regulatory framework can also be used in this regard. The chapter further concludes that a one-size-fit-for-all approach picked up by the Indian government would not help in achieving the stated objectives of accessibility and technology transfer. A comparison of different models shows that India can benefit substantially from an open source regime instead of following a patent based framework.
II. Academic Innovations and Open Licensing Strategies

A. The Bayh-Dole Act of 1980 (US)\textsuperscript{567}

In the United States, the role of universities in respect of innovation has been shaped by a series of policy interventions and transformations in the marketplace.\textsuperscript{568} Historically, universities in the United States were seen as institutions deeply rooted in the traditions of social values and public interest. Grounded in the tradition of academic freedom, the creative and academic atmosphere in universities was always aimed at optimising the public benefit. It was widely believed that universities had their social responsibility towards the community and the academy should play that role to enhance the social well-being of the masses. This public mission of universities was defined in terms of promoting the common good through academic policies and practices.\textsuperscript{569} The initial scientific research was heavily influenced by the notion of ‘communalism’, in which scientific innovation was treated as a common good, and intellectual property rights were waived.\textsuperscript{570} The knowledge so created should be then freely communicated and distributed.


\textsuperscript{568} David C. Mowery et al, Ivory Tower and Industrial Innovation: University-Industry Technology Transfer Before and After the Bayh-Dole Act in the United States (California: Stanford University Press, 2004).

\textsuperscript{569} American Association of University Professors ‘1940 Statement of Principles on Academic Freedom and Tenure’ (1940) at http://www.aaup.org/NR/rdonlyres/EBB1B330-33D3-4A51-B534-CEF0C7A90DAB/0/1940StatementofPrinciplesonAcademicFreedomandTenure.pdf. The statement maintains that: ‘Institutions of higher education are conducted for the common good and not to further the interest of either the individual teacher or the institution as a whole. The common good depends upon the free search for truth and its free exposition.’

\textsuperscript{570} Robert Merton identified four norms underpinning the operation of the scientific community:
Throughout this period, public funding played a pivotal role in determining the scope and direction of universities research priorities. According to Professor Rebecca Eisenberg of the University of Michigan Law School, universities in this era were not directed to adopt a uniform and strict ownership regime in the form of a coherent patent policy, and campuses were given freedom to determine the best mode of dissemination and transfer of technology. She notes that:

Congress did not follow the suggestion of the Attorney General to adopt a uniform policy vesting ownership of all federally sponsored research discoveries in the government, although over the years it did enact such a policy on a more limited basis in a number of statutes applicable to particular programs or agencies. Agencies not bound by such explicit statutes had considerable discretion to choose whatever patent policy best suited their missions. Not surprisingly, there was considerable variation in the policies adopted by the different agencies.571

(Footnotes omitted)

However, this policy was fundamentally changed with the promulgation of two laws in the United States aimed at streamlining the intellectual property management of


publicly funded innovations and transfer of technology. The statutes include the *Stevenson-Wydler Technology Innovation Act of 1980* (US) and the *Bayh-Dole Act of 1980* (US).

Birch Bayh, one of the sponsors of the *Bayh-Dole Act of 1980* (US) has reflected upon the significance of the legislation: ‘This legislation combined the ingenuity and innovation from our university laboratories with the entrepreneurial skills of America’s small businesses.’ He contends that ‘this combination created the incentive necessary for private investment to invest in bringing new ideas to the marketplace’.

A wealth of literature is now available on the implications of *Bayh-Dole Act of 1980* (US) covering issues from technology transfer to the effect of this law on universities patents profile and income generation. Researchers have also analysed the actual implications of this law in terms of patenting activity in the pre- and post-legislation era, and how the law has changed the dynamics of learning, innovation and research in United States universities. An analysis along these lines does not lie within the scope of this section and I refrain from engaging in this discussion.

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575 Ibid.

Nevertheless, it is important to mention that the *Bayh-Dole Act of 1980* (US) changed the presumption of ownership of government funded inventions. This shift in the presumption is in favour of the recipient of the funding unless a contrary intention arises. Since its enactment, the *Bayh-Dole Act of 1980* (US) has drastically changed the patenting practices of universities. Shortly after the implementation of the law, a manifold increase was reported in the number of patents secured by the universities. In 1979, before the adoption of the law, universities secured merely 264 patents. This number grew almost ten times with 2,436 patents filed in 1997. A more than 12% increase was witnessed in the year 2000 when universities filed 8,534 patents. Likewise, massive patenting activity was noticed related to the National Institutes of Health funded inventions.577

This increase in university patents on publicly funded inventions is not static and some recent studies show that the trend is now downward within the United States. The statistics about the large number of university patents are often misleading, as they tend to overstate the potential benefits of the *Bayh-Dole Act of 1980* (US). Despite this caveat, a significant impact of the *Bayh-Dole Act of 1980* (US) on university patents is undeniable. The *Bayh-Dole* factor coupled with the advent of biotechnology and several advancements in the area of chemistry contributed towards new modes of wealth creation and resource generation in United States universities.578 Several new drugs were


developed and successfully licensed to private companies which encouraged the adoption of royalty based licensing strategies. Technology transfer offices of universities had been established to facilitate licensing arrangements between universities and their private commercial partners.  

The *Bayh-Dole Act of 1980* (US) contains a march-in provision which allows the funding agency, on its own initiative or at the request of a third party, to effectively ignore the exclusivity of a patent awarded under the act and grant additional licenses to others. This right is limited and can only be exercised if the agency determines, after an investigation, that one of four criteria is met. The most important of these are a failure by the licensee to take 'effective steps to achieve practical application of the subject invention' or a failure to satisfy 'health and safety needs' of consumers.  

Though it looks a promising safeguard, in practice this right has never been successfully used in the history of the legislation. Indeed, all attempts to invoke the march-in right clause for public health purposes thus far, have failed. Three unsuccessful petitions have so far been filed with the NIH requesting the exercise of march-in rights on the ground

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581 The negotiation history of the *Bayh-Dole Act of 1980* (US) reveals that march-in rights were once exercised by a government department prior to enactment of this law. David Halperin reports that march-in rights were exercised in respect of one of two patents held by MIT, which were not being effectively utilised. For details see: David Halperin, 'The Bayh-Dole Act and March-In Rights', *Essential Inventions*, (May 2001) at [http://www.essentialinventions.org/legal/norvir/halperinmarchin2001.pdf](http://www.essentialinventions.org/legal/norvir/halperinmarchin2001.pdf)
that the licensee had failed to achieve practical application of the subject invention. There is also a new petition under consideration in 2010.

In the first case, *In Petition of CellPro, Inc*, the NIH denied the petition of CellPro that The Johns Hopkins University should be directed to license the petitioner the patent necessary to continue its business. The petitioner argued that The Johns Hopkins University and Baxter Healthcare failed to take reasonable steps to commercialise certain patented stem cell technologies. NIH declared that The Johns Hopkins University had adequately licensed its technology which was sufficiently practiced by the licensee and that the exercise of the march-in right would have adverse effects on commercialisation of federally funded research.

In the second case, *In the Case of Norvir*, the NIH again rejected a petition of Essential Inventions to exercise march-in rights for patents owned by Abbott Laboratories related to the drug ritonavir, marketed under the trade name Norvir. This drug was used as an important antiretroviral and Abbott was marketing it at a considerably high price. Essential Inventions’ petition was also supported by the members of United States Congress. In dismissing the petition the NIH observed that:

Ritonavir has been on the market and available to patients with HIV/AIDS since 1996, when it was introduced and sold under the trade name Norvir® as both a

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standalone protease inhibitor and a booster to increase the effectiveness of protease inhibitors marketed by other companies. Thus, the invention has reached practical application because it is being utilized and has been made widely available for use by patients with HIV/AIDS for at least eight years ... Accordingly, this drug has reached practical application and met health or safety needs as required by the *Bayh-Dole Act*.\textsuperscript{584}

On the question of the high price and consumers’ inability to afford this medicine, the NIH referred this matter to Congress and other government agencies empowered to consider these arguments.

For the third time, *In the Case of Xalatan*, the NIH was petitioned to exercise a march-in right related to Pfizer’s glaucoma drug. The petitioner, Essential Inventions, asked that the NIH should adopt a policy of granting march-in licenses to patents when the patent owner charged significantly higher prices in the United States than they did in other high income countries. Citing its determinations in the earlier two cases, the NIH once again denied an exercise march-in right under the *Bayh-Dole Act of 1980* (US) maintaining that price cannot be regulated through the extraordinary remedy of march-in.\textsuperscript{585}

In August 2010, Joseph M. Carik, Anita Hochendoner, and Anita Bova requested the Secretary of DHH to exercise Bayh-Dole march-in rights and grant an open license to use patents related to the manufacture of Fabrazyme® (agalsidase beta). The grounds for the request are that the patent owner and its exclusive licensee have harmed the

\textsuperscript{584} National Institutes of Health-Office of the Director, ‘In the Case of Norvir® Manufactured by Abbott Laboratories, Inc. (July 29, 2005) 5-6 at http://www.ott.nih.gov/policy/March-in-norvir.pdf

public health by severely rationing the supply of agalsidase beta, the only approved therapeutic treatment for Fabry disease. Fabry disease (also known as Fabry’s disease, Anderson-Fabry disease, angiokeratoma corporis diffusum, and alpha-galactosidase A deficiency) is an X-linked recessive (inherited) lysosomal storage disease, which can cause a wide range of systemic symptoms. The petition states that:

The initial production of Fabrazyme® was sufficient to meet the needs of all patients in the United States. However, in mid-2009, Genzyme decreased production as a result of a viral infection of their Allston, MA manufacturing plant. Further, in November 2009, Fabrazyme® was produced which contained contaminants. The FDA initiated action against Genzyme which resulted in a consent decree including $175 million dollars fines as profit disgorgement and oversight of the manufacture of Fabrazyme® for at least 7 years. Genzyme is only producing 30% of Fabrazyme estimated to meet the needs of patients. Current patients cannot have dosage increases, and no new patients being diagnosed are eligible to receive therapy. Although the most recent communication from Genzyme indicates that it expects to increase production by late 2011, there is no substantial guarantee that the projected date will be met.586

These cases demonstrate that safeguard provisions can face several practical limitations and their mere incorporation in the law or licensing document is not sufficient. NIH had construed the march-in provision very narrowly by giving much consideration to the commercialisation objective of the Bayh-Dole Act of 1980 (US). The fact that march-in rights have never been practised in the United States should, however, have been

586 Petition To Use Authority Under The Bayh-Dole Act To Promote Access To Fabryzyme® (Agalsidase Beta), An Invention Supported By And Licensed By The National Institutes Of Health Under Grant No. Dk-34045 at http://patentlawyersite.com/files/Download/Fabryzyme_Petition_5_0.doc
construed in right context. The pharmaceutical market in the United States is very different from markets such as India and other developing countries. There might have not been very pressing cases of inaccessibility in the United States which can build up an appropriate case for march-in type interventions. The point is simple: that practical failure of the march-in clause should not become an argument to avoid the incorporation of this right in the statutes of other countries. A march-in right can achieve desirable policy goals with institutional support and political will.

Birch Bayh, one of the sponsors of the *Bayh-Dole Act of 1980* (US) has defended the refusal by the NIH to exercise march-in rights, arguing:

> It would be the ultimate folly to march in and alleviate the problem addressed by the petition, availability of a drug to treat AIDS today, and in so doing dampen the ingenuity, entrepreneurial skills and incentives necessary to develop a permanent cure for AIDS, or for that matter the cure for other diseases that plague all too many American mothers, fathers, children and seniors today.\(^{587}\)

However, in my view, these failed attempts to exercise march-in rights show the inherent limitations of the *Bayh-Dole Act of 1980* (US). Despite the safeguard provisions and related flexibilities, the licensing practices could not be modified to protect public interest. It is troubling that one of the sponsors of the *Bayh-Dole Act of 1980* (US) should be so hostile to the use of march-in rights.

There have been some unsuccessful attempts to ameliorate the *Bayh-Dole Act of 1980* (US). In the United States, Senator Patrick J. Leahy introduced the *Public Research in the Public Interest Act of 2006* (US) on September 29, 2006 to ensure that inventions

\(^{587}\) Birch Bayh, ‘Statement to the National Institutes of Health’, the National Institutes of Health, 25 May 2004, 6 [www.orpc.unh.edu/Bayhstatement.pdf](http://www.orpc.unh.edu/Bayhstatement.pdf)
developed at federally-funded institutions are available in certain developing countries at the lowest possible cost.\textsuperscript{588} Although this Bill never became law, the Bill is viewed as symbolic of dissatisfaction with the \textit{Bayh-Dole Act of 1980} (US), the workings of the National Institutes of Health, and limitations to access to publicly funded research. While introducing this Bill in the House, Senator Leahy observed that:

If passed, my bill would greatly lessen the cost burden of generic drugs in the developing world. It would achieve this by requiring federally funded research institutions to permit their inventions, such as drugs, vaccines, and innovative medical devices, to be provided inexpensively by generic companies distributing medical supplies to the developing world. Federally funded labs and research institutions have a vital role to play in meeting this goal ... It is time to ensure that public funds truly serve public purposes – in this instance, delivering essential health care needs at minimal costs to American taxpayers, universities, and pharmaceutical companies.\textsuperscript{589}

This Bill specifically would have required that universities adopt such licensing provisions to allow generic competition in developing countries to reduce prices.\textsuperscript{590}

Given the lack of bipartisan support and strong industry lobbying, this Bill will not be

\textsuperscript{588} The Senate of the United States, \textit{‘Public Research in the Public Interest Act of 2006-S4040’} (109\textsuperscript{th} Congress, 2\textsuperscript{nd} Session) at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_bills&docid=f:s4040is.txt.pdf


\textsuperscript{590} The Senate of the United States, \textit{‘Public Research in the Public Interest Act of 2006-S4040’} (109\textsuperscript{th} Congress, 2\textsuperscript{nd} Session) Section 5 at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_bills&docid=f:s4040is.txt.pdf
adopted in the foreseeable future and university licensing practices will continue to be governed by the *Bayh-Dole Act of 1980* (US).

In this context, universities and academic institutions are left with one option and that involves changing their own licensing practices. Professor Arti Rai and others have provided a list of safeguards which can serve the public interest and which universities should adhere to while entering into technology licensing agreements. They are of the view that licences negotiated within the framework of the *Bayh-Dole Act of 1980* (US) can also ensure that public interests are served. Under the notion of social responsibility and public interest, universities and academic institutions are considering options regarding humanitarian licensing.

**B. Licensing University Technology**

Since the enactment of the *Bayh-Dole Act of 1980* (US), universities have developed several breakthrough drugs for the treatment of emerging diseases and epidemics which were then licensed to pharmaceutical companies for commercial exploitation of technologies. In addition to stavudine discussed earlier, several key treatments were developed as a direct outcome of public funding which universities then licensed exclusively to private companies. The University of Minnesota licensed its patented drug, carbovir, to GlaxoSmithKline which was used to develop the antiretroviral drug, Ziagen. This drug was developed with NIH funding and its annual sales went up to US $800 million. The University of Minnesota secured 5 to 10% of sales revenue as

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592 Evelyn Cottle Raedler, ‘Chemical Cures’ University of Minnesota Alumni Association (November 13, 2003) at [http://www.alumni.umn.edu/Chemical_Cures.html](http://www.alumni.umn.edu/Chemical_Cures.html)
royalty payments. Other examples include Duke University’s patent on enfuvirtide and Emory University’s patent on lamivudine.

A recent study shows that academic institutions in the United States still have a substantial share of total drug patents granted during the period of 1988 to 2005. During the research period, out of 1,947 patents on new drug applications, 96 were academic patents. Though lesser in number, most of these patents belong to the upstream category which is very crucial for further research and development. The study further shows that 12 of 72 drugs with academic patents belong to HIV/AIDS drugs and the ratio of academic patents in the HIV/AIDS category is unusually high. The study concludes that:

The overall share of drugs approved between 1988 and 2005 on which universities own patents was relatively low – 7.7% – and the share for new molecules was only slightly higher – 10.3%. However, universities own patents for nearly 1 in 5 (19.2%) of the drugs that are arguably the most innovative – new molecular entities that received “priority” approval by the FDA; this share has been basically stable since the late 1980s. In addition, universities own key patents on over one quarter of the HIV/AIDS drugs approved since 1988, which is particularly important given the potentially catastrophic impact of this disease in the developing world.\(^{93}\)

These findings are critical for two reasons. First, this study presents the most updated picture of academic patents and confirms the relevance of these patents to the access to medicine debate. Second, the study clearly establishes that academic patents can be leveraged to ensure accessibility of drugs in developing countries. Though the problem

of the research gap, according to this study, cannot be effectively dealt with university-level intervention, these institutions can definitely play a crucial role in improving access conditions.

Exclusive licensing and restricted access clause are common features of university license agreements. The ownership of these crucial patents by the universities has further aggravated the dismal state of access to essential medicines in developing countries. These technologies are quite often licensed to pharmaceutical companies, giving them full rights to determine the countries where they intend to file subsequent patents. The companies generally file strategic patents in many developing countries to minimise the risk of generic competition.

Over the years, a strong resentment and frustration has emerged regarding university licensing and patent policies. Commentators have started raising questions about the role which universities actually play through their licensees who restrict the access to essential products in the developing world. The controversy about the role of Yale University regarding the Zerit (stavudine) patent triggered a thorough debate among academics and students and strong voices emerged calling for revisiting universities’ licensing policies and practices.

Indeed, the case of stavudine was merely a point of culmination as the debate had already started yielding some positive outcome in some American universities. The concept of socially responsible licensing first emerged in 2002 when Eva Harris, an Associate Professor at the School of Public Health, started negotiating a license related to dengue fever’s diagnosis technology with the University of California, Berkeley. This

technology known as ImmunoSensor was believed to help greatly in reducing the burden of dengue fever, a leading cause of death in many developing countries. Acumen Fund, a non-profit global venture fund, agreed to invest in the development of this technology and they proposed a licence to the university which would allow them to use this technology free, or at cost, in developing countries. According to the arrangements, the university was allowed to earn future royalties from this technology by marketing it in developed countries.595

This served as a starting point and many agreements were then concluded between the University of California, Berkeley and its partners, opening the door for free access for patients in developing countries. Josefina Coloma observes that:

SSI helped set the stage for this concept by developing an agreement with the UC Berkeley Office of Technology Licensing to obtain the right to market one of UC Berkeley’s patents “at cost” in the developing world. This was swiftly followed by several widely publicized agreements involving royalty-free licenses for developing countries’ use of products-including the Gates-funded project for artemisinin synthesis in Escherichia coli being conducted at UC Berkeley, the Institute for OneWorld Health, and Amyris Biotechnologies, and an agreement between UC Berkeley and Samoa for development of plant-derived pharmaceuticals. Importantly, a new movement for “socially responsible licensing” has been born, led by UC Berkeley, Harvard University, Massachusetts Institute of Technology, Yale University, University of Minnesota, and Columbia

University, to share ideas on bringing access to technology and medical treatments to the developing world.596

The concept of socially responsible licensing worked in certain cases but there is no evidence that it was practically adopted by the academic institutions as a norm and standard licensing practice.597

In 2007, top US universities and the Association of American Medical Colleges issued guidelines for responsible licensing policy guidelines. These guidelines, entitled ‘In the Public Interest: Nine Points to Consider in Licensing University Technology’598, consider various aspects of technology licensing and its social impacts. The points include universities’ right to retain the power to practice licensed technology; the appropriate scope of exclusive licensing; attempts to minimise the risk of licensing future improvements; avoiding conflict of interest, access to research tools; careful


597 Some universities have taken serious initiatives towards adopting policies and guidelines on socially responsible licensing but most of the universities have yet to respond. For University of California, Berkeley see: Office of Intellectual Property and Industry Research Alliances, ‘Socially Responsible Licensing at U.C. Berkeley: An Intellectual Property Management Strategy to Stimulate Research Support and Maximize Social Impact’ (accessed on June 22, 2009) at http://ipira.berkeley.edu/docs/sociallyresponsible11-07.pdf

598 Participating institutions include: California Institute of Technology, Cornell University, Harvard University, Massachusetts Institute of Technology, Stanford University, University of California, University of Illinois, Chicago, University of Illinois-Urbana-Champaign, University of Washington, Wisconsin Alumni Research Foundation, Yale University and Association of American Medical Colleges (AAMC). For the full text and details: http://news-service.stanford.edu/news/2007/march7/gifs/whitepaper.pdf
enforcement actions and the unmet needs of patients in developing countries. It is pertinent to note that these guidelines do not specifically address the problem of academic patents in developing countries. The focus of these guidelines is limited to licensing practices and the role of patents in developing markets is conspicuously missing in this document. The last point acknowledges some of the access barriers in the developing world but do not categorically place a social responsibility on academic institutions to ensure that their licensing agreements must stipulate that licensee would not expand market exclusivity to developing and least developing countries.

Amidst the controversy of the Yale-stavudine patent in 2001, the Universities Allied For Essential Medicines (UAEM) was established as a private non-profit organisation and it includes more than 46 campus chapters in leading universities of the United States, Canada and United Kingdom.\(^{599}\) UAEM aims to promote access to medicines for people in developing countries by changing norms and practices around university patenting and licensing. It further aims to ensure that university medical research meets the needs of the majority of the world’s population and empower students to respond to the access and innovation crisis.\(^{600}\) The UAEM has also adopted the ‘Philadelphia Consensus Statement on Universities Policies for Health Related Innovations’.\(^{601}\) The statement highlights the problem of access to essential medicines in developing countries and builds up a case for university action. Universities can play their role in three distinct ways by promoting equal access to university research, undertaking research for

\(^{599}\) For details see: the Universities Allied For Essential Medicines (accessed on June 23, 2009) at http://www.essentialmedicine.org/?page_id=40

\(^{600}\) Ibid.

neglected diseases and measuring research success according to the impact on human welfare.602

To materialise the objectives of this statement, the UAEM has developed and advocated a case for universities’ action in addressing global health inequities and calls for the adoption of open licensing approach. The group supports the Equitable Access License (EAL) and campaigns that major universities and academic institutions should adopt this license to demonstrate their commitment to social responsibility. The details of the Equitable Access License are discussed in Part III of this Chapter. The UAEM follow a simple and straightforward approach by proposing that universities’ technology licenses should encourage generic competition in developing countries.

C. The Protection and Utilisation of Public Funded Intellectual Property Bill 2008 (India)

The Bayh-Dole Act of 1980 (US) represents an influential model of public sector licensing and over the last decade many countries attempted to adopt this model for their academic and research institutions. A report of the Organization of Economic Cooperation and Development (OECD) claims that the treatment of government funded research as a public good may not be sufficient for economic growth. The report suggests that academic institutions and researchers should be provided opportunities to commercialise their inventions by creating spin-off companies and joint ventures with the commercial sector.603 Though the report does not specify a particular model which countries can adopt to achieve the goal of intellectual property commercialisation, it categorically refers to some of the benefits which US institutions have reaped after the

602 Ibid.

enactment of the *Bayh-Dole Act of 1980* (US). With regard to the practices of OECD countries, the report states that:

Across OECD countries, laws and policies governing the ownership of IP generated with public research funds are being re-examined with a view to encourage ownership of inventions by the institution performing the research ... Austria, Denmark, Germany and Norway have recently introduced new legislation to grant universities title to IP resulting from publicly funded research ... In Japan and Korea, recent reforms in funding regulations have given universities more control over the IP generated by their researchers. These policy trends echo the landmark US *Bayh-Dole Act* of 1980.604

This trend is not only confined to economically developed countries and recently many developing countries have also shown their interest in this direction.

In 2008, Indian government introduced the *Protection and Utilisation of Public Funded Intellectual Property Bill 2008 (India)* in the parliament to provide for the protection and utilisation of intellectual property originating from public funded research.605 According to the statement of objects and reasons:

To compete in a global environment, it is necessary for India to innovate and promote creativity. For promoting creativity and innovation, India needs to protect and utilise the intellectual property created out of public funded research and development. Over the years, the Government has invested large funds in research and development. To provide incentives for creativity and innovation, it is

604 Ibid. 11.

605 For the full text see:

necessary to develop a framework in which the protection and utilisation of intellectual property is put in place. The ultimate objective, however, is to ensure access to such innovation by all stakeholders for public good ... Such innovations can be utilised for raising financial resources of these establishments, through royalties or income.\textsuperscript{606}

This Bill has been largely criticised in India and it was lamented as the Indian \textit{Bayh-Dole} which would restrict access to publicly funded research.\textsuperscript{607}

Before turning to the substantive provisions of the \textbf{Protection and Utilisation of Public Funded Intellectual Property Bill 2008 (India)}, it is pertinent to analyse some broader policy issues underlying the legislative proposal in India. Three basic questions can be raised about this proposed law and their answers will determine the appropriateness of this proposition. First, is the Indian science and technology environment fully prepared to respond to the so-called opportunities which this law will create? Second, given the level of development and technological advancement, what is the best model which India can follow to promote the culture of innovation? To what extent would a law modelled on the \textit{Bayh-Dole Act of 1980} (US) help achieve policy objectives? Third, what are the main concerns regarding the provisions of the proposed law and how can India learn from best practices used elsewhere?

The adoption of a law on the lines of the \textit{Bayh-Dole Act of 1980} (US) clearly presumes the existence of requisite innovative capacity on the part of Indian universities. However, it is arguable that the current state of science and technology in Indian

\textsuperscript{606} Ibid. 8.

\textsuperscript{607} For a detailed analysis of this Bill see: Shamnad Basheer, 'India Unveils National Innovation Act' \textit{Spicy IP Blog} (1 October 2008) at \url{http://spicyipindia.blogspot.com/2008/10/breaking-news-india-unveils-national.html}
universities is not very promising. There is no doubt that India is ‘shining’, particularly in the information and technology sector, and has achieved a tremendous growth rate during last few years but the educational institutions in India are still lagging behind. The public sector investment in research and education is marginal and Indian universities produce very little research. Most of the existing innovative capabilities are located in government agencies, particularly in the Council for Scientific and Industrial Research (CSIR), the Department of Science and Technology (DST), the Department of Biotechnology (DBT), the Ministry of Science and Technology, the Indian Council of Medical Research (ICMR), and the National Research and Development Council (NRDC). Although these institutions have produced great scientists and academics, the innovative capacity of the institutions has been relatively weak. In terms of patent filing, India’s ratio of resident to foreign is just 0.58% which is less than Russia, South Africa, China and Poland. This is notwithstanding that India is

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608 The slogan ‘shining India’ became popular in 2003-04 during information technology boom. However, commentators have challenged this notion by raising questions about malnutrition, poverty, illiteracy and poor governance. See: H. S. Virk, ‘Does India Shine in Scientific Research?’ (July 2004) 87 (1) Current Science 7 at http://www.ias.ac.in/currsci/jul102004/7.pdf

609 The Council for Scientific and Industrial Research at http://www.csir.res.in/

610 The Department of Science and Technology at www.dst.gov.in

611 The Department of Biotechnology at http://dbtindia.nic.in/index.asp

612 The Ministry of Science and Technology at http://www.dst.gov.in/

613 The Indian Council of Medical Research at http://icmr.nic.in/

614 The National Research and Development Council at http://www.nrdcindia.com/

also emerging as a key destination of global R&D outsourcing; the pharmaceutical sector is prominent in this regard.

As a matter of comparative law, the suitability and relevance of transplanting the legal model of the Bayh-Dole Act of 1980 (US) to India in the 21st century is another crucial question. The Protection and Utilisation of Public Funded Intellectual Property Bill 2008 (India) suggests that Indian policy makers are fully satisfied with the United States model and they have simply replicated the same provisions in the proposed law. Arguably, this is an instance of what Australian pundits would call ‘a cultural cringe’.616 The sponsors of this Bill have failed to address the fundamental question of the relevance of the United States model to India and its possible implications on the innovation culture and public domain. The proponents of a Bayh-Dole type model argue that universities in the United States hugely benefited from this law and universities secured better licensing royalties as a result of the new regulation. However such claims are not necessarily supported by empirical evidence. Professor Eisenberg analysed the data in this regard and held that the impact of the Bayh-Dole Act of 1980 (US) was marginal.617

In fact, the latest data shows that academic patents are in decline domestically in the United States and with the emergence of new criteria for the ranking of universities, patents are increasingly losing their importance for universities. Relying on data from 1990 to 2008, Loet Leydesdorff and Martin Meyer suggest that there is a decline in university patenting in United States and European Union:


At the global level university patenting is still gaining momentum, but in the most advanced economies the effects of the Bayh-Dole Act of 1980 seem to have faded away since the turn of the millennium. In our opinion, the reason for this is structural. More universities are nowadays increasingly ranked in terms of their knowledge output, and patents or spin-offs are usually not part of this ranking ... The nature of the competition among universities is changing, and the incentive to patent has thus withered. International collaborations and co-authorships, for example, have become more important in research assessment exercises than university-industry relations.618

Given that there are few university patents in India, the legislation may result in the same chilling effects which are now reported in other countries. It is a simplistic approach to expect that the introduction of a new Bill would have purely positive effects on innovative culture. The Indian Government should engage with the empirical evidence garnered from the experiment of the Bayh-Dole Act of 1980 (US).

One of the objectives of the Bayh-Dole Act of 1980 (US) was to mobilise additional revenues and financial resources for academic institutions. Indeed, the Protection and Utilisation of Public Funded Intellectual Property Bill 2008 (India) also envisages similar objectives. The failure of the Bayh-Dole Act of 1980 (US) is well established in this regard. Anthony D. So observes that the commercial benefits of patenting to universities have been overstated:

In 2006, US universities, hospitals, and research institutions derived US$1.85 billion from technology licensing compared to US$43.58 billion from federal,

state, and industry funders that same year, which accounts for less than 5% of total academic research dollars. Moreover, revenues were highly concentrated at a few successful universities that patented “blockbuster” inventions. A recent econometric analysis using data on academic licensing revenues from 1998 to 2002 suggests that, after subtracting the costs of patent management, net revenues earned by US universities from patent licensing were “on average, quite modest” nearly three decades after [Bayh-Dole] took effect.\textsuperscript{619}

Lita Nelson, former president of the Association of University Technology Managers goes one step ahead and states that: ‘The direct economic impact of technology licensing on the universities themselves has been relatively small (a surprise to many who believed that royalties could compensate for declining federal support of research).’\textsuperscript{620} In light of such research, the Indian government should conduct a cost-benefit analysis on these lines to determine how much the proposed Bill would contribute towards revenue generation.

There are several additional points which establish that the Bayh-Dole Act of 1980 (US) is not an ideal model and it has many negative implications on public science. To promote innovation and technological development, the Indian government should itself adopt an innovative policy approach. So far we have seen that India’s innovative capacity is still at its nascent stage, it needs more creative space rather than exclusivity based property rights, to flourish. Furthermore, the Bayh-Dole Act of 1980 (US) does not represent an ideal model which India can readily adopt for its domestic purposes.


The Bill fails to address one of its stated objectives as no mechanism is envisaged to protect the public interest. According to ex-Indian science minister, Kapil Sibal, ‘the benefits of publicly funded research are not reaching the public’. But the policy response to this situation in the form of *Protection and Utilisation of Public Funded Intellectual Property Bill 2008 (India)* is less likely to improve this situation. It rather goes to introduce measures which will narrow the public domain by creating new intellectual property rights. According to its proposed scheme:

The bill is modelled on the 1980 US *Bayh–Dole Act*, which allowed US universities to patent discoveries derived from federally funded work. According to the Indian bill, scientists would be allowed to retain 30% of the net income earned from patents and licences. The scientist’s institute would retain 40%, with the rest going into a fund maintained by the institute for managing intellectual property. Researchers in publicly funded institutes or universities would also be allowed, for the first time, to set up and work in private companies without having to leave their academic jobs.

There is no effective public use mechanism envisaged in the *Protection and Utilisation of Public Funded Intellectual Property Bill 2008 (India)*. The drafters even failed to incorporate a march-in right provision which was discussed earlier in the preceding section. It is ironical that the law is drafted along the lines of the *Bayh-Dole Act of 1980* (US), but it does not contain a march-in right provision. There is only one similar provision in the Bill with quite restricted language. According to this provision government has a right to refuse the title of a research institution within ninety days of

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622 Ibid.
learning of the research institutions' intention to retain a patent.\textsuperscript{623} This brief period of ninety days is a big limitation and beyond that period, government would not be able to exercise this right. In pharmaceuticals, the decisions about retaining patent rights are made at very early stages and they would be accordingly communicated to the government. How the government can react within ninety days of such communication when the application of a patented invention is not yet known for the treatment of an epidemic? This time bound access clause is indeed narrower than the march-in right provided in \textit{Bayh-Dole Act of 1980 (US)}.\textsuperscript{624}

Another problematic aspect of the \textit{Protection and Utilisation of Public Funded Intellectual Property Bill 2008 (India)} is its scheme which is designed to ensure that universities and publicly funded institutions must apply for patent protection. Universities will have to follow strict timelines throughout their research processes to ensure compliance. A researcher must disclose the invention immediately after learning of the patent right.\textsuperscript{624} Thereafter, the research institute has sixty days to notify the government about the invention and the institution has ninety more days to show its intention to retain patent rights over the disclosed intention.\textsuperscript{625} These compressed timelines are unprecedented as the \textit{Bayh-Dole Act of 1980 (US)} merely demands such notifications within a reasonable time. It is anticipated that when universities will not been given appropriate time to make their decisions, it may lead to excessive strategic patents notification at an early stage to secure future interests.

\begin{footnotesize}
\begin{itemize}
\item \textsuperscript{624} Ibid. Section 9.
\item \textsuperscript{625} Ibid. Section 4 and Section 5 (1).
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\end{footnotesize}
This analysis show that the Indian attempt to adopt a licensing regime for publicly funded research and development suffers from serious deficiencies. In my view, the Indian government should withdraw the proposal, and initiate a new process to formulate a coherent and consistent policy regarding public sector licensing. The Indian National Knowledge Commission declared in 2007 that intellectual property infrastructure and assets should be used in the best public interest and for the overall benefit of society.626 The Protection and Utilisation of Public Funded Intellectual Property Bill 2008 (India) is an antithesis of this approach as it restricts the public domain by encouraging private rights over public benefit.

III. Open Source Drug Discovery

Richard Stallman introduced the concept of free software amidst the strong wave of commercialisation in the field of computer programs and software.627 As a member of the Massachusetts Institute of Technology’s Artificial Intelligence Laboratory, Stallman laid the foundation of the free software movement by advocating that software users should be able to run a program for any purpose. Software is free if a user can analyse and improve it for further distribution and its source code is disclosed and copyright restrictions are removed though a typical copyleft licence. The free software movement was later institutionalised thorough the Free Software Foundation628 which adopted the

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628 For an overview and introduction, see the Free Software Foundation: http://www.fsf.org/
General Public Licence (GPL) approach to facilitate software distribution in a non-
proprietary fashion.

In 1998, Bruce Perens and Eric S. Raymond established the Open Source Initiative
which prompted the beginning of the open source software movement. Perens and
Raymond did not share Stallman’s position on proprietary software and their initiative
was basically the establishment of a certification body for open source licences.

The non-proprietary software movement and open source initiative rapidly attracted
considerable attention and contributed in the development of several important
computer programs which were later expanded by successive generations of
programmers. Despite the peculiarity of the term ‘open source’ with regard to computer
programs, the term is now widely used in other disciplines, too, as denoting the notion
of unrestricted and free access. Open source techniques are now suggested in certain
unconventional areas such as biotechnology, ecology and medicines and open source
ideology propagates lesser or no use of intellectual property protection in the form of
copyright and patents.

Open source drug discovery is a relatively new phenomenon which is proposed to off-
set the problems which are typically associated with patented medicines and
pharmaceuticals. The existing patent system provides incentives for pharmaceutical
research and development for the treatment of certain disease categories which
generally affect the affluent group of patients. This system has shown established failure
in the area of neglected and tropical diseases. The open source drug discovery

629 For details see, the GNU Operating System: http://www.gnu.org/

630 For the objectives and products of the Open Source Initiative: http://www.opensource.org/

631 Bernard Pécoul et al., ‘Access to Essential Drugs in Poor Countries: A Lost Battle?’ (1999) 281 The
Journal of the American Medical Association 361-367 at http://jama.ama-
proposal is aimed at addressing this problem by locating the incentives for new drug
discovery away from traditional intellectual property methods.

A. Philosophy of Open Source Drug Discovery

A number of commentators have provided detailed theoretical justifications for the
remarkable success of the open source movement in the area of computer programs and
software.\textsuperscript{632} The nature of information technologies, incentives associated with the open
programming, the probability of low cost production and the assimilation of a critical
mass of technically skilled people are some reasons which are commonly attributed to
the success of the open source movement. Lately, some commentators have started
exploring more generic explanations of the open source initiative with the aim to
explore a feasible open source model for technologies other than computer programs.

The most comprehensive account of open source development – both as a theory and
technique – is provided by Yochai Benkler, a professor of law at Harvard Law School.
In his seminal article\textsuperscript{633} for the \textit{Yale Law Journal} in 2002, Benkler used a ‘Coasean’\textsuperscript{634}
rationale to explain commons-based approaches to managing resources in networked
environments. This work was later expanded through \textit{The Wealth of Networks: How

\textsuperscript{632} Josh Lerner and Jean Tirole, ‘The Open Source Movement: Key Research Questions’ (May 2001) 45
(4-6) \textit{European Economic Review} 819-826 and Eric von Hippel and Georg von Krogh, ‘Open Source
Software and the “Private-Collective” Innovation Model: Issues for Organization Science’ (March-April

369-446 at \url{http://yalelawjournal.org/112/3/369_yochai_benkler.html}

\textsuperscript{634} Refers to the theory presented by Ronald Coase about the efficiency of firms’ decisions and
transaction cost. For details see: Ronald H. Coase, ‘The Problem of Social Cost’ (October 1960) 3 \textit{The
Journal of Law and Economics} 1-44.
Social Production Transforms Markets and Freedom\textsuperscript{635} where Benkler explains his view of networks, social production and open source methods. The book contains several intriguing ideas and in this section, I will confine myself to the extent of a brief explanation of the theoretical foundation of Benkler’s thesis.

At least three elements of Benkler’s thesis are directly related to the discussion of open source drug discovery and its objectives. The notion of social production and appropriate changes in existing intellectual property norms are key factors which can play a pivotal role in the transformation of the existing production process. Benkler advocates that social production will lead to the transformation of society by eradicating poverty and empowering masses living in developing countries.

Benkler asserts that most of the wealth accumulated in society is generated through non-proprietary motivations. In the realm of production methods, Benkler identifies at least six types of social production where half of them are inspired by propriety motives. He places ‘Scholarly Lawyers’\textsuperscript{636}, ‘Know-How’\textsuperscript{637} strategies and ‘Learning Networks’\textsuperscript{638} in the category of non-exclusive markets because they make money from information production but not by the exercise of exclusive rights. Benkler offers a list of another three non-exclusive non-market social production approaches. The first is dubbed ‘Joe Einstein’, where information is given away free of cost in return for status and the benefits for reputation. The second non-exclusive non-market social production approaches.


\textsuperscript{636} Lawyers writing blogs in public domain offering great insight of legal knowledge with a motive to attract and inspire new clients.

\textsuperscript{637} Firms that offer better or cheaper production process because of their research.

\textsuperscript{638} Making money through early access to information by sharing information with similar networks such as news wire services.
approach is labelled ‘Los Alamos’, where in-house information is shared with the
government departments to obtain additional funding and status. Benkler’s third
category is ‘Limited Sharing Networks’ where academicians share their papers with
peers for comments and improvements before publication and instances of information-
sharing on the condition of reciprocity such as ‘copyleft’ conditions.639 Benkler favours
the adoption and expansion of non-exclusive non-market approaches and compares
them with rights based on the exclusion approach where money is made by exercising
intellectual property rights such as patents and copyright.

Benkler argues that social production is often a better method of creating wealth as
compared to market based production which depends upon traditional incentives such as
monetary payments and intellectual property rights. Before turning to the point of
intellectual property, it is crucial to go through the theoretical basis of Benkler’s claim
about the superiority of social production. While elaborating his choice of production
regimes, Benkler relies upon Ronald Coase’s theorem in respect of transaction costs.640
His well-known theorem suggests that the transaction cost is a decisive factor when
firms choose to adopt a particular transaction model. If the transaction cost of
outsourcing is high then a firm will be inclined to undertake in-house production.

Instead of engaging with the diversity of data and its policy implications, Benkler
declares that intellectual property rights are not useful regulatory tools. He describes
that:

(New Haven and London: Yale University Press, 2006), 43. Benkler provides this comparison in the
tabular format and subsequently discusses some of these approaches at length.
640 This term is first used by Lior Strahilevitz while analyzing the work of Benkler. Lior Strahilevitz,
http://www.yalelawjournal.org/116/7/strahilevitz.html
When one cuts through the rent-seeking politics of intellectual property lobbies like the pharmaceutical companies or Hollywood and the recording industry; when one overcomes the honestly erroneous, but nonetheless conscience-soothing beliefs of lawyers who defend the copyright and patent-dependent industries and the judges they later become, the reality of both theory and empirics in the economics of intellectual property is that both in theory and as far as empirical evidence shows, there is remarkably little support in economics for regulating information, knowledge, and cultural production through the tools of intellectual property law.\textsuperscript{641}

Open source is a manifestation of social production and Benkler describes some promising features of open source which I will elaborate in the next section. Social production and open source methods are not merely alternative modes of production. To Benkler both means and ends are critical and he advocates that social production will ultimately transform the lives of the people and that ‘information policy has become a critical element of development policy’.\textsuperscript{642}

In the beginning of Chapter 9, ‘Justice and Development’, Benkler raises a key question: how non-exclusive production in the information economy will affect questions of distribution and human wellbeing? The answer is not simple and Benkler recognises the multiplicity of factors responsible for global inequality, poverty, hunger and injustice. After realising the pessimistic response to this question, Benkler pleads his case by maintaining that information, knowledge and culture are core inputs in human welfare and social production can provide a normative basis to resolve some of


\textsuperscript{642} Ibid. 302.
these sufferings. Benkler provides a detailed account of relevant elements through the
survey of liberal theories of justice and the network information economy and then
builds a case for concrete and asserted action in the realm of human welfare and
development, industrial organisation, access to medicines, food security and biomedical
research. He observes that social production "offers a new path, alongside those of the
market and formal governmental investment in public welfare, for achieving definable
and significant improvements in human development throughout the world."  

B. A Practical Model of Open Source Drug Discovery

The application of the open source model to the discovery of new drugs requires a
considerable adaptation of conventional open source techniques. Against the backdrop
of Benkler's theoretical approach towards social production and commons-based peer
production, it is now widely agreed that open source methods can be effectively used
for the production of resources and products beyond traditional computer programs and
software. The open source movement in bioinformatics has come to an age where the
bulk of the information and databases in this new field are available as non-proprietary
resources. The convergence of biology and computing has given rise to a phenomenal
expansion of open source software such as Biojava, BioPython, Bio-SPICE, BioRuby,
Simple Molecular Mechanics for Proteins, and Generic Software Components for Model Organism Databases (GMOD).

643 Ibid. 301-302.
644 Ibid. 355.
645 Biojava: http://biojava.org/wiki/Main_Page
646 BioPython: http://biopython.org/wiki/Main_Page
647 BioSpice: http://biospice.sourceforge.net/
648 BioRuby: http://bioruby.org/
649 Simple Molecular Mechanics for Proteins: http://www.smmp05.net/
In addition to these computing technologies in the area of bioinformatics, some basic science projects were also launched with open source modalities in the areas of biology, chemistry, and disease mapping. The SNP Consortium of the Wellcome Trust aimed to discover the genome data and place it in the public domain. An element of copyleft was introduced in the SNP Consortium’s public domain model with the HapMap Consortium’s funding which is aimed at comparing multiple human genomes to find disease causing variations.\textsuperscript{651}

Why is an open source drug discovery model important at all? Benkler has a clear answer to this question and he relates open source drug discovery to his desirable outcomes of social production. Benkler particularly states that:

One of the lessons we learn as we look at the networked information economy is that the work of governments through international treaties is not the final word on innovation and its diffusion across boundaries of wealth. The emergence of social sharing as a substantial mode of production in the networked environment offers an alternative route for individuals and non-profit entities to take a much more substantial role in delivering actual desired outcomes independent of the formal system. Commons-based and peer production efforts may not be a cure-all. However, as we have seen in the software world, these strategies can make a big

\textsuperscript{650} Generic Software Components for Model Organism Databases: \url{http://gmod.org/wiki/Main_Page}

\textsuperscript{651} For HapMap Consortium see: \url{http://www.hapmap.org/}. For a description and analysis of SNP Consortium database see: Gudmundur A. Thorisson and Lincoln D. Stein, "The SNP Consortium Website: Past, Present and Future" (2003) 31 (1) \textit{Nucleic Acids Research} 124-127 at \url{http://nar.oxfordjournals.org/cgi/content/full/31/1/124
contribution to quite fundamental aspects of human welfare and development. And this is where freedom and justice coincide.\(^652\)

But how will this transformation occur through open source drug innovation? Benkler recognises that there are practical bottlenecks and he offers a three pronged strategy which can be used to facilitate access to medicines through commons-based biomedical research. His model heavily relies upon academic institutions and universities and Benkler strongly advocates a major shift in the attitude of these institutions towards their existing patenting and licensing practices.

Universities can play a key role in improving the dismal state of access to medicines in the developing world by revisiting their intellectual property policies. Empirical evidence also shows that universities in the United States can actually afford forgoing some of their patent rights by entering into licensing arrangements which allow generic competition in certain jurisdictions. Benkler argues that the revenue of top United States universities generated through patent licensing is only a minor portion of their gross income.\(^653\) These universities would not loose substantial revenues if they adopted an Equitable Access License, a legal device engineered by Yochai Benkler and Samantha Chaifetz.\(^654\)

The centrality of the Equitable Access License in Benkler’s model is evident both from his book and subsequent writings. An Equitable Access License is aimed at achieving


\(^{653}\) Ibid. 340.


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the goal of marginal cost pricing for health related products in low and middle income countries. The details of this licence are important as it contains some critical features to ensure access through generic production. By adopting an Equitable Access License, university technology transfer agreements will allow generic competition by providing open licences which will guarantee third party manufacturers the right to compete in low and middle income countries. The inclusion of middle income countries along with low income is important to ensure the practical feasibility of this proposal as generic competition can come only from some middle income countries. An Equitable Access License does not deliberately adopt the 'so-called' fair pricing approach where universities can stipulate appropriate pricing caps on manufacturers. Such an obligation will increase the risk of litigation and involves the establishment of detailed and elaborated monitoring mechanism which universities may not like to do. Thus, a simple market-based mechanism is proposed to facilitate generic competition.655

The scope of an Equitable Access License is less restrictive and it covers a wide range of health technologies and products. It categorically rejects the notion that developing countries only need some medicines for the treatment of infectious diseases. An Equitable Access License is thus designed to cover chronic non-communicable diseases too which constitute a major portion of the burden of disease in the developing world.

An Equitable Access License works in three steps. In the first step, a licence of innovation is exchanged between the university and the licensee. University grants rights which enable the licensee to practice the technology in designated jurisdictions. At this stage, the licensee will grant back certain rights to the university which include all the exclusive rights which the licensee has that could prevent a third party from using the end product. This is a critical aspect of an Equitable Access License as the

655 Ibid.
granting back of these rights is crucial for a third party manufacturer in a low or middle income country. However, a licensee is not supposed to grant back its own material property rights such as cell lines. The second stage involves the notification procedure from an intended third party which wants to exploit licenced technology in low and middle income countries. The grant of this right to a third party will be almost automatic after notification because of the licensee’s grant back. A third party can be a generic manufacturer, a government body or even a non-governmental organisation and the Equitable Access License envisages a probability of multiple notifications to ensure a true competition to achieve the objective of marginal cost pricing.\textsuperscript{656} To comply with the provisions of the \textit{Bayh-Dole Act of 1980} (US), third parties will be asked to pay a small amount of royalties both to the university and the licensee. As a last step, an Equitable Access License requires that all improvements made by the third party manufacturers should be granted back to the university for the purpose of sublicensing.\textsuperscript{657}

In addition to this public-minded licensing proposal, Benkler offers another practical model for open source drug discovery. His second proposal is a peer to peer production model for research and development. It is useful to see Benkler’s definition of open source paraphrased by Stephen M. Maurer as follows:

\begin{quote}
We will define open source as

(a) a method of producing complex economic products;

(b) capable of supporting medium-large-scale collaborations, potentially includes thousands of people; and
\end{quote}

\textsuperscript{656} Ibid.

\textsuperscript{657} For model provisions of Equitable Access License, see: \url{http://www.essentialmedicine.org/EAL.pdf}
organized according to signals that are neither hierarchical commands (as in firms or academic laboratories) nor prices (as in markets) but voluntary or social.658

The convergence of computing and drug discovery methods has opened new and innovative ways and science is no more considered to be too expansive to be done in this way. Along the pipeline of the drug discovery process, Benkler clearly sees the relevance of open source methods at more than one place. The task can start with the identification of the critical mass of young scientists who are ready to volunteer their time and energies for computer modelling of disease patterns and candidate substances.

Modularity and granularity are typical conditions for the successful implementation of any social production initiative and in the context of drug discovery it is not always possible to adopt this pattern. However, Benkler thinks that:

Increasing portions of biomedical research are done today through modeling, computer simulation, and data analysis of the large and growing databases, including a wide range of genetic, chemical, and biological information. As more of the process of drug discovery of potential leads can be done by modeling and computational analysis, more can be organized for peer production. The relevant model here is open bioinformatics. Bioinformatics generally is the practice of pursuing solutions to biological questions using mathematics and information technology ....659

University of Missouri-Kansas City Law Review 1-31 at 3 at

Once computer modeling is completed and candidate compounds are identified then the real challenge to commons-based peer production emerges in the form of wet-lab experiments.

A relatively more clear account of these options comes from a 2007 article by Stephen M. Maurer. Maurer discusses various practical options which can be used to undertake open source drug discovery throughout the life cycle of pharmaceutical innovation ranging from *in silico* discovery to clinic trails.

A slightly different model of open source drug discovery is presented by Professor Arti Rai in the form of the Tropical Disease Initiative. This approach is less focused on licensing formats and instead focused upon developing a web portal where feasible open source projects can be launched. The idea is explained as follows:

What would open-source drug discovery look like? As with current software collaborations, we propose a Web site where volunteers use a variety of computer programs, databases, and computing hardware ... Individual pages would host tasks like searching for new protein targets, finding chemicals to attack known targets, and posting data from related chemistry and biology experiments. Volunteers could use chat rooms and bulletin boards to announce discoveries and debate future research directions. Over time, the most dedicated and proficient volunteers would become leaders.

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661 For details see: www.tropicaldisease.org

662 Stephen M. Maurer, Arti Rai and Andrej Sali, 'Finding Cures for Tropical Diseases: Is Open Source
Professor Rai and her colleagues do not worry much about intellectual property constraints in the way of open source drug discovery and think that big pharmaceutical companies pay less attention to revenues generated in developing markets. They suggest that any open source licence can be adopted to facilitate the process of social production which does not have far-reaching viral implications.\textsuperscript{663} This position is understandable in the context of an initiative which is solely reserved for tropical diseases. However, a project with much broader and ambitious objectives will need a comprehensive licensing regime such as the Equitable Access License.\textsuperscript{664}

\textbf{C. Open Source Drug Discovery and India}

The application of the open source model for the development of medicines offers both challenges and opportunities for India. The Indian local pharmaceutical industry is uniquely placed to benefit from open source drug discovery initiatives which can ultimately narrow the access gap within and outside India. However, India’s position as a major emerging economy has already started precipitating key shifts in a range of public policies including the national industrial and innovation framework. The

\textsuperscript{663} Professor Rai discussed various options of adopting different licenses depending upon nature of a project. Possible licenses for the Tropical Disease Initiative include a public domain license, license similar to Creative Commons Attribution License, or the General Public License.

relevance of the open source model is less promising in this context when the Indian
government is fully on track to introduce changes in its patent laws and providing
incentives to local researchers who apply for domestic and foreign patents.

There are several positive signals for a successful implementation of open source drug
discovery projects in India. The most optimistic is that none of the alternative research
and development models discussed in this chapter other than open source methods
could actually start building their roots in India. The Indian Council for Scientific and
Industrial Research has taken a pioneering lead in this regard by launching the Open
Source Drug Discovery Foundation.665 The Government has earmarked over US$120
million in its 11th Five Year Plan for open source drug discovery projects and this
money will be gradually increased with the implementation of the project.666

This project is currently focused on tuberculosis but in the future it will also target other
neglected tropical diseases. The selection of tuberculosis at the start is understandable
given its share in India’s burden of diseases. The rationale of this project is stated as
follows:

OSDD is a CSIR Team India Consortium with Global Partnership with a vision to
provide affordable healthcare to the developing world by providing a global
platform where the best minds can collaborate and collectively endeavor to solve
the complex problems associated with discovering novel therapies for neglected
tropical diseases like Malaria, Tuberculosis, Leshmaniasis, etc. It is a concept to

665 For Details see: http://www.osdd.org/
666 Samir K. Brahmachari, ‘Remarks by the Chair’ (Proceedings of the China-India-US Workshop on
Science, Technology and Innovation Policy, Bangalore, India, July 7-9, 2008) at
http://www.law.gmu.edu/nctl/stpp/us_china_pubs/china_india_us_workshop/sec7_session5/sec7_item1_c
over_chair_remarks.pdf
collaboratively aggregate the biological and genetic information available to scientists in order to use it to hasten the discovery of drugs. This will provide a unique opportunity for scientists, doctors, technocrats, students and others with diverse expertise to work for a common cause.667

The project started with the creation of a database which includes virtually everything about tuberculosis. This huge information base known as SysBorgTB serves as an open source community portal to attract participants across the world.668 The project is still in its infancy and it will take some time before any substantial breakthrough is achieved. Almost 27 targets are so far identified and in 11 of them people are already working on proteins.669 The Government has separately established the Centre for Genomic Application670 with facilities such as testing, screening, sequencing and proteomics analysis. This Centre, along with massive infrastructure of other public sector laboratories and academic institutions, can provide important information and technical input to the open source initiative.

Beyond project infrastructure and funding commitments, open source drug discovery needs a foundation of pre-existing research which participants can improve through their individual efforts. In the area of tropical diseases such background work is essentially missing or is under proprietary control and not available for open source buildup. This barrier was even faced by the Tropical Disease Initiative and to overcome

667 Open Source Drug Discovery at http://www.osdd.net/what_is_osdd.htm

668 For details about SysBorgTB: http://sysborgtb.osdd.net/bin/view/Main/WebHome


670 For details see: http://www.tcgaresearch.org/
this problem, a team of experts developed a kernel\textsuperscript{671} for open source drug discovery in tropical diseases. The practical coordination among the two projects is not really known but one thing is clear, that this new kernel can be a useful starting point for Indian open source project.

It is worth mentioning that the Indian open source drug discovery is indeed a hybrid model as it incorporates an element of direct incentives in the form of credit and prizes. The project is envisaged with a view that small prizes will be awarded to those who contribute in finding solutions. The ‘InnoCentive\textsuperscript{672}’ model is readily available for this purpose. Professor Samir K. Brahmachari explains this reward mechanism as follows:

Credit sharing, through a micro-credit system and eventually, the dream is that if you are contributing to the cause of tuberculosis, you carry a credit-card-like thing with you which gives you special favours in hospitals and insurance and so on, and there are sponsors to give awards. So there is no more IPR. Everything that you use, you have to pay it back. It is all click-wrap – not hard IPR as you wanted. But what is interesting here is that you still get credit as prizes and awards, and are not forgotten.\textsuperscript{673}


\textsuperscript{672} InnoCentive: http://www.innocentive.com/. It is interesting to note that the ‘innoCentive’ model has already started rewarding an Indian InnoCentive solver for his achievement to find a new methods to cost-effectively manufacture tuberculosis drug candidates. See: http://blog.innocentive.com/tag/india/

The Indian scientific and technological landscape is another positive consideration which can help in successful implementation of a domestic open source drug discovery project. India has a large cadre of skilled scientists who can take the open source model as a thrilling opportunity to produce new and innovative solutions. Indian scientists do not have much exposure to patent lead research and development and a new model can become a popular and mainstream approach if implemented carefully.\textsuperscript{674}

The Indian open source model is largely dependent upon its public sector academic and research institutions because advanced drug discovery is not possible without the heavy involvement of sophisticated scientific establishments. Institutional dynamics will be changed with the introduction of an intellectual property based system in the public sector research and development institutions.

Another practical bottleneck relates to the scarcity of open source expertise. We have seen earlier that open source methods are unique and this system works optimally if requisite conditions are met. In the absence of an open source culture in India, the success of open source drug discovery is subject to several factors including the appreciation of the concept by the critical mass, identification of the right projects, organisation of innovative activity and its final culmination. Merely one government sponsored project may not lead to the wider acceptability of open source methods unless it is to become a standard in the public institutions.

IV. Patent Pools

In 2006, the World Health Organization’s Commission on Intellectual Property Rights, Innovation and Public Health observed that:

Patent pools, therefore, could be most useful for technologies particularly relevant to developing countries, because the lack of strong market incentives may enable agreements that would otherwise be more difficult to engineer. Low-margin research directed towards problems of poor people might be promoted.675

This proposition was reinforced by the World Health Organization’s *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property* which categorically recommends the member states to explore the potential role of patent pools in promoting innovation in upstream and downstream technologies.676

In 2008, UNITAID’s Executive Board approved a proposal to establish a patent pool for medicines.677 UNITAID’s move attracted substantial attention from almost all stakeholders and this initiative is now at an advanced stage and is discussed at length in subsequent sections. India is a major supplier of HIV/AIDS medicines to many African

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countries and it can potentially play a key role in the implementation of the UNITAID patent pool.

On 13th February 2009, Andrew Witty, Chief Executive Officer of GlaxoSmithKline (GSK) announced some unusual steps to deal with the challenges of improving global public health.\(^{678}\) While addressing the Harvard Medical School, Andrew unleashed his company’s four point strategy to accomplish the huge task to lowering the burden of diseases in the developing world. His speech delivered under the title of ‘Big Pharma as a Catalyst for Change’ set out an ambitious plan of action and gave a strong signal of possible policy shifts which the pharmaceutical industry may elect to pursue following GSK’s lead. One of the points presented was about GSK’s willingness to participate in a patent pool for the development of medicines for neglected tropical diseases.

\textbf{A. The ‘Tragedy of the Anticommons’}

The law and economics movement has taken a keen interest in patent pools. In 1962, Kenneth Arrow explained the crucial role that intellectual property rights play in the disclosure of information.\(^{679}\) Contrary to the conventional approach, Arrow assigned an independent market to intellectual property rights separable from the assets associated with them. Thus, the patent plays a vital role in facilitating information exchange in the markets. However, this facilitating role becomes somewhat problematic when several layers of property rights are created. The transaction cost then escalates to the extent that information bargain becomes a futile exercise for players operating in a market.


This situation typically exists in the form of patent thickets creating 'a dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology'.

In an influential article in 1998, Michael A. Heller and Rebecca S. Eisenberg used a property law metaphor of the 'commons' to explain the problem of the dense web of overlapping patents. Employing the terminology of Garrett Hardin, Heller and Eisenberg explained how too much property rights in the form of excessive patents can create the 'tragedy of anticommons'.

In 1968, Garrett Hardin coined the term 'tragedy of commons' in his paper published in the same journal, Science. The tragedy of commons is its excessive use and ultimate relinquishment given the lack of private ownership.

The 'tragedy of anticommons' refers to the under-utilisation of an asset because of multiple proprietary claims over it. Heller introduced this term in his article for the Harvard Law Review in 1997-98 as following:

In an anticommons, by my definition, multiple owners are each endowed with right to exclude others from a scarce resource, and no one has an effective privilege of use. When there are too many owners holding rights of exclusion, the

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680 The term is used first time in SCM Corp. v. Xerox Corp., 507 F.2d 358 (2d. Cir. 1974)


682 Michael A. Heller and Rebecca S. Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1 May 1998) 280 (5364) Science 698 -701 at http://www.sciencemag.org/cgi/content/full/280/5364/698

683 Garrett Hardin, 'The tragedy of the commons' (1968) 162 Science 1243-1248.
resource is prone to underuse – *a tragedy of the anticommons*. Legal and economics scholars have most overlooked this tragedy, but it can appear whenever governments create new property rights.684

Here, Heller in fact provides an expansive definition of tragedy for which one can expect arguably strong empirical evidence in support of this assertion. The whole theory is indeed construed in the context of biotechnology patents, an area from which Heller cites many existing and potential examples of tragedy. However, the beneficial aspects of the tragedy of anticommons such as wealth creation need further systematic analysis from Heller.

In their article in 1998, Heller and Eisenberg applied the concept of anticommons in the field of biomedical research to elaborate the problem associated with excessive patenting in this area. Thus the ‘tragedy of anticommons’ in biomedical and pharmaceutical research is indeed a tragedy of millions of poor patients living without access to secure life saving drugs. The authors note that:

The tragedy of the anticommons refers to the more complex obstacles that arise when a user needs access to multiple patented inputs to create a single useful product. Each upstream patent allows its owner to set up another tollbooth on the road to product development, adding to the cost and slowing the pace of downstream biomedical innovation … Current examples in biomedical research demonstrate two mechanisms by which a government might inadvertently create an anticommons: either by creating too many concurrent fragments of intellectual property rights in potential future products or by permitting too many upstream

patent owners to stack licenses on top of the future discoveries of downstream users.685

The main concern is about the entry barrier which an existing or future user may face because of already granted patents. These patents usually have very broad claims and their upstream location give them an advantage in seeking high rents and licence royalties from downstream users. Up to an optimal point users may find it worth pursuing and they can continue operating within the system but beyond that point, exit strategies are followed which leave the innovation underutilised.

In 2008, Heller published his book, The Gridlock Economy686, where he discussed the economic implications of his anticommons thesis. The basic idea is that too many stakeholders can virtually kill the optimal usefulness of a property and Heller provides the justification of his conclusion through examples. Heller maintains that the anticommons can be found in places like medical research, and this is where the book gets excited. He narrates the story of Compound X, a treatment for Alzheimer’s that remains undeveloped because there are too many owners of relevant patents, each of whom can demand a substantive share in the form of royalties.687

Heller warns that the potential threat of gridlock in biomedical research does not come mainly from litigation or uncertainty about patent claims. He notes that:


687 Ibid.4-5.
A firm might be confident that it will win a particular patent suit but not that it will prevail against every single one of a hundred weak claims. Fragmented ownership can be enough, by itself, to deter innovation. For example, consider the potential gridlock effect of patents related to brain receptors (proteins in the brain that respond to particular molecules and stimulate brain-cell responses). Bennett Shapiro, Merck’s vice president for worldwide basic research, explains that people who take “compounds for schizophrenia often develop other disorders some of which resemble Parkinson’s disease, another disease involving the dopamine system. A rational approach to discovery of improved schizophrenia drugs would be to target specific dopamine receptors. But if different companies hold patents on different receptors, the first step on the path to an important and much needed therapeutic advance can be blocked.”

The question of whether the tragedy of anticommons is a feature of pharmaceutical research and development has generated conflicting opinions. Commentators generally agree that the patent thickets and associated tragedy of anticommons is evidently prevailing in the area of information technology and related fields where standard-setting is a key issue.

Empirical research has not yet provided conclusive evidence of the existence of this problem in the area of pharmaceutical research. Nevertheless, leading commentators

688 Ibid. 53.

689 Economists do not have a uniform position on this and some studies still maintain that enough empirical data is not yet available to construe the existence of patent thickets. For details see: Birgit Verbeure, Esther van Zimmeren, Gert Mthijs and Geertrui Van Overwalle, ‘Patent Pools and Diagnostic Testing’ (March 2006) 24 (3) TRENDS in Biotechnology 115-120 at http://www.epip.eu/conferences/epip02/lectures/Verbeureetal-2006-TIB-Publication.pdf

690 It is generally believed that low patenting standards encourage patent thickets. For details and survey
in this field have discussed various situations where overlapping patent rights create entry barriers for follow-on research and development. According to the ‘Preliminary Pharmaceutical Sector Inquiry Report’ of the European Commission: ‘individual blockbuster medicines are protected by up to 1,300 patents and/or pending patent applications EU-wide and that, as mentioned above, certain patent filings occur very late in the life cycle of a medicine’.691

Heller raises a number of remedial measures which can offset the tragedy of anticommons. His list includes market-driven solutions, property-preventing investments, patent pools and cooperative solutions and a wide array of regulatory solutions.692 Heller starts with a positive note on patent pools and considers it a workable solution in a particular technological sphere. He is specifically appreciative of a history of patent pools which have worked largely well in aircraft and sewing machine cases.693 However, Heller acknowledges the complexity of the law and economics of


patent pools and warns that patent pools may not work in all cases as ‘their internal dynamics are fraught with peril for bargaining failure’.\textsuperscript{694}

Heller is not alone in his prescription of patent pools as a plausible solution to the problem of anticommons. Many commentators have recently considered this option and concluded that patent pools can effectively address the problems associated to patent thickets and anticommons.\textsuperscript{695} However, certain qualifications are attached to this proposal and most of the studies conclude that patent pools work well only in certain areas of technology and their universal application and relevance is not clear. This scepticism is even reflected in Heller’s approach as follows: ‘Patent pools may be a good solution to gridlock in some circumstances – for example, in telecommunications, semiconductors, or nanotechnology, where standard-setting is important – but it is doubtful they will do the same for biomedical research.’\textsuperscript{696} There have been concerns raised by competition regulators that patent pools may have anti-competitive effects for biomedical and pharmaceutical research.\textsuperscript{697}

\textsuperscript{697} In 2003, United States Federal Trade Commission analyzed the scope and application of patent pools in
B. UNITAID’s Proposed Patent Pool: A Search for Workable Model

According to Professor Amartya Sen, justice is served when equal opportunities are granted to individuals and their capabilities are strengthened.\(^{698}\) Globally, developing countries’ capabilities are significantly lower and they face added disadvantages due to poor health conditions and the burden of diseases. The vast divide between developed and developing countries illustrates the need for developing countries to be supported so as to catch up to the more prosperous and healthy nations. Amartya Sen’s focus on cosmopolitanism and global justice illustrates the role developed nations can play in improving global health rights and access to medicines.\(^{699}\)

What is the best mode of assembling the patent rights\(^{700}\) to facilitate the research and development of new drugs for the treatment of neglected and tropical diseases? Among the several options stated in this regard, patent pools have some obvious merits. As an arrangement among patent holders to license one or more of their patents, patent pools can substantially help in remedying the tragedy of anticommons created in biomedical various fields of technologies and concluded that patent pools may not help in the biotechnology industry. See for details: Federal Trade Commission, \textit{To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy}, (2003) at http://www.ftc.gov/os/2003/10/innovationrpt.pdf


and pharmaceutical research and development. This role of patent pools is well recognised and the idea of pooling patent rights for the development of new and effective drugs is very well reflected in many studies and declarations.701

On June 6, 2006, Médecins Sans Frontières (MSF) submitted its proposal to the Government of France and UNITAID suggesting the creating of a patent pool initially as a test case for a limited number of diseases. Over the years working in many countries in the world as a humanitarian organisation, MSF faced the problem of access to medicines and high costs. Other non-governmental organisations also started lobbying on the same lines and asked for the implementation of a patent pools proposal. A study in 2006 observed that: ‘This commitment to back up the Doha Declaration with purchasing power should signal to global holders of HIV, tuberculosis and malaria drug patents that the time has come to open their products to competition in developing countries, for example by voluntarily creating a patent pool.’702 This call was clearly for a patent pool which could cater to the need for essential medicines to tackle HIV, tuberculosis and malaria. However, UNITAID has an inherent limitation of its mandate and it was not possible for the organisation to launch an initiative covering the broader areas stated in the study.

701 Some of these instances are mentioned earlier in the form of WHO Global Strategy and WHO’s Commissions Report. The relevance of patent pools for pharmaceutical research and development is also recognized in the OECD Noordwijk Medicines Agenda. See for details: Organization for Economic Cooperation and Development (OECD), Noordwijk Medicines Agenda: Changing the Face of Innovation for Neglected and Emerging Infectious Diseases (Paris: OECD, 2007) at http://www.oecd.org/dataoecd/30/5/39671218.pdf

In 2008, the Board of UNITAID adopted a resolution which principally agreed on the creation of a patent pool. The significant move was applauded throughout the world as an important concrete step towards patent assembly for public health purpose.\textsuperscript{703} The UNITAID Board resolved that: ‘The Board further acknowledges the potential described in the update on a patent pool presented by the Secretariat EB8/2008/11 and supports the principle of establishing a Patent Pool.’\textsuperscript{704} In the light of this mandate, UNITAID is still working on the modalities of the proposed patent pool and the process involves extensive consultation and negotiations with relevant stakeholders. Though the UNITAID’s model is not fully known at this stage\textsuperscript{705}, it can be anticipated that it will be largely based upon the initial proposal of MSF in terms of its scope and diseases coverage. At least two studies can be cited in this regard which attempt to chalk out an appropriate model of a patent pool for neglected diseases.

The Innovation Partnership (TIP) conducted a preliminary legal review of the MSF proposal in 2007.\textsuperscript{706} This review provides a comprehensive survey of issues which may


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be involved in the creation of a medicines patent pool. It also gives a practical snapshot of how a patent pool can be initiated and what measures are important for the successful implementation of such pool. The UNITAID patent pool will start with a limited scope and it is mainly aimed at putting ‘fixed-dose antiretroviral combination medicines (FDCs) and new formulations of existing medicines adapted to developing countries’.  

The focus on new antiretroviral combinations is obvious for two reasons. First, this problem is increasingly confronted by international humanitarian organisations such as MSF when they outreach in far-flung areas to distribute HIV/AIDS medicines. Second, the organisational mandate of UNITAID warrants that the organization can channel its resources to meet the particular needs of the developing world.

Seven drugs and combinations are identified as targeted medicines which include: Efavirenz; heat-stable Ritonavir; Tenofovir; Lamivudine; Abacavir; a combination of Lopinavir with heat-stable Ritonavir; and a combination of Atazanavir with Ritonavir. All of these drugs are critical for a treatment program in developing countries but some of them have no generic substitute. Some of them are more important in certain countries given the patients’ profiles and resistance patterns. Evidence also shows that most of these drugs are patented in major developing countries which have manufacturing capacity in this field. A patent pool can simplify the licensing process and help in reducing the costs and overhead expenditures. As Richard Gold and his colleagues note: ‘Without a patent pool, coordination of the right to manufacture and


707 Ibid. 1.
708 Ibid. 5.
709 Ibid. 2. Limivudine and Heat stable Ritonavir are not patented in India. There is no patent on Limivudine in Brazil too. Tenofovir is also not patented in Brazil. All of these drugs are patented in South Africa.
sell combinations and new formulations of antiretroviral medicines for developing countries is costly and time consuming.\textsuperscript{710}

A patent pool can be established both through voluntary and compulsory measures but a UNITAID pool will adopt a voluntary licensing scheme.\textsuperscript{711} The selection of participants will be a crucial aspect of a patent pool and in addition to patent holders, the identification of licensees is highly critical. Given the fact that very few developing countries have sophisticated medicines' manufacturing capacity, a pool should be created with a good mix of licensees both from developed and developing countries. Indian companies are in a unique position to lead this process and a detailed analysis is provided in the next section.

James Love conducted a cost-benefit analysis for the UNITAID patent pool in 2008 and he presented different scenarios in which a patent pool could efficiently work.\textsuperscript{712} This analysis also presumes that a patent pool will be initially focused on fixed-dose combinations of antiretroviral drugs and James Love provides a cost analysis of first and second line treatments for AIDS. The main objective is to establish a point at which a patent pool can contribute in lowering the prices of concerned antiretroviral drugs. The role of patent pools in price reduction and enhancing affordability is a crucial issue. Love estimates that a UNITAID patent pool will approximately cost US$1.5 million per year. This figure is based upon the calculations which he has worked out in three

\textsuperscript{710} Ibid.3.

\textsuperscript{711} Though some non governmental organization consistently argue a case for the creation of non-voluntary patent pool but industry is adamant to this demand. For GSK position: GlaxoSmithKline, ‘Voluntary Licensing of ARVs, Global Public Policy Issues: GlaxoSmithKline’s Position’ (November 2007) at http://www.gsk.com/policies/GSK-on-voluntary-licensing-of-ARVs.pdf

different scenarios by comparing and varying innovators’ prices, generic savings, patients’ estimated population and other related factors. Love contends that patent pooling will be one factor among several in determining outcomes in respect of access to essential medicines.

This analysis shows that establishment and implementation of a patent pool is quite possible if relevant factors are considered carefully. Two factors play a crucial role in this regard. One, the scope and disease coverage which will determine not only costs but also the identification of the source of supply is possible when the nature of the patent pool is clear. Second, the overall cost of implementation of a proposal such as UNITAID’s patent pool is understandably very high and resources should be mobilised accordingly to operationalise such an initiative.

The UNITAID’s patent pool received a boost in September 2010 when the United States National Institute of Health announced the first patent to share in the patent pool. Dr Charles Clift, Chair of the Medicines Patent Pool Board, welcomed this development and said: ‘We are delighted that with this first license, the NIH is demonstrating its support for the Medicines Patent Pool and its commitment to making the fruits of its research globally available.’ This is an important development as the

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714 Ibid.


National Institute of Health holds several key patents and it can set an example for other public sector organisations and universities to participate voluntarily in this process.

C. Patent Pool and India

In the context of India, patent pools as an alternative research and development strategy for the discovery of new and improved drugs raise various questions. First, the very notion of patent pools within a domestic policy framework presumes the existence of certain key patents in a particular field of technology which have the potential to restrict future research and development. To overcome this barrier, a patent pool solution is considered. This situation is unlikely to exist in India at least for the time being when substantial patenting is yet to be recorded in the area of pharmaceuticals and biomedical research. Nevertheless, an international patent pool proposal such as initiatives launched by UNITAID and GSK has many promising implications both for Indian local manufacturers and poor patients.

UNITAID’s patent pool offers many opportunities for Indian pharmaceutical manufacturers. The creation of a patent pool for HIV/AIDS medicines would not automatically mean that pooled patented innovations will be licensed to Indian manufacturers giving them unprecedented business opportunities throughout the world. Patent holders involved in a patent pool may decide that manufacturing will take place in a particular developing country such as South Africa and indeed there are some indications in this regard. However, both market dynamics and technological superiority favour Indian manufactures and it can be anticipated that if not exclusively but substantially, Indian companies will capture the opportunities arising out of a patent pool.

India’s track record in the supply of HIV/AIDS medicines to international humanitarian organisations supports this assertion. In Chapter 4, we discussed the importance and
volume of Indian pharmaceuticals for procurement programs of many international organisations such as MSF, UNITAID, and WHO. The proposed patent pool of UNITAID will probably start with these drugs: Efavirenz; heat-stable Ritonavir; Tenofovir; Lamivudine; Abacavir; a combination of Lopinavir with heat-stable Ritonavir; and a combination of Atazanavir with Ritonavir. This pool will be aimed at achieving the objective of fixed-dose combinations. The Indian position is very advantageous to be involved in this arrangement. Indian manufacturers are already producing most of the first and second lines of antiretroviral drugs and even in the market of adult fixed-dose combinations, Indian generic manufactures are at the forefront.

Tables 6.1, 6.2, and 6.3 show the comparative advantage which Indian manufacturers are enjoying at the moment. This data reveals interesting insights of HIV/AIDS drugs and their manufacturers. It is evident that Indian generic manufacturers play a vital role in producing affordable generic versions of medicines and they have over the period developed a sophisticated technological base which is required to undertake this task. The share of Indian companies is almost 85% of the total generic volume purchased in Sub-Saharan Africa which equates with 53% of the total volume.717

With the implementation of the UNITAID patent pool for HIV/AIDS medicines, Indian firms will simply increase their manufacturing base by assuming a strong position as potential licensees. Both for economic and technological reasons, developing new manufacturing facilities through patent pools will not be a viable option. It is also important to note that this vast scale generic activity in the area of HIV/AIDS medicines is not merely because of limited patent portfolios of brand name companies. It is not

even the case that brand name companies are finding it hard to enforce their patent rights and Indian manufacturers are thus producing these drugs. The reality lies somewhere in between the two situations. Many Indian generic manufacturers entered into the HIV/AIDS medicines’ business only after the announcement of the United States President’s Emergency Plan for HIV/AIDS Relief Initiative (PEPFAR) in 2004, and they are already in licensing arrangements with brand name companies. Other companies are getting the benefit of automatic licensing provisions incorporated in Indian patent law as they started manufacturing these drugs before the enactment of the new law and were given a blanket immunity from infringement prosecution.

A patent pool on these lines can be highly useful for Indian patients too. There is a huge domestic market in India for the consumption of HIV/AIDS medicines. As philanthropy starts from home, Indian companies can initially address the needs of the local segment and while doing so they can build a strong case to become a partner in the proposed patent pool. India has the second highest number of patients in the world living with HIV/AIDS and most of these patients desperately need affordable drugs. The UNITAID patent pool can become a great hope for them.

718 Ibid. 40.


720 HIV/AIDS data from India has created some unease during recent years. UNAIDS estimated in 2006 that there were 5.6 million people living with HIV in India, which indicated that there were more people with HIV in India than in any other country in the world. However, National AIDS Control Organization (NACO) did not agree with this estimate, and claimed that the actual figure was lower. In 2007, UNAIDS and NACO agreed on a new estimate – between 2 million and 3.6 million people living with HIV. The figure was confirmed to be 2.4 million in 2008. For details: UNAIDS, ‘2.5 million people in India living with HIV, according to new Estimates’ (Press Release, 6 July 2007) at
However, a careful consideration of additional facts can reveal that Indian companies will not be the absolute beneficiaries of a patent pool windfall. The GSK patent pool is aimed at facilitating the development of new drugs for the treatment of neglected tropical diseases. GSK has provided a list of 16 diseases in this regard which includes: tuberculosis, malaria, blinding trachoma, buruli ulcer, cholera, dengue/dengue haemorrhagic fever, racunculiasis, fascioliasis, human African trypanosomiasis, leishmaniasis, leprosy, lymphatic filariasis, onchocerciasis, schistosomiasis, soil transmitted helminthiasis and yaws.\(^{721}\) GSK’s patent pool is exclusively for the development of products for least developed countries and domestic use in India is thus automatically out of the question. This is regardless of the fact that some of the designated diseases have a very high incidence in India.

The remaining question is about the commercial prospects which Indian generic manufactures may have under GSK’s arrangements. Theoretically, there should be fair and equal chances for Indian manufacturers to compete for licences of pooled patents. GSK’s position is clear on this point as follows:

GSK will offer licences to third parties on available technologies on favourable terms that will include geographical and therapeutic area restrictions and other terms relevant to the transaction. For pool licensees looking to sell outside the LDCs, GSK may be willing to discuss two options in appropriate circumstances. We may either allow a third party to sell into developing countries on a royalty-bearing basis or we might agree to take a licence (for which we pay a one-off fee

or royalties) which would allow us to sell the products into non-LDCs countries ourselves. The preferred option would be chosen on mutually agreed terms, on a case by case basis.\footnote{GlaxoSmithKline, ‘An Intellectual Property Pool for Neglected Tropical Diseases in Least Developing Countries’ (Press Release, 27 March, 2009) at http://www.gsk.com/reseaarch/patent-pool.htm}

So for domestic purposes, Indian companies would have to negotiate a royalty fee with GSK or in turn will need to sell their follow-on inventions back to GSK. It is important to note that GSK has categorically excluded HIV/AIDS patents\footnote{It is interesting to note that GSK has a defined position on voluntary licensing of HIV/AIDS drugs and want to pursue this option independently from its patent pool proposal. In September 2001, GSK granted South Africa’s Aspen Pharmacare a voluntary licence for the manufacture and sale of their own versions of Combivir, Epivir and Retrovir in the public sectors of South Africa and Zimbabwe. For details: GlaxoSmithKline, ‘Voluntary Licensing of ARVs, Global Public Policy Issues: GlaxoSmithKline’s Position’ (November 2007) at http://www.gsk.com/policies/GSK-on-voluntary-licensing-of-ARVs.pdf} from this patent pool and given the patents data on antiretroviral drugs mentioned above and GSK’s share in that, a large segment of the patient population will not benefit from this pool. The incidence of tuberculosis is very high in India and the Indian government is keen to invest in the development of tuberculosis treatment. GSK’s tuberculosis related patents will be available in the patent pool but again it would have less significance for Indian patients given that India is not a least developing country. Indian companies can, however, seek licences from the proposed pool to improve their technology base in this area with very little effects on affordability and accessibility of these drugs in India.

There is additional evidence that most of Indian companies will obtain little benefit from GSK’s patent pool. In May 2009, GSK acquired 16% of the shares in South Africa’s largest pharmaceutical firm, Aspen Pharma.\footnote{Roshni Gajjar, ‘Aspen and GSK Agree on Strategic Deals’ (Press Release, 12 May 2009) at http://www.aspenpharma.com/newsroom/prdetail.cfm?ID=295} It is noteworthy that GSK is
engaged in several patent disputes in India with generic manufacturers and India is seen as a troubled jurisdiction by pharmaceutical multinational companies for its enforcement policies.\textsuperscript{725} The likelihood of a partnership is thus rare in the Indian case and GSK will probably prefer to operate in the most favourable business circumstances.

This analysis shows the potential application of a patent pool in an Indian context. The relevance of a patent pool within India largely depends upon the nature and arrangements of such a pool. It is argued here that an international patent pool initiative such as UNITAID will be extremely relevant to India and both patients and industry will benefit from such scheme. It is further argued here that a purely industry based initiative such as GSK’s patent pool may not be useful for practical reasons. The Indian industry’s strategic positioning, and the dynamics of ongoing competition in the pharmaceutical market, will dictate the terms and conditions of the patent pool alliances.

V. Conclusion

Academic institutions have a great potential to transform the existing state of patent policies and practices by revisiting their role amidst the global access to medicines crisis. There are indications that universities in the United States are increasingly showing their interest in new forms of socially responsible licences and in certain cases equitable licensing terms are indeed incorporated in recently concluded technology

commercialisation agreements. However, in the sphere of government policy, the case for an equitable licensing regime is not high on the agenda and the existing rules would more likely remain in the foreseeable future. The options are then considerably limited for the introduction of a cogent and public minded licensing regime.

The most promising opportunities lie in the transformation of institutional principles which can allow unique experiments in the area of intellectual property licensing. Relying upon the notion of equitable licensing, three distinct options are discussed in this chapter with the objective to predict their relevance in the Indian context. Existing practices attached to the licensing of publicly funded research and development are shaped under the influence of the Bayh-Dole Act of 1980 (US) which poses serious challenges to developing economies. India’s proposed legislation also fails to consider the level of its own economic and scientific development.

Open source licensing offers numerous opportunities for India with almost no risks associated with it. The Indian government can also enhance its developmental policy goals through open source initiatives. A policy framework which encourages open source methods will strengthen India’s support and push for the Development Agenda at the platform of World Intellectual Property Organization. Alternatively, a patent based incentive system to stimulate publicly funded research will hamper India’s position at different multilateral forums. An offshoot of intellectual property management through collective licensing can be developed in the form of patent pools. The patent pools option is equally promising for India but practically India cannot get outstanding benefits from this mechanism. The Indian domestic patent base is weak and sporadic and patent barriers have not yet started playing their role in the Indian innovation system. The objectives which are generally targeted through patent pools can be easily managed with the help of safeguard provisions of Indian patent law. India, however, can become the largest beneficiary of an international patent pool.
In the light of this analysis, it can be concluded that open source drug discovery is the best option which India can use to build a strong scientific base with equitable access norms. Such a socially responsible licensing regime can create a mutually beneficial relationship for universities and funding agencies by allowing patients to benefit from India’s innovative capabilities.
### Table 6.1: First-Line Antiretrovirals

<table>
<thead>
<tr>
<th>Antiretroviral</th>
<th>Manufacturer/Developer</th>
<th>Companies/Manufacturers</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stavudine (d4T)</td>
<td>Bristol Myers Squibb</td>
<td>Cipla, Hetero, Matrix, Ranbaxy, Aurobindo, Strides Acrolabs, Emcure</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Zerit</td>
<td>Duopharma (Malaysia), Aspen Pharmacare (South Africa), Ranbaxy (Malaysia)</td>
<td></td>
</tr>
<tr>
<td>Zidovudine (ZDV)</td>
<td>GlaxoSmithKline (UK)</td>
<td>Ranbaxy, Cipla Ltd, Hetero, Strides Acrolabs, Aurobindo, Emcure, Matrix</td>
<td></td>
</tr>
<tr>
<td>Retrovir</td>
<td></td>
<td>Aspen Pharmacare (South Africa)</td>
<td></td>
</tr>
<tr>
<td>Zidovudine (AZT)</td>
<td>GlaxoSmithKline (UK)</td>
<td>Matrix, Strides Acrolabs, Hetero, Aurobindo, Cipla, Ranbaxy, Micro Labs</td>
<td></td>
</tr>
<tr>
<td>Retrovir</td>
<td></td>
<td>Aspen Pharmacare (South Africa), Apotex Inc (Canada)</td>
<td></td>
</tr>
<tr>
<td>Lamivudine (3TC)</td>
<td>GlaxoSmithKline (UK)</td>
<td>Cipla Ltd, Aurobindo, Micro Labs, Ranbaxy, Matrix, Strides Acrolabs, Hetero, Emcure</td>
<td></td>
</tr>
<tr>
<td>Epivir</td>
<td></td>
<td>Aspen Pharmacare (South Africa)</td>
<td></td>
</tr>
<tr>
<td>Nevirapine (NVP)</td>
<td>Boehringer Ingelheim</td>
<td>Ranbaxy, Cipla Ltd, Hetero, Strides Acrolabs, Emcure, Matrix, Micro Labs</td>
<td></td>
</tr>
<tr>
<td>Viramune</td>
<td>(USA)</td>
<td>Aspen Pharmacare (South Africa), Huahai Pharmaceutical (China), Duopharma (Malaysia)</td>
<td></td>
</tr>
<tr>
<td>Efavirenz (EFV)</td>
<td>Merck</td>
<td>Runbaxy, Aurobindo, Strides Acrolabs, Hetero, Micro Labs, Cipla Ltd.</td>
<td></td>
</tr>
<tr>
<td>(200 mg) Stocrin</td>
<td>200</td>
<td>Bristol Myers Squibb (Puerto Rico), Merck Sharp and Dohme (Australia)</td>
<td></td>
</tr>
<tr>
<td>Efavirenz (EFZ)</td>
<td>Bristol Myers Squibb</td>
<td>Cipla, Hetero, Matrix, Aurobindo, Strides Acrolabs, Ranbaxy, Emcure, Micro Labs</td>
<td></td>
</tr>
<tr>
<td>(600 mg) Stocrin</td>
<td>600</td>
<td>Duopharma (Malaysia)</td>
<td></td>
</tr>
<tr>
<td>Emtricitabine (FTC)</td>
<td>Gilead Sciences but Merck owns the rights for Canada and Australia</td>
<td>Aurobindo, Matrix, Cipla</td>
<td></td>
</tr>
<tr>
<td>Emtrival</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Didanosine (DDI)</td>
<td>Bristol Myers Squibb</td>
<td>Aurobindo, Micro Labs, Cipla Ltd.</td>
<td></td>
</tr>
<tr>
<td>(200 mg) Videx</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Didanosine (DDI)</td>
<td>Bristol Myers Squibb</td>
<td>Aurobindo, Ranbaxy, Micro Labs</td>
<td></td>
</tr>
<tr>
<td>(400 mg) Videx EC</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: Padmashree Gehl Sampath

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http://www.genomicsnetwork.ac.uk/media/India’s%20Pharmaceutical%20Sector%20in%202008.pdf
<table>
<thead>
<tr>
<th>Second-Line Antiretrovirals</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tenofovir diosoproxil fumarate (TDF) Viread</td>
<td>Gilead Sciences</td>
</tr>
<tr>
<td>Indinavir (IVD) Crixivan</td>
<td>Merck</td>
</tr>
<tr>
<td>Lopinavir (LPV/r) Kaletra</td>
<td>Abbott</td>
</tr>
<tr>
<td>Nelfinavir (NFV) Viracept</td>
<td>Pfizer, but Roche has the distribution rights</td>
</tr>
<tr>
<td>Abacavir (ABC) Ziagen</td>
<td>GlaxoSmithKline</td>
</tr>
<tr>
<td>Atazanavir (ATV) Riyataz</td>
<td>Bristol Myers Squibb</td>
</tr>
<tr>
<td>Saquinavir (SQV) Fortovase or Invirase</td>
<td>Roche</td>
</tr>
<tr>
<td>Ritonavir Norvir,</td>
<td>Abbott</td>
</tr>
</tbody>
</table>

Source: Padmashree Gehl Sampath

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<table>
<thead>
<tr>
<th>Table 6.3: Adult Fixed-Dose Combinations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Abacavir + Lamivudine</strong></td>
</tr>
<tr>
<td>600 mg + 300 mg (ABC + 3TC)</td>
</tr>
<tr>
<td><strong>Abacavir + Lamivudine + Zidovudine</strong></td>
</tr>
<tr>
<td>300mg + 150 mg + 300mg (ABC + 3TC + AZT)</td>
</tr>
<tr>
<td><strong>Didanosine + Efavirenz + Lamivudine</strong></td>
</tr>
<tr>
<td>(ddl + EFV + 3TC) 400mg + 600mg + 300mg</td>
</tr>
<tr>
<td><strong>Efavirenz + Emtricitabine + Tenofovir</strong></td>
</tr>
<tr>
<td>600mg + 200mg + 300mg (EFV + FTC + TDF)</td>
</tr>
<tr>
<td><strong>Efavirenz + Lamivudine + Stavudine</strong></td>
</tr>
<tr>
<td>600mg + 150 mg + 30mg/40 mg (EFV + 3TC + d4T)</td>
</tr>
<tr>
<td><strong>Efavirenz + Lamivudine + Zidovudine</strong></td>
</tr>
<tr>
<td>600mg + 150mg + 300mg (EFV + 3TC + AZT)</td>
</tr>
<tr>
<td><strong>Emtricitabine + Tenofovir</strong></td>
</tr>
<tr>
<td>200mg + 300 mg (FTC + TDF)</td>
</tr>
<tr>
<td><strong>Lamivudine + Zidovudine</strong></td>
</tr>
<tr>
<td>150mg + 300mg (3TC + AZT)</td>
</tr>
<tr>
<td><strong>Lamivudine + Nevirapine + Zidovudine</strong></td>
</tr>
<tr>
<td>150 mg + 200mg + 300 mg (3TC + NVP + AZT)</td>
</tr>
<tr>
<td><strong>Lamivudine + Stavudine</strong></td>
</tr>
<tr>
<td>150 mg + 30 mg/40 mg (3TC + d4T)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Company</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GlaxoSmithKline (UK)</strong></td>
<td>Aurobindo, Cipla Ltd., Hetero Drugs</td>
</tr>
<tr>
<td><strong>Merck Sharp and Dohme</strong> (Canada; the Netherlands), Bristol Myers Squibb and Gilead Sciences Int. (Canada)</td>
<td>Matrix Laboratories, Cipla Ltd</td>
</tr>
<tr>
<td><strong>Matrix Laboratories</strong></td>
<td>Strides Acrolabs, Emcure, Ranbaxy</td>
</tr>
<tr>
<td><strong>Cipla Ltd.</strong></td>
<td>Hetero Drugs, Strides Acrolabs</td>
</tr>
<tr>
<td><strong>Cipla Ltd., Hetero Drugs, Cadila Pharmaceuticals, Ranbaxy, Matrix Laboratories, Aurobindo, Strides Acrolabs, Emcure Strides Acrolabs, Hetero Drugs Ltd.</strong></td>
<td>Aspen Pharmacare (South Africa)</td>
</tr>
</tbody>
</table>

Source: Padmashree Gehl Sampath\(^728\)

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Chapter 7
India’s Slumdog Millions: 
New Models of Medical Innovation

I. Introduction

During his historic visit to India in November 2010, the United States President, Barack Obama, declared that ‘the United States does not just believe, as some people say, that India is a rising power; we believe that India has already risen’. These comments, which clearly acknowledge India’s marvellous political and economic achievements during the last decades, were further elaborated by the President in his remarks to the joint session of the Indian Parliament. While appreciating India’s overall economic development, President Obama also highlighted key challenges which are continuously haunting the country’s economic development because of India’s widespread disease burden and poor health infrastructure. He noted that:

Because the wealth of a nation also depends on the health of its people, we’ll continue to support India’s effort against diseases like tuberculosis and HIV/AIDS, and as global partners, we’ll work to improve global health by preventing the spread of pandemic flu.


The White House, Office of the State Secretary, Remarks by the President to the Joint Session of the Indian Parliament in New Delhi, India Parliament House, New Delhi, India (8 November, 2010) at
Tuberculosis and HIV/AIDS are just two illustrative cases. Several other diseases coupled with acute poverty and malnutrition have further aggravated the situation for India’s ‘Slumdog Millions’. The country’s Burden of Disease statistics shows that widespread problem of communicable and non-communicable diseases is undermining India’s performance as an emerging economic power. Indian patients need curative treatments for these epidemics. The Indian epidemic landscape is rapidly becoming complex with the emergence of new strains of tuberculosis and malaria which are offering resistance to existing medicines. HIV/AIDS has increased the tuberculosis incidence all around the world and in the case of India it is estimated that HIV would


731 The term ‘Slumdog Millions’ is adapted in a documentary sponsored by UK’s Department for International Development after the success of Academy Awards winner Slumdog Millionaire. The documentary shows that over 42 million Indians live in slums, 18 million of them in cities. For details see: Department for International Development, ‘India’s Slumdog Millions’ (20 February 2009) at http://www.dfid.gov.uk/Media-Room/News-Stories/2008/Indias-Slumdog-Millions/

732 Indian economic growth and country’s accumulation of wealth during last few years is an unprecedented phenomenon. Several studies focused on the issues of equity and social justice in the context of new opportunities of wealth generation. Department for International Development-UK’s 2008 Annual Plan for India characterizes India as multilayered entity with three distinct faces: Global India, Developing India and Poorest India. India’s policy dilemma is how to improve its largest but somehow neglected face. See for details: Department for International Development, Three Faces of India: DFID India Country Plan 2008-2015 (New Delhi, India, 2008) at http://www.dfid.gov.uk/Documents/publications/india-cap%5B1%5D.pdf

increase tuberculosis prevalence (by 1%), incidence (by 12%), and mortality rates (by 33%) between 1990 and 2015.\textsuperscript{734}

The solution lies in the adoption of an integrated policy encompassing an increased health care budget, infrastructure development, poverty alleviation and the provision of drugs. In pharmaceuticals, Indians consumers are not yet facing the typical problem of inaccessibility because of patent protection. However, they are the victim of a much-talked about 10/90 gap.\textsuperscript{735} It is a paradox that India provides generic medicines for millions of patients around the globe, but is nonetheless still dependent upon multinational pharmaceutical companies for the development of new drugs. The research based pharmaceutical companies clearly lack the incentives to invest in the development of drugs for neglected and tropical diseases.\textsuperscript{736}

\textsuperscript{734} B. G. Williams et.al., ‘The Impact of HIV-AIDS on the Control of Tuberculosis in India’ (July 5, 2005) 102 (27) PNAS: Proceedings of the National Academy of Sciences of United States of America 9619–9624 at http://www.pnas.org/content/102/27/9619.full.pdf+html

\textsuperscript{735} The term ‘10/90 gap’ is coined by Global Forum for Health Research to demonstrate their statistical finding that only 10% of worldwide expenditure on health research and development is devoted to the problems that primarily affect the poorest 90% of the world’s population. For details: Global Forum for Health Research, The 10/90 Report on Health Research 1999 (Geneva: Global Forum for Health, WHO, 1999) at http://www.globalforumhealth.org/en/Media-Publications/Publications/10-90-Report-on-Health-Research-1999

The role of alternative research and development models is crucial to address this problem and recently these models have been discussed quite extensively both in the academic literature and in policy circles. These models are generally categorised under the broader streams of pull and push mechanisms which include: prizes, patent pools, open source drug discovery, health impact funding, compulsory licensing, advance market commitments, priority review vouchers and competitive tender treaty. In this chapter, I have considered two alternative research and development models: prizes, and the Health Impact Fund. The original contribution of this chapter is to evaluate whether such models would be appropriate for the Indian government to adopt. Given the importance of the Indian pharmaceutical industry and India’s health profile, it is important to predict how new policy proposals would be perceived within India. Part II of this article deals with prizes and explores the theoretical foundations and practical details of this model followed by its application in India. Part III considers the proposal of the Health Impact Fund and relates it to the Indian situation. The chapter concludes that, while India’s commitment to the global economic order is intact, there is a strong case for the adoption of alternative research and development models for both domestic and international reasons. Rather than relying upon one model of innovation, it is argued that a hybrid mix of models should be adopted to harness innovation in public health sector.

II. Prizes and Pharmaceutical Research

In a 2006 editorial for the *British Medical Journal*, the famous economist and Nobel laureate, Professor Joseph E Stiglitz lamented the failure of intellectual property rights to provide a sufficient stimulus for research and development into pharmaceutical drugs designed to meet the needs of the poorest population of the world. Referring to the character of Scrooge from Charles Dickens’ 1843 novel, *A Christmas Carol*, Professor Stiglitz criticises the existing state of patent monopolies and pharmaceutical innovation and argues that often these restrictions outweigh the benefits which are generally anticipated by the policy makers. He proposes a medical prize fund to supplement the existing patent system to improve the financing of drug innovation.

The idea of the use of prizes to stimulate research and development is not a new proposal. Economists have dedicated considerable attention to this idea in the past and a wealth of literature can be found on this topic. However, the idea has been resurrected

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over the last decade in the field of patent law and access to medicine issues, and it is now widely discussed in policy circles and academic research.\textsuperscript{740}

The limitation of the existing patent regime in spurring an equitable innovation model is a major issue. Professor Amartya Sen comments that:

The counterproductive patent regimes that exist – and rule – at the moment also provide very inadequate incentives for medical research aimed at developing new medicines … that would be particularly useful for the poor people of the world whose ability to offer a high price for such medicines is quite limited. The reach of incentives in producing medical innovations of specific benefit to low-income people can be puny indeed. This is well reflected in the heavy bias of pharmaceutical research in the direction of catering to those with more income to spend. Given the nature of the market economy and the role that the profit calculations inescapably play in its operation, the concentration has to be made on departures that can change the incentive patterns radically. They can vary from altered legal arrangements for intellectual property rights (including different tax treatment of profits from different types of innovation) to providing public incentives through specially devised programs of support.\textsuperscript{741}

This statement signifies the need to develop alternative strategies to address the need of poor patients. These strategies may include revised intellectual property norms because existing models have failed to deliver to the objectives of global justice.

\textsuperscript{740} James Love and Tim Hubbard have given an account of recent debates about prizes within industry and academic circles. Lately the prizes appeared continuously on the agenda of several civil society organizations and international bodies such as MSF and WHO.

A. Theoretical Underpinnings

The prize model for medical innovation has many different variants.\textsuperscript{742} This section will focus upon the work of James Love, the executive director of the Knowledge Ecology International, and Tim Hubbard, a genetics and bioinformatics researcher with the Wellcome Trust Sanger Institute.

Numerous incentive models exist to boost research and development activities in the scientific sphere. The grant of patent protection is generally presumed to be the most effective and efficient model in this regard and its widespread adoption all over the world is generally presented as supporting evidence. However, there is an equally strong discontent as well which highlights the shortcomings and failure of the patent system in crucial areas of public goods, such as drug innovation and access to medicines. James Love and Tim Hubbard provide a summary of such limitations:

The current system of financing research and development ("R&D") for new medicines is deeply flawed by the impact of high prices on access to medicine, the wasteful spending on marketing and R&D for medically unimportant products, and the lack of investment in areas of greatest public interest and need. It can and should be replaced with something better. The system for financing new drug development can be radically improved – spending less overall, aligning investment incentives more efficiently – while making drugs available to everyone at cheap generic prices. Reforming the way we pay for R&D on new

medicines involves a simple but powerful idea. Rather than give drug developers the exclusive rights to sell products, the government would award innovators money: large monetary "prizes" tied to the actual impact of the invention on improvements in health care outcomes that successful products actually deliver.743

Love and Hubbard recommend the use of monetary prizes as an alternative model to stimulate investment in research and development. Considering prizes as 'an appalling answer to a thorny dilemma', they suggest that a patent right should be de-linked from the market exclusivity and generic competition should be encouraged in the market to affordable and stable prices.744 A patent owner in return should be compensated in the form of prize money according to a set criterion. They also assert that 'prizes can extend the community of actors working to solve innovation challenge beyond those who would be supported by grant programs'.745 Furthermore, access problems can be readily addressed through prizes once patent monopolies are waived under the new innovation model.746

Love and Hubbard present a case for a compulsory replacement of prizes for marketing monopolies and they are sceptical about the success of any voluntary scheme.747 Some


744 Ibid.


commentators think that a non-volunteer and compulsory mechanism is less likely to be adopted anywhere in the world and they suggest a slightly different variant of volunteer prize model.\textsuperscript{48} Love and Hubbard argue that a volunteer prize system would be the most expensive and the companies would always opt for a larger sum after weighing their options carefully.\textsuperscript{49} They are, however, ready to consider the possibility of a volunteer mechanism too if an appropriate model can emerge.

The patent system heavily relies on marketing and exclusivity rewards to the patent owner. A prize system is different with the possibility of having many players in the market manufacturing the same product. Love and Hubbard have proposed a fixed prize fund with payments divided among innovators based upon the merits of each product.\textsuperscript{50} Unlike Hollis and Pogge, they have not strictly linked their prize fund with the Quality-Adjusted Life Year (QALY).\textsuperscript{51} A QALY based system has the potential to over-reward certain products on the cost of others which are otherwise important for a group of patients. They have cited the example of Gleevec in this regard and observed that:

\begin{quote}
\end{quote}


\textsuperscript{50} Ibid. 1536.

\textsuperscript{51} A quality-adjusted life-year (QALY) takes into account both quantity and the quality of life generated by healthcare interventions. It is the arithmetic product of life expectancy and a measure of the quality of the remaining life-years.
We prefer a system where the administrators of a prize fund have the flexibility to consider different approaches, rather than only one that is strictly proportional to QALYs. Larger QALYs are associated with both the efficacy of the products and the number of patients who use them. Diseases like breast cancer, heart disease, diabetes, and asthma have very large patient populations. Some diseases or conditions have very few patients. In the current market, governments and private insurers are willing to pay higher prices for products that have relatively small client populations, such as the high prices paid for Gleevec (STI571) or Ceredase (Alglucerase), medicines used to treat diseases classified as “orphans” by the United States FDA.\textsuperscript{52}

It is also proposed that the prize amount will be paid over the period of time when more is known about the efficacy, utilisation and safety of the product and a ten year time period can be one option. Love and Hubbard have left the issue of prize size open and subject to several other factors. This should be resolved in the light of the overall objectives of a prize system and the broader context should help in determining the prize size.\textsuperscript{53}

How would a prize system would co-exist with the patent laws? Love and Hubbard comment:

Prize mechanisms can be implemented in ways that are consistent with a robust patent system, but are best implemented in systems where the patent system is used to establish ownership of inventions and thus claims on the prize rewards,


\textsuperscript{53} Ibid. 1540.
rather than through exclusive rights to market products. It is important that those incentives are linked to broad research priorities, and not be overly prescriptive in terms of diseases, mechanisms or technologies. By eliminating marketing monopolies on products, there is an opportunity for much greater efficiency through unrestricted competition to manufacture the resulting medical products.\textsuperscript{754}

There are other suggestions as well where prizes can co-exist with strong patent monopolies.\textsuperscript{755} James Love and Tim Hubbard clearly favour a system where marketing rights are detached from patent monopoly and a weaker patent system operates to establish ownership rights and priority claims.

Despite the endorsement of Professor Joseph Stiglitz and the subsequent elaboration by James Love and Tim Hubbard, the practical relevance of a prize model is still to be established. During the last few years, several initiatives –such as open source drug discovery patent pools, advanced market commitments etc. – have been launched to boost the global access to medicines situation but developed countries, international organizations and major donors have avoided experimenting with the prize model. High administrative cost, commercial uncertainty and the scarcity of resources are major reasons behind this reluctance.\textsuperscript{756} The proponents of the prize model have failed to

\begin{footnotes}
\footnote{754} Ibid. 1554.


\end{footnotes}
realise the potential of this idea in the context of developing economies and the so-called BRIC alliance. These economically affluent developing countries have a strong interest in the development and production of new drugs but the prize model could not be developed according to needs and requirements of these economies.

B. US Medical Innovation Prize Bill 2007 (The Sanders Bill)

The Medical Innovation Prize Bill of 2007 (US), or S.2210\textsuperscript{757} introduced by Congressman Bernie Sanders, uses a prize mechanism as a non-voluntary substitute for patent monopoly. This bill creates a shift away from relying on high drug prices as the incentive for R&D and towards directly rewarding innovators on the basis of the incremental therapeutic benefit to consumers through a new Medical Innovation Prize Fund. The purpose of the Bill is stated as following:

It is the purpose of this Act to provide incentives to encourage entities to invest in research and development of new medicines through the establishment of a Medical Innovation Prize Fund and to enhance access to such medicines by allowing any person in compliance with Food and Drug Administration requirements to manufacture, distribute, or sell an approved medicine.\textsuperscript{758}

Section 5 of the Bill prohibits any person from having the right to exclusively manufacture, distribute, sell, or use a drug, a biological product, or a manufacturing process for a drug or biological product in interstate commerce, notwithstanding current Federal laws providing otherwise, including laws governing patent rights or exclusive marketing periods. A Fund for Medical Innovation Prizes would be established under

\textsuperscript{757} The Medical Innovation Prize Act of 2007 (US) at http://www.opencongress.org/bill/110-s2210/show.

The Bill was earlier introduced in 2005 as H.R. 417 and details are available on:


\textsuperscript{758} Ibid. Section 3.
Section 6. The Bill mandates the Board of Trustees for the Fund to award prize payments for medical innovations relating to a drug, biological product, or manufacturing process for a drug or biological product. An eligible award recipient can be either the first person to receive market clearance or the holder of the patent. Section 9 elaborates the eligibility criteria to receive a prize payment and directs the Board to consider: (1) the number of patients who benefited from the drug, including non-U.S. patients; (2) the incremental therapeutic benefit of the drug to treat the same disease or condition; (3) the degree to which the drug addresses priority health care needs, such as global infectious diseases and neglected diseases that primarily afflict the poor in developing countries; and (4) the improved efficiency of manufacturing processes for drugs or biological processes.

This Section further mandates the Board to award prize payments for no more than ten years. It also allocates certain minimum payments from the Fund for priority research and development and requires the Comptroller General to conduct an audit to determine the Board’s effectiveness in bringing to market new drugs, vaccines, biological products, and manufacturing processes in a cost-effective manner and addressing society’s global medical needs.759

The legislation attracted considerable support from a number of consumer groups, civil society organisations and educational institutions but the requisite level of political backing did not emerge to get the legislation through the legislative process.760

759 Ibid.

760 For the list of organisations and individuals supporting this initiative see: Consumer Project on Technology, ‘Letter to ask World Health Organization to Evaluate New Treaty Framework for Medical Research and Development’, 24 February 2005,

http://www.cptech.org/workingdrafts/mdsignonletter.html
However, some commentators have also criticised the legislation and its ambitious objectives. Professor Henry Grabowski observes:

While little evidence of broad political support exists for such radical change as prizes as alternatives to patents, this could be an important long-term issue for the biopharmaceutical industries. Though some foundations and prominent academics appear enamored by prize funds as a substitute for patents in the medical area to improve access and result in lower prices for new medicines, the cost of compulsory elimination of the patent system would likely be a significant stall in innovation and medical advancement.761

The introduction of *Medical Innovation Prize Bill* of 2007 (US) has a symbolic value and there is no evidence that such legislation will be formally adopted by the United States. Given the political landscape of the United States and strong bipartisan support for patents on pharmaceuticals, an expectation of a major shift in the United States domestic policy will be unrealistic.762 In fact the United States is not a good starting point to test and apply the ideas of prize model and the focus should be diverted towards developing countries such as India and China to launch targeted prize funds.


C. Medical Research and Development Treaty

Knowledge Ecology International has a multi-tier strategy to advance the notion of prizes as a suitable substitute to the existing patent system. At a domestic level in the United States, the organisation is lobbying for the adoption of the Medical Innovation Prize Bill of 2007 (US) to develop a model for the successful implementation of a prize system. At the international level, Knowledge Ecology International has drafted a Medical Research and Development Treaty which also reflects the same objectives of prize incentives in the area of drug innovation.763

The proposed treaty is aimed at increasing the sharing of the high costs of research and development, providing flexibility to countries on ways to finance Research and Development (R&D), and create obligations and incentives to invest in priority R&D projects.

The proposal would set minimum obligations to finance R&D based on internationally agreed-upon proportions of member states’ Gross Domestic Product. Countries could count all qualifying R&D spending, which would promote local research and the targeting of local health priorities. In this regard member states may use a variety of mechanisms such as public sector funding, tax credit, and purchases of patented medicines. The treaty also proposes a system of tradable ‘credits’ for investments in priority R&D, traditional medical knowledge, open public goods (such as free and open source public databases), and technology transfer.

The proposed draft specifically addresses the issue of patent law and suggests mechanisms to restrict patents on inventions which are derived from open public goods databases. It further provides exceptions in copyright laws. The objective is to change the trend toward stronger intellectual property protection and new rights on data. The

shift would supposedly introduce more innovation and competition into the current business methods.

This model of a Medical Research and Development Treaty was first publicised on the 24th February 2005 when the draft treaty was submitted to the World Health Organization for consideration, accompanied by an open letter signed by 162 scientists, lawyers, public health experts, government officials and parliamentarians. A plea for a multilateral Research and Development Treaty is explicitly endorsed in this letter and a case was made that:

A trade framework that only relies upon high prices to bolster medical R&D investments anticipates and accepts the rationing of new medical innovations, does nothing to address the global need for public sector R&D investments, is ineffective at driving investments into important priority research projects, and when taken to extremes, is subject to a number of well-known anti-competitive practices and abuses. Policy makers need a new framework that has the flexibility to promote both innovation and access, and which is consistent with efforts to protect consumers and control costs. To this end, a number of experts and stakeholders have proposed a new global treaty to support medical R&D. This effort has produced a working draft that illustrates a particular approach for such a treaty – one that seeks to provide the flexibility to reconcile different policy objectives, including the promotion of both innovation and access, consistent with human rights and the promotion of science in the public interest.764

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The joint communication showed that pressure on the international community was rising to precipitate efforts to implement a public health strategy for neglected diseases.

In April 2008, just before the annual meeting of the World Health Assembly, Barbados and Bolivia made six different proposals for the possible use of new incentive mechanisms for pharmaceutical innovation. Barbados and Bolivia made proposals to the WHO’s Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG) for prizes to reward innovation. They suggested exploring multiple prizes: for the development of a low-cost rapid diagnostic test for tuberculosis; for new treatments for Chagas disease; for priority medicines and vaccines prize fund to reward mechanisms for new cancer treatments in developing countries; for clinical trials on medicines as global public goods and for a licensed products prize fund for donors.765

After the adoption of WHO’s Global Strategy and Plan of Action in 2008766, the negotiations started to work out the details of an appropriate R&D model which could address the needs of poor and developing nations. In March 2010, the Secretariat of the World Health Organization tabled its report, Public Health, Innovation and Intellectual Property: Global Strategy and Plan of Action767, before the Sixty-Third World Health Assembly highlighting key developments and the state of implementation of the Global

765 For details and full texts:
http://www.keionline.org/index.php?option=com_content&task=view&id=3&Itemid=1#KEI%20Documents


Strategy. A new consultative working group was established in this meeting to further review and evolve the modalities of the Global Strategy.\textsuperscript{768}

D. Prize Incentives and Indian Pharmaceutical Sector

Like most of the alternative R&D models, the prize fund proposal was intended to stimulate research and drug discovery in the area of neglected diseases. The prize model proposed by James Love and Tim Hubbard was intended to address the acute problem of access to new medicines in the developing world. The Indian situation is pivotal in this regard being a major generic medicine supplier and expanding pharmaceutical market. Given the diverse structural details of the prize model, it is worthwhile considering the prize mechanism in the Indian context in two different scenarios.

In the first scenario, I am pessimistic about the introduction of any kind of prize model within India's domestic context. There are several independent reasons for this ranging from policy considerations to structural impediments in the industry. It is thus quite unlikely that India will show a positive inclination towards the adoption of any policy or law similar to the Medical Innovation Prize Bill of 2007 (US). The cost associated with the prize initiative is prohibitive in India where almost 80% of health care expenses are paid out-of-pocket by patients in the absence of adequate health insurance systems.\textsuperscript{769} The government does not have current budgetary allocations in this area which can be redirected towards prize financing.


The potential for private sector financing is relatively more promising but the current level of Indian firms’ R&D investments does not provide a convincing case. The latest statistics show that major Indian pharmaceutical firms have invested almost 10% of their total sales into R&D since 2000.\textsuperscript{770} After 2005 when Indian patent law became TRIPS compliant, leading Indian firms increased their R&D spending by 47% totalling US$192.3 million. However, it is important to understand the nature of these low cost R&D operations which are largely dedicated to the development of novel delivery systems, non-infringing processes and similar activities. Given the interest in the secondary level of R&D ventures, the combined R&D expenditures of the top five Indian firms is less than 3% of Pfizer.\textsuperscript{771} A somehow shocking aspect of existing investments is related to priorities. According to a survey conducted in 2008:

The surveyed firms were also asked to quantify the amount of their total research that is focused on local disease conditions ... Only 6% of the 49 firms that participated in the survey conducted all of their research on local disease conditions, 18% of the firms admitted to conducting up to half of their R&D on local conditions, and a large majority of the firms (75%) conducted only 25% or less of their R&D on local disease conditions.\textsuperscript{772}

Against this backdrop, the relevance of a prize mechanism and its domestic application in India is questionable. The private sector’s investment decisions are clearly linked with the potential incentives in the regulated markets where these firms can recover


\textsuperscript{771} Ibid. 24.

\textsuperscript{772} Ibid. 20.
their R&D costs through licensing or patenting devices. So a case for the introduction of a domestic prize mechanism lacks a sound economic basis in India.

A second international scenario presents a relatively more plausible case for the involvement of India in a multilateral framework about prizes. A multilateral treaty also involves enormous costs and initial proposals linking member states’ contribution with their gross domestic product or gross national product, have major disincentives for countries such as India to subscribe them. Nevertheless, there are promising aspects too for Indian pharmaceuticals for a multilateral research and development treaty membership. Any attempt to delink patent rights from exclusive marketing rights should be welcomed in India as it will open substantial manufacturing opportunities for Indian generic companies. However, recognising the nature of multilateral negotiations and the existence of the *TRIPS Agreement 1994*, the chances of an outright substitution of patent monopolies with a workable prize system are not very high.

### III. Health Impact Fund

In the field of applied philosophy, there has been an interest in questions of justice and equity underlying development issues – such as access to essential medicines. In his recent book, *The Idea of Justice*, Amartya Sen raised the issue of transcendental institutionalism and global neglect while discussing the problem of overemphasis on the relevance of global structures and institutions. He criticises currently dominated theories of justice which attempt to overcome the problem of injustices through global

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773 In *The Idea of Justice*, Amartya Sen discusses two different approaches towards the question of justice. The first approach, which he calls transcendental institutionalism, is advocated by Kant, Lock and Rawls. The second approach, which is preferred by Amartya Sen, is manifested in the works of Smith, Condorcet, Bentham, and John Stuart Mill.
institutions and regulatory structures. Amartya Sen specifically mentioned the problem of patents and access to justice and notes that:

Consider any of the great many changes that can be proposed for reforming the institutional structure of the world today to make it less unfair and unjust (in terms of widely accepted criteria). Take, for example, the reforms of patent laws to make well-established and cheaply producible drugs more easily available to needy but poor patients (for example, those who are suffering from AIDS)—an issue clearly of some importance for global justice. The question that we have to ask here is: what international reforms do we need to make the world a bit less unjust? 

This is an important observation highlighting the inherent limitation of different proposals which are developed to address the problem of patents and access to medicines. Amartya Sen’s conception of justice rejects an overwhelming reliance on global institutions and instead provides a detailed critique of the Rawlsian approach of justice.

William Fisher and Talha Syed provide a comprehensive survey of work undertaken by leading philosophers in the area of patent law and access to essential medicines. Their work demonstrates that significant interest has emerged among the scholars of philosophy and theoretical economics suggesting distinct proposals and suggestions to address the problem of access to medicines. The authors themselves have advanced several moral and ethical justifications for establishing a mechanism which can address

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the problem of R&D gaps in the area of neglected diseases. The most recent initiative in this regard came from Professor Thomas Pogge. Thomas Pogge along with Aidan Hollis has taken a step further by proposing the idea of the Health Impact Fund to stimulate the process of pharmaceutical innovation in the area of neglected diseases.\textsuperscript{776} The Health Impact Fund is an optional advance market commitment system offering financial incentives to patentees of new drugs, which are globally marketed at a low price.

\textbf{A. Theoretical Justifications of the Health Impact Fund}

A student of Rawls\textsuperscript{777}, and a philosopher of justice and development\textsuperscript{778}, Thomas Pogge approaches the problem of the pharmaceutical research gap and access to medicines in the broader context of poverty and human rights. He offers a two tiered justification for his solution: The Health Impact Fund. First, Pogge engages with the arguments of libertarians and vehemently dismisses the approval of patent exclusivity as a natural right. Second, he questions the efficiency and optimality of the existing framework of pharmaceutical innovation which relies largely on patent protection.

Pogge questions the conventional philosophical justifications provided for patent rights. The libertarian theorists assert that patent rights are part of a natural rights stream and they enjoy the same status of inviolability and protection. Thus, any attempt to appropriate these rights on the basis of a social needs argument such as a public health crisis, lacks theoretical validity. Pogge questions this approach by rejecting some of the fundamental premises of a leading libertarian philosopher, Robert Nozick. He writes:


[L]et me here focus on the more fundamental difficulty of justifying any natural right of inventors to control the use of their inventions at all. Even the most property-friendly accounts of rights – those of right-wing libertarians – have trouble explaining how the innovative creation of a physical object should earn the innovator property rights not merely in this object *token* but in all objects of its *type*.\footnote{Thomas Pogge, *World Poverty and Human Rights* (Cambridge, United Kingdom: Polity, 2nd ed, 2008) 227-228.}

Pogge then concludes that Nozick’s construction of a Lockean argument to support his position fails to the extent that:

>Far from supporting intellectual property in particular types of medicine, libertarian and deontological accounts such as Nozick’s actually refute such property rights: specific quantities of medicine (token) can be owned exclusively only because and insofar as such ownership leaves undisturbed the freedom of others to produce (if they can) medicine of the same type.\footnote{Ibid. 229.}

He then discusses other sets of theories which rationalise the importance of intellectual property rights on the basis of beneficial consequences. While approving part of these theories that intellectual property rights do encourage some kind of research and development in the pharmaceutical sector, Pogge draws our attention to certain specific groups which have varying attitudes towards the patent regime. Pharmaceutical and biotechnology companies and their shareholders can be categorised as a happy group for obvious reasons. Affluent populations of the world could see this situation with mixed feelings. They pay more for drugs and miss opportunities to buy cheaper generics.
However, the overall pattern of pharmaceutical innovation suits them as there is a clear R&D bias in their favour.

Pogge contends that patent monopolies are a setback for generic pharmaceutical drug manufacturers in the developing world because they are rapidly losing opportunities to sell their medicines both to the affluent and poor patients around the world. Pogge notes that poor patients are disadvantaged in this scenario:

The newly globalized patent regime effectively cuts them off from advanced essential medicines by rendering such medicines unaffordable to them and by massively diluting the capacity of national health systems, international development agencies, and non-governmental organizations to buy these medicines for them. Millions of deaths from AIDS and other treatable or curable diseases are due to the suppression of manufacture and trading of generic drugs.781

A consequentialist approach towards patent law should also be informed from these facts to fix the shortcomings of patent monopolies.

Beside this theoretical critique of global intellectual property rules and their negative implications for public health and access to medicines, Pogge offers additional points in support of his alternative model. Pogge enumerates at least seven main drawbacks of the globalised patent regime.782 First, the problem of high prices is essentially linked with patented medicines because of market exclusivity. The mark ups in excess of 1,000% on patented medicines are not exceptional and this leads to a massive accessibility problem. Second, the existing patent system is instrumental in neglecting

781 Ibid. 232.
the diseases concentrated among the poor because this population group is not a lucrative target for pharmaceutical R&D. This problem is also identified as the 10/90 problem alluding to only 10% of all pharmaceutical research being focused on diseases that account for 90% of the global burden of diseases. Third, the existing patent regime provides optimal returns and profits for symptom-relieving medicines. So the most attractive group of patients is the one who are not cured and who do not die either. Vaccines and other preventive solutions are far less lucrative options for R&D priorities. Fourth, the system lacks efficiency and is ridden with wastefulness. Patent rights are territorial in nature and patentees are supposed to secure patents in multiple jurisdictions of their choice. Huge amounts are spent on this followed by litigation which discourages generic companies from challenging the patents of dubious quality. Fifth, huge mark ups and optimal profits, and the associated problem of accessibility, encourage the illegal manufacturing and counterfeiting of medicines. Sixth, excessive marketing is another problem linked with the attempts to reap maximum profits within the exclusivity period. This problem is exacerbated in the case of competition among ‘me-too’ brands which share the same market despite their respective patents.

The final drawback which Pogge highlights is the last mile problem. He observes that:

While the present regime provides strong incentives to expose affluent people to patented medicines they do not need, it provides no incentives to ensure that poor people benefit from medicines they do need. Even in affluent countries, pharmaceutical companies have incentives only to sell products, not to ensure that they are actually taken, properly, by patients whom they can benefit. This issue is compounded in poor ones, where the infrastructure is severely lacking to

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distribute, prescribe, and supervise the proper consumption of medicine. In fact, the present regime gives pharmaceutical companies the opposite incentives. To profit under this regime, a company needs not merely to develop and patent a medicine that is effective in protecting paying patients from a disease and/or its detrimental symptoms. It also needs this target disease to thrive and spread because, as a disease waxes or wanes, so does market demand for the remedy.784

The central theme of the Health Impact Fund model is the creation of a substantial fund which can be used to allocate incentives for medicines with considerable health impact. This fund will be contributed by the members of the Health Impact Fund on the basis of their gross national income. It essentially involves a much larger contribution from economically developed and rich countries and in consequence, the tax-payers in these countries will share this additional burden. What is the moral justification for placing the responsibility of financing pharmaceutical R&D for neglected diseases on the affluent population of developed countries?

B. Structure of the Health Impact Fund

The Health Impact Fund is aimed at resolving the problems of the innovation gap in pharmaceutical research which badly affect the poor masses of the world. The proponents of this model designate it as a ‘full pull program’785 for the provision of


medicine, because it overcomes the shortcomings of other existing pull and push mechanisms.\textsuperscript{786} As noted earlier, the general idea of the Health Impact Fund is that governments and other donors will establish a pool of funds, which will be used for annual payments to firms with patented pharmaceutical products, which they agree to sell at a negotiated low price. The amount payable to the patentee will be measured on the basis of health impact of the product. This health impact will be calculated against a baseline of previous state of the art. Aiden Hollis and Thomas Pogge provide a comprehensive account of the Health Impact Fund structure and its operational details. Some of these details are discussed in the following.

The Health Impact Fund is an ambitious model by all means. Unlike some other alternative R&D models, it is not a disease focused proposition and as a matter of general principle it is there to accommodate \textit{all} medicines which have the potential to demonstrate substantial health impact. The health impact of a given medicine will be measured in terms of the increase in Quality-Adjusted Health Years (QALYs) and obviously the medicines produced for diseases responsible for a greater number of deaths will have better chances to enter in the system for the reward. This includes type II and type III diseases according to the criteria of the World Health Organization.\textsuperscript{787}

\begin{itemize}
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HIV/AIDS, malaria, tuberculosis and other infectious diseases still constitute a major part of burden of diseases in low income and middle income countries.\textsuperscript{788}

The Health Impact Fund will be a major attraction for pharmaceutical firms which have invested in medicines having larger potential consumption in low income and middle income countries. Traditionally, consumers in these countries cannot afford to pay higher drug prices and manufacturers were reluctant to target these markets. With the Health Impact Fund an incentive now exists and the firms can use this option to address the needs of a huge but poor market. However, there is a problem associated with this aspect of the Health Impact Fund. The problem of rare diseases and orphan drugs will continue to exist even after the introduction of this proposal. This model essentially links the incentive with the health impact and the firms have no incentive to engage in R&D for rare diseases. On this account, this proposal shares the drawback of the existing patent regime. Hollis accepts that the problem of rare diseases may not be resolved through their proposal and he suggests that some alternative solution may be considered in this regard.\textsuperscript{789}

The whole idea of the Health Impact Fund revolves around the payment of incentives from the pot of money which will be collected from members’ contributions. This money will be allocated on the basis of the health impact of a product; the higher the health impact, the higher the amount paid to a patentee. A precise and accurate calculation of the health impact which a drug can achieve is a challenging task. Hollis and Pogge propose the creation of an Independent Assessment Committee (IAC) which will be authorised to calculate the incremental health impact of a particular medicine.


The committee may consider the data provided by the patentee and independent sources, and it can also generate its own information to reach certain conclusions.790

The Quality-Adjusted Life Years (QALYs) metric will be used to calculate the health impact of a product and a final formula can be further refined for practical application. The authors have also considered other options available but they consider that QALYs best fits the given situation. It is noted that:

... We do not prescribe any particular metric; however, the [Health Impact Fund] will need to choose one, and for the present we assume that it is QALYs. The [Health Impact Fund] then needs to make an estimate of the number of incremental QALYs achieved because of the use of a given medicine globally rather than the baseline technology. This is properly the field of pharmacoepidemiology. Developing such an estimate is obviously challenging and this section examines a number of approaches which can be used.791

Given the extensive nature of measurements involved, the controversy about the use of the QALYs metric is not unusual and different commentators have proposed some alternatives or adjustments in this approach. Some have simply suggested that a Disability-Adjusted Life Years (DALYs) based approach should be adopted because a reduction in the burden of a disease could be measured in this term.792 Others think that

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791 Ibid. 29.

a QALYs metric provides an appropriate starting point but to reflect more complex situations, the formula would need to be adjusted in mathematical terms.793

It is still not clear how the Health Impact Fund will calculate the health impact of products such as vaccines which may not have a demonstrable health impact in immediate terms. Other problems include the refinement of the formula to avoid the inclusion of the improved health impact of a situation which can be attributed to other factors such as improved sanitation conditions, and better nutrition. Such a situation may lead to an unjust enrichment of drug companies.794

The Health Impact Fund is indeed an off-shoot of the prize model with considerable distinct characteristics and variations. Like prizes, it needs the creation of a large funding pool which can be used to finance the alternative incentive scheme. There are two clear issues which the fund will confront in immediate term. First, what investment is needed to start this program on a sustainable basis? Second, what funding sources and on what basis will the investment funds be generated from member countries. Hollis and Pogge project that the Health Impact Fund needs an annual budget of US$6 billion with about $600 million expenditures on administration and assessment.795


795 Aidan Hollis and Thomas Pogge, The Health Impact Fund: Making New Medicines Accessible for All
budget required for this initiative cannot be left undetermined as it will induce an element of uncertainty and ambiguity. An alternative suggestion was to fix the price per incremental QALY and leave the total budget undermined. However, this was dropped in favour of a fixed predetermined annual budget.\textsuperscript{796}

Once the fund is established, its allocation among the candidate drugs is another crucial step. There can be more than the required number of drugs with excellent health impact profiles and in this case the allocation of money may become difficult to effect. Hollis notes in this regard:

\begin{quote}
In the absence of breakthrough drugs such as completely effective vaccines, the risks in this mechanism are considerably reduced by the fact that there is the possibility of substitution from the HIF mechanism to and from exploitation of patent exclusivity. If the payments fall too low, the HIF will not attract other drug products, which will instead be sold at monopoly prices. This will allow the payments on products remaining in the HIF to be higher. In effect, because of the possibility of substitution, the riskiness of the HIF payments is considerably reduced.\textsuperscript{797}
\end{quote}

Membership of the Health Impact Fund is open to all governments and the members will be required to contribute annually to the fund. Though not binding the \emph{Incentives for Global Health} suggests a contribution of 0.03\% of members’ Gross National Income (GNI) to reach the target of US$6 billion. This ratio can be changed subject to the


\textsuperscript{797} Ibid. 128.
number of countries initially willing to participate in the system and the total amount is indeed a humble sum keeping in view annual global spending on pharmaceuticals. This amount is roughly equivalent to 0.01% of global income.798

The latest report of the Global Funding of Innovation for Neglected diseases (GFINDER) shows that ‘just over US$2.5 billion was invested into R&D of new neglected disease products in 2007’.799 The Health Impact Fund funding projections presumes that all major OECD countries and the European Union (EU) will be fully involved with their proportional contributions, and the funding target achieved. The projected budget of the Health Impact Fund, therefore, looks an ambitious target and difficult to be matched by the participating members.

Unlike the prize model, patent exclusivity will not be compromised if a drug company elects to enter in the Health Impact Fund system. The system does not require any kind of automatic licensing to the generic companies and the patentee can exclude others from manufacturing and marketing. However, after the lapse of the reward period (10 years), a patentee shall have contractual liability to waive their exclusive rights and share the relevant technical know-how with competitors. It is expected that with these arrangements, this proposal will attract a positive response from the pharmaceutical industry and in the long run it will be beneficial for generic competitors as well.800


Hollis observes: 'the HIF would determine a price at approximately the variable cost of manufacturing, so that the patentee would earn profits chiefly from the payments made by the HIF, rather than from high prices charged to consumers'.

Pogge and Hollis do not necessarily advocate substantive reforms to the patent regime. William Fisher and Talha Syed also favour this cautious approach and they persuasively argue that a model suggesting changes in the patent regime is less likely to be implemented. They note that a non-exclusive prize system will be a potential infringement of Article 27 of the TRIPS Agreement 1994.

Dr Kathy Liddell has also raised several points to show that the patent-Health Impact Fund nexus is a complex issue and it has not been fully explored by the authors of the concept. She argues that the quality of patents granted by national patent offices is not always the same and many trivial inventions are patented. A heavy reliance of the Health Impact Fund on the patent status of a medicine may not work in a real situation realising the limitations of patent system and significant litigation among rival pharmaceutical companies. Furthermore, patents are territorial in nature and the application of a patent based incentive mechanism such as the Health Impact Fund will be undermined in countries where patents are granted. The criteria of patentability are another challenging aspect which needs to be addressed by the proponents of the Health Impact Fund. A medicine patentable in one jurisdiction may be refused a patent in

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801 Ibid. 127.
another jurisdiction on the basis of different guidelines and practices. All these aspects are currently ignored in the design of an effective Health Impact System. 803

C. India and the Health Impact Fund

As an alternative incentive model for research and development into neglected diseases, the Health Impact Fund can offer some promising outputs for India. The main objective of the fund is to accelerate the process of pharmaceutical innovation for the benefit of poor consumers. India is categorised a middle income developing country with a huge population living below the poverty line. A successful implementation of the Health Impact Fund model could benefit millions of patients in India living with the diseases of poverty. In an overall public health perspective, India can be the beneficiary of a Health Impact Fund facilitated innovation regime.

The implementation of the Health Impact Fund proposal may create several opportunities for Indian pharmaceutical firms. Contrary to the general belief, the relationship of Indian firms with multinational pharmaceutical companies is not always antagonistic. In recent years, research cooperation and business alliances between the firms from both sides have increased and this can produce tremendous business and expansion opportunities for Indian firms if the Health Impact Fund proposal materialises. Admittedly, the Health Impact Fund scheme allows patentees to retain their patent exclusivity and there is no compulsion for automatic licensing to generic

companies. However, the patentees will practically find it feasible to outsource their manufacturing and marketing operations to maximise the health impact of their products. Indian firms are best placed in this regard and their R&D and manufacturing facilities can play a major role in a widespread dissemination of new technology and products.

Many factors establish India pharmaceutical firms’ credentials to assume this role. With 100 approved plants, India has the largest number of FDA approved pharmaceutical manufacturing units outside the United States.\textsuperscript{804} Indian firms have demonstrated capabilities in various stages of the drug discovery and development process and conduct contract research and manufacturing for foreign firms. Local companies now have agreements with multinational companies for advanced stage drug trials in the laboratory facilities of multinationals. Some recent, interesting forms of contract research include basic molecular research, gene mapping, drug discovery and managing clinical trials, discovery chemistry for domestic and global pharmaceutical companies.\textsuperscript{805}

Such a robust industry will positively construe the Health Impact Fund proposal as an opportunity and a new business model may emerge in India with the help of the Health Impact Fund rules. Indian firms may not have to wait for the lapse of the 10 year exclusivity and may be the beneficiary of early harvesting options. The application of the Health Impact Fund model in the Indian context may become less relevant in view of certain negative considerations such as the cost of participation, the disease profile, 


\textsuperscript{805} Ibid. 27.
the response of the generic industry and the rules of patentability. India is a huge market with diverse policy considerations and corporate interests interacting at the same time to make the fate of a scheme such as the Health Impact Fund, vulnerable to several factors.

The Indian Government may blanch at the cost of membership of the scheme. Like all other funding partners, India is supposed to contribute at least 0.03% of its GNI on an annual basis. According to World Bank’s statistics, India’s GNI per capita for the year 2007 was US$950. The total GNI for the same year was around US$1,069.4 billion. To fill the gap, out-of-pocket expenditures on healthcare are on rise: ‘in 2001-02, households accounted for 72% of total health expenditure (3.5% of GDP), followed by state (13%), central (6%), private insurance (5%) and external aid (2%)’. Pharmaceutical related expenditure constitutes a small proportion of public budgets. In the Ministry of Health and Family Welfare’s budgets, it accounts for 1.4% (US$8 million) out of US$598 million. At the state level it accounts for 1.7%, US$59 million out of US$3.5 billion.

Another factor which further complicates the prospects of Indian willingness is related to India’s transforming burden of disease landscape. As seen in Table 7.1, I have discussed India’s burden of disease data and the projected changes which are anticipated

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809 Ibid. 11.
in the near future. The most prevailing diseases responsible for the loss of maximum DALYs are not typical poverty related diseases. The data shows that a substantial proportion of India’s burden of disease belongs to type I and type II categories, and the prevalence of type III diseases in India is not major public health concern. What has this to do with the Health Impact Fund application in India? The answer is simple. Though the Health Impact Fund proposal is not a disease specific solution, this fund will at least initially attract products targeted towards type III diseases. Hollis makes this point clear:

Poor people in low-income countries are just as much in need of drugs for Type I diseases (those with a common global distribution), such as cancer, diabetes and hypertension, as of drugs for the infectious diseases which particularly plague them. However, a reward fund with annual payments of a few billion dollars would have relatively little effect on incentives for innovation into global diseases, but could be very important in stimulating research into Type III diseases.810

Pogge and Hollis persuasively elaborate that the system will expand gradually and at some later stage, it could even address the broader problem of innovation in the healthcare sector beyond the medicines, but this initial focus can become a barrier for India. Unlike many affluent countries, India cannot afford to support a long term process which is not immediately focused on its domestic problems. Selling such a mechanism is a hard task on the domestic political front as well.

The third criticism that could be made of the Health Impact Fund is that it favours brand-name pharmaceutical drug companies. The implication of the Health Impact Fund on generics has been a much debated topic and views are divergent in this regard.

proponents of the Health Impact Fund, however, disagree with this observation and they simply do not find negative consequences. Hollis replies that:

We expect the [Health Impact Fund] to have approximately zero impact on the generic drug industry. It would reduce barriers to competition at the end of the reward period of ten years, by requiring open licensing of all outstanding patents required for the manufacture and sale of the registered product at that time. This would of course reduce litigation costs in those markets where litigation occurs, which would benefit generic manufacturers. The [Health Impact Fund] could result in decreased sales of some generic medicines if there were cheaper and better [Health Impact Fund]-registered drugs available at low prices, which could harm generic manufacturers. (Of course, in the latter case, consumers would benefit.) Generic firms might also benefit from increased opportunities for contract manufacturing of [Health Impact Fund]-registered drugs.\(^{811}\)

The objection has a solid basis from the public health perspective. Though the Indian generic firms will not lose substantial business opportunities if a Health Impact Fund type mechanism is implemented because most of their export revenues are already coming from regulated US and EU markets. But the continuous presence of a resilient and efficient generic sector is important for the production of medicines which may not be an optimal financial option for the firms. If an alternative research and development model threatens the growth and viability of generic firms per se then the long terms implications would be quite negative.

Additional problems can also be highlighted in the implementation of the Health Impact Fund within Indian context. Building upon the argument of Dr Kathy Liddell, the interaction between the Health Impact Fund and Indian patent law reveals a potentially

\(^{811}\) Ibid.
problematic situation. With a new patent regime in the country, the Indian Patent Office had already rejected many patent applications by drug companies which were issued patents elsewhere in the world. With Section 3(d) of the patent law playing a major role in the scrutiny of pharmaceutical patent applications, this trend will probably continue to boost the quality of patenting in the country. How will this situation be tackled if India chooses to become the member of this fund? A drug which is not patented in India but with patents elsewhere (such as Gleevec) may have a tremendous health impact but the attribution of this impact to a particular producer will not be possible because of generic competition in the market. Another associated issue is the substantial problem of irrational use of medications in India. With almost all kinds of drugs available over-the-counter and irrational prescription practices, the measurement of the health impact will be next to impossible in many cases.

This analysis shows the diverse nature of opportunities and risks which are associated with the introduction of the Health Impact Fund in India. The objectives of the Health Impact Fund corresponds with the future needs of the Indian public health sector and the growing segment of the generic pharmaceutical industry, but the cost of participation may be prohibitive for a developing country like India. The dynamic changes which the Indian economy has witnessed during the past decade have helped in lifting the quality of life and thus transformed the domestic patterns of disease burden. This makes India a difficult case for the implementation of the Health Impact Fund reform strategy which is mainly designed to address the problems of poor populations suffering from neglected diseases around the globe. The Health Impact Fund proposal therefore seems a less attractive proposition for Indian policy circles.
IV. Conclusion

Alternative research and development incentives for drug discovery have attracted considerable academic attention during the past few years and several proposals were floated to address the problems of access to medicines and existing research gaps. None of these models were conceived specifically to cater to the needs of developing countries and proposals made in this regard are generally applicable across all fields of technologies. However, the special needs of developing countries came in the context of policy debates about neglected and tropical diseases, and commentators started contextualising the general themes in particular situations. This adaptation has given rise to an array of alternative research and development models which are exclusively designed to address the problem of access to essential medicines.

On the basis of the analysis in this chapter, it is clear that each model has the potential to facilitate the task of new drug discovery. While applying these models in the Indian situation, we further noticed that there are considerable challenges which these alternative models can face during the implementation phase. This analysis also shows that no single model can fully substitute for the existing system of patent monopolies and a viable alternative model will operate parallel to patent system. This is particularly true at least in the transition period. It is suggested that India can adopt a hybrid model of alternative research and development mechanisms.

As a starting point Indian policy can incorporate a mix of three alternative models discussed in this thesis namely prizes, open source and patent pools. The Health Impact Fund is left out of this equation for two reasons. First, the Health Impact Fund with its current form and details is primarily directed towards developed countries to generate sufficient resources and institutional support. The moral arguments advanced by Thomas Pogge suggest that developed countries and the world’s affluent populations
should act to resolve the global health crisis. The outcome of such an initiative will be beneficial for developing countries like India but these countries cannot play any pivotal role at this formative stage of the Health Impact Fund. On the contrary, India can play an immediate positive role in boosting the ideas of open source drug discovery, prizes and patent pools. Second, the details of the Health Impact Fund and its operational aspects are still under review and the associated high cost of implementation does not allow us to group it with other relatively low cost methods. This critique partly applies to the prize model as well which needs substantial financing for its implementation. There is, however, an important distinction between prizes and the Health Impact Fund on this point. The idea of floating miniature prizes targeted at tropical diseases is very attractive for economically emerging developing countries and, with relatively less cost, India can demonstrate a successful implementation of the prize system.

Prizes also share some commonalities with open source and patent pools which are discussed in Chapter 6. They can co-exist in a carefully crafted policy instrument. We have already seen that the Indian open source drug delivery initiative which is focused on tuberculosis is indeed a hybrid model because it provides a prize incentive. In case of prizes, market actors are key stakeholders and this model can be implemented with a lesser involvement of regulatory bodies through contractual mechanisms. A prize incentive will be mainly relevant for new and pipe-line products and it has less relevance for existing products in the market. In India small prizes can be announced for innovative projects to bargain with future patent holders as an alternative incentive. The open source model ideally suits non-market actors. In the Indian context, state funded research and academic institutions can be directed to this track. Patent pools again involve market actors but they differ from prizes because pools are created mainly for existing patents to create future products. A mix of these instruments will enable the
Indian government to use a specific tool or a combination thereof according to the needs of a particular situation.

Table 7.1: India-Burden of Diseases

<table>
<thead>
<tr>
<th>Disease / Health Condition</th>
<th>DALYs Lost (x1000)</th>
<th>Share in Total Burden of Disease (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Communicable diseases, maternal and perinatal conditions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>7,577</td>
<td>2.8</td>
</tr>
<tr>
<td>HIV/AIDS</td>
<td>5,611</td>
<td>2.1</td>
</tr>
<tr>
<td>Diarrhoeal diseases</td>
<td>22,005</td>
<td>8.2</td>
</tr>
<tr>
<td>Malaria and other vector-borne conditions</td>
<td>4,200</td>
<td>1.6</td>
</tr>
<tr>
<td>Leprosy</td>
<td>208</td>
<td>0.1</td>
</tr>
<tr>
<td>Childhood diseases</td>
<td>14,463</td>
<td>5.4</td>
</tr>
<tr>
<td>Otitis media</td>
<td>475</td>
<td>0.1</td>
</tr>
<tr>
<td>Maternal and perinatal conditions</td>
<td>31,207</td>
<td>11.6</td>
</tr>
<tr>
<td>Others</td>
<td>49,517</td>
<td>18.4</td>
</tr>
<tr>
<td><strong>Non-communicable conditions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cancers</td>
<td>8,992</td>
<td>3.4</td>
</tr>
<tr>
<td>Diabetes</td>
<td>1,981</td>
<td>0.7</td>
</tr>
<tr>
<td>Mental illness</td>
<td>22,944</td>
<td>8.5</td>
</tr>
<tr>
<td>Blindness</td>
<td>3,699</td>
<td>1.4</td>
</tr>
<tr>
<td>Cardiovascular diseases</td>
<td>26,932</td>
<td>10.0</td>
</tr>
<tr>
<td>COPD and asthma</td>
<td>4,061</td>
<td>1.5</td>
</tr>
<tr>
<td>Oral diseases</td>
<td>1,247</td>
<td>0.5</td>
</tr>
<tr>
<td>Others</td>
<td>18,801</td>
<td>7.0</td>
</tr>
<tr>
<td><em>Injuries</em></td>
<td>45,032</td>
<td>16.7</td>
</tr>
<tr>
<td><strong>All listed conditions</strong></td>
<td><strong>200,634</strong></td>
<td><strong>74.6</strong></td>
</tr>
<tr>
<td><strong>Others</strong></td>
<td><strong>68,319</strong></td>
<td><strong>25.4</strong></td>
</tr>
</tbody>
</table>

Source: National Commission on Microeconomics and Health\(^\text{12}\)

Chapter 8
India, TRIPS-Plus Free Trade Agreements
and the Future of Access to Essential Medicines

I. Introduction

In 2010, the Delhi Network of Positive People wrote a letter to members of the Indian Parliament, expressing its concerns about the impact of free trade agreements upon access to medicines. The group exclaimed:

We are alarmed that the Indian government is trading away our lives and right to health, in the name of a free trade agreement ... As patients relying on life long treatment, we are intimately familiar with provisions on intellectual property in such trade agreements and their impact on access to treatment. Our new HIV medicines have been patented in India and cannot be domestically produced because India signed the WTO TRIPS Agreement.

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The Delhi Network of Positive People emphasised: ‘It is not only our lives that are at stake but those of millions around the developing world in Asia, Africa and Latin America that rely on India as a source of affordable generic medicines.’814 The letter underscores the concerns about the impact of TRIPS-Plus Free Trade Agreements with the United States and the European Union upon the capacity of India to develop and disseminate pharmaceutical drugs.


814 Ibid.
Economists have divergent views about the welfare impacts of bilateral and plurilateral trade agreements. Lawrence H. Summers and Paul R. Krugman argue that regional trade agreements are likely to have trade creation effects with welfare enhancing consequences. However, this view is contested by Professor Bhagwati and other scholars who think that free trade and preferential trade agreements generally cause trade diversion. Bhagwati contends that the United States policy shift to regionalism is a main reason behind the proliferation of free trade agreements which are negatively impacting the multilateral trading system. A strong push to bilateral trade agreements is weakening the position of developing countries in multilateral trade negotiations and in this process developed countries are often successful in including aggressive trade liberalisation clauses.

Instead of assisting developing countries in the process of implementation of the TRIPS Agreement 1994, the United States launched a new strategy to achieve higher standards of intellectual property rights. In 2002, the United States Trade Representative, Robert

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B. Zoellick, highlighted the dynamics of President Bush’s administration’s policy on bilateral and free trade agreements. He wrote that

As our FTA negotiation with Singapore showed, our agreements can also serve as models by breaking new ground and setting higher standards. The United States-Singapore FTA will help advance areas such as e-commerce, intellectual property, labor and environmental standards, and the burgeoning services trade. As we work more intensively with nations on FTAs, the United States is learning about the perspectives of good trading partners. Our FTA partners are the vanguard of a new global coalition for open markets.②⁰

Central to this new strategy was the instrument of free trade agreements which imposed intellectual property standards stricter than those agreed in the TRIPS Agreement 1994.

Susan Sell comments:

It should come as no surprise that the US and the EU aggressively have been pursuing efforts to ratchet up TRIPS standards, to eliminate TRIPS flexibilities and close TRIPS loopholes. Playing a multi-level, multi-forum governance game, countries like the United States have been able to extract a high price from economically more vulnerable parties eager to gain access to large, affluent markets. Bilateral Investment Treaties, Bilateral Intellectual Property Agreements, and regional FTAs concluded between the US and developing countries, and between the European Union and developing countries invariably have been TRIPS-Plus. According to Dylan Williams, “a recent US Congressional Research Service report states that the United States main purpose for pursuing bilateral

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FTAs is to advance US intellectual property protection rather than promoting more free trade”. TRIPS permits countries to exceed TRIPs standards and the US has been pressuring them to do so. It has offered countries WTOPlus market access in exchange for TRIPs-Plus policies.821

This new wave of free trade agreements, coupled with United States Trade Representative’s Special 301 mechanism, has played a key role in shaping the world of TRIPS-plus intellectual property standards.822 As at December 2010, the United States Trade Representative (USTR) has concluded twenty free trade agreements with its trading partners and some active negotiations are still in the process of negotiation.

The typical format of a free trade agreement which is negotiated between United States and its trading partners contains a stand-alone chapter on intellectual property rights. The mandate of the United States Trade Representative under the Trade Act 2002 (United States) is very clear in this regard. It states that:

The principal negotiating objectives of the United States regarding trade-related intellectual property are ... ensuring accelerated and full implementation of the Agreement on Trade-Related Aspects of Intellectual Property Rights ... particularly with respect to meeting enforcement obligations under that Agreement; and ensuring that provisions of any multilateral or bilateral trade


agreement governing intellectual property rights that is entered into by the United States reflect a standard of protection similar to that found in United States law.\textsuperscript{823}

In the light of this mandate, the United States Trade Representative has attempted to impose United States-style intellectual property protection on other countries resulting in TRIPS-plus standards across a range of fields of intellectual property law.

The issue of TRIPS-plus intellectual property standards is not confined only to the countries which are signatory to a free trade agreement with the United States. There is now a proliferation of such bilateral and multilateral regional trade agreements which effectively hinder the policy space of developing countries. A prominent example is the European Union’s Economic Partnership Agreements which, like the United States free trade agreement, also contain provisions on intellectual property rights.\textsuperscript{824}

The issue of TRIPS-plus standards and its implications for access to essential medicines are discussed in this chapter in the Indian context. As a leading manufacturer and supplier of generic drugs, the Indian case is crucial to be considered from the perspective of the TRIPS-plus regime and its negative consequences. Given the absence of a free trade agreement between the United States and India, this chapter analyses the potential implications of such an agreement in the future. The argument extended in this chapter relates to the existing norms of TRIPS-plus standards in the United States trade negotiations. It is argued that both for public health and trade policy reasons, India

\textsuperscript{823} Section 2101 (B) (4) (A) (i) of The Trade Act of 2002 (Public Law 107-210, 116 Stat. 933, enacted August 6, 2002; 19 U.S.C. § 3803–3805; U.S. Trade Promotion Authority Act)


should not engage in any TRIPS-plus trade agreement with the United States as it would harm its interests on domestic and foreign fronts. India has recently adopted a new patent policy and a reasonable time should be given to relevant institutions to build an operational framework and capacity before further changes are made. This task will be challenging as there is very little evidence about any positive change in the position of the United States as it would continue imposing TRIPS-plus standards through variety of trade instruments. It is further argued in this chapter that the best mitigating strategy for developing countries such as India lies in the combination of multilateralism and networking across under a rights based approach.

Part II deals with a situational analysis of the pharmaceutical trade between India and the United States. The prospects of an India-United States free trade agreement are also discussed in this part. Part III provides a detailed account of elements of TRIPS-plus standards and the possible implications of such rules for India. TRIPS-plus standards are analysed in this part in the light of the domestic practices of the United States. Part IV deals with ongoing negotiations on the EU-India free trade agreement. Part V considers the ramifications of the development of plurilateral agreements, such as the mooted Anti-Counterfeiting Trade Agreement 2011 (ACTA).825

II. The Proposal for an India-United States Free Trade Agreement and Pharmaceuticals

A. United States-India Free Trade Agreement?

Currently, there is no free trade agreement between India and United States despite growing trade ties and close co-operation.

Historically, India has maintained a protectionist trade regime and its international trade policy revolved around multilateralism. After 1990, marked trade reforms were introduced in India especially with respect to the trade in pharmaceuticals. Until recently Indian trade policy was characterised by two key reform strategies: unilateral trade liberalisation and active participation in multilateral trade agreements. Bilateral trade agreements such as free trade agreements with the United States were not a top priority agenda in India for political and economic reasons. However, a recent shift can be seen in the Indian stance and India is now gradually moving towards bilateral trade negotiation and has signed some regional trade agreements. India is now in a process of active negotiations with the European Union to conclude a free trade agreement and it is expected that this agreement will be signed by the end of 2010. The United States is India’s second largest trading partner after the European Union with a total annual turnover of US$30 billion. India enjoys a US$19 billion surplus in exports as compared to US $11 billion in imports.

Despite some key economic and political problems, the likelihood of a free trade agreement between India and United States cannot be totally dismissed. There is at least some evidence that different stakeholders are actively engaged with the question of signing a free trade agreement between the two countries and three distinct levels of efforts and evaluation can be identified in this regard. First, the most conservative assessment of an India-United States Free Trade Agreement is made in different

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826 European Parliament, ‘EU-India: Free Trade Agreement to be signed by the end of 2010 say MEPs’ (Press Release March 26, 2009)


technical and economic studies. The majority of the economic experts think that in the light of empirical data and economic analysis, an India-United States Free Trade Agreement is not a likely option in near future. After analysing the existing nature of trade between India and United States, Sandra Polaski and her colleagues conclude that 'the prospects of a free trade agreement between India and the United States are not strong in the foreseeable future'. They state that: 'the most striking overall result of the simulations in this study is that the gains for the Indian economy from both multilateral and bilateral trade agreements are surprisingly modest'. The study considers a number of possible scenarios:

The three potential bilateral agreements simulated in this study result in smaller gains for the Indian economy than a Doha agreement and losses for Indian households. This suggests that the Indian government should proceed cautiously with bilateral agreements. It appears that such agreements would unambiguously increase investment in the Indian economy, a welcome development, but by extremely modest amounts. However there would be a trade-off to achieve these investments, with reductions in household welfare under free trade with the EU and United States, at least in the short term. Given the low incomes of most Indian households and the country's high poverty rate, inflicting even short-term welfare losses on these households is not to be taken lightly.

The chemical sector in United States will be a winner under a free trade agreement with exports of US$230 million. Indian pharmaceutical companies will gain very little under a bilateral trade liberalisation regime as the current level of entry barriers in the United

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828 Ibid.
829 Ibid. 65.
830 Ibid. 66.
States pharmaceutical market are not insurmountable for Indian manufacturers and they are independent of any FTA conditions.

Some commentators think that India should sign a free trade agreement with the United States despite it making less economic sense at this stage because it can help in introducing broader reforms in Indian economy. Robert Z. Lawrence and Rajesh Chadha argue that:

India also has positive reasons to enter into an FTA, namely, the role the FTA can play in stimulating Indian liberalization and reform. The agreement could be used to propel change in a host of areas including trade policy, tax reform, services, industrial policy, foreign direct investment, regulatory policy, competition policy, customs administration, public sector enterprises, agricultural policy, public procurement, governmental transparency, and technical and sanitary standards.831

This report fails to address the social implications of such reforms in a country where issues of poverty and inequality are profound. An industrial policy reform which automatically includes the modernisation of patent law through a TRIPS-plus model will create huge barriers for access to essential medicine regimes. There is a need to account for any welfare losses associated with the impact of a free trade agreement upon the Indian pharmaceutical market. Any such analysis should not be confined within India as Indian drugs are critically important for millions of patients all over the world.

The second tier of analysis to assess the potential of an India-United States Free Trade agreement can be made on the political front. Interestingly, there is more activity in the

United States in this regard and Indian politicians seldom express their views on this issue. In January 2008, Republication Congressman, David Dreier, introduced a Resolution in the Congress to express the sentiment of the House of Representatives with respect to trade relationship between India and the United States. This Resolution was co-sponsored by Joseph Crowley, a Democratic Congressman from New York. This Resolution categorically demanded that ‘the United States should initiate negotiations to enter into a free trade agreement with India’. This Resolution could not be adopted by the House and it was referred to the House Committee on Ways and Means.

David Dreier highlighted the importance of trade relations with India and said that:

In an increasingly inter-connected world, our relationship with India is especially critical. From a national security perspective, we should do all we can to engage with allies like India. From an economic perspective, India represents a huge economic opportunity for American farmers, workers and businesses, particularly in California. From a humanitarian perspective, increasing trade with India could help lift millions of people out of poverty. Increased trade with India would be a win-win-win. Maintaining a strong U.S.-India relationship is strategically, politically, and economically important to both of our nations.

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832 House Resolution 928 Expressing the sense of the House of Representatives with respect to the trade relationship between the United States and India (January 17, 2008) at http://www.govtrack.us/congress/bill.xpd?bill=hr110-928

833 Ibid.

The trade policy agenda of Barack Obama in 2010 also demonstrates that the conclusion of a free trade agreement between India and the United States is not possible in the near future. Most of the focus in the President’s 2010 Trade Policy Agenda was on trade talks through the US-India Trade Policy Forum which was established in 2005. According to this new policy:

In 2010, as part of the Trade Policy Forum, we intend to address key trade irritants and develop cooperative initiatives - especially on issues related to innovation, services, agriculture, market access, and investment. Our plans also include work on a commercial space launch agreement and continued negotiation of a Bilateral Investment Treaty.835

Perhaps the most candid view about a free trade agreement with India was expressed by the former Bush administration United States Trade Representative, Susan Schwab, who categorically excluded the possibility of signing a free trade agreement with India in the near future.836

The absence of a focus on free trade agreement with India does not mean that the United States is not interested in the implementation of TRIPS-plus standards in India. Realising the limitations of a bilateral trade agreement and its possible constraints on the agriculture and services sector, the United States is using its diplomatic and trade sanction regimes to impose a TRIPS-plus regime on India. The recent initiative of technical collaboration with the Indian Patent office for modernisation and training purposes clearly establishes the emergence of the United States’ subtle influence in the

area of policy implementation and statutory interpretation. Yet the aggressive push for TRIPS-plus standards comes through the United States Trade Representative’s Special 301 mechanism. In its Annual Report 2009, USTR observed that:

India will remain on the Priority Watch List in 2009 … the United States remains concerned about weak IPR protection and enforcement in India. The United States continues to urge India to improve its IPR regime by providing stronger protection for copyrights and patents, as well as effective protection against unfair commercial use of undisclosed test and other data generated to obtain marketing approval for pharmaceutical and agrochemical products … Piracy and counterfeiting, including of pharmaceuticals, remain a serious problem in India. India’s criminal IPR enforcement regime remains weak.


There is a clear demand for TRIPS-plus measures in this statement as India already has a functional system for the protection of undisclosed data. This system is obviously different from the one which is practised in the United States and as such there is no obligation in the TRIPS Agreement 1994 calling for a particular form of protection in this regard. However, the United States is consistently pushing its own slanted interpretation of the relevant provisions of the TRIPS Agreement 1994 and demanding that India adopt TRIPS-plus measures.

A third tier of evaluation of a free trade agreement between India and the United States comes from the business and commercial sector. On this front, several Indian companies are active, seeing a great potential in terms of market access. The advocacy efforts of the US-India Business Council are prominent in this regard. The Council supports a ‘U.S.-India Free Trade Initiative: The initiative seeks to reduce bilateral trade and investment barriers in a socially sustainable manner, and ultimately lead the way to a U.S.-India Free Trade Agreement – potentially the largest ever negotiated’.840

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In June 2009, the US-India Business Council released a report criticising India’s existing approach towards pharmaceutical innovation. The Report specifically questioned the rationale of Section 3(d) of the *Patents Act 1970 (India)* and proposed an alternative regime which can encourage incremental innovation in healthcare and the pharmaceutical sector. The Report recommended that;

> [R]emoval of Section 3(d) from the Patents Act will not lead to an increase in drug prices or a decrease in access to medicine in India ... Providing the right incentives for incremental pharmaceutical innovation can move India forward on this path and encourage the development of drug products that meet the needs of Indian patients. Reforming Section 3(d) to encourage and protect incremental pharmaceutical innovation would create such incentives and help India become a true powerhouse of innovation.\(^{841}\)

Realising that there is no obligation under the *TRIPS Agreement 1994* which requires the removal of Section 3(d), the demand on the part of a leading business organisation is an attempt to impose TRIPS-plus measures. This TRIPS-plus agenda further intensified in the light of the fact that PhRMA had also expressed the same view about Section 3(d) in its latest submission to USTR.\(^{842}\)


\(^{842}\) Pharmaceutical Research and Manufacturers of America, Special 301 Submission 2009 (February 17, 2009) 57 at http://www.phrma.org/news_room/press_releases/phrma_301_submission_supports_global_intellectual_property_priorities
The dynamics of pharmaceutical trade between India and the United States is another important factor which needs appropriate analysis. Indian drug manufacturers have significant trade opportunities in the United States which is the world’s largest pharmaceutical market. However, at present, Indian pharmaceutical imports are currently marginal. India’s share in the pharmaceutical imports of the United States is less than 2%. On the contrary, the United States market is extremely important for Indian manufacturers as it is the largest export destination for Indian companies. The future role of Indian drug manufactures in the United States generic market is bound to change as Indian companies are aggressively filing Abbreviated New Drug Applications (ANDA). Initially very few Indian companies could obtain ANDA approvals but the rate of success has improved to 701 ANDAs filed by 17 companies in 2007. However, the Indian manufacturer may face significant challenges in the United States generic market, including competition from Chinese generic manufacturers. Indian companies have demonstrated reliable technical skills in the area of small molecular chemistry and formulations, but it has significant constraints in the area of biotech products.

India’s domestic pharmaceutical market is less attractive from the perspective of the United States pharmaceutical companies. Despite its huge population, India is a high volume and low profit country and there is a little interest in the Indian domestic

844 Ibid.
845 Reji K Joseph, India’s Trade in Drugs and Pharmaceuticals: Emerging Trends, Opportunities and Challenges (Research and Information System for Developing Countries Discussion Paper No # 159: Delhi, November 2009) 20.
market. However, the United States pharmaceutical firms are keenly interested in Indian drug and pharmaceutical regulations for two different reasons. First, drug manufacturing in India is commercially an attractive proposition and multinational pharmaceutical companies can shift some of their high cost operations to India. Second, the ability of Indian pharmaceutical companies to export generic medicines is a disturbing feature for multinational firms and they want to curb this comparative advantage through stricter patent standards.

This is the context in which the whole debate of TRIPS-plus norms should be analysed from the Indian perspective. There are threats and opportunities for different segments of the Indian industrial sector and no balanced approach has yet evolved which can address this crucial policy challenge.

Despite widespread rhetoric about the economic and commercial significance of free trade agreements, it is crucial to measure a potential and actual impact of such agreements on developing countries. Most of the feasibility studies conducted on the United States-India and EU-India free trade agreements rely upon mainstream economic modeling which is indeed inadequate both in terms of its content and process. Professor Joseph Stiglitz, Professor Amartya Sen and Professor Jean-Paul Fitoussi have discussed the limitations and inadequacies of measurement techniques which are generally used to study economic performance and social progress. They analyse the limits of Gross Domestic Product (GDP) as an indicator of economic performance and social progress and assess alternative measurements of performance. The long term impact of free trade agreements should also be calculated on the basis of such inclusive measurement methods which also consider the well-being of the citizens. Amartya Sen’s capability

approach can further enrich such an analysis which goes beyond pure economic gains and trade benefits.

B. Bayer Corporation v. Union of India

Should India follow the United States’ approach on the issue of patent-regulatory approval linkage or it should adopt a distinct model allowing operational space to generic manufacturers?

In a recent case of Bayer Corporation v. Union of India, the question of patent-drug registration linkage was considered by the High Court of Delhi and Bayer’s stance was dismissed both by the Single Bench and Appellate Court.

This controversy was basically between Bayer Corporation and Cipla Limited. In March 2008, Bayer Corporation secured a patent for the drug, sorafenib tosylate (Nexavar) which is used to treat renal cell carcinoma. In the United States, sorafenib was approved by the U.S. Food and Drug Administration (FDA) in December 2005 and the Orange Book lists two relevant patents with the expiry date of January 12, 2020. A corresponding Indian patent was granted in March 2008. In the meanwhile, Bayer Corporation also secured a license under the Drugs and Cosmetics Rules 1945 (India) to

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848 Bayer Corporation v Union of India (High Court of Delhi: February 9, 2010) LPA 443/2009 at http://lobis.nic.in/dhc/

import sorafenib tosylate into India. In July 2008, Cipla, a leading Indian generic manufacturer, announced the launch of its generic version of sorafenib tosylate under the brand name of *Soranib*. Bayer Corporation approached the office of the Drug Controller General of India and requested that marketing approval should not be granted to Cipla’s generic product. Bayer Corporation also wrote a similar letter to Cipla asking it to confirm the launch of *Soranib* but no reply was received in this regard.

Finally, Bayer Corporation filed a writ petition in the Delhi High Court on October 31, 2008 to seek a restraining order against the Drug Controller General of India from granting license to Cipla ‘to manufacture and market, to imitate/substitute sorafenib tosylate protected under subject patent number 215758’. Cipla was also made a party in the case and an undertaking was demanded from Cipla to certify that its drug did not infringe Bayer Corporation’s patent. This matter was heard by Justice S. Ravindra Bhat and initially an interim ex-parte restraining order was passed in favour of the petitioner. Cipla then applied for vacation of the order and in the final order, Justice S. Ravindra Bhat dismissed the plea of Bayer Corporation with ‘costs quantified at Rs. 6,75,000/- payable in equal shares to the Union of India, and Cipla’. The Bayer Corporation subsequently appealed this order before the Divisional Bench of Delhi High Court which announced its judgment on February 9, 2010. The *Bayer Corporation v. Union of India & Others* is the first case in India in which the question of patent-regulatory approval linkage has been decided by the court. In support of its position, Bayer Corporation presented the following three arguments.

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850 Ibid. 2.

851 Ibid. 4.

First, Section 48 of the *Patents Act 1970* (India) states that a patent holder has exclusive right to restrain anyone from making, using, offering for sale, selling or importing the patented drug. This provision should be read with Section 2 of the *Drugs and Cosmetics Act 1940* (India) which states that the provisions of this law are not in derogation of any other law. Bayer Corporation also relied upon statutory interpretations given by the Supreme Court of India in *Cadila Healthcare Ltd. v. Cadila Pharmaceutical Ltd.*

Second, the concept of patent-regulatory approval linkage is not a new phenomenon in India and relevant forms developed by the health authorities do require the mention of patent status. Form 44 of the *Drugs and Cosmetics Rules 1945* (India) is specifically referred in this regard. Third, Bayer Corporation also maintained that Cipla’s generic version of sorafenib tosylate would be a spurious drug within the meaning of the *Drugs and Cosmetics Act 1940* (India).

In response to the contentions of Bayer Corporation, Cipla argued that Indian law did not acknowledge the notion of Patent-regulatory approval linkage and the Parliament had cautiously avoided the introduction of such a regime in India. The scheme and objectives of patent law and drug regulations are totally different and any linkage would result in delays and inefficiencies. It was further argued that any mention of patent status in Form 44 was mainly to indicate bio-availability and bio-equivalence. The grant of patent can be challenged and if such proceedings are pending then the linkage would create unnecessary delay in the introduction of generic drugs.

The Union of India through the Drug Controller General of India (DCGI), the Cancer Patient Association and the Indian Pharmaceutical Alliance also supported the position

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of Cipla and argued against the creation of the linkage system. In their judgment, Honourable the Chief Justice and Justice S. Muralidhar thoroughly reviewed the arguments extended by the parties and rejected the case of Bayer Corporation. On the question of a relationship between patent law and drugs regulation, the judgment states that:

In the considered view of this court, the purport of Section 156 is not that the DCGI, who is no doubt an officer of the central government, is prevented from granting marketing approval to a non-patentee in respect of a patented drug. No such obligation flows from Section 156 Patents Act as such. This submission also misses the point that the right conferred under Section 48 is essentially a private right and negative right as is and does not confer a right to market the product even on the patent holder.

Thus, the court did not read any link between patent law and marketing approval of pharmaceutical products and the matter was therefore left to the policy makers. The issue of Form 44 is also elaborately discussed in the judgment and it was concluded that an entry in a statutory form requiring the mention of patent status should be read against the overall scheme of legislation. Such an approach clearly suggests that no linkage was ever conceived within the framework of the Drugs and Cosmetics Act 1940 (India).

The outcome of Bayer Corporation v. Union of India & Others is definitely disappointing for Bayer Corporation and other multinational pharmaceutical companies operating in India. However, from a public health perspective, it is a welcoming development which would have a positive impact on the introduction of generic

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855 Ibid. 11-13.
856 Ibid. 15-16.
857 Ibid. 19-20.
medicines in Indian market. The timing of this decision is also crucial as Indian patent law is gradually settling down and its future largely depends upon administrative and judicial interpretations.

Beside the outcome of this case, India should consider adopting a clear policy about patent-regulatory approval linkage and this is precisely indicated by the learned judges as following:

Whether patent linkage should be introduced is an issue that requires a policy decision to be taken by the government. It is not for the court to determine if the government should bring in a system of patent linkage. There is considerable literature on the topic with many a developing country resisting it in the interests of public health care that is both affordable and accessible. The court cannot and ought not to dictate that policy shift ... There is also merit in the contention that patent linkage is a TRIPS Plus concept and India has only signed on to TRIPS. Worldwide there is a raging debate on whether patent linkage should be permitted. There is no uniformity in the policy of different countries.\footnote{858}

An expansive interpretation giving effect to TRIPS-plus standards would have long term adverse consequences which Indian generic manufacturers and patients cannot afford at this point. Yet the situation is fragile as the matter has been again appealed by the Bayer Corporation in the Supreme Court.

\subsection*{C. Syngenta India v. Union of India}

The issue of protection of undisclosed data came under judicial scrutiny in the case of \textit{Syngenta India Ltd. v. Union of India}.\footnote{859} Syngenta India Ltd. filed this writ petition to

\footnote{858}Ibid.23-24.

\footnote{859} Syngenta India Ltd. v Union of India (High Court of Delhi: July 1, 2009) W.P. (C) 8123/2008 at
challenge the decision of the Registration Committee established under the *Insecticides Act 1968* (India) granting the approval of an agrochemical product, Emamectin Benzoate 5% SG to one of the respondents in this case, Jaishree. In the process of product registration, Jaishree submitted bio-efficacy data mainly referring to data already submitted by Syngenta India Ltd. The proprietor of the data, Syngenta India Ltd, objected on this practice and argued that:

> [T]he value in data protection is that it is the basis for the application (for registration) about the source, the raw materials, the nature of production of the insecticide, etc. Unless some measure of protection is afforded, the “data originator” would do all the toil and the “me too” applicant would reap the rewards ... The petitioner argues that Article 39.3 of TRIPS, clearly recommends that protection be accorded to the data submitted by an Originator, against unfair commercial use and disclosure, meaning thereby that a Statutory Authority (in this case the Committee) cannot rely on the data submitted by the Originator for approving the second and subsequent applications for the same insecticide. This protection and data exclusivity, however, would be for a limited period and not in perpetuity.\(^\text{860}\)

The assertion that the *TRIPS Agreement 1994* provides for a data exclusivity regime is misleading. A reference is also made to the recommendations of the Reddy Committee’s Report but it was ignored by the petitioner that the data exclusivity regime was deliberately avoided by the Committee in its final recommendation. This case is not related to a pharmaceutical product and the rules recommended by the Committee with regard to agrochemical products are somewhat different. However, those

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860 Ibid. 3-4.
recommendations cannot be equated to supporting a TRIPS-plus data exclusivity regime.

In his judgment, Justice S. Ravindra Bhat rejected the plea of Syngenta India Ltd. on the basis of fact that its product was not subject to data exclusivity rules at the time of registration of competing product. He concluded that:

In view of the above discussion and findings, the petition has to fail. The court is of the opinion that this litigation was speculative, as the attempt was clearly to invite the court to make a policy declaration, which could not have been made under any circumstances. The pendency of this proceeding has also resulted in prejudice to the third respondent, who was constrained to give an undertaking not to give effect to its registration; that has subsisted all this while.\(^{861}\)

**D. The Reddy Report**

India is increasingly facing pressure from the United States to implement a TRIPS-plus data exclusivity regime.\(^{862}\)

India has conventionally maintained that its existing regime, based upon a combination of common law protection of trade secrets law\(^{863}\) and the provisions of the *Drugs and Cosmetics Act 1940* (India), is sufficient to fulfil the obligation of the *TRIPS Agreement*

\(^{861}\) Ibid. 27.


1994. Realising the inadequacies of its current system, the Indian government had constituted an inter-ministerial committee in February 2004 to recommend an appropriate framework for the implementation of the obligations of Article 39.3 of the TRIPS Agreement 1994. This Committee took considerable time in its deliberations and finally submitted its report on May 31, 2007. The Committee, which is commonly known as the Reddy Committee, recommended separate protection regimes for agrochemical products, traditional medicines and pharmaceuticals. To protect undisclosed information submitted to the drug regulatory authority, the Report recommends that:

There is an established system of marketing approval and evaluation of test data generated for drugs in India. While there is need to improve the system and make necessary legal changes and explicitly provide for the minimum requirements under Article 39.3 of TRIPS, any higher standards of data protection should be done after a careful study of its impact on the sector and public to avoid any adverse repercussions in the long run. India has adopted product patent regime with effect from 1st January, 2005, the impact of which is yet to be seen. Therefore, a somewhat cautious approach may be in the interest of the country. Any misgivings in the public mind about the need or the justification for the new system need to be addressed over a period of time. A calibrated approach with a transitional period, therefore, appears to be best suited for India. During the transitional period, the minimum requirements under Article 39.3 of TRIPS can be implemented. Also, this period can be utilized to educate the public and industry so as to allay their apprehensions on the issue. The capacity and the

physical infrastructure available with the Regulatory Authority would need to be suitably strengthened and upgraded.865

The Report clearly rejected the option of adopting a TRIPS-plus data exclusivity regime and instead proposed an alternative model with transition arrangements. The compromise reached in the Report has some negative implications as well. Ideally, India should adopt a more enabling data protection regime which can allow generic companies to use proprietary data subject to the payment of royalties. A complete restriction on the use of data, though for a limited period of time, would inevitably affect the functioning of generic companies. There are apprehensions that such a system would gradually move to a full-fledged data exclusivity regime. This Report contains several important recommendations which are yet to be adopted by the government. The initial response of the Ministry of Health was not welcoming on certain aspects of Committee's recommendation but it is recently reported that the Ministry has now requested the World Health Organization to commission a 'study on the impact of Satwant Reddy Committee Recommendations on the Indian Pharmaceutical Industry'. 866

III. Anatomy of a TRIPS-plus Regime and its Implications for India

In a variety of forums, the United States government has been pressing for TRIPS-Plus Agreements. TRIPS-plus standards in free trade agreements are mainly informed and influenced by the domestic laws and regulations of the United States. The TRIPS-plus

865 Ibid. 39.

866 Ramesh Shankar, 'Health Ministry's nod to WHO for a study on data exclusivity raises concern'

PharmaBiz.com (Delhi: December 16, 2009) at

http://www.gnaipr.com/Articles/Health%20Ministry%5C's%20nod%20to%20WHO%20for%20a%20study%20on%20data%20exclusivity%20raises%20concern.pdf
standards which deal with patent law and pharmaceuticals are designed to maximise the advantage of patent holders and multinational pharmaceutical companies. The most prominent TRIPS-plus provisions relate to patent term extension, data exclusivity and patent-regulatory approval linkage. The model for such treaty obligations is the legislative template of the Drug Price Competition and Patent Term Restoration Act of 1984 (US), often referred to as Hatch-Waxman Act.\(^{867}\) It is worthwhile analysing such measures in detail.


The *Hatch-Waxman Act* contains provisions covering drug price competition, the abbreviated new drug application (ANDA) process for generics and patent term restoration.

The *Drug Price Competition and Patent Term Restoration Act of 1984* (US) was co-sponsored by Democratic Congressman Henry A. Waxman and Republican Senator Orrin Hatch and reflected trade-offs between the interests of brand-name drug manufacturers, generic suppliers, and consumer interests.\(^{868}\) The enactment has created a balance between the interests of research-based pharmaceutical industry and generic companies by providing patent term extension and a path for filing ANDAs. Title I of the law deals with a drug price competition component limiting the authority of the Food and Drug Administration to demand the results of extensive clinic trails before generic medicines are registered. The drug registration authority can only demand bio-


availability studies from generic applicants. This part also provides five years exclusivity for new molecular entities and this additional protection runs independent of patents. The Act also provides for the so called Paragraph IV Certification process which is essentially a drug patent challenge notification. The first generic manufacturer who satisfies the requirements of the Act is entitled to a 180-Day exclusivity period which gives enormous incentive to generic companies. A complex regime of patent term extension is envisaged in the Act which addresses a range of situations.\(^\text{669}\)

A brief snapshot of the *Drug Price Competition and Patent Term Restoration Act of 1984* depicts the nature of a complex regulatory regime which governs pharmaceuticals and the patent law. TRIPS-plus standards which are used by the United States cannot be understood in isolation and it is extremely important to properly contextualise the emergence of such a regime. Some of the TRIPS-plus provisions dealing with the patent law and medicines are discussed in the following with an aim to see their relevance and implications for India.

**B. Patent Term Extension**

In the 2003 case of *Eldred v. Ashcroft*, dealing with the constitutionality of copyright term extensions, Justice Stevens of the Supreme Court of the United States wrote in his dissenting opinion:

> The issuance of a patent is appropriately regarded as a *quid pro quo* – the grant of a limited right for the inventor’s disclosure and subsequent contribution to the public domain ... Neither the purpose of encouraging new inventions nor the overriding interest in advancing progress by adding knowledge to the public domain is served by retroactively increasing the inventor’s compensation for a

completed invention and frustrating the legitimate expectations of members of the public who want to make use of it in a free market.\textsuperscript{870}

Although \textit{Eldred v. Ashcroft} concerned the constitutionality of copyright term extensions, Justice Stevens drew parallels between patents and copyright in rejecting arguments in favour of statutory term extensions.

For years, the pharmaceutical industry lobbied the United States Congress, protesting that the term of patent protection for pharmaceutical drugs was unduly compromised by delays associated with new drug approval processes. Without a substantial patent term after the approval of a drug from the Food and Drug Administration, pharmaceutical companies cannot recoup the high cost incurred in the drug discovery cycle. In the light of reforms introduced under the \textit{Hatch-Waxman Act}, the \textit{Patent Act} (United States) now provides for the extension of patent term with respect to drugs that undergo the rigorous regulatory approval process of the Food and Drug Administration. The regime governing the extension procedure is complex and subject to several conditions which are summarised as follows:

According to the statute, a patent which claims a product, method of using a product, or a method of manufacturing a product covered by the statute shall be extended if (i) the patent has not expired before an application for extension is submitted, (ii) the patent has not been previously extended under the Hatch–Waxman Act, (iii) a complete application for extension is submitted, (iv) the product has been subject to a regulatory review period before its commercial

\textsuperscript{870} \textit{Eldred v. Ashcroft} (01-618) 537 U.S. 186 (2003).
marketing or use, and (v) this will be the first permitted commercial marketing or use of the product.871

The determination of period of extension is sophistically elaborated in the law and no extension can exceed a maximum period of 5 years. It is crucial to note that no such limit is mentioned in the text of the free trade agreement between Bahrain and the United States.

Patent term extensions are a standard feature of United States bilateral trade agreements. With the exception of the United States-Israel Free Trade Agreement, all major bilateral trade agreements contain a patent term extension provision on the lines of the scheme originally envisaged under the Hatch-Waxman Act.872 For example, Article 16.8.4 of the United States-Singapore Free Trade Agreement states that:

With respect to any pharmaceutical product that is subject to a patent:

(b) the Party shall provide that the patent owner shall be notified of the identity of any third party requesting marketing approval effective during the term of the patent.873


This extension is independent of the general provision of patent term extension which is provided in Article 16.7.7 of the United States-Singapore Free Trade Agreement that provides:

Each Party, at the request of the patent owner, shall extend the term of a patent to compensate for unreasonable delays that occur in granting the patent. For the purposes of this paragraph, an unreasonable delay shall at least include a delay in the issuance of the patent of more than four years from the date of filing of the application with the Party, or two years after a request for examination of the application has been made, whichever is later, provided that periods attributable to actions of the patent applicant need not be included in the determination of such delays. 874

In the case of pharmaceutical drugs, there is no mention of a total period of patent term extension which occurs in case of delays in the drug approval process. However, according to Article 16.7.7, a 2-4 year extension is stipulated in case delay occurs during the course of patent registration. In some free trade agreements, an extended period is mentioned to compensate delays in patent registration and drug approval procedures. 875

Given that the TRIPS Agreement 1994 does not mandate any scheme of patent term extension, these provisions in the bilateral trade agreement are clearly TRIPS-plus obligations. However, almost all developing countries lack experience and expertise to

874 Ibid.

implement such a complex system of patent term extension. Even within the United States, there are conflicting opinions and varying interpretations about the details of relevant provisions of the *Hatch-Waxman Act.* It would be unjust to expect developing countries to apply the same standards without appropriate regulatory and institutional arrangements. The safeguards and flexibilities which have developed over a period of time in the United States through litigation and jurisprudence cannot be easily transplanted elsewhere. A TRIPS-plus patent term extension regime would have adverse effects on the Indian pharmaceutical sector and it would ultimately jeopardise the interests of poor patients across the world.

Pragmatically, considering the existing political and business environment, India is well placed to resist bilateral pressures for revising its laws to provide patent term extension. The situation in this regard is even changing in the United States and in 2007, the requirement for patent term extension was removed from then-pending free

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876 Ibid. 660-661.

877 For an overview of India's emerging economic power and its impact on politics and international diplomacy see: Stephen P Cohen, *India: Emerging Power* (Washington DC, Brookings Institution: 2001). Also see: Diana Tussie & Marcelo Saguier, *The Sweep of Asymmetric Trade Negotiations: Overview* (Buenos Aires, Latin American Trade Network: 2011) at [http://www.iadb.org/intal/intalcdi/PE/2011.08165.pdf](http://www.iadb.org/intal/intalcdi/PE/2011.08165.pdf). The ongoing negotiations on EU-India free trade agreement also prove that India can effectively resist TRIPS-plus demands. The latest updates show that the EU is withdrawing from its data exclusivity and patent term extension demands. There are some signs that the EU may extend further relaxation in the area of intellectual property enforcement. This establishes India's ability to negotiate a free trade agreement without substantial TRIPS-plus measures. See: Ramesh Shankar, 'Health groups welcome exclusion of data exclusivity from India-EU free trade pact' *PharmaBiz.com* (Bombay: June 24, 2011) at [http://www.gnaipr.com/Articles/Health%20groups%20welcome%20exclusion%20of%20data%20exclusivity%20from%20India-EU%20free%20trade%20pact.pdf](http://www.gnaipr.com/Articles/Health%20groups%20welcome%20exclusion%20of%20data%20exclusivity%20from%20India-EU%20free%20trade%20pact.pdf)
trade agreements. The Waxman Report also observed that such ‘provisions can work to delay access to low-cost generic drugs in developing nations’.878

C. Patent-Regulatory Approval Linkage

In the United States, a linkage mechanism has been established under the Hatch-Waxman Act 1984 (United States), where the process of approval of generic drugs is linked with the status of patents.879 If a case does not fall within the purview of Paragraph IV certification mentioned earlier, then one of the following three certifications should be made by a generic manufacturer along with an ANDA filing: (i) the drug has not been patented; (ii) the patent has already expired; or (iii) the generic drug will not be marketed until the patent expires.880 The patent holder is notified about the intention of the generic manufacturer and the United States domestic system allows him to initiate litigation. This is followed by an automatic stay of 30 months. The sophisticated, complex system also requires the patent holders to list their patents on the Orange Book to provide a clear picture of relevant interests.881

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In 2002, the United States Federal Trade Commission reported that generic companies were facing legal challenges by the brand name companies in attempts to introduce new drug applications under the *Hatch-Waxman Act* 1984 (United States). It states that:

> Beyond any doubt, Hatch-Waxman has increased generic drug entry. Generic drugs now comprise more than 47 percent of the prescriptions filled for pharmaceutical products – up from 19 percent in 1984, when Hatch-Waxman was enacted. In spite of this record of success, two of the provisions governing generic drug approval prior to patent expiration (the 180-day exclusivity and the 30-month stay provisions) are susceptible to strategies that, in some cases, may have prevented the availability of more generic drugs. These provisions continue to have the potential for abuse.\(^{882}\)

The patent linkage provisions delay the entry of generic drugs and often encourage the evergreening of patents. The Federal Trade Commission recommended that only one injunction against a generic manufacturer should be allowed under the legislation to discourage the evergreening trend.\(^{883}\) It is important to note that the United States legislative response to the problem of evergreening is complex and largely unsuccessful.

Notwithstanding such policy problems, the United States has frequently incorporated provisions on TRIPS-plus linkage mechanisms in several free trade agreements with developing countries. The *United States-Morocco Free Trade Agreement* states that:

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With respect to any pharmaceutical product that is subject to a patent, and where a Party permits authorizations to be granted or applications to be made to market a pharmaceutical product based on information previously submitted concerning the safety and efficacy of a product, including evidence of prior marketing approval by persons other than the person that previously submitted such information, that Party:

(a) shall implement measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent during the term of that patent, unless by consent or with the acquiescence of the patent owner, and

(b) if it allows applications to be made to market a product during the term of a patent covering that product, shall provide that the patent owner shall be notified of the identity of any such other person who requests marketing approval to enter the market during the term of a patent notified to or identified by the approving authority as covering that product.884

If such a linkage is created then generic manufacturers will be exposed to lengthy and expensive litigation with resourceful multinational companies. Frederick M. Abbott notes that:

Designing a system which prevents the effective marketing approval of a medicine during the term of a patent without significantly impairing the ability of

generic producers to place drugs on the market at the end of the patent term has proven exceedingly difficult.885

There is some evidence that the United States is easing its pressure on developing countries to adopt such TRIPS-plus standards but the efficacy of new measures is under serious apprehension. In May 2007, new trade policy mandated by the Congress removed the condition of linkage provisions from pending free trade agreements.886

Robert Chalmers notes in the context of the *Australia-United States Free Trade Agreement 2004* that:

The “pro-evergreening” elements of the AUSFTA extend protection by creating peripheral mechanisms rather than making fundamental changes to patent laws. Specifically, the mechanisms introduce regulatory “data exclusivity” and impose tightened controls over advertising by generics companies. The core obligation imposed by these changes is to require those seeking to market pharmaceuticals to certify their products as “patent-friendly”, under threat of significant penalty.887

The implications of evergreening are more dangerous for developing countries which lack legislative and administrative capacities to overcome the problem associated with this trend.


D. Data Exclusivity

The third TRIPS-plus standard which stems from the provisions of the Hatch-Waxman Act is related to the highly controversial issue of data exclusivity. The protection of undisclosed information is an obligation under Article 39.3 of the TRIPS Agreement 1994 but there is no consensus on the interpretation of this provision. Most of the developing countries do not agree with the interpretation of this clause which has been adopted by the United States since 1994. This position is manifested in many USTR Special 301 Reports which suggest that a US styled data exclusivity regime will be a satisfactory implementation of the TRIPS Agreement 1994. India and several other developing countries do not subscribe to this understanding of Article 39.9 and argue that the negotiation history of the TRIPS Agreement 1994 categorically proves that US styled data exclusivity regime was not the intended outcome.

The heart of the dispute is not about the protection of undisclosed information per se. The controversy is about the nature and structure of a regime which will protect undisclosed information including the data submitted to drug regulatory authorities. Multinational pharmaceutical companies allege that their data is misused by generic manufacturers and they apply for the registration of their products on the basis of

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proprietary data. Thus, a data exclusivity regime should be implemented to protect them from the fraudulent use of regulatory data. On the contrary, generic manufacturers believe that a data exclusivity regime pushed by the United States would create another entry barrier. This concern has merit as the data exclusivity system works independently of patent status and this protection can be used to block the entry of generic competition.

Most of the free trade agreements of the United States contain data exclusivity clauses posing serious threat to generic competition.890 Brook K. Baker notes that:

Data exclusivity ... in their most absolute form can prevent registration of follow-on generic products even when those products are needed to respond to compelling public health needs like HIV/AIDS ... Despite its inability to win clear language on data exclusivity and its setback at Doha, the USTR persisted in twisting the language of minimalist data protection to maximalist data exclusivity.891

Some of these problems are now recognised within the United States after extensive lobbying and advocacy of civil society organisations.

In 2003, Congressman Henry A. Waxman expressed his concerns about the way in which the data exclusivity regime is imposed on developing countries. He said that:

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[The Hatch/Waxman period of data exclusivity] works in this country because most people in the U.S. have health insurance that pays for essential drugs and because we have a health care safety net to assure that the poorest in our society are not left without medical care and treatment. But to impose such a system on a country without a safety net, depriving millions of people of life-saving drugs, is irresponsible and even unethical. In developing countries, we must do everything in our power to make affordable drugs for life-threatening diseases available now ... Whether in Central America, Latin America, Morocco, or Southern Africa, there is a long slate of USTR negotiations where the Hatch-Waxman could have devastating results.892

After facing immense pressure, the United States partially revised its data exclusivity approach under the New Trade Policy for America 2007. Some technical details relating to the data exclusivity provisions of free trade agreements were changed to limit its scope.893

Protection of pharmaceutical regulatory data is a hotly debated issue in India and despite several attempts; the Indian government could not adopt a clear policy on this issue. The conflicting interests of generic manufacturers and the multinational pharmaceutical industry have largely shaped this debate in terms of national interest and public policy issues.


E. Restrictions on Compulsory Licences and Parallel Importations

Putting additional restrictions on the issuance of compulsory licensing is another TRIPS-plus measure which is often used by the United States in free trade agreements. An aggressive strategy of USTR can also be identified in this regard which essentially demands that developing countries avoid the grant of compulsory licences even if they are badly required to meet public health needs. The United States-Singapore Free Trade Agreement 2003 provides for one of the most restrictive compulsory licensing provisions allowing the use of this instrument only to remedy anti-competitive behaviour.894 Some other free trade agreements such as Australia-United States Free Trade Agreement895 also contain similar provisions restricting the scope and operation of compulsory licensing beyond the mandate of the TRIPS Agreement 1994.

This policy has, however, been lately shifted after it was severely criticised by public interest groups and non-governmental organisations. Compulsory licensing provisions of the TRIPS Agreement 1994 are considered to be the most important safeguard measures and in the post Doha Declaration 2001 scenario, its importance has tremendously increased.896 In its new strategy, the United States is no longer pushing its harsh conditions through free trade agreements and the focus is now on the Special 301 mechanism. In 2009, Thailand was placed on a Priority Watch List after it engaged in the compulsory licensing of pharmaceutical drugs.897

894 Article 16.7.6 of the United States-Singapore Free Trade Agreement, signed 6 May 2003 (entered into force 1 January 2004).
895 Article 17.9.7 of the United States-Australia Free Trade Agreement, signed 18 May 2004 (entered into force 1 January 2005).
896 Relevant provisions of the TRIPS Agreement 1994 and the subsequent developments in WTO and elsewhere are discussed in Chapter 4.
897 Jonathan Burton-MacLeod, ‘Tipping point: Thai Compulsory Licences Redefine Essential Medicines 382
It is ironic that the United States felt encouraged by a policy limiting the application of compulsory licensing and a reference is made to the *Doha Declaration 2001* to express this view. In its submission to USTR, Global Health Organizations demanded that the United States should refrain from listing countries on its Special 301 Watch List for use of flexibilities such as compulsory licensing.\(^{898}\)

Another disturbing aspect of TRIPS-plus standards is related to conditions which restrict or prevent parallel imports. For instance, the *United States-Australia Free Trade Agreement 2004* gives an exclusive right to the patent holder to prevent the importation of patented product without his consent.\(^{899}\) In the absence of obligation of the *TRIPS Agreement 1994*, preventing parallel imports compulsorily will reduce the ability of developing countries to import cheaper drugs. Such a sweeping application of these standards becomes more disturbing in the light of internal United States rules governing parallel importation, which are not consistent and uniform and lately, in some cases, parallel imports have been allowed subject to some conditions.\(^{900}\)

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Article 17.9.4 of the United States-Australia Free Trade Agreement, signed 18 May 2004 (entered into force 1 January 2005).\(^{900}\)

The TRIPS-plus compulsory licensing regime will reduce the powers of the Indian government to issue a compulsory licence in the case of domestic public health needs. India's public health problems and the relevance of a compulsory licensing mechanism have already been discussed in Chapter 4. TRIPS-plus regimes adopted elsewhere in the world, especially in developing countries, will also have a direct taxing effect on Indian generic manufacturers. Indian generic manufactures have a great interest in the drug markets of African and other developing countries which are increasingly facing pressures from the United States to reform their patent laws. Thus, resisting TRIPS-plus standards is not only a domestic policy issue for India. India should assume a leading and active role in the global campaign to resist the TRIPS-plus movement.

**F. Side Letters**

A number of developments could be cited in support of a proposition that a positive shift has occurred in the stance of the United States towards the imposition of TRIPS-Plus standards. The best evidence in this regard are the side letters which were issued by the United States Trade Representative after facing severe criticism about its policies of restricting the flexibilities of the *TRIPS Agreement 1994* and *Doha Declaration 2001*. The most common language of the side letters is as following:

The obligations of Chapter Fifteen [intellectual property rights] do not affect a Party’s ability to take necessary measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency. In recognition of the commitment to access to medicines that are supplied in accordance with the Decision of the General Council of 30 August 2003 on the Implementation of Paragraph Six of the Doha Declaration on the TRIPS Agreement and public health (WT/L/540) and the WTO
General Council Chairman’s statement accompanying the Decision (JOB(03)/177, WT/GC/M/82) (collectively the “TRIPS/health solution”), Chapter Fifteen does not prevent the effective utilization of the TRIPS/health solution.901

Such side letters were later issued with regard to different free trade agreements to address concerns about the impact of TRIPS-plus provisions on the access to medicines regime.902 The actual impact of side letters is unclear as these letters do not override the obligations established under the original text of free trade agreements.903

Moreover the terms of side letters are considerably restrictive and they hardly provide a practical leeway which can be used consistently with the *TRIPS Agreement 1994*. This problem was also recognised by a group of Congressmen including Representative Henry Waxman who wrote a letter to the United States Trade Representative on March 12, 2007. The group specifically mentioned that:

> USTR has also refused to reference the right to compulsory licensing – or other public health exceptions – in the text of FTAs. Instead, USTR has relied upon the use of vaguely worded “side letters” that are subordinate to the agreements and non-binding on the parties. The letters also fail to provide clear and specific

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assurances affirming the ability of governments to take various measures to address public health needs.\textsuperscript{904}

Part of these concerns was addressed by the US Congress in 2007 when it supported a Senate Resolution urging the United States to reaffirm its commitments to the \textit{Doha Declaration 2001}. Brook K. Baker notes that the requirement of patent term extensions was removed from several treaties:

> The clearest evidence, however, of cracks in the armor of registration-related rights can be found in the New Trade policy adopted by a new Democrat-led Congress and incorporated in U.S.-Peru, U.S.-Panama, and U.S.-Columbia FTAs, and to a lesser extent in the U.S.-Korea FTA.\textsuperscript{905}

The changes introduced through the New Trade Policy were also appreciated by the Global Health Organizations in their latest submission to USTR.\textsuperscript{906} The actual impact of developments is yet to be seen beyond the fact that some of the most restrictive TRIPS-plus clauses were removed from the new generation of FTAs.

However, since the adoption of New Trade Policy and subsequent reforms introduced by Congress, the executive arm of the United States government has not shown any change in its traditional approach. The United States Trade Representative has been

\textsuperscript{904} Joint Letter of Henry A. Waxman, Jim McDermott, Tom Allen and Lloyd Doggett addressed to Susan Schwab, United States Trade Representative (March 12, 2007) at http://www.cpath.org/sitebuildercontent/sitebuilderfiles/ipcongressstoustr3-07.pdf


using the mechanism in the same old-fashioned way and countries were listed on the basis of failure to comply TRIPS-plus measures.

**G. The Special 301 Report Consultation Process**

Recently, the Obama Administration announced an open and consultative process of public hearings in respect of the Special 301 Report process which is undoubtedly an important development.\(^{907}\) The whole process of determination of the annual Special 301 Report was heavily influenced by different industry groups and this new consultation process will open an opportunity both for non-governmental organisations and developing countries. However, the real question is about the change in policy rather than the process and operational strategy of the USTR. Beyond the use of side-letters and the promise of consultation, there has been a lack of substantive change in the approach of the Obama Administration to patent law and access to essential medicines.

**IV. European Union-India Free Trade Agreement**

On October 7, 2010, Médecins Sans Frontières launched a global campaign, *Europe! Hands Off Our Medicine*, to stop the European Union’s multiple attempts to restrict access to generic drugs in developing countries.\(^{908}\) Though the focus of the campaign is on the European Union’s trade and intellectual property policies, it particularly


addresses concerns about ongoing negotiations between India and the European Union to conclude a free trade agreement. This agreement which was initially expected to be entered into before the end of 2010 contains provisions on patents and intellectual property enforcement. In its Press Release, Médecins Sans Frontières noted that:

The India-EU agreement is just one of many attacks on generic medicines currently being undertaken by the EC. Through other bilateral trade agreements around the world, Europe is threatening the production of safe, effective and affordable medicines by demanding tougher intellectual property provisions than anything required under international law. Europe is also a driving force in the secret negotiations for an Anti-Counterfeiting Trade Agreement, where it is leading the push for measures that would put limits on the generic production of medicines.

Unlike the United States, the bilateral trade agreements of the European Union did not come under much academic scrutiny despite Europe’s long-standing interest in intellectual property enforcement (Table 8.2). It is generally presumed that the European Union’s approach towards TRIPS-plus standards is relatively mild, and its different trade agreements usually do not contain substantive provisions on key areas


911 The European Union employs a complex strategy to engage in wide range of bilateral trade
of intellectual property rights. The focus in these agreements is on enforcement issues to curb piracy and anti-counterfeiting. Nevertheless, the problem of TRIPS-plus standards is still there and almost every trade agreement dealing with intellectual property protection negotiated after the *TRIPS Agreement 1994* incorporates TRIPS-plus standards. As mentioned earlier, the European free trade agreement model is more inclined towards enforcement details of intellectual property rights and certain non-traditional areas of intellectual property such as geographical indications have been pushed through these agreements. A study of the Centre for International Environmental Law finds that: ‘The inclusion of TRIPS-Plus intellectual property provisions in the [Economic Partnership Agreements] will alter, in a single action, the entire landscape of international intellectual property negotiations.’


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The significance of a bilateral trade agreement between India and the European Union is often expressed in economic terms. During the last few years, bilateral trade between the two countries have significantly increased and the European Union is the largest trading partner of India, representing more than 20% of Indian exports and imports.\(^{914}\) It is anticipated that a free trade agreement may provide improved market access to India by easing existing quota pressures and market competition.\(^{915}\) This view is, however, contested in view of the rapid market transformation and multilateral trade integration. A study conducted by LEI Wageningen UR concludes that:

The results suggest that India’s interests in a regional trade agreement with the EU are downplayed by the fact that India’s economy is not well integrated in global markets. Impacts on the EU are minor and further reduced if a Doha agreement is in place when the FTA is implemented. Results indicate the rationale for a strongly asymmetric arrangement: it would be in the interest of both partners if the EU provides large concessions to India for market access, while India maintains the bulk of current border protection. An EU-India FTA delivers little scope for achieving efficiency gains via adjustments to the pattern of international specialization. An EU-India agreement on merchandise trade is unlikely to embody substantial preferential treatment with regard to market access. Probably, India can find more suitable FTA partners.\(^{916}\)


\(^{916}\) Thom Achterbosch, Marijke Kuiper and Pim Roza, *EU-India Free Trade Agreement: A Quantitative*
Can India really benefit from a bilateral trade deal with the European Union? The answer of this question is complex and subject to various interpretations.

Trade agreements are tools for economic liberalisation and market access. According to Professor Amartya Sen, economic growth and wealth generation are not self-serving objectives of international trade agreements. The litmus test to measure a satisfactory outcome of trade flows is equity, poverty eradication and resource allocation. Professor Amartya Sen notes that:

Indeed, we cannot reverse the economic predicament of the poor across the world by withholding from them the great advantages of contemporary technology, the well-established efficiency of international trade and exchange, and the social as well as economic merits of living in an open society. Rather, the main issue is how to make good use of the remarkable benefits of economic intercourse and technological progress in a way that pays adequate attention to the interests of the deprived and the underdog. That is, I would argue, the constructive question that emerges from the so-called anti-globalization movements ... A crucial question concerns the sharing of the potential gains from globalization – between rich and poor countries and among different groups within a country. It is not sufficient to understand that the poor of the world need globalization as much as the rich do; it is also important to make sure that they actually get what they need. This may require extensive institutional reform, even as globalization is defended.917


Thus, the relevance of a free trade agreement between India and the European Union should be judged in this context instead of simplistic economic appraisals.

In *Development as Freedom*, Professor Amartya Sen further states that:

> As the fast economic progress of East Asian and Southeast Asian economies gets more fully analyzed, it is becoming increasingly clear that it is not only the openness of the economies—and greater reliance on domestic and international trade—that led to such rapid economic transition in these economies. The groundwork was laid also by positive social changes, such as land reforms, the spread of education and literacy and better health care. What we are looking at here is not so much the social consequences of economic reforms, but the economic consequences of social reforms.\(^{918}\)

This is indeed an important reminder for Indian policy makers to rethink their existing approach towards bilateral trade agreements. These agreements will limit the ability of Indian generic manufacturers to produce affordable drugs. It will be indeed a reversal of the positive social change which India has achieved over the last few decades.

The negotiations for the EU-India free trade agreement started in 2006 as a part of the European Union’s Global Europe strategy.\(^{919}\) The tenth round of negotiations will be held from 6-8 March, 2011 in New Delhi to resolve outstanding issues between the parties.\(^{920}\) Despite considerable lobbying and public outcry, the parties did not formally release any text which is currently being negotiated. In February 2009, a working draft was leaked by Wikileaks showing the possibility of inclusion of several TRIPS-Plus

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\(^{919}\) European Trade Commissioner, India (accessed on 22 November 2010) at [http://ec.europa.eu/trade/creating-opportunities/bilateral-relations/countries/india/](http://ec.europa.eu/trade/creating-opportunities/bilateral-relations/countries/india/)

\(^{920}\) Ibid.
provisions in the final agreement. It is, however, difficult to predict safely the actual scope of any agreement given India’s long-term resistance to stringent patent rights. Furthermore, recent controversy between India and the European Union on the detention of Indian generic drugs also suggests that India will resist a demand for many TRIPS-plus measures.

Unlike United States free trade agreements, the European Union bilateral trade agreements are diverse and it is difficult to identify typical TRIPS-plus elements of these agreements affecting access to essential medicines. One feature which is widely reported as an important negotiation issue between India and the European Union will have significant potential impact on Indian access to medicine regime. The European Union is reportedly pushing India to adopt a data exclusivity regime to provide additional protection to pharmaceutical products. Data exclusivity provisions will apply to all drugs by creating a new patent-like monopoly, which will delay the registration of generic medicines. Even drugs without patents will be entitled to enjoy data exclusivity protection. For example, a patent on Gleevec was rejected by the Indian patent office, allowing generic producers to begin manufacturing. If data exclusivity had been in place, generic firms would have had to wait up to ten years to be able to start producing this drug, even though it could not secure a patent. Realising the apprehensions about the impact of free trade agreement on generic drugs, the European Parliament called ‘on the European Union and India to ensure that commitments under

the FTA do not preclude access to essential medicines whilst India is developing its capacity from a generic to a research-based industry'.

It is pertinent to note that in 2007, the European Parliament specifically resolved against the European Commission’s attempts to negotiate TRIPS-plus standards through bilateral trade negotiations. The Resolution calls on the European Commission:

[T]o meet its commitments to the Doha Declaration and to restrict the Commission’s mandate so as to prevent it from negotiating pharmaceutical-related TRIPS-plus provisions affecting public health and access to medicines, such as data exclusivity, patent extensions and limitation of grounds of compulsory licences, within the framework of the EPA negotiations with the ACP countries and other future bilateral and regional agreements with developing countries.

The final outcome of the EU-India free trade agreement will eventually determine the long-term direction of India’s patent policy and its impacts on the access to medicine regime. India should continue resisting TRIPS-plus standards. Any change in the Indian stance will lead towards further compromises.

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V. The Anti-Counterfeiting Agreement

The proliferation of TRIPS-plus standards and their negative consequences are not just limited to countries which signed free trade agreements with the United States and the European Union. Other developing countries are also increasingly facing bilateral pressures to adopt stricter intellectual property standards following the lead of group of countries signed FTAs.

By signing these free trade agreements, the United States and the European Union are successfully creating a framework of intellectual property norms which would become default agenda of future multilateral talks. Peter Drahos calls it a global intellectual property ratchet which is dependent upon three factors. First, the forum shifting is an essential technique which is used by the United States to achieve its policy objectives. The historical shift of the United States from World Intellectual Property Organization to GATT and subsequent shift to bilateralism clearly indicate that different forums have been smartly used to attain policy objectives. Second, the global intellectual property ratchet works through coordinated bilateral and multilateral strategies which helps in early compliance of higher standards while putting pressures on the rest of the world. Third, ‘in order for the ratchet to take hold there must be a re-setting of minimum standards through multilateral entrenchment’.

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926 Ibid.

There has been much debate as to whether the negotiations over the *Anti-Counterfeiting Trade Agreement* (ACTA) will have an impact upon access to medicines. The earlier negotiations on ACTA started in 2006-07 among the United States, European Union, Canada, Switzerland and Japan (see Table 8.2). The first formal public announcement was made in 2007 when these countries simultaneously announced their participation in ACTA negotiations. Since then seven rounds of negotiations have been completed and two rounds were scheduled in April and June 2010. ACTA is conceived as a plurilateral agreement with the aim to introduce new intellectual property enforcement norms beyond the threshold set in the *TRIPS Agreement 1994*. The negotiation process of ACTA has been marred by extreme secrecy and very little information has been so far released through official channels.

The apprehensions about the potential implications of this agreement on developing countries and access to essential medicines are intensified as doubts are rising amidst the secretive process of talks behind closed doors. Developing countries like India are not participating in ACTA negotiations but there are concerns that this agreement may reduce policy space for non-member countries. Eddan Katz and Gwen Hinze write that:

> Although not participating in negotiations, developing country governments will nevertheless find their domestic policy space reduced by ACTA ... ACTA

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standards likely will be a requirement of future bilateral agreements and evaluation criteria in the annual Special 301 report. In addition to the international trade framework, ACTA may have its own enforcement mechanism overseen by an ACTA Oversight Council.930

The lack of transparency is another point of concern and participating governments are releasing very patchy information about the scope and coverage of this new agreement. Some commentators have seen it as a coordinated move of ‘nodal actors’931 where networks of states and private actors are engaged in a process of creating higher intellectual property norms.932

The adverse implications of this approach on developing countries have already been witnessed during the Uruguay Round Negotiations when higher intellectual property standards were eventually imposed on developing countries, ignoring their

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developmental status and regulatory capacity. Charles McManis summarises the key procedural problems in relation to ACTA:

From the outset, however, the negotiations have been embroiled in controversy, for at least four reasons. First, while the negotiations are being carried out behind closed doors, industry representatives are apparently being supplied with information that is not being disseminated to the public. Second, the “plurilateral” nature of the negotiations has aroused suspicions that the ACTA negotiations are but the latest example of “forum-shifting”, a well-documented tactic that is apparently being deployed as a part of a nodally coordinated effort on the part of intellectual property owners to ratchet up international standards for the protection of private intellectual property rights.

The negotiating parties to the Anti-Counterfeiting Trade Agreement released an official draft text in April 2010. Thereafter, an updated draft of the Anti-Counterfeiting Trade Agreement was formally released on November 15, 2010. This draft, which is still subject to legal review, shows that participating countries had successfully resolved most of their differences which were shown in heavily bracketed language of earlier

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texts. To address concerns about patent enforcement issues and stringent border measures, the latest text provides that for the purpose of this Agreement, Parties may exclude patents and protection of undisclosed information from the scope of civil enforcement section.\textsuperscript{937} It is nevertheless important to note that this language was different in an earlier draft where the United States suggested that for the purpose of this Agreement, parties agree that patents do not fall within the scope of this Section.\textsuperscript{938} The latest text apparently provides more flexibility to parties which are interested in adopting a strong border protection and seizure procedure. From an access to medicines perspective, the final outcome of ACTA is still unsatisfactory as it allows member countries to adopt TRIPS-plus enforcement measures inhibiting the smooth trade of generic drugs.

\section*{VI. Conclusion}

Since the adoption of the \textit{TRIPS Agreement 1994}, the proliferation of TRIPS-plus standards since then has largely shaped the agenda of global intellectual property debates. There is an emerging agreement among developing countries and academia that stricter intellectual property standards, which are often enforced through a free trade agreement, restrict the policy space for developing countries and adequate mitigating strategies should be evolved to off-set the negative consequences of such agreements. A TRIPS-Plus regime is especially problematic for access to medicine programs and patent-related TRIPS-plus measures have been particularly criticised by public health advocates and policy commentators. India should resist adopting TRIPS-plus standards

\textsuperscript{937} Ibid. Footnote 2 to Section 2: Civil Enforcement.

in its patent regime because of the potential severe negative impact both on domestic consumers and poor patients elsewhere in the world.

There is a growing realisation in India that reforms in patent law should be aligned with its public health needs. Several members of the Lok Sabha and Rajya Sabha have raised concerns regarding TRIPS-plus standards during Parliamentary debate on the *Patents (Amendment) Bill 2005* (India).\(^9\)\(^3\)\(^9\) It was resolved that India should not introduce TRIPS-plus standards as any move in this regard would jeopardise the interests of the Indian pharmaceutical industry and consumers. Subsequent developments in Indian courts also show a positive trend towards discouraging reliance on TRIPS-plus measures. Although Indian courts have consistently responded against an expansive reading of relevant provisions of patent law and drug regulations, a proactive policy is conspicuously missing. It is perhaps the right time for the Indian government to adopt clear policy on issues related to data exclusivity and the patent-marketing approval nexus. These matters cannot be left to interpretations for a longer period of time, and even courts need policy guidelines from government.

Moreover, this chapter suggests that India should be wary of developments such as the plurilateral ACTA, which are further efforts by the USTR to raise the minimum standards of intellectual property protection at an international level.

### Table 8.1: Free Trade Agreements of the United States

<table>
<thead>
<tr>
<th>No</th>
<th>Country</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Australia</td>
<td>January 2005</td>
</tr>
<tr>
<td>2</td>
<td>Bahrain</td>
<td>August 2006</td>
</tr>
<tr>
<td>3</td>
<td>Canada</td>
<td>January 1994</td>
</tr>
<tr>
<td>4</td>
<td>Chile</td>
<td>January 2004</td>
</tr>
<tr>
<td>5</td>
<td>Costa Rica</td>
<td>August 2004</td>
</tr>
<tr>
<td>6</td>
<td>Dominican Republic</td>
<td>August 2004</td>
</tr>
<tr>
<td>7</td>
<td>El Salvador</td>
<td>August 2004</td>
</tr>
<tr>
<td>8</td>
<td>Guatemala</td>
<td>August 2004</td>
</tr>
<tr>
<td>9</td>
<td>Honduras</td>
<td>August 2004</td>
</tr>
<tr>
<td>10</td>
<td>Israel</td>
<td>April 1985</td>
</tr>
<tr>
<td>11</td>
<td>Jordan</td>
<td>December 2001</td>
</tr>
<tr>
<td>12</td>
<td>Mexico</td>
<td>January 1994</td>
</tr>
<tr>
<td>13</td>
<td>Morocco</td>
<td>January 2006</td>
</tr>
<tr>
<td>14</td>
<td>Nicaragua</td>
<td>January 2004</td>
</tr>
<tr>
<td>15</td>
<td>Oman</td>
<td>January 2009</td>
</tr>
<tr>
<td>16</td>
<td>Peru</td>
<td>April 2006</td>
</tr>
<tr>
<td>17</td>
<td>Singapore</td>
<td>January 2004</td>
</tr>
<tr>
<td>18</td>
<td>Colombia*</td>
<td>November 2006</td>
</tr>
<tr>
<td>19</td>
<td>Korea*</td>
<td>June 2007</td>
</tr>
<tr>
<td>20</td>
<td>Panama*</td>
<td>June 2007</td>
</tr>
</tbody>
</table>

Source: Office of the United States Trade Representative\(^{940}\)

*These agreements are yet to be implemented through enactment of Congress.

### Table 8.2: Participants in the Negotiations of Anti-Counterfeiting Trade Agreement

<table>
<thead>
<tr>
<th>No</th>
<th>Parties</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Australia</td>
</tr>
<tr>
<td>2</td>
<td>Canada</td>
</tr>
<tr>
<td>3</td>
<td>The European Union (EU) and its Member States, represented by the European Commission and the EU Presidency</td>
</tr>
<tr>
<td>4</td>
<td>Japan</td>
</tr>
<tr>
<td>5</td>
<td>Korea</td>
</tr>
<tr>
<td>6</td>
<td>Mexico</td>
</tr>
<tr>
<td>7</td>
<td>Morocco</td>
</tr>
<tr>
<td>8</td>
<td>New Zealand</td>
</tr>
<tr>
<td>9</td>
<td>Singapore</td>
</tr>
<tr>
<td>10</td>
<td>Switzerland</td>
</tr>
<tr>
<td>11</td>
<td>United States of America</td>
</tr>
</tbody>
</table>

Source: Australian Government, Department of Foreign Affairs & Trade\(^{941}\)

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\(^{940}\) Office of the United States Trade Representative (Last Updated 2 June 2009) at http://www.ustr.gov/trade-agreements/free-trade-agreements

\(^{941}\) Australian Government, Department of Foreign Affairs & Trade at http://www.dfat.gov.au/trade/acta/
Chapter 9
Conclusion

I. Introduction

In his book, *The Idea of Justice*, Amartya Sen comments that the question of access to essential medicines raises fundamental questions about global justice:

Take, for example, the reform of the patent laws to make well-established and cheaply producible drugs more easily available to needy but poor patients (for example, those who are suffering from AIDS) – an issue clearly of some importance for global justice. The question that we have to ask here is: what international reforms do we need to make the world a bit less unjust?942

Taking this fundamental, philosophical question as its cue, this thesis has engaged in an analysis of Indian patent law, with a view to providing recommendations not only for domestic reform, but also for a rearticulation of the international framework of treaties and declarations governing access to essential medicines.

In a *cri de Coeur* in June 2010, an Indian delegate to the World Trade Organization expressed his concerns about the impact of the *TRIPS Agreement* 1994 and new initiatives upon public health, development, and access to knowledge:

My delegation also wishes to draw Members’ attention to some systemic implications of the multitude of initiatives launched by a group of largely developed country Members to enforce TRIPS Agreement in a manner that is considerably more extensive than the level enshrined in TRIPS Agreement. India

has had to expend significant resources and make legislative changes to protect and enforce IPRs in line with TRIPS within the ten year transition period which ended in 2005. Among the developing countries, the least developed are still in the transition period till 2013-16.

Our concerns arise from the surge of TRIPS plus initiatives in multilateral fora, RTAs and plurilateral initiatives like the Anti-Counterfeiting Trade Agreement (ACTA). Texts of such RTAs, and more recently the negotiating text of ACTA, have appeared in public domain. Such higher levels of protection are likely to disturb the balance of rights and obligations in the Agreement enshrined, inter alia, in the Preamble, the Objectives and Principles (Art 7-8) and have the potential to constrain the flexibilities and policy space provided by the TRIPS Agreement to developing country Members like India particularly in areas such as public health, [Technology Transfer], socio-economic development, promotion of innovation and access to knowledge. They could also potentially negate decisions taken multilaterally such as the Doha Declaration on Public Health in WTO and the Development Agenda in WIPO.943

The Indian delegate highlighted a stark division between progressive initiatives such as the Doha Declaration on the TRIPS Agreement and Public Health 2001, the WTO Waiver Decision 2003, and the WIPO Development Agenda; and the threats represented by the push for greater enforcement of patent rights both within the World Trade Organization and from new outside initiatives – such as TRIPS-Plus Free Trade Agreements, and the menacing new proposed Anti-Counterfeiting Trade Agreement.

943 India’s Intervention to the WTO TRIPS Council: TRIPS plus Enforcement Trends (June 9, 2010) at http://keionline.org/node/864
In light of such developments, it is imperative to evaluate the impact of the *TRIPS Agreement 1994* on public health and access to essential medicines with the aim to draw key lessons and appropriate policy response for developing countries. This thesis explores the role of the Indian pharmaceutical sector and generic manufacturers in the supply of affordable and safe drugs to developing countries. The question of India’s continuing role as the pharmacy of the developing world is the central theme of this thesis. Placing the question of access to medicines in the Indian context, this thesis provides an analysis of India’s future as a leading generic manufacturer with the help of case studies portraying a broader picture of access to essential medicines in developing countries. Highlighting the significance of Indian generic supplies for the most vulnerable populations of world, the Indian case studies are used to show some inherent inadequacies and shortcomings of the global patent law architecture.

This concluding chapter is divided into several main sections. Part II provides a summary of preceding chapters highlighting the main arguments and conclusions presented in each chapter. Part III deals with recommendations which I have made in the light of case studies and analyses conducted in core chapters. Four distinct sets of recommendations have been provided for India, the World Trade Organization, the World Health Organization and the World Intellectual Property Organization. Part IV suggests that future research should consider a number of outstanding issues – including the emergence of new international agreements, such as the proposed Anti-Counterfeiting Trade Agreement; the advent of new scientific disciplines, such as nanotechnology, stem cell research, and synthetic biology; and the appearance of new infectious diseases, such as the SARS virus, avian influenza, and porcine influenza.
II. Summary of Key Arguments

After providing a literature review of the debate over Indian patent law and access to medicines, Chapter 1 contends that Amartya Sen’s theory of development as freedom can help explain the interactions between patent law, access to essential medicines, innovation policy, and human rights. It suggests that Amartya Sen’s capability approach has a great potential to explain several contemporary developments such as the global access to medicines campaign, alternative innovation models and the WIPO Development Agenda. The chapter concludes that the global crisis of access to medicines can be approached as a state of un-freedom which severely limits the abilities of poor individuals in many developing countries. Sen’s capability model offers certain promising insights that can help in identifying and building appropriate solutions and alternative paradigms.

Chapter 2 charts the historical evolution of Indian patent law and highlights a number of transformations – notably the debate over the Patents Act 1970 (India), the Patents (Amendment) Act 2002 (India), and the Patents (Amendment) Act 2005 (India). Chapter 2 maintains that, notwithstanding the consensus of major political forces on key aspects of patent law, the Indian Parliament has failed to address broader policy issues of access to medicines and pharmaceutical innovation. Nevertheless, it is important to note that certain features of patent law discussed in the Parliament provide important safeguard provisions from a public health perspective. The impact of advocacy networks and lobbying of non-governmental organisations – such as the Indian Cancer Patients Association, Médecins Sans Frontières, and the Lawyers Collective – also played a crucial role in the law-making process.

Chapter 3 looks at the domestic implementation of the TRIPS Agreement 1994 through the case study of the Gleevec patent application in India. The rejection of this patent on
the basis of Section 3(d) of the Patents Act 1970 (India) has raised a wide range of questions associated with patent law, international law and the Constitution of India. The judgment of Chennai High Court in Novartis AG v. Union of India\textsuperscript{944} provides crucial insights about the domestic implementation of international law and the flexibilities of the TRIPS Agreement 1994. It is argued that the judgment of the Chennai High Court has rightly upheld the legality of Section 3(d) on the basis of patentability criteria and the constitutional right of equality before the law and the right to health. The chapter further deals with the question of the legality of Section 3(d) in purview of the TRIPS Agreement 1994 and argues that the Chennai High Court should have considered this question instead of declining its jurisdiction on TRIPS related matters. The chapter concludes with this observation that Section 3(d) of the Patents Act 1970 (India) is fully compatible with the TRIPS Agreement 1994 and India should aggressively defend this provision as an important safeguard measure.

Moreover, it is submitted that other developing countries – both in the neighbouring regions of Southeast Asia and elsewhere – should also incorporate similar provisions in their patent laws to avoid the problem of evergreening. Section 3(d) is gradually developing into an effective tool to counter evergreening practices in patent filing. Recently some countries have shown interest in implementing a similar provision in their patent laws to ensure that only quality patents are granted in the filed of pharmaceuticals.\textsuperscript{945} The Philippines approved and signed in the changes to its patent law in June 2008 to incorporate a Section 3(d) type amendment.\textsuperscript{946} The amended Act

\textsuperscript{944} Novartis AG v Union of India and others, (2007) 4 Madras Law Journal 1153 at:
http://judis.nic.in/chennai/qrydisp.asp?tfnum=11121

\textsuperscript{945} Tahir Amin, ‘India’s Patent Act on Trial’ (February-March 2007) Bridges 15-16 at

\textsuperscript{946} Section 5 of Universally Accessible Cheaper and Quality Medicines Act of 2008 (The Philippines)
provides that:

The following shall be excluded from patent protection:

"22.1. Discoveries, scientific theories and mathematical methods, and in the case of drugs and medicines, the mere discovery of a new form or new property of a known substance which does not result in the enhancement of the known efficacy of that substance, or the mere discovery of any new property or new use for a known substance, or the mere use of a known process unless such known process results in a new product that employs at least one new reactant.

"For the purpose of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations, and other derivatives of a known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

This provision is essentially similar to India’s Section 3 (d) but it has not been fully applied to achieve those objectives for which it was actually enacted. An overview of patents through the database of Medicines Patent Pool shows that not a single patent on antiretroviral drugs was opposed and rejected in Philippines through the application of this provision. Whereas several such patents had been successfully opposed and rejected in India on the basis of Section 3(d). Despite its limited practical impact, the United States Trade Representative placed Philippines on 2011 Watch List observing that “the United States remains concerned about amendments to the Patent Law that limit the patentability of certain chemical forms unless the applicant demonstrates increased efficacy. The United States urges the Philippines to make progress in the short term to amending Section 22 of the Intellectual Property Code of the Philippines at http://www.lawphil.net/statutes/repacts/ra2008/ra_9502_2008.html.

address these and other matters.\textsuperscript{948}

Chapter 4 examines the issue of pharmaceutical exports and compulsory licensing provisions of Indian patent law in the light of the Pfizer-Natco controversy.\textsuperscript{949} In the Natco compulsory licensing controversy, two applications were made for the grant of compulsory licences to export drugs to a least developing country, Nepal. Although the relevant provisions of Indian patent law are more flexible than the \textit{Waiver Decision 2003}, the applicant ultimately withdrew its application because of frustration with the process of compulsory licensing. Despite the technical capability of Indian firms to manufacture quality generic drugs, poor citizens in many developing countries lack the freedom to access them. The solutions imposed to address these concerns further aggravate this problem instead of facilitating the smooth flow of generic drugs across different countries. The chapter concludes that WTO’s \textit{Waiver Decision 2003} and the proposed Article 31bis of the \textit{TRIPS Agreement 1994} should be completely revised. The ambiguities in Indian law should also be resolved with a strong political will. Within the current scheme, Indian pharmaceutical exports will be undermined and sabotaged, leaving millions of poor patients’ needs unattended.

Chapter 5 focuses on patent enforcement mechanisms and border measures which have recently attracted considerable attention. The first part of the chapter mainly considers the challenges which Indian generic manufacturers are now experiencing and I have used the case study of \textit{Roche v. Cipla} to explain some of the contentious issues in this

\textsuperscript{948} United States Trade Representative, \textit{2011 Special 301 Report}, (2011) [39].

This controversy involved an alleged non-authorised manufacturing of Roche's patented drug, Tarceva, which were made and marketed by Cipla under a different brand name. After elaborating key arguments of the parties, I specifically deal with the issues of injunctive relief in the light of public health and access to drug considerations. The main argument in this regard deals with the institutional capabilities of considering public interest as a key driver of the patent enforcement agenda. This occurred when the Delhi High Court refused to grant an injunctive relief on grounds related to the public health implications of any such order.

This chapter finally develops an argument that recent instances of the seizure of Indian generic exports are against the letter and spirit of the TRIPS Agreement 1994. In the light of relevant provisions of the TRIPS Agreement 1994, Doha Declaration 2001 and the jurisprudence of European courts, detention of generic drugs destined for humanitarian programs in developing countries are absolutely unwanted. A TRIPS-plus patent enforcement agenda employed by the European Union disadvantages the poor countries who heavily rely upon Indian exports. Several intellectual property enforcement initiatives have been recently launched and India should resist an upward harmonisation of the patent enforcement agenda to protect the policy space afforded in the TRIPS Agreement 1994.

Chapter 6 establishes an argument in favour of equitable licensing and the open source drug discovery regime in India and in this regard evaluates different applicable models. It starts with a critical analysis of the Bayh-Dole Act 1980 (US) and concludes that limitations of these models are now well known and there is an increasing dissatisfaction with the way in which publicly funded research and development projects are commercialised. The Indian policy response to regulate publicly funded

950 F. Hoffmann-La Roche Ltd v Cipla (I.A 642/2008 IN CS (OS) 89/2008).
research is manifested in the form of the *Protection and Utilisation of Public Funded Intellectual Property Bill 2008* (India). This Bill is modelled on the United States approach and restricts avenues of equitable licensing. It is argued that the Indian government should abandon this legislation in its current form and some innovative thinking is required before a law is proposed on this subject.

The chapter then discusses two alternative paradigms of equitable licensing mechanisms in the form of open source drug discovery and patent pools. Based on the notion of Yochai Benkler's peer production and commons-based social production techniques, open source drug discovery projects contain some promising prospects for poor patients in developing countries. A case for open source drug discovery in India is argued in this chapter to help overcome the problems associated with the conventional model of innovation. Instead of focusing on proprietary drug research and collaborative schemes with multinational pharmaceutical companies, it is argued that the Indian government should encourage open source projects in drug discovery.

The last part of the chapter deals with patent pools, to argue a case for India's active participation in an international patent pool aimed at solving the crisis of HIV/AIDS and other epidemics. The UNITAID's patent pool is discussed in this context in the light of the Heller and Eisenberg theory of the tragedy of anticommons in biomedical and pharmaceutical research. Patent pools may have greater significance for India as Indian generic manufacturers will cease new production and partnership opportunities under an international institutional arrangement. It is, however, important to note that the technological capability of Indian companies will only be an advantage if India continues exploiting its own safeguard provisions of patent law. The chapter concludes

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with a note that a delicate mix of open source and compulsory licensing policies at a domestic level will help in boosting the national agenda of access to medicine. Patent pooling will be a useful tool to build technological capabilities and to ensure the availability of drugs for rest of the world.

Chapter 7 specifically considers the issue of the gap in research and development in the area of tropical and neglected diseases. While India can adopt several policies and legislative frameworks to continue its existing role of the pharmacy of the developing world, the challenge of access to medicines is far more complex amidst the emergence of new disease patterns and massive drug resistance tendencies. It is argued that India could benefit from a prize-based incentive mechanism which delinks patents from products, and realising its existing technological and industrial base, India would be a major beneficiary of this system. The chapter then evaluates the proposal of Professor Thomas Pogge for a Health Impact Fund.952 The work of Professor Pogge, suggesting the moral responsibility of affirmative action in favour of poor patients, is briefly discussed in the context of a patent law framework and its limitations.953 The chapter provides a critical overview of the Health Impact Fund and its key components and concludes that this model may have limited utility in the Indian context. The chapter concludes with a note that India should explore its niche in the prize model which is now getting some institutional support from the World Health Organization. This model is relatively flexible and adequately addresses the problem of patents on pharmaceutical


products. This strategy is in accord with the proposal made in earlier chapters dealing with open source, patent pools and compulsory licensing.

The final substantive chapter of this thesis looks at the future direction of India’s access to medicine regime in the light of TRIPS-plus free trade agreements. Analysing two recent Indian cases, Syngenta India v. Union of India954 and Bayer Corporation v. Union of India955, it is contended that a TRIPS-plus patent regime will have severe adverse impacts on the access to medicines regime. It is further argued in this chapter that India has very little to gain from a proposed United States-India free trade agreement. On the contrary, it would compromise substantially on regulatory freedom provided under the TRIPS Agreement 1994. For the pressures of the free trade agreement, India should not adopt TRIPS-plus measures because it will disturb the balance of patent law which has the potential to facilitate global access to medicine regimes. In particular, it should resist the Anti-Counterfeiting Trade Agreement which is aimed at accelerating the standardisation of TRIPS-plus norms.

III. Recommendations

In the light of this comprehensive analysis, it can be concluded that India’s traditional role as the pharmacy of the developing world is in jeopardy, as a result of its adoption of the TRIPS Agreement 1994. Without structural and institutional changes, India will lose its pre-eminent role as the key provider of generic drugs and medicines. Although India has adopted flexibilities of the TRIPS Agreement 1994 – such as Section 3(d) and its compulsory licensing regime – there are increasing pressures within India to change

954 Syngenta India Ltd. v Union of India (High Court of Delhi: July 1, 2009) W.P. (C) 8123/2008 at http://delhicourts.nic.in/jul09/SYNGENTA%20INDIA%20VS.%20UOI.pdf

955 Bayer Corporation v Union of India & Others (High Court of Delhi: February 9, 2010) LPA 443/2009 at http://lobis.nic.in/dhc/
its domestic policies. Any change in this regard (such as patent based innovative strategies) will not only harm Indian consumers but it will seriously affect the plight of poor patients around the world. A number of recent international trends, including the seizure of generic drugs in transit, TRIPS-plus free trade agreements, and the negotiation of the Anti-Counterfeiting Trade Agreement have the potential to further threaten India’s access to medicines regime. However, India could nonetheless safeguard its role as the pharmacy of the developing world through the adoption of several alternative schemes – including open source drug discovery, prizes, and the fostering of rights-based advocacy networks.

To improve and safeguard India’s role as a key provider of safe and affordable generic medicines, a number of key recommendations are made in this thesis.

A. Domestic Indian Patent Law

The debate about patent law development and possible reforms is intense and has attracted considerable academic focus. In the United States, several commentators have considered this question from a policy perspective and suggested various substantive and procedural patent law reforms to overhaul the existing framework. The situation in India is, however, quite different where the policy debate about the operation of patent law is largely absent. India is amending its old laws, implementing new statutes and creating regulatory bodies but a serious and informed dialogue about the objectives

and scope of this exercise is non-existent. The need for such a dialogue is immensely felt at this critical juncture of Indian legal history.

At a domestic level, India should introduce a wide range of policy and legislative measures to improve the access to medicine regimes by setting a leading example. Currently, there is no comprehensive patent policy in the country which frequently leads towards confusing policy signals generated by different stakeholders and government departments. Though India has adopted a fairly balanced patent regime, it still requires a long term policy vision to crystallise thinking on patents and access to medicines. This gap was clearly reflected during Parliamentary debates on patent law amendments where only a few issues dominated the whole debate and major policy matters had never been considered and discussed. It is recommended that the Indian government should articulate a long term policy vision on issues of patent law and pharmaceutical drugs – dealing with the role of the generic industry, the use of safeguard measures, and the enhancement of local capabilities to continue producing cheaper versions of patented drugs.

The ongoing debate on the Protection and Utilisation of Public Funded Intellectual Property Bill 2008 (India) shows the state of confusion which prevails among different government departments and ministries due to the lack of an overarching innovation policy and its implications for access to medicines. The most notable absence in the policy-setting arena is the Ministry of Health which has virtually left the whole debate in the hands of intellectual property and trade professionals. This does not go well with India’s stated positions at different multilateral forums where a strong focus on the health perspective is a top priority. Recently, an Indian Parliamentary Committee has recommended several amendments to the Protection and Utilisation of Public Funded Intellectual Property Bill 2008 (India) after surmounting criticism from academics and
non-governmental organizations. The actual scope and impact of these changes will not be known unless a modified Bill is tabled before the Parliament. However, it reflects the problematic approach which the Indian government is adopting in the arena of innovation and its commercialisation. It is recommended that India should find its niche in alternative modes of incentivising research and development.

At a domestic level, four specific recommendations can be made with regard to Patents Act 1970 (India). First, India should shun all internal and external pressures to change or modify Section 3(d) of the Patents Act 1970 (India). With the introduction of this section in 2005, India took a major step to counter evergreening and dubious quality patents. Starting with Novartis’ Gleevec case, the Indian patent office has now developed expertise in determining the exact scope of Section 3(d) and its multifaceted implementations. Nonetheless, India is facing constant pressures to amend or repeal this provision.

The Report of the US-India Business Council and the Coalition for Healthy strongly advocating the deletion of Section 3(d) in its current form by alleging that it disadvantages Indian innovators who mainly rely on incremental inventions. It concludes that: ‘Reforming Section 3(d) to encourage and protect incremental pharmaceutical innovation would create such incentives and help India become a true

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powerhouse of innovation.\textsuperscript{959} The same views have been expressed by the Pharmaceutical Research and Manufacturers of America (PhRMA) in its Special 301 Submission 2010. According to PhRMA: "Some of the standards for patentability in India are inconsistent with the TRIPS Agreement, depart from the mainstream of practice internationally, or are not transparent.\textsuperscript{960} These attacks on Section 3(d) are aimed at discrediting the legality of India’s provision. Such pressures have intensified after the release of the report of Technical Expert Group on Patent Law Issues. Although this report categorically excludes the review of Section 3(d) from its mandate, its earlier version issued in 2007 was used by multinational pharmaceutical firms to highlight the problem of Section 3(d).\textsuperscript{961}

The Technical Expert Group was established as a result of a compromise between the Congress led Indian government and the Left parties at the time of the 2005 amendments in patent law. The report deals extensively with the issues of patentability of micro-organisms and new chemical entities. It raises the spectre of a violation of the requirement of technological neutrality under Article 27 of the \textit{TRIPS Agreement 1994}: "Reading this obligation in the light of the overall purpose of the Agreement, it appears that linking the grant of patents for pharmaceutical substances only to a new chemical

\textsuperscript{959} Ibid. 18.

\textsuperscript{960} Pharmaceutical Research and Manufacturers of America (PhRMA), \textit{Special 301 Submission 2010}, 49 at http://www.phrma.org/sites/phrma.org/files/attachments/2010_Special_301_Review_Submission_PhRMA_A_.pdf

entity or to a new medical entity may prima facie amount to "excluding a field of technology" even when they satisfy the basic requirements of patentability.  

It is therefore recommended that the Indian government should not consider any revision of Section 3(d) and the patent office and Indian courts should be given considerable time to develop appropriate doctrinal interpretations in the field of pharmaceutical innovation.

A second recommendation regarding Indian patent law deals with its pre-grant opposition proceedings. The practice of the last five years proves that pre-grant opposition proceedings were highly useful in bringing actions against patent applications which were not qualified under Indian law. Feroz Ali Khader notes with regard to the purpose of pre-grant opposition, that:

Pre-grant opposition procedure can act as a touchstone to test the genuineness of an invention. It can be used to distinguish the real Black Swans from the ones that are painted black. Pre-grant opposition procedure is instrumental in checking the quality of patents and in notifying their boundaries. The procedure offers incentives to the competitors to bring patent related information into the Patent Office.

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964 Feroz Ali Khader, The Touchstone Effect: The Impact of Pre-Grant Opposition on Patents (New
It is interesting to note that in its Special 301 Submission 2010, PhRMA raised the issue of pre-grant opposition procedure and affiliated delays with regard to some countries but no reference was made about Indian law. It is perhaps for this reason that there are a number of other substantive issues in Indian law from PhRMA’s perspectives which require immediate attention. However, for the Indian government, the local generic industry and civil society organisations, the retention of this provision is extremely important from a public health perspective. This thesis has shown that the pre-grant opposition mechanism is effectively used by patient rights groups and other non-governmental organisations, and such an oversight is crucial in a country which lacks institutional capacity in the examination of drug patents.

The third recommendation about Indian patent law deals with compulsory licensing provisions and its practical dimensions. Although India’s regulatory structure features a range of compulsory licensing provisions, such measures have not been optimally used in practice by Indian companies. It is expected that Indian companies will soon start filing compulsory licensing applications for domestic use. The issue of a compulsory licence for export purposes needs serious attention by the Indian government. However, India should approach this issue from a broader and futuristic perspective. Despite the fact that Médecins Sans Frontières (MSF) procures the bulk of its drugs from India, it had to contact Apotex to test the efficacy of the WTO’s Waiver Decision 2003. It can be argued here that for all practical reasons, India should assume a leading role in this regard by issuing compulsory licences for humanitarian purposes. It is therefore recommended that India should revise its existing strategy of non-engagement on compulsory licensing issues by easing the administrative difficulties in its domestic law in light of the outcome of the Natco case.

Our last recommendation is about the Indian Patent Office and its role in ensuring the issuance of quality patents according to the *Patents Act 1970* (India). The Patent Office has multiple responsibilities in the form of grants of patents, opposition proceedings, administrative appeals, and the issuance of compulsory licences. There are growing institutional linkages between the Indian Patent Office and the United States Patents and Trademark Office. The undue influence of government officials is a growing concern and on June 7, 2010, nine non-governmental organisations wrote a letter to the George Washington University (GWU) regarding its India Project. The letter states that:

GWU ostensibly created the “India Project” with the intent to bring together academics, government officials and business leaders to discuss IP issues including the international and domestic aspects of patent law. Despite these objectives, in practice, GWU’s India Project has failed to present a balanced discussion on intellectual property, and especially the importance of protecting public health in developing countries. Instead, the Project, which receives funding from multinational pharmaceutical corporations and software companies, has misrepresented an industry-centered perspective as an independent academic exercise. These sponsors have vested interests in an outcome where India adopts stricter intellectual property rules and their presentations are indicative of heavy industry bias. Instead of offering a true forum for discussion and debate on these critical issues, these summits are one-sided and only seek to impose a U.S.-style IP regime on India.

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966 Open Letter from Universities Allied for Essential Medicines et al to George Washington University
This letter clearly reflects the nature of concerns which are associated with capacity building projects and joint initiatives. It is recommended that India should develop its own independent capacity building program with the support of patent offices of developing countries – such as other members of the BRICS Group. It will also help India in sharing lessons about Section 3(d) and pre-grant opposition proceedings and other developing countries will benefit from this experience.

B. World Trade Organization

In the World Trade Organization, India can play a critical role, both through the strategic use of complaint mechanisms, and leading policy debate over the topic of patent law and access to essential medicines.

In May 2010, India and Brazil formally requested the initiation of a consultation process with the European Union on the issue of seizure of generic drugs in transit. These consultation requests which were made under Article 4.4 of the WTO’s Dispute Settlement Understanding contain similar grounds challenging the legitimacy of the European Union’s internal laws and regulations which empower its Customs authorities to detain drugs in transit. In its communication, India submitted that:

Based on complaints of alleged infringement by alleged owners of patents over the last two years, customs authorities in the Netherlands have seized a substantial number of consignments of generic drugs from India in transit through the Netherlands. India understands that these seizures were made by applying the so-called “manufacturing fiction” under which generic drugs actually manufactured in India and in transit to third countries were treated as if they had been manufactured in the Netherlands. These consignments were initially detained and

Law School Dean to Cease Industry-Sponsored Intellectual Property Training in India, June 7, 2010 at

http://keionline.org/node/863

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later, either destroyed or returned to India. In a few cases, the consignments were permitted to proceed to the destination country after considerable delay. Available evidence confirms that the customs authorities seized at least 19 consignments of generic drugs in 2008 and 2009 while in transit through the Netherlands, 16 of which originated in India.\textsuperscript{967}

India also enlisted specific provisions of the \textit{TRIPS Agreement 1994} along with other WTO legal texts which do not allow the seizure of generic drugs. Such a measure on part of the European Union, India argues, is particularly a violation of Paragraphs 2, 3, 4, 5 and 7 of Article V of the GATT 1994. Furthermore, it is a violation of Article X of the GATT 1994.

India further relied on Article 28 read together with Article 2, Articles 41 and 42 and Article 31 of the \textit{TRIPS Agreement 1994} to establish that the detention measures, in several respects, are inconsistent with the obligations of the European Union. It was submitted that:

India considers further that the measures at issue also have a serious adverse impact on the ability of developing and least-developed country members of the World Trade Organization to protect public health and to provide access to medicines for all. Accordingly, the provisions of the TRIPS Agreement referred to above must be interpreted and implemented in light of the objectives and principles set forth in Articles 7 and 8 of the TRIPS Agreement, the Doha Ministerial Declaration on the TRIPS Agreement and Public Health adopted on 14 November 2001 and in the light of Article 12(1) of the International Covenant on

\textsuperscript{967} European Union and a Member State – Seizure of Generic Drugs in Transit, WTO Doc WT/DS409/1, IP/D/29, G/L/922 (19 May 2010) (Request for Consultations by India).
Economic, Social and Cultural Rights, which recognizes the right of all persons to the enjoyment of the highest attainable standard of physical and mental health.\textsuperscript{968}

This intervention shows that India is seriously pursuing its role as a leading developing country which is ready to take up trade disputes impacting its pharmaceutical exports. The timing of this move is also crucial from the point of view India-EU free trade agreement negotiations which are at final stage. Although the European Union had earlier indicated that the issue of the detention of generic drugs can be bilaterally settled, India and Brazil have preferred to start WTO dispute settlement proceedings.

India’s leadership role in the area of pharmaceutical patents and access to medicines needs to be further explored and consolidated. This thesis clearly establishes that India’s role as an agenda-setting member of multilateral trade bodies is somehow compromised and there is a strong need to revisit certain aspects of the domestic and international approaches.

At a meeting on the 8\textsuperscript{th} to 9\textsuperscript{th} of June 2010, members of the World Trade Organization discussed the issues of the \textit{TRIPS Agreement} 1994, public health and patent law enforcement in a meeting of the TRIPS Council.\textsuperscript{969} During the meeting, many developing countries – including Pakistan, Brazil and a group of African countries – expressed their concerns about the implementation of the \textit{Waiver Decision 2003}. India and China have raised a number of specific objections about the impacts of draft ACTA provisions on public health and the access to medicines.\textsuperscript{970} These concerns about the

\textsuperscript{968} Ibid.

\textsuperscript{969} World Trade Organization, ‘Council debates anti-counterfeiting talks, patents on life’ (WTO, 2010 News Items: 8 and 9 June 2010) at \url{http://www.wto.org/english/news_e/news10_e/trip_08jun10_e.htm}.

\textsuperscript{970} India’s Intervention to the WTO TRIPS Council: TRIPS plus Enforcement Trends (June 9, 2010) at \url{http://keionline.org/node/864}
implications of TRIPS-plus enforcement agenda in the form of ACTA negotiations contain multiple threats for developing countries.971

India specifically highlighted the potential impacts of stricter enforcement rules on access to generic medicines with reference to transit drugs and border measures. The member countries also discussed the state of implementation of the Waiver Decision 2003 and the proposed Article 31bis of the TRIPS Agreement 1994. Developing countries expressed their concerns about the implementation of the Paragraph 6 solution and asked for an open and candid debate on the effectiveness of this mechanism. In this regard, they have proposed to arrange a public workshop to discuss Paragraph 6 mechanism in the presence of all stakeholders including industry and non-governmental organisations. The Intellectual Property Watch reports that: ‘Developing countries have expressed doubts on the effectiveness of the paragraph 6 mechanism given its limited use so far, and have begun to seek a discussion on it, including outside experts such as a company that tried to use the system.’972

India also raised the issue of the compulsory licensing scheme under the Paragraph 6 mechanism and clarified its position.

India told Intellectual Property Watch that it was misquoted as what was really said was that “there have been several efforts” made, not that several countries had tried the system. This also does not appear in the prepared statement of India. The delegate said those efforts related mainly to the efforts of Médecins Sans Frontières (Doctors without Borders) trying to help the paragraph 6


implementation in its only use with Canada before getting weary of the process and deciding to bypass the mechanism and asking an Indian generic drug company to supply Rwanda with an AIDS medicine ....

The last point which India has raised is extremely pertinent and brings the WTO into the centre of debate of patents and access to medicines. The *Waiver Decision 2003* was definitely a compromised deal among WTO member countries but now it is time to re-evaluate the effectiveness of this mechanism. This system could not simply work and deliver the objectives which were mentioned in *Doha Declaration 2001*. In fact just before the TRIPS Council meeting, the WTO Secretariat released an updated note about members’ notifications of the acceptance of the Protocol amending the *TRIPS Agreement 1994*. It shows that only 29 countries have notified their acceptance leaving a large number of developing and least developing countries unmoved on the implementation of proposed Article 31bis.

What should be done within the WTO to resolve these concerns of developing countries about the failure of the Paragraph 6 mechanism? Indeed, the failure of this system is not an unexpected outcome and many commentators have already predicted this problem, realising the limitations of the *Waiver Decision 2003*. The practical problems

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973 Ibid.


associated with the *Waiver Decision 2003* have been thoroughly discussed in this thesis to demonstrate that successful implementation of this mechanism is highly unlikely. This thesis presents three recommendations which may help the WTO to achieve the objectives of *Doha Declaration 2001* in a relatively effective way.

First, in light of its cumbersome procedural and administrative details, there is a need to replace the *Waiver Decision 2003* with a simple, quick and effective mechanism for the export of pharmaceutical drugs. An ideal solution would take the form of permanent waiver of obligation under Article 31(f) of the *TRIPS Agreement 1994* without linking it with conditions and limitations which are currently attached to it. WTO members should be allowed to determine the grounds and conditions on which they may consider the issuance of compulsory licences both for domestic and export purposes. It is recommended that a matter of compulsory licensing for an export purpose should not be unnecessarily linked with additional requirements. Most developed countries have already opted out of this system. Given the relatively small size of the pharmaceutical market in least developing countries, there is no evidence that exports from India and other developing countries will harm the substantial economic interests of multinational pharmaceutical companies. It is therefore important that a straightforward and simple compulsory licensing mechanism should be allowed.

The second recommendation of this thesis concerns the introduction of a product patent regime in least developing countries. As a part of *Doha Declaration 2001*, the deadline for least developing countries was further extended to 2016. It is recommended that a long term moratorium should be imposed in this regard to allow the importation of

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generic drugs in countries which are economically and socially disadvantaged. None of
the least developing countries has the technological base and infrastructure capacity to
manufacture sophisticated drugs for HIV/AIDS and other epidemics. Such an extension
of the transitional period will ease pressures on developing countries which are
currently locked in the ambiguities of patents and compulsory licensing requirements.

The third recommendation of this thesis deals with patent law and enforcement issues.
India and China have raised their concerns in this regard, but currently there is no
collective movement among developing countries to counter the TRIPS-plus
enforcement agenda emanating from the forum of the World Trade Organization. The
WTO’s institutional structure provides some unique opportunities to member countries
and the latest example is the generic drug seizure case which India and Brazil have
recently initiated. However, the WTO is itself a member driven organisation and
developing countries can greatly influence some of its outcomes and policy decisions. It
is therefore recommended that India should assume a strong role to promote a proactive
agenda for developing countries about patent law and public health issues.

C. World Health Organization

The constitution of the World Health Organization specifically identifies a critical role
of this body in the control and eradication of communicable diseases.\textsuperscript{976} Disease
surveillance is, therefore, a crucial aspect of the World Health Organization’s work plan
which is implemented in the form of the Epidemic and Pandemic Alert and Response
(EPR) Program.\textsuperscript{977} Currently the World Health Organization is monitoring nineteen

\textsuperscript{976} Jennifer Prah Ruger and Derek Yach, ‘The Global Role of the World Health Organization’ (Fall
2008/Spring 2009) II (2) \textit{Global Health Governance} 1-11.

\textsuperscript{977} For details see: World Health Organization, ‘Global Alert and Response (GAR)’ (accessed on 14
September 2010) at \url{http://www.who.int/csr/en/}
emerging disease threats including Avian influenza, Hepatitis, Influenza, and Severe Acute Respiratory Syndrome. Although the role of the World Health Organization in disease surveillance is largely appreciated, it is not free from political influence and other controversies. The efficacy and the relevance of some of the World Health Organization’s guidelines and practices are criticised for the lack of transparency and conflicts of interest. There is no doubt that the organisation operates in a difficult political environment which impedes its ability to deliver satisfactory outcomes in certain cases. Patents and access to essential medicines is one area which has long been ignored by the World Health Organization before its recent attempts to catch-up.

The Sixty-third World Health Assembly was held in Geneva on 17-21 May 2010. On the final day of its meeting, the World Health Assembly took an important step towards financing research and development in the area of health innovation by establishing a Consultative Working Group on Research and Development: Financing and Coordination. This Working Group is entrusted with the task of furthering the recommendations of an earlier working group by recognising the need to:

promote a range of incentive schemes for research and development including addressing, where appropriate, the de-linkage of the costs of research and development and the price of health products, for example through the award of

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978 Ibid.
prizes, with the objective of addressing diseases which disproportionately affect developing countries.982

In 2001, the World Health Assembly started referring to intellectual property rights in the context of access to medicines. The Resolution of the Fifty-Fourth World Health Assembly on Scaling up the Response to HIV/AIDS urges member states ‘to increase access to medicines’ and ‘to cooperate constructively in strengthening pharmaceutical policies and practices, including those applicable to generic drugs and intellectual property regimes’.983

In a separate Resolution on WHO Medicine Strategy, reference is made to the impacts of international trade agreements on access to essential medicines in developing countries.984 In 2003, the World Health Organization took a further step when its Secretariat submitted a report to the Fifty-Sixth World Health Assembly specifically referring to the flexibilities and safeguard provisions of the TRIPS Agreement 1994. This report, *Intellectual Property Rights, Innovation, and Public Health*, stated that:

Rigorous analysis of the scientific, legal, economic, ethical, and human rights aspects of intellectual property as it relates to public health, and careful monitoring of this relationship in different national contexts could prove invaluable for national and international policies and practices that ensure both

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982 Ibid.


innovation to respond to unmet needs and access to existing technologies for
health.985

In the light of this report, the World Health Assembly established a Commission on
Intellectual Property Rights, Innovation and Public Health which was tasked with the
mandate of providing ‘an analysis of intellectual property rights, innovation and public
health, including the question of appropriate funding and incentive mechanisms for the
creation of new medicines and other products against diseases that disproportionately
affect developing countries’.986

In 2006, the Commission on Intellectual Property Rights, Innovation and Public Health
provided a comprehensive report on the topic of patent law and access to essential
medicines: ‘We analysed the complexity of scientific challenges in biomedical
innovation and sought reasons why, in spite of a greater effort, R&D has not yet
produced the results hoped for, or even expected, for the people of developing
countries.’987 The composition of the Commission on Intellectual Property Rights,
Innovation and Public Health and the representation of corporate stakeholders had
made it clear at the very outset that its recommendations would be compromised
solutions. Two members of the Commission on Intellectual Property Rights, Innovation
and Public Health, Professor Carlos Correa and Pakdee Pothisiri, wrote their separate
commentaries and observed that:

985 Ibid.

(May 28, 2003) (World Health Assembly Res. 56.27)


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We regret the Commission was not able to elaborate in more detail proposals for mobilizing the financial resources and the scientific talent, particularly that available in developing countries, necessary to address the diseases that predominantly affect the poor. This report will fulfil its objective, however, if it helps WHO member countries and other stakeholders to set R&D priorities and develop a global sustainable framework to respond to that imperative.988

As compared to earlier resolutions and statements of the World Health Organization, the Commission on Intellectual Property Rights, Innovation and Public Health first time elaborated the limitations of global intellectual property norms and its possible impacts on research and development.

This process finally culminated in the form of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG) which was created in 2006 to develop a medium-term framework on the basis of recommendations suggested by the Commission on Intellectual Property Rights, Innovation and Public Health.989 After two years of deliberations and regional consultation, the outcome of this working group surfaced in the form of a draft strategy which was ultimately adopted by the Sixty-First World Health Assembly in 2008. The Global Strategy on Plan of Action on Public Health, Innovation and Intellectual Property contains the following eight key elements:

1. Prioritizing research and development needs
2. Promoting research and development
3. Building and improving innovative capacity

988 Ibid. 201-202.
4. Transfer of technology

5. Application and management of intellectual property to contribute to innovation and to promote public health

6. Improving delivery and access

7. Promoting sustainable financing mechanisms

8. Establishing monitoring and reporting systems.\(^9\)

The World Health Organization is still in the process of devising a plan of action to implement the *Global Strategy on Plan of Action on Public Health, Innovation and Intellectual Property*. It is anticipated that this process will take place between 2009 and 2015 with an estimated cost of US$2.1 billion.\(^9\)

Even after ten years of its first resolution, the practical impact of the World Health Organization's work on patents and access to medicines is very marginal. It is still locked in the process of implementation modalities, monitoring and evaluation processes, budgetary allocation and administrative bottlenecks without a single concrete step towards establishment of an alternative health innovation system. It is also crucial to note that throughout this period, the role of the World Health Organization has been virtually non-existent when major controversies have emerged about patents and generic medicines. A full length TRIPS-plus regime has in fact emerged during the last ten years or so with huge public health consequences, but the World Health Organization

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could not be moved. The World Health Organization could have assumed a leading role after the announcement of the *Doha Declaration 2001* in terms of suggesting better alternatives to its member states which ultimately failed to agree a solution. It was again missing recently when the generic drug detention controversy emerged and the World Health Organization could only issue a weak statement on this issue.

This thesis shows that, despite its shortcomings, the role of the World Health Organization is extremely important at least in one area of access to medicines: addressing the challenges of the research and innovation gap. Unlike other institutions discussed in this thesis, the World Health Organization has an institutional mandate to act on this issue by devising alternative incentive models and resource mobilisation.

There are already indications that the World Health Organization is gradually moving in this direction through the Global *Strategy on Plan of Action on Public Health, Innovation and Intellectual Property*. However, there are two concerns in this regard. First, the pace of the World Health Organization’s initiative on innovation and intellectual property is prohibitively slow, leaving the needs of millions of poor patients unattended. Although it is a consensus-driven member organisation, the United Nations agency can do much better on issues of patents and access to medicines, given its funding, and infrastructure of regional networks.

Second, the World Health Organization has equivocated over support for alternative models of medical innovation. After almost ten years of deliberations, it is not clear to the World Health Organization what alternative models will be suitable for bridging the gaps of pharmaceutical innovation. It is recommended that the World Health Organization should focus on prizes and open source drug discovery projects with full

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financial and institutional support. The patent pool initiative has already been launched from the platform of the UNITAID and the World Health Organization can play a significant role in boosting the potential of alternative models.

The World Health Organization can also help in tackling the problem of economies of scale in the case of compulsory licensing. It has been noticed in this thesis that despite legal avenues, the issuance of compulsory licences is restricted for reasons related to market dynamics and large scale commercial production. This problem can hardly be resolved individually by countries who are interested in importing drugs for access to medicine programs. The World Health Organization has significantly downplayed its role in strengthening and facilitating compulsory licensing regimes in its members’ countries despite the fact that these measures are absolutely legal under the TRIPS Agreement 1994. The organisation should find its niche in this area with the help of leading generic manufacturers in India and other developing countries.

**D. World Intellectual Property Organization**

While delivering his speech at the World Bank Conference on Judicial and Legal Development, Professor Amartya Sen said:

In making effective use of the approach of Comprehensive Development Framework, there is a good case for bringing in the freedom-based considerations explicitly into the accounting. This gives an immediate reason to ask about the end product of legal and judicial reform and other institutional changes, and the need to be clear about what they are aimed at. This is where the foundational objective of the expansion and consolidation of human freedom becomes central as constitutive of development. It is in these ways that the freedom-based
approach can effectively supplement the [comprehensive Development Framework] strategy.993

This statement was made in the context of development strategies which was evolved and implemented by the World Bank, but it contains a broader message for global development initiatives. To Amartya Sen, the role of international institutions, including the United Nations and its affiliated organisations, is critical in adopting freedom-based developmental considerations.994 Amartya Sen’s conception of development and justice can provide illuminating insights for ongoing discourse in the area of intellectual property and development. Amartya Sen provides two key objectives for any development discourse in the form of justice and capability enhancement.

In his acceptance speech to the General Assembly of the World Intellectual Property Organization (WIPO), Dr Francis Gurry, Director General of the WIPO, shared his vision about key issues of global intellectual property framework. He specifically talked about the potential and direction of the WIPO Development Agenda and stated that:

No less important are developments that call upon the IP system to broaden its horizon and to make its mission more attuned to the collective consciousness of the international community. First and foremost is the question of how IP can contribute to the reduction of the knowledge gap and to greater participation on the part of the developing and least developed countries (LDCs) in the benefits of innovation and the knowledge economy. IP alone is not going to bring about the solution to differential levels of development, but the recent consensus on the


WIPO Development Agenda provides a wonderful opportunity for the Organization to be part of the solution. For the WIPO Development Agenda to fulfil this promise, I believe that it is essential that we translate the political consensus into concrete and effective projects.\textsuperscript{995}

He further elaborated the relevance and importance of this issue and stated that: ‘There is also a dimension to the Development Agenda which calls for a continual analysis and reflection on the best means of making IP work to the advantage of all countries, regardless of their level of development.’\textsuperscript{996}

The WIPO Development Agenda has attracted considerable global attention as a key countervailing strategy by developing countries to the onslaught of the TRIPS-plus bilateral and regional agreements.

Since the adoption of the TRIPS Agreement 1994, there was a strong feeling of loss and undue compromise among many developing countries and these feelings became prominent during the implementation of the national patent laws. Developing countries have questioned the rationale of global intellectual property policies and their implications on public health, access to knowledge and public goods. In this regard references were made to the failure of existing institutions to devise balanced intellectual property norms. The Report of United Kingdom’s Commission on Intellectual Property Rights finds that:

The danger for developing countries is that harmonisation would be around developed country standards of protection, which may not be suitable for them.


\textsuperscript{996} Ibid.
For developing countries the concern must be to ensure that they do not accept in these discussions new international rules further limiting their freedom to design appropriate patent policies, unless it can be shown it is in their interests to do so.997

The role of the World Intellectual Property Organization has been frequently discussed to reflect upon the gains and losses of the Uruguay Round Negotiations.998 Some attempts have also been made to construct a totally new and different theoretical approach towards intellectual property norms, and the objectives of the **TRIPS Agreement 1994**, mentioning Article 7 and Article 8, were discussed in this regard.

The mere rhetoric of materialising the objectives of Articles 7 and 8 of the **TRIPS Agreement 1994** was not sufficient on the part of developing countries, and they were expected to suggest concrete steps. The breakthrough in this regard was achieved in 2004 when Brazil and Argentina along with 12 other developing countries floated the proposal of Development Agenda on the forum of World Intellectual Property Rights (WIPO).999 There were four main components to the original proposal aimed at


999 World Intellectual Property Organization, ‘Proposal by Argentina and Brazil for the Establishment of a Development Agenda for WIPO’, (Geneva, August 27, 2004) WO/GA/31/11. The proposal was later
integrating the notion of development in the body of existing and future WIPO initiatives.

The first component deals with the institutional mandate and direction of the World Intellectual Property Organization and suggests that WIPO should review its function in the light of United Nations’ Millennium Development Goals. It was stated that:

The proposal for the establishment of a “Development Agenda” is also based on the premise that development concerns should be given emphasis in WIPO activities, so that the Organization may comply with its UN mandate. One of the intentions of the “Development Agenda”, therefore, is to promote a deeper reflection on the development implications of current and new approaches to different IP policy choices and international norm setting, as well as a more accurate and pervasive discussion on the consequences of their adoption by countries at different stages of social, economic and technological development. It is important to promote a critical examination of the implications for developing countries of the adoption of increased IPR protection, rather than seek to approach this highly controversial issue as if it were governed by absolute truths, solely under the one dimensional perspective of the private rights holders, ignoring the broader public interest.¹⁰⁰⁰

It was generally believed that WIPO's capacity building initiatives and technical assistance programs operating in developing countries serve this purpose and these countries could therefore cope with the challenges of intellectual property policies. However, this proposal has for the first time, articulated a strong case for the comprehensive development agenda at the level of the World Intellectual Property Organization.

The second component of the original proposal deals with treaty-making and the norms-setting process at the World Intellectual Property Organization. The rising level of patent protection, especially the negotiating process of the *Substantive Patent Law Treaty*, and its implications for economic development should be considered as a fundamental concern.

The third component proposed a critical re-evaluation of policies related to the transfer of technology and innovation. Questioning the efficacy of objectives laid down in Articles 7 and 8 of the TRIPS Agreement 1994, the proposal seeks the development of effective and corrective measures to address this problem. Existing standards of intellectual property protection have failed to facilitate the dissemination of technology and caused adverse effects on developing countries. It was said that:

> Intellectual property law and policy as well as other regulatory regimes relating to innovation and transfer of technology have implications beyond the regulation of monopoly rights over inventions, copyrights, trademarks and other related subject matter. They impact on a much wider range of issues from access to education and learning materials to the availability and affordability of essential medicines as well on the efforts to bridge the digital divide and the technological gap. When rules and standards touch upon such fundamental issues, they cannot be
formulated in accordance only with the expertise and concerns of specialized IP
lawyers and rightholders groups.\textsuperscript{1001}

The last component dealt with the enforcement of intellectual property rights. The
enforcement regime should be balanced and informed by the needs and requirements of
different countries. Any enforcement regime without appropriate safeguard provisions
would complicate the problem of access to knowledge and essential medicines in
developing countries.\textsuperscript{1002}

In its reaction to the proposal of the \textit{WIPO Development Agenda}, the United States tried
to downplay the significance of this suggestion and alternatively suggested a WIPO
Partnership Program, an ‘internet-based tool to facilitate the strategic use of intellectual
property by developing countries and to maximize WIPO’s positive impact on
development’.\textsuperscript{1003} The United States further questioned the rationale of launching a
development initiative at WIPO level and asserted that the development objectives
could only be marginally achieved through intellectual property policies. Reference was
also made to other specialised agencies of the United Nation with a clear message that
WIPO was not the proper forum to discuss development related issues.\textsuperscript{1004} In fact, this
response was not completely unexpected. The United States has an old and traditional
position on the role of intellectual property rights and in that context, patents and other
forms of intellectual property rights have never been construed as development policy
instruments.

\textsuperscript{1001} Ibid. 12.
\textsuperscript{1002} Ibid. 8
\textsuperscript{1003} World Intellectual Property Organization, ‘Proposal by the United States of America for the
Establishment of a Partnership Program in WIPO’ (Geneva, March 18, 2005) IIM/1/2, 3 at
http://www.wipo.int/edocs/mdocs/mdocs/en/iim_1/iim_1_2.doc
\textsuperscript{1004} Ibid.
It is also important to note that India was not among the sponsors of *WIPO Development Agenda* but it showed full support to the objectives laid down in the proposal. In its official response, the Indian delegate stated that:

Given the huge disparities existing across the world it is open to question whether IP harmonization benefits developing countries. The developed countries to pay lip service to “development” in the context of Intellectual Property protection, but they do so rather self-servingly. The term “development” as used by these countries, including in WIPO, means quite the opposite of what developing countries understand when they refer to the “development dimension” … A *WIPO Development Agenda* would, obviously need to take into account any possible negative impact on the users of IP, on consumers at large, or on public policy in general, not just the promotion of the interest of Intellectual Property owners. It is vital to inject this balance and equity into the various WIPO bodies.1005

In the subsequent process of negotiations and formalisation of the *WIPO Development Agenda*, India has played a significant role along with several other developing countries and this process culminated in the form of 45 agreed recommendations.1006 These recommendations are arranged under six different clusters dealing with technical assistance and capacity building; norms-setting, flexibilities, public policy and public domain; technology transfer, information and communication technologies and access to knowledge; Assessment evaluation and impact studies; institutional matters including

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mandate and governance and other issues.\textsuperscript{1007} It is apparent that developing countries can raise patents and access to essential medicines issues under various clusters. However, their success depends upon future negotiations, and the process of implementation will actually reflect upon the efficacy of these recommendations.\textsuperscript{1008}

The future of the \textit{WIPO Development Agenda}, and its possible implications in redesigning the global intellectual property standards, needs a thorough assessment. The institutional capacity of the WIPO and its willingness to harness the resources required for an effective implementation of the proposed recommendation, is doubted. Our discussion and analysis in this thesis reveals that like the World Health Organization, the role of the World Intellectual Property Organization in dealing with patents and the access to medicines issue is marginal and sidelined. A series of events have highlighted the problems which developing countries are facing since the adoption of the \textit{TRIPS Agreement 1994} but the role of the World Intellectual Property Organization was completely invisible throughout this time. This is an alarming situation for both the United Nations bodies, but especially for the World Intellectual Property Organization which is specifically mandated in this regard.\textsuperscript{1009}

\textsuperscript{1007} Ibid.


http://www3.interscience.wiley.com/journal/123476731/abstract?CRETRY=1&SRETRY=0
With the emergence of the *WIPO Development Agenda*, it is a good opportunity for this body to realign itself with the needs of developing countries. From the perspective of developing countries, the World Intellectual Property Organization is currently operating as a global royalty collection agency. The WIPO needs to change this impression by taking initiatives indicated in the Development Agenda. Three distinct recommendations are therefore suggested in this regard. First, it is extremely important that the World Intellectual Property Organization should chalk out a clear plan of action on Development Agenda proposals. The role of the Secretariat is extremely important in this regard. During the debates on the *WIPO Development Agenda*, developing countries raised concerns about some of Secretariat’s policies.\(^{10}\) It is important to change this culture and align the organisation with developmental objectives.

Second, the ongoing negotiations on the *Substantive Patent Law Treaty* need to be carefully considered because they have the potential to culminate in a multilateral TRIPS-plus regime. Any attempt to trade-off between the Development Agenda and the *Substantive Patent Law Treaty* would be undesirable. The last recommendation deals with the existing capacity building programs of the World Intellectual Property Organization. Most of these programs are merely co-ordinated by the World Intellectual Property Organization and conducted through leading intellectual property offices around the world. This creates a critical mass of intellectual property maximalists among the officials of patent offices and intellectual property policy makers. This practice should be immediately curtailed, and adopting an alternative capacity building policy in the light of the objectives of the Development Agenda.

IV. Future Research

This research has explored the link between patent law and access to essential medicines by identifying India as a key player in providing access to affordable drugs in developing countries. This significance of the Indian generic drugs is traced in an historical context and then analysed in the light of different changes and developments which are re-shaping India’s role as the pharmacy of the developing world. The analytical template used in this thesis cut across crucial themes of regulatory changes, domestic practices, use of safeguard provisions and the emerging norms of research and development. This thesis also makes several policy recommendations for key stakeholders which have emerged throughout our analysis.

In the process of conducting this research to contextualise India’s role as pharmacy of developing world, new areas of potential research have been identified. There is a growing literature on Indian patent law and its access to medicines regime but several important linkages are still missing. The Indian pharmaceutical industry is rapidly transforming amidst mergers, acquisitions, and product development partnerships. There is a need for ongoing empirical research on the evolution, development and diversification of the Indian pharmaceutical industry.

Another area which needs systematic and in-depth research deals with patents-related jurisprudence produced by Indian courts during the last five years. Some of these cases are referred to and analysed in this research but there are now many cases which provide a sufficient basis for doctrinal analysis. Such work may be especially relevant from a public health perspective as the Indian jurisprudence on fundamental rights and the right to health is immensely rich.1011 It would also be interesting to expand upon the

1011 To see Indian jurisprudence on right to health: People’s Union for Civil Liberties v. Union of India (1997) 1 SCC 301, ESC Ltd v. Subhash Chandra Bose (1992) 1 SCC 441 at 462, Bandhua Mukti Morcha
contribution of this thesis in the area of alternative models of pharmaceutical innovation. With substantial indigenous resources and the booming Indian economy, prizes and open source drug discovery models can be further studied.

Further research is needed on data exclusivity and its impact on Indian generic industry. I have argued in this thesis that India should refrain from adopting a data exclusivity regime similar to the one which United States has been advocating through bilateral trade agreements. This will, however, not ease pressures on India to overhaul its existing data protection system and there is a strong likelihood that India will be asked to revise its existing practices. India currently maintains that its existing system is fully compliant to Article 39.3 of the *TRIPS Agreement 1994*. We have seen that India’s major trading partners including the European Union are not satisfied with this regime and they are demanding for the justification of India’s regulatory system. Though currently India is not ready to change its domestic data protection regime but there are several questions about the effectiveness of Indian system. It is important to carry out future research on following questions in Indian context: what is the difference between data exclusivity and market exclusivity in terms of IP legislation? Should India introduce a

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data protection regime within IP framework or it should revise and develop a system under pharmaceutical regulations? What should be an appropriate term of data protection for pharmaceuticals? Do clinical trials undertaken by pharmaceutical companies for introducing new indications of existing drugs qualify for data protection?

The impact of emerging bilateral and regional trade agreements on the Indian medicines sector is another important area which needs further research and academic focus. The ongoing negotiations on the ratification of the Anti-Counterfeiting Trade Agreement 2011 will impact upon the future agenda of intellectual property norm-setting. It is crucial to evaluate the implications of such agreements from the perspective of India and the access to medicines. India is currently negotiating a bilateral trade agreement with the European Union. More work is needed to contextualise and understand the Indian patent regime in the light of these developments. There has also been much concern about whether the proposed Trans-Pacific Partnership Agreement – covering a number of nations in the Pacific Rim; but not India as yet - will have an adverse impact on access to essential medicines. Future research should consider whether such a regional agreement will affect intellectual property norms and public health standards in the region of the Asia-Pacific.

More focused research and analysis is required on the ongoing discussions over the need for a European Union-India free trade agreement. These negotiations started in 2006 and in view of recent high level summit in New Delhi, it is anticipated that a final

1012 Michael Gasiorek et al, Qualitative analysis of a potential Free Trade Agreement between the European Union and India (Sussex, United Kingdom: Centre for the Analysis of Regional Integration at Sussex and CUTS International, Undated) at http://trade.ec.europa.eu/doclib/docs/2007/june/tradoc_135101.pdf
deal will be signed in near future. The European Union is currently the largest trading partner of India. It will be critical to see how trade influences will reshape India’s domestic policies after a free trade agreement is concluded between India and the European Union. The EU is no longer demanding data exclusivity and patent term extensions but there is a strong push for stricter enforcement provisions related to injunctions and border measures. Future studies should evaluate how India’s enforcement system is compatible with the TRIPS Agreement 1994 and why India should not go beyond minimum enforcement mechanism envisaged under TRIPS. This thesis also shows that Indian judicial decisions are helpful in creating necessary policy and functional space for generic companies. Future studies should consider whether an European Union-India free trade agreement will change or disrupt the delicate balance achieved through various cases under Indian domestic law.

Our case studies do not deal with the challenges of new infectious diseases such as Severe Acute Respiratory Syndrome (SARS), Avian Influenza and Porcine Influenza. Future research on the impact and cures of these diseases is important for variety of reasons. With a huge population influx and poor health conditions, the possibility of disease outbreak in India is significant. The battles over patenting the SARS virus

and its impact on the access to medicines regime need to be further explored.\textsuperscript{1016} There has also been much debate about access to viral samples of influenza, and benefit-sharing; as well as issues about stockpiling key pharmaceutical drugs, such as Tamiflu.\textsuperscript{1017} India has traditionally played a significant role in manufacturing generic versions of cancer and HIV/AIDS medicines. How will this role be balanced in future with the advent and spread of new infectious diseases? The question of pandemic planning and the role of patents are becoming increasingly crucial as a greater number of patent applications are granted in relevant fields. The facilitating or inhibiting role of these patents needs to be judged before developing nations move to adopt a domestic strategy.\textsuperscript{1018}

The opportunities and challenges in the field of gene patents also need to be fully explored in the Indian context.\textsuperscript{1019} With massive national scientific resources, India is experiencing increasing internal and external pressures to ease regulatory control over


\textsuperscript{1017} Dennis D. Crouch, ‘Preparing for Pandemic Influenza: Nil: The Value of Patents in a Major Crisis Such as an Influenza Pandemic’ (2009) 39 Seton Hall Law Review 1125. Also see: Edward G Saravolac and Jonathan P Wong, ‘Recent Patents on Development of Nucleic Acid-based Antiviral Drugs against Seasonal and Pandemic Influenza Virus Infections’ (June 2007) 2(2) Recent Patents on Anti-Infective Drug Discovery 140-147.


\textsuperscript{1019} For a detailed discussion, see Matthew Rimmer, Intellectual Property and Biotechnology: Biological Inventions (Cheltenham, United Kingdom: Edward Elgar Publishing, 2008)
gene patents. There has been much controversy in the United States over the validity of patents held by Myriad Genetics in respect of BRCA1 and BRCA2, which are related to breast cancer and ovarian cancer. A challenge by the American Civil Liberties Union to the validity of the patents is currently under review.\textsuperscript{1020} There is a need for further research to determine India’s future plan of action in this field. There is also a need to further consider the ramifications of the recent decision of the Supreme Court of the United States on patentable subject matter in \textit{Bilski v. Kappos}, for medicine and biotechnology.\textsuperscript{1021} There is a need to evaluate whether the scientific and medical benefits are being shared evenly with developing and least developed countries.

Beyond the challenges of international agreements and infectious diseases, India can gain substantially from new scientific disciplines to strengthen its pharmaceutical sector and technological base. These new disciplines — such as bioinformatics\textsuperscript{1022}, nanotechnology\textsuperscript{1023}, stem cell research\textsuperscript{1024} and synthetic biology\textsuperscript{1025} — can open enormous


\textsuperscript{1021} \textit{Bilski v. Kappos} 130 S. Ct. 3218 (2010).


\textsuperscript{1025} Arti Rai and James Boyle, ‘Synthetic Biology: Caught between Property Rights, the Public Domain,
opportunities for the Indian drug industry to develop indigenous R&D capabilities. With a strong pharmaceutical industry, India has a comparative advantage in developing collaborative initiatives with the international research community. It is, however, not clear whether patents in these new areas will compromise India's access to cutting-edge technologies.

India has also experienced difficulties with the issues of bio-prospecting and biopiracy. With the introduction of the *Traditional Knowledge Digital Library*, India has taken a lead to check future incidences similar to the Basmati rice patent. However, the questions about the future of pharmaceutical innovation and bio-prospecting are yet to be fully explored in the Indian context. India possesses a great potential in this field and Indian firms have already started the use of intellectual property protection to launch and market their products. So, the simple solution of denying patent protection on such subject matters would no more be a feasible policy option and the Indian government will soon be confronted with tough choices.

Lastly, there is a need to develop a comparative perspective on patents and access to medicines regimes in BRICS economies. It is beyond the scope of this research to

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work on this aspect but an analysis about the future of Indian generic exports cannot be completed without studying trends in other BRICS countries.\textsuperscript{1030} India is one important source of generic drugs and it is important to study the future of access to medicines in a broader context.

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