Tailoring patent policy for developing economies

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Hazel V J Moir
Adjunct Associate Professor
Research School of Social Sciences
College of the Arts & Social Sciences
The Australian National University
Canberra, Australia
hazel.moir@anu.edu.au

Ping-Kun Hsu
Assistant Professor
Department of International Business
Management
Tainan University of Technology
Tainan, Taiwan
t90014@mail.tut.edu.tw

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Abstract

As intellectual property chapters are now regularly part of free trade agreements, countries need to have a clear view of what elements of a patent system will encourage domestic innovation and what elements will simply raise the cost of goods and services. Drawing on the range of empirical material available about patent systems, this paper presents an initial analysis of critical design elements to maximise economic welfare while implementing patent policy in developing and technology-importing economies. Key issues considered are: patent policy objectives; limitations to patentable subject matter; the height of the inventive step; the privileges provided by patents; incentives, penalties and strategic gaming; and transparency issues particularly oversight, evaluation and audit. Development of a set of policy principles which align with maximising national economic well-being goes some way to meeting the goals of the Development Agenda Group put forward in the context of WIPO's Committee on Development and Intellectual Property. Such a set of principles would also play a useful role in assessing the value of patents in trading for improved market access for goods and services thus assisting an evidence-based approach to trade negotiations.
Tailoring patent policy for developing economies

1. Introduction

Since the Uruguay Round most "free trade" agreements – whether multi-lateral, regional or bilateral – have included the government-backed monopolies known as "intellectual property rights". They cover patents, copyrights, trademarks and a variety of other restraints on competition. The draft Agreement on Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS), adopted as a requirement for World Trade Organization (WTO) membership, was put forward by the business sector (Drahos 2002; Sell 2003). The more recent agreements usually include a TRIPS-plus agenda – more extensive restraints on trade than those included in TRIPS (Drahos 2001, 2007a; Sell 2011).

These negotiations take place in great secrecy. Parties to the current negotiations on the Trans-Pacific Partnership Agreement (TPPA) have undertaken not to disclose copies of the draft text. It is not clear who proposed this secrecy nor why participants agreed, as all participating nations are democracies. A secret text makes it impossible for governments to undertake the kind of consultations about major changes to policy that are expected in a democracy. The available leaked draft of the TPPA "intellectual property" chapter suggests that such draft treaties continue to be written by major global companies.

This secrecy makes it essential that civil society and democratic governments develop their own agenda for such legislated monopolies. This paper sets out an alternative agenda on patents.

The patent arena can be as contentious domestically as it is in international forums. Perhaps the most trenchant criticisms come from the USA, a technology-exporting nation (e.g. Jaffe and Lerner 2004; Quillen Jr. 2006; Bessen and Meurer 2008; Boldrin and Levine 2008). Yet these concerns have not led Congress to rebalance the US patent system nor the agenda pursued in international "trade" negotiations. Those favouring the business model embedded in TRIPS and post-TRIPS proposals do not base their proposals on any evidence about their effectiveness in inducing innovation.

But there is substantial empirical evidence that can be used to inform patent policy. This paper draws on that evidence to put forward some initial proposals for an agenda for patent policy designed to encourage domestic innovating firms without incurring the large deadweight losses of the current system. These goals are critical to developing economies, which usually import technology. Indeed they would suit any nation better than the TRIPS system. The proposals cover patent policy objectives; limitations to patentable subject matter; the height of the inventive step; the privileges provided by

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1 The one exception is the 2001 Doha Agreement. This Ministerial Declaration affirms that "the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health" (http://www.who.int/medicines/areas/policy/doha_declaration/en/).

2 Interestingly neither the US Trade Representative website (http://www.ustr.gov/tpp) nor the official Australian website (http://www.dfat.gov.au/fta/tpp/) mention this. But see sites such as http://keionline.org/node/1362; http://www.citizen.org/TPP; and http://en.wikipedia.org/wiki/Trans-Pacific_Strategic_Economic_Partnership.

3 Article 8(1) proposes, inter alia, that "a new form, use, or method of using a known product may satisfy the criteria for patentability, even if such invention does not result in the enhancement of the known efficacy of that product" (emphasis added). The focus on efficacy indicates the origin as the pharmaceutical industry. The leaked intellectual property chapter is at http://keepthewebopen.com/assets/pdfs/TPP%20IP%20Chapter%20Proposal.pdf.

4 There was a brief hesitation in 2007 when the US Congress removed "tough public health provisions" from bilateral trade treaties. Provisions about data exclusivity, patent extensions and patent linkage were removed from Free Trade Agreements with Colombia, Peru and Panama (Sell 2011: 449). Subsequent bilateral or regional treaties have returned to the agenda which preferences pharmaceutical profits over the Doha Declaration.

5 To a lesser extent there are some empirical data on the impact of copyright, in particular on the extent to which copyrights benefit publishers compared to authors. Towsé and colleagues (2008) find that empirical progress lags theoretical progress. There are however some data on UK and German author earnings (Kretschmer and Hardwick 2007) and on economic returns to Australian artists (Throsby and Zednik 2010). In the trademarks area there is as yet very little empirical data on how trademarks are used or their impact (see Greenhalgh and Rogers 2007).
2. Some issues about assumptions and perspectives

There are some disciplinary tensions in discussions about patent policy. Although the objectives of patent policy are economic, lawyers have long claimed the field within academia. Effective reform requires input from both economists and lawyers as this important economic policy is delivered through the legal system. But both disciplines address patent policy with embedded assumptions. For good evidence-based policy these assumptions need to be identified and tested against empirical reality.

The essence of patent policy is the incentive to change investment behaviour. Because of this the normal rules of law (for criminal behaviour or contracts over physical property) will not always deliver good outcomes. Similarly economic theories are based on inaccurate assumptions will be a poor guide to effective policy.

An example of the need to challenge "automatic" legal presumptions is the onus of proof. In economics the dangers of regulatory intervention in markets are well-known and so clear evidence of a net increase in welfare is required to justify the intervention. In addition the cost of the intervention must be less than that of any alternative means of achieving the goals. If these two criteria cannot be achieved, then a country will be worse off for adopting the intervention. "Clear evidence" aligns with the legal standard "beyond reasonable doubt." But lawyers are reluctant to use this standard outside criminal law. But a granted patent provides a powerful exclusive right that can impact strongly on firms which have not been a party to the decision to grant a monopoly. The patent privilege is the right to prevent others from commercially exploiting a particular area of technology. A very high standard of proof is therefore indicated.

An example of the need to challenge economic assumptions is the frequent assumption that copying new knowledge is costless and so there will be no incentive for any invention or industrial innovation without patents. As Bonatti and Comino (2011) show, if imitation takes time – demonstrated empirically by Mansfield and reinforced by data from the Yale survey – then social welfare is higher without patents, particularly where there are R&D subsidies. Theoretical economic analyses of "optimal" patent design tend to focus on issues of duration versus breadth. Yet the former has a fixed minimum under TRIPS and "breadth" is not a concept that aligns well with practical patent administration. Patent systems need to be designed on the basis of a sound understanding of their practical effect. One cannot, for example, simply assume inventiveness (as is shown in Section 5).

It is also important to bear in mind that the major benefits from trade agreements arise from domestic reform (Armstrong 2012: 1641). It is the dismantling of barriers to competition that delivers the greatest economic benefit – a benefit spread throughout the economy. Consumers benefit directly from lower tariff barriers. So too do firms who can then reduce input prices and compete more effectively both at home and overseas. Increased access to overseas markets provides only a small part of the benefits from trade, and these benefits are often concentrated.

In contrast to the pro-competition agenda of free trade, patents are designed to restrain competition. If they do not have this effect, they cannot work to increase investment in R&D. Patent systems run directly counter to competition agendas and sit poorly in the context of "free trade". However the principles of the free trade agenda apply to the extent that the greatest domestic benefits will be from reform of patents to maximise the impact on domestic innovation and minimise the deadweight costs of restraints on competition.

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6 As Quillen has said, the critical issue for proceeding with an innovation is the soundness of the innovation and whether it is impeded by others' patents, not whether you own patents on it (Quillen Jr. 2008: 61).

3. **Patent policy objectives**

In its essence patent policy is a simple trade-off between the goals of fostering industrially applied domestic innovation and the costs of reduced competition. The traditional argument for patent policy is that firms undertaking industrial innovation have insufficient exclusive time in the market to recoup their development costs if competition is unrestrained. Patents, by granting an exclusive period in the market, overcome this problem and should thus induce resources to move into industrial research and development (R&D) which in turn should increase the level of commercialised industrial innovation.

This dynamic efficiency benefit comes at the cost of suppressing competition during the patent period, causing static efficiency losses. Design of an effective and efficient patent system centres on this trade-off between dynamic efficiency gains and static efficiency losses. If gains can be maximised and losses minimised, then a patent system can provide a net economic benefit for an economy. The principles developed in this paper are directed to achieving such welfare-enhancing balance in a patent system.

Unfortunately these objectives of patent policy are rarely mentioned in national patent legislation. However in the TRIPS Agreement the objectives are spelled out:

"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." (TRIPS, Article 7)

Article 7 thus provides a clear articulation of the principle goal of patent policy – to encourage technological innovation.

A policy is not efficient if it rewards behaviours that would occur absent the policy. Such waste simple provides unearned benefits (windfall gains) to some parties. Given the strong exclusionary right of a patent – the right to prevent independent invention – providing patents for innovation that would have taken place anyway has an extremely high cost. As Bessen and Meurer (2008) have pointed out, those who face patent infringement challenges are other innovating firms. So the patent goal needs to be refined to:

**Encourage technological innovation that would not otherwise take place.**

As well as encouraging technological innovation, TRIPS Article 7 indicates clearly that patent systems should ensure benefits to users as well as producers of new technology. This perspective has a sound economic basis. The reason that possible failure in the innovation market attracts government intervention is the anticipated spillover benefits from the induced innovation. If an induced innovation does not provide social benefits\(^8\) that are greater than the costs of the restraint on competition, then grant of a patent would impose costs on society rather than providing benefits. As clarified in the recent Indian Supreme Court decision, the purpose of a patent system is to benefit the nation not to reward individual inventors.\(^9\) Private returns are not the issue here. Where private returns to innovation are high, patents are not needed to induce the innovation. Only where private returns are low are patents needed, but they are efficient only if spillover benefits are high enough to offset the associated static efficiency losses. This indicates a second important requirement that should be set forward as a key policy objective.

**Encourage technological innovation that would not otherwise take place and whose spillover benefits are greater than the cost of the restraint on competition.**

\(^8\) Social benefits are private benefits plus positive externalities such as spillovers from new knowledge; social costs are private costs plus negative externalities, such as the suppression of competition and reduced consumer welfare.

\(^9\) "Patent systems are not created in the interest of the inventor but in the interest of national economy. The rules and regulations of the patent systems are not governed by civil or common law but by political economy." Cited in *Novatis AG v Union of India and others*, Civil Appeal Nos. 2706-2716 of 2013, Supreme Court of India at 36.
This is a more detailed specification of the "mutual advantage of producers and users" phrase of TRIPS Article 7, but specified in terms of the underlying economics.

Of course there are substantial real-world challenges in implementing such a policy goal. But unless goals are clear and agreed there is little point developing implementation measures. To date the height of the inventive step has been used as the major (but unstated) proxy for benefits exceeding costs. This would be one means of implementing this policy goal and is addressed in Section 5.

Both these policy goals raise the question of how technological innovation should be defined (Section 4), but are otherwise unexceptional. Those less familiar with the actual practices of patent systems may wonder why such simple statements are needed.

The goal of inducing technological innovation that would not otherwise take place is quite straightforward in policy (if not in political) terms. But the use of the inventive step to ensure that the benefits should exceed the costs seems to require discussion. There is a wide gulf between legal and economic views as to what is the quid pro quo to the nation for the monopoly grant which is the essence of a patent. From an economic perspective the economic basis for intervening in the innovation market is the view that the social returns from innovation are substantially greater than the private returns. If the spillover benefits from the patented technology are high enough, then patent grant is rational and the nation is better off. For a patent system to provide a net benefit to a nation there needs to be a strong likelihood that each granted patent provides social benefits greater than the social costs.

What is a reasonable proxy for spillover benefits from an invention? Mansfield’s much-quoted study on social returns is based on gross consumer surplus from 17 innovations (Mansfield et al. 1977). Only six of these had both a high gross social return and a low private return, thus needing a patent or other incentive. Consumer surplus is difficult to measure and the relevant policy standard is not gross consumer surplus from the invention (the Mansfield metric) but net consumer surplus from the invention and the products displaced by it. Net consumer surplus would generally be a highly impracticable approach from an administrative viewpoint. In the specific case of inventions such as pharmaceuticals, consumer benefit can be more readily proxied as an improved health outcome. If these improved health outcomes – compared to other treatments available – exceed the cost of the restraint on competition, then there is a sound basis for the patent grant.

The other major recognised form of external benefit from innovation is new knowledge – indeed the standard economic argument for patents is that new knowledge is costlessly and immediately copyable. Knowledge spillovers can flow along a number of pathways to other firms and innovators. Their magnitude is variable and contingent. Both technological and geographic proximity are important variables for spillovers to occur and this raises issues of whether spillovers can be assumed to exist if either distance is large. A large technological distance may exist between patents granted to leading-edge foreign firms and domestic firms in a country in the earlier stages of development. In many cases granting patents for products which are imported raises substantial doubt as to the existence of positive spillovers in the patent-granting country. These issues are discussed further in Section 6.

Setting aside for the moment the questions as to whether positive spillovers from new knowledge can always be assumed to exist, the extent of new knowledge contributed might be a practical and workable way of specifying the benefit to the community that is expected when a patent monopoly is granted. It also aligns well with the social contract theory of patents.

Legal commentators often suggest that the quid pro quo for grant of a patent is the disclosure of the invention in the specification (Ghosh 2004: 1315). But if the patented invention contains no new knowledge, no amount of disclosure can create a benefit for the public. Disclosure is thus a means

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10 Some in the patent community consider that patents are a right rather than a societally-approved privilege (and that this right exists regardless of whether the R&D would have been undertaken absent patent policy).

11 Sena discusses the variety of channels through which knowledge spillovers flow (Sena 2004: 318); Jaffe (Jaffe 1986, 1988) and Porter (1990) demonstrate the importance of technological or geographic proximity; and Bernstein and Nadiri (1991) show there are substantial differences between industries in the magnitude of such spillovers.
through which new knowledge might flow – though as many familiar with the patent system argue, not a very efficient means. Effectively disclosure is a condition of the grant, but it is not the reason for making the grant and it does not constitute a benefit to the public unless what is disclosed is of some value.

Some argue that without patents many inventions would be kept secret. This is not an argument that holds water from an economic perspective. Boldrin and Levine (2013: 9-10) cogently argue, as others have done before them, that it would be irrational to patent an invention that can be kept secret. The history of innovation shows that inventors and innovators exchange ideas as a matter of course and that secrecy, where it occurs, normally only occurs in the last stages of commercialisation.

The two objectives of patent policy can be drawn out to incorporate the economic (or social contract) view of the quid pro quo:

"to encourage technological innovations which would not otherwise occur and which provide sufficient new knowledge, know-how or net consumer benefit to the community to offset the costs of the monopoly to innovating firms and the community."

4. Limitation to technological innovations

The language of TRIPS Article 7 introduces a critical aspect of patent policy – one that has been so fundamental that it is rarely spelled out. This is that the patent system is designed only for technological innovations. The reasons for this centre on the experimentation (and hence cost) required to develop new technological artefacts. It is these lumpy costs which underlie the view that time in the market can be too short to ensure an adequate return to the R&D investment. In contrast, in other parts of an economy, such as business methods, the R&D phase can frequently be limited to the idea itself. Implementation usually incurs only production costs not R&D costs, so the argument that early competitors will undermine returns to R&D does not withstand scrutiny. Given that it always takes competitors some time to deliver their version of the product to the market, where R&D costs are low or there are network effects, first-mover advantages can be considerable and will usually be sufficient to induce the innovation without the need for a patent monopoly.

The theoretically optimal standard for what should be granted patents – only "inventions that need the patent incentive" (Duffy 2008: 344) – is impossible to administer. But it does draw attention to a very important policy issue – not all inventions should be patentable. Empirical and theoretical analyses show that those inventions which may not occur absent patents are those where the initial period of market exclusivity is too short to recoup research and development (R&D) costs. This will typically be discrete product inventions which are highly codified and can therefore be imitated more quickly. The most obvious policy conclusion from this range of empirical evidence is that innovations should be patentable only in selected technologies/industries. This first-best option is precluded by TRIPS which mandates no discrimination between technologies.

While this preferred option cannot therefore be adopted, it does suggest the need for careful design of other policy elements to minimise the damage done by the technology-neutral TRIPS mandate. There is, for example, substantial evidence that chemical and pharmaceutical innovation proceeds faster if compounds are unpatentable, but processes can be patented. After reviewing the impact of the

12 Assumptions that are fundamental to agreed views on how society does and should work are so generally shared that they are rarely mentioned (Hirschman 1977: 69). When there is a paradigm shift – such as the inclusion of legislated monopolies in “free trade” agreements – there is often an accompanying shift in underlying assumptions.
13 The original empirical research demonstrating the costs and time required for copying was undertaken by Mansfield and colleagues (Mansfield, Schwartz and Wagner 1981). Their results were replicated in the larger Yale survey (Levin, Klevorick, Nelson and Winter 1987).
14 Key theoretical analyses are Arrow 1962, Boldrin and Levine 2004 and Bonatti and Comino 2011. The major empirical analyses are well summarized in López 2009. For a much fuller discussion of this argument, and the range of relevant evidence see Moir 2013b Chapter 2.
The first-best option for a focused and efficient patent system is to limit patent grant to highly codified inventions with large lumpy R&D costs. This first-best option is denied by TRIPS.

The technological neutrality clause (Article 27(1)) is perhaps the most damaging feature of TRIPS, when considering the design of efficient and effective patent policy. A first step in overcoming the damage caused by this clause would be to limit patentability to technological innovations. At the time TRIPS was agreed, it was clearly understood that software was not patentable subject matter (New Zealand Ministry of Economic Development 2002). TRIPS specifies that copyright is to be provided for software (Article 10). TRIPS also allows exclusion from patentability for protection of "human animal or plant life or health or to avoid serious prejudice to the environment" (Article 27(2)); diagnostic, therapeutic and surgical methods for treating humans or animals; and plants and animals other than micro-organisms (Article 27(3)). Such exclusions were prevalent when TRIPS was negotiated – indeed most countries did not – or had not until recently – allowed patents for chemical and pharmaceutical products. There is no evidence that providing patents for these subject matters increases the rate of invention.

A third issue in what can be patented (patentable subject matter) revolves around the distinction between a discovery and an invention. There are good economic and policy reasons why discoveries are not patentable – and there is widespread agreement that newly discovered knowledge about the laws of nature should be available for all to use. But inventions based on the application of these new discoveries are patentable. Such inventions usually require experimentation and can be costly to develop. Over the past 30 years there have been rapid developments in understanding genetics. A number of countries have and do grant patents over genes, gene fragments, proteins and related aspects of how genes work. These are clearly discoveries and should remain in the public domain. The approach of some patent offices (for example in Australia, Europe and the USA) that the "isolation and purification" of genetic information constitutes an invention undermines patent policy. Recently the US Supreme Court has corrected the US Patent Office and the Court of Appeals for the Federal Circuit (CAFC) advising that patents cannot cover pure genetic information. Although this decision has its limitations, it does undermine the "isolated and purified" doctrine that so many countries, including Australia, adopted to justify granting patents for gene sequences.

Limiting patentability to technological innovations will go some way towards focusing on those innovations where large lumpy R&D costs do actually lead to market failure, without contravening TRIPS. Further, maximising the use of these "TRIPS flexibilities" will ensure that patents are not granted where they are not needed. These flexibilities include excluding all software from patentability as well as methods of medical treatment.

15 The process of taking out a number of secondary patents to extend the patent life of a major new compound. These secondary patents take the form of variations in the compound (such as salts, esters and metabolites); alternative methods of delivery (tablets and capsules; delayed, extended or normal release); different treatments etc (Moir and Palombi 2013).

16 Association for Molecular Pathology v. Myriad Genetics, Inc. 569 U.S. 12-398 (2013). The decision, however goes on to say that complementary DNA (cDNA) can be patented. There are a variety of well-known methods of making cDNA. Any cDNA with the functionality of an existing gene is not genuinely new and should not pass the patent tests of novelty and inventiveness. If cDNA were not identical, diagnostic tests based on cDNA would not work.
Patents were historically limited to technological inventions, but patent statutes rarely specify this. Germany, which undertook substantial research before designing its patent laws, has a fundamental, but **unwritten**, limitation to technology. Bakels notes that the limitation to technical inventions was always considered a rule of customary law (Bakels 2012: 42). This viewpoint is clearly stated in a 1976 decision by the German Federal Court of Justice:

"The patent system is also not conceived as a reception basin, in which all otherwise not legally privileged mental achievements should find protection. It was on the contrary conceived as a special law for the protection of a delimited sphere of mental achievements, namely the technical ones, and it has always been understood and applied in this way."  

17 Pilch provides this translation from the Court’s 1976 Disposition Program decision (Pilch 2003: 293).

For patent policy to be effective and efficient it must as nearly as possible provide patents for inventions which would not otherwise occur, but not provide windfall benefits for inventions which would occur anyway. As noted above a close practical approximation to this policy goal is to focus patents in areas with large lumpy development costs where exclusive time in the market would prevent these costs being recouped. To a large extent a technology base aligns with this goal.

| Only technological inventions are patentable. |
| Things that are not markedly different from things found in nature are discoveries and are not patentable. |
| Inventions based on mathematical algorithms, including all software, should be excluded from patentability as they do not meet the technology requirement. |
| Methods of medical treatment should be specifically excluded within a broad exclusion where inventions are required to protect life, health and the environment. |

It was the pharmaceutical industry which drove the TRIPS requirement of technological neutrality. In a great act of inconsistency this industry successfully lobbied for an extension in the term of all patents to 20 years in TRIPS, then argued for further extensions to offset "regulatory delays". The pharmaceutical industry has thus succeeded in an overall extension in patent term for all technologies, on the basis of argument about their own industry, 18 and then in many nations, including Australia has gained another 5 years, giving a possible 25 years of patent protection.

| Patent term extensions should be resisted. Where they are allowed a condition should be presentation of financial data to government showing that a risk-adjusted return on the R&D investment has not yet been achieved. |

5. **Requiring genuine inventiveness**

If a technological limitation were combined with other features designed to identify innovations which would not take place absent patents, the benefit-cost outcome of patent systems could be considerably improved. Ideally one would require evidence of large lumpy R&D outlays and of high-speed imitation. These yardsticks come far closer to evidence on the underlying market failure that the current thresholds for grant of a patent (novelty, inventiveness and industrial application). Unfortunately these traditional features of anglo patent law are written into TRIPS (Article 27(1)).

TRIPS allows countries the flexibility to define their own standards of novelty, inventiveness and industrial application. Patents are nowadays being granted – in very large volumes – for all kinds of "inventions" that seem quite obvious in the ordinary meaning of that word. The issue of very low patent quality – a mere scintilla of inventiveness – has been well documented (see, for example, Pilch 2003; Lunney 2004; Blonder 2005; Quillen Jr. 2006; Lawson 2008; Lunney and Johnson 2012; Moir 2013b). So

18 Argument, not evidence. The pharmaceutical industry has never tabled data showing they are unable to achieve a risk-adjusted return on their R&D investments without these term extensions.
too has the lack of precision in patent claims, creating substantial uncertainty over what is in the public realm and what is private property (Bessen and Meurer 2008).

There are no empirical data on the distribution of inventions by degree of inventiveness – indeed one of the difficulties with inventiveness as a threshold criterion for the grant of a patent is its subjectivity. However, it seems reasonable to suppose that truly radical inventions are far rarer than those exhibiting only a small degree of inventiveness. Dahlin and Behrens (2005) develop a measure for identifying truly radical patented inventions. In applying their approach to 581 tennis racquet patents they discard measures identifying first 118 patents then 25 patents before settling on a measure which identifies just six patents – around 1 per cent of the total. They find this aligns well with independent evidence.

Similarly there is little information about the distribution of inventions by the quantum of new knowledge they embody. This is despite economists' focus on spillovers from new knowledge as the critical factor justifying intervention in the market for inventions and innovations. Again, however, it seems likely that many inventions would embody a small quantum of new knowledge while only a small number would contain a very large quantum of new knowledge.

For any given set of inventions, those which are radically inventive are not necessarily those which contribute most new knowledge and vice versa. Nonetheless there may be some degree of alignment and certainly it seems likely that the distribution of inventions along either dimension would be skewed towards those that are less inventive and/or contain less new knowledge. A possible distribution is shown in Figure 1.

**Figure 1: Distribution of inventions**

![Distribution of inventions](image)

If the goal of patent policy is to grant patents only for those inventions which contain a benefit to the nation which exceeds the cost of the monopoly provided, then the "inventiveness" standard needs to be set towards the right-hand side of the distribution. The Australian parliament was recently advised that patents were granted only for things that are "a significant advance over what is known or used". Such

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a standard is shown in Figure 2, broken line AA. Only inventions to the right of this line would be granted patents. This standard might also perhaps be close to Dahlin and Behrins' first-cut measure identifying 20 per cent of granted patents as relatively inventive.

But what happens in patent law and administration is quite different. While the process of construing applications involves identifying what is different from existing knowledge (prior art), subsequent steps do not involve either the question "is it inventive?" or "what new knowledge has been contributed?" Indeed patent statutes have imported a different question from case law. The Australian statute\(^{20}\) and the European Patent Convention (EPC)\(^{21}\) state that a patent application is *taken to be inventive unless it is shown to be obvious*. The onus of proof therefore lies with the patent office to show that an application does not meet patentability standards, rather than with the applicant to show that a patent is merited. This presumption of inventiveness sets up the wrong question, shown in Figure 2 as broken line BB. Those applications which are found to be obvious – to the left of line BB – are refused patents.\(^{22}\) This leaves a large set of inventions – those between lines AA and BB – which are granted patents but which do not contribute enough to the community to offset the monopoly costs.

![Figure 2: Distribution of inventions by current and proposed tests](image)

Granting patents to the set of "inventions" which fall between BB and AA means that the spillover benefits will be few (if any) while there will be (possibly substantial) costs in reduced competition, higher prices, and the diversion of resources to finding out "how to do in a somewhat different way what we

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\(^{20}\) The *Patents Act 1990* states "For the purposes of this Act, an invention [application] is to be taken to involve an inventive step when compared with the prior art base *unless the invention would have been obvious* to a person skilled in the relevant art in the light of ..." Section 7(2), emphasis added.

\(^{21}\) "An invention [application] shall be considered as involving an inventive step if, having regard to the state of the art, *it is not obvious to a person skilled in the art*" (EPC, Article 56, emphasis added).

\(^{22}\) Interestingly very few patent offices refuse applications. Where examiners raise substantial problems, there will usually be a series of correspondence. In the end either the applicant gives up (actively, by withdrawing the application or, more often, passively by ceasing to pay renewal fees) or the patent office gives in.
have already learned to do in a satisfactory way" – a policy-induced shift that "would hardly be given highest priority in a rational allocation of resources" (Machlup 1958: 51).

No amount of refinement to the question "is it obvious" will overcome the fact that this is the wrong question and does not work to limit patents to genuinely inventive applications. An example can assist in clarifying. Another subjective dimension is that which runs from ugly to beautiful. Determining a short-list of who is beautiful cannot be done by removing from the set only those deemed ugly.

If the wrong question is currently being asked, there is no point tinkering with its myriad details, from the requirement that the inventiveness judge have no imagination, to the rules determining just what sub-set of existing knowledge is allowable as "prior art". These rules – established by courts rather than through careful policy design – have resulted in systems biased to the grant of uninventive patents, radically affecting the economic impact of the patent system (FTC 2003).

The quantum of inventiveness is essentially a subjective measure, though it can be constrained to a greater degree of objectivity by asking what is the new knowledge contributed. Importantly, inventiveness as a criterion for patentability is based on the distance between the knowledge contributed and the previous existing knowledge. The greater the distance, the more radical the invention. As a consequence there are few usable empirical studies of the quantum of inventiveness. Campbell-Kelly and Valduriez (2005) assess the inventiveness of 50 of the best US software patents against the low standards of the USPTO. While finding only two of these potentially invalid, they comment that they are all only incremental inventions – i.e. that they embody only a low degree of inventiveness.

My research on a small universe of granted patents, identifying the essence of the invention and comparing this to existing knowledge to identify what new knowledge was contributed, found no new knowledge in any of the patented "inventions" (Moir 2013b). My study confirmed that the anecdotes cited by others as evidence of low inventiveness standards are not just anecdotes but are the norm. My work also identifies a range of legal doctrines (policy rules) which drive the standard to low levels. Particularly important are rules about assessing inventions which combine already known elements; applying known processes in (often marginally) different fields; and allowing semantics to trump technology in defining inventiveness. The patent world also includes that surprising feature that something which is not inventive acquires inventiveness if it becomes less (its scope narrows).

An important policy rule that used to prevail in Europe, the USA and Australia was the synergy test. This was that a new combination of known elements had to contain a surprising and unexpected result or give rise to a result that is greater than the sum of the elements to be patentable. This rule still prevails in Europe. But in Australia and the USA it was abandoned in the early 1980s and replaced with a rule requiring documentation that the specific combination was obvious. Without such documentation examiners are not allowed to reject a new combination of known parts as being obvious. In 2007 the Supreme Court partially addressed this new doctrine, advising the CAFC of "the need for caution in granting a patent based on the combination of elements found in the prior art" going on to note that a simple combination of known elements that has predictable results is obvious (i.e. unpatentable).

23 A rule clearly overturned by the US Supreme Court in 2007 (KSR v. Teleflex 127 S.Ct. 1727 (2007)) but still operating elsewhere, for example in Australia.

24 There is a mixed literature on the value of citations, particularly forward citations (citations of the patent of interest in subsequent patent applications). This is well summarized by Moser and colleagues (2013) who present empirical data showing that forward citations are positively correlated with test data on comparative yields for new corn hybrids. Interestingly, their set of granted patents shows (in Figure 1) a distribution of relative yields centred on zero improvement, with a long negative tail. Thus while the forward citations are positively related to relative yields, the patents are often of less productive rather than more productive hybrids.

25 The shift from the synergy to the suggestion test occurred in Australia in 1980 (Minnesota Mining and Manufacturing v Beiersdorf (Australia) (1980) 144 CLR 253). In the USA Lunney and Johnson (2012) trace it to the 1984 ACS Hospital Systems, Inc. v. Montefiore Hospital, 732 F.2d 1572 (Fed. Cir. 1984).

The analogous use doctrine dates from the nineteenth century and was designed to exclude from patentability the simple use of a known thing for a different use for which it is entirely suitable. This doctrine is either defunct or is not being used in Australia and the USA for process applications. There are many famous examples of business method patents which are simply the analogous use of known processes particularly on the internet. For example Amazon's one-click patent simply uses centuries old processes of a customer adding items to an account.

Simple differences in non-technical elements also seem to confer patentable inventiveness. In some cases these are just differences in wording. In the case of one Australian banking patent an invention that was virtually identical to an existing product was patented because it offered benefits not rewards, and because account linking was compulsory not optional. In some cases patents are granted because a human actor is different. A centuries old process for holding goods while checking credit was allowed in the USA because the party undertaking the credit checking was a freight forwarder (shipper). In a patent for sending email alerts for anomalous financial events, the addition of user definition to the anomalous events lifted the invention over the inventiveness threshold.

Another trick in acquiring patents with the low current inventiveness standard is to narrow the scope of the claimed monopoly. Only in the patent world is this surreal outcome possible – that making an "invention" smaller can give it inventiveness that it did not previously have. Examples from my dataset include an expert medical system with the added feature of the server going to stand-by mode once the message has been sent, a system for authenticating access to financial systems where the argument with the examiner was over the location of the encrypted fingerprints, the addition of an interface to a business data mapping invention, and converting dates to binary code for a diary management process.

These examples clearly demonstrate the dysfunctional rules currently used to determine grant of a patent. With such rules it is not surprising that the grant of obvious patents is the norm. Such obvious patents contain no new knowledge. If they dominate the patent system – as seems likely given the rules – they can more than offset any positive benefits from genuinely inventive inventions. They show how the practical application of the scintilla standard allows almost any trivial invention to be patented.

Another shock to the economist when investigating how the patent system works in practice is that the patentability tests of novelty and inventiveness are applied after certain categories of knowledge have been ruled out. Novelty, for example, is tested against only one written document at a time, and a footnote in that document to another document is not sufficient evidence to allow both documents to be used. In the USA and Australia the practice has grown up of defining the relevant technological field narrowly, thus excluding some existing knowledge from the base against which inventiveness is tested.

In the USA examiners must state why a patent should be granted in the Notice of Allowance. Sometimes such statements are uninformative, simply regurgitating large extracts of legalistic claims language. More often they provide an insight into just what element of a clearly uninventive process has allowed the application to pass the inventiveness test. This approach contrasts with that at the EPO where no such statement is required. It is not therefore possible to understand, for example, just what element in shifting words from a dependent to an independent claim suddenly gives an application both technicality

27 Westpac's Integrated financial service product (AU2005204292, priority August 2005).
30 Medical data warning notifying system and method, AU2003281184, priority July 2002.
31 Method of conducting transactions over a network, AU2004203415, priority February 2000.
32 A system and method for representation of business information, AU2004201587, priority April 2004.
33 A method of determining a target event of a reoccurring event, AU2006200104, priority May 2005. All computerised diaries have to convert dates (and all other inputs) to binary code.
34 See Bagley (2001) for evidence in regard to the USA and Welcome Real-Time SA v. Catuity Inc, [2001] FCA 445 (17 May 2001) at 140 for evidence that a well-known IT technique is inventive to persons in the consumer loyalty field.
and inventiveness (see section 7C). Requiring examiners to make a clear statement as to why a patent grant is merited focuses attention on the duty to the public not to grant patents for trivial inventions.

The test for inventiveness needs to be recast into a positive form. The examination process – and any legal wrangles about validity – must centre on identifying the benefit arising from the invention, either in terms of new knowledge contributed or a contribution to net consumer surplus, such as a significant increase in health outcomes. The onus of proof must shift to the applicant to demonstrate that the privilege of preventing competition is merited. Doctrines which excise sets of existing knowledge before applying tests for patentability must be removed. Patent systems can be re-designed to use an inventiveness test set to ensure each granted application would deliver a net benefit to the nation. Such an approach contrasts sharply with the leaked text of the TPPA IP chapter which would provide patents to "any new forms, uses, or methods of using a known product ... even if such invention does not result in the enhancement of the known efficacy of that product." This very low standard would encourage rent-seeking and a shift of resources into the process of patenting rather than into genuine innovation.

Proposals to ensure a strong inventive step requirement

Countries must be free to set the inventive step at a high level. They must have the right to reform the dysfunctionally low "is it obvious" approach replacing this with a positive approach designed to ensure sufficient inventiveness to produce a net benefit from each granted patent. The appropriate threshold questions for patent grant are:

- "what new knowledge or social benefit is contributed?"
- "is this sufficient to provide total benefits which outweigh the costs of reduced competition?"

The onus must rest with applicants to demonstrate that they meet patentability standards. Applications should not be presumed either novel or inventive.

All exclusions from existing knowledge for the novelty and inventiveness tests must be removed: i.e. the whole concept of prior art needs to be abandoned. It is entirely inappropriate to tilt the playing field against the public interest before applying tests for patentability.

The following types of "inventiveness" must be specified as below the threshold for patent grant:

- new uses of known things or processes (including use in new environments);
  → specifically excluding new therapeutic treatments using known compounds
- combinations of known elements or processes
  → unless an unexpected outcome delivers sufficient spillover benefits to outweigh the costs of reduced competition

The higher standard would be reinforced if examiners were required, in authorising the patent grant, to clearly specify the benefit which will pass to the public. This should include a clear description of the new knowledge contributed and how this will create a spillover benefit or a substantial improvement in health outcomes. Such documents should be part of the public record.

These principles do not have nice sharp unarguable boundaries. But nor does the current "not obvious" system. Further the current system has developed built-in complexity, increasing costs for business and the community alike. Over the centuries since ordinary courts have adjudicated on these matters they have systematically avoided making precise definitions of what is patentable. They have developed a number of specific tests, many of which have later been replaced as insufficiently useful. The key issue is

35 Article 8 (http://keepthewebopen.com/assets/pdfs/TPP%20IP%20Chapter%20Proposal.pdf)
that at the end of the day patents should be granted **only when it is clear they have at least some chance of producing external benefits to offset the costs they impose on other firms and on consumers.**

The proposed approach would make it harder for applicants to demonstrate the merit of their inventions. But for genuinely inventive inventions – for example for pharmaceuticals which produce a genuine improvement in efficacy – there should be no difficulty. The intent of these reforms is to eliminate trivial workshop modifications and improvements not to stop the grant of patents for genuine inventions. This approach will clean much of the rubbish out of the system, making life simpler and easier for innovating firms. No longer will firms have to spend large amounts on gaining patents to swap with their competitors so they can all proceed as though the patent system does not exist. These activities simply divert resources away from productive R&D and into non-productive regulatory activity. Where a firm (or individual) has made a genuine advance in technology there should be no difficulty in demonstrating the benefit and gaining the patent privilege.

What would be ideal would be to experiment with approaches along these lines. At present experimentation to ensure that the inventive step balances costs and benefits is actively discouraged, particularly by "Big Pharma" backed up by the USTR. Such experimentation would be useful in developing workable practices to implement the positive "is it inventive enough?" test. It would be ideal if at least a sub-set of countries could be allowed to experiment without incurring trade sanctions. Ideally these would be either countries which have relatively small markets (for example Australia which is two per cent of the OECD market and just one per cent of the global pharmaceutical market), which do not have an embedded tradition of granting patents for every trivial variation (for example India) or countries which can start with a clean slate (new WTO members with no history of patent privileges such as Cambodia and Laos).

6. **Privileges**

The patent system is a very blunt instrument – providing an incentive for one party's invention by allowing the prevention of invention by other parties. Patent policy therefore needs to be carefully crafted to ensure that the privileges granted are well targeted and parsimonious. Privileges that are not needed to create the R&D incentive must be avoided because of the high risk that they will impede invention by other firms and individuals.

TRIPS spells out the privileges which must be embodied in the patent grant. The patent owner must be allowed to prevent third parties from "making, using, offering for sale, selling, or importing" the patented invention unless permission has been granted (Article 28). These are the privileges which were conferred in the late 1800s when a condition of "local working" was the norm in patent systems. Local working required that a patented invention be actually produced in the country. This requirement had the effect of creating pathways along which knowledge benefits could spill over to other firms and craftsmen. Generally if a patent was not worked within a period of (usually) three years, any other party could seek to use the patented invention. Over recent decades local working has come into disfavour as being an implicit form of non-tariff barrier. While there is a certain element of truth in this perspective, this would be more persuasive if the privileges granted had been re-assessed when the local working requirement was removed. With no local working requirement, there will frequently be no benefit to the patent-granting nation. The patent thus becomes a simple rent-extraction device.

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36 The US Trade Representative regularly reports on countries which do not meet US requirements on patenting, threatening these with trade sanctions. In the recent legal dispute between Novartis and the Indian Patent Office over the refusal of a patent which did not provide demonstrated improved efficacy, the USTR has made its displeasure clear and both the EU and the USA have exerted pressure on India to reduce its inventiveness standard to the current low levels applying in the USA and in Europe (R Ramachandran, "Western warnings", *Frontline*, 29:8 [http://www.frontlineonnet.com/fl2908/stories/20120504290801800.htm](http://www.frontlineonnet.com/fl2908/stories/20120504290801800.htm)).

37 Only the right to prevent import is qualified – Article 6 states that, in the context of dispute settlement, nothing in TRIPS shall be taken to address the issue of exhaustion of privileges (parallel importing).
regardless of the returns already made on the R&D investment. It simply leads to income flows from technology-importing nations.\textsuperscript{38} In such situations it is questionable whether a patent system achieves its goal of increased R&D investment. If this effect is sufficiently large – for example in economies where most patented inventions are imported – it can make a nation much worse off. The technology-exporting nation thus benefits from spillovers at home and rent-extraction from overseas – a kind of double-dipping.

An example illustrates. In Australia, where term extensions are regularly granted for pharmaceutical compounds, the situation can frequently arise where a compound is out of patent in an overseas economy but still in patent in Australia.\textsuperscript{39} Generic companies are prevented from making the product for export to the overseas market until the patent ceases in Australia. This situation makes generic companies operating from Australia less globally competitive than those in overseas countries where the patent has already expired. The benefit to the patent owner is small; it ensures that Australian generic companies will be delayed in their local market entry after the patent has expired. This delay – which occurs for a range of practical reasons – is effectively an unapproved extension in the already lengthy patent term.

The core of the privilege conferred on the patent owner is the privilege to prevent others from undermining the higher price that can be charged when competition is restrained. This is the action of selling in the jurisdiction where the patent has been granted. In a world without any local working requirement the only privilege that should be granted by the patent should be the privilege of preventing others from selling into the protected market.

This privilege however raises issues about parallel importing and whether it is appropriate for governments to support specific business models which simply increase prices for their consumers. Where a global company owns patents in a number of countries it is likely to set prices differentially for many of these countries. Such “what the market will bear” pricing models are a long way from the economists’ welfare-maximising world of marginal-cost pricing. One consequence is parallel importing – where retailers act on opportunities to import officially produced goods (ie goods produced with the authority of the patent holder) if they can source these more cheaply. Naturally this undercuts demand for the higher-priced goods sold directly by the patent holder.

Clearly this undermines the profit that can be obtained for the patented product. If the market where this happens is a major market for the patent holder this might reduce profits below those required to obtain a reasonable return on the R&D. This would destroy the patent incentive. But if the market is a small part of global markets, and/or a good return has already been achieved, parallel importing acts to ameliorate the negative impact of patent systems on consumers, re-introducing an element of competition. A solution would be to grant a right to prevent import if (and only if) the product being sold was produced domestically \textbf{and} the company could demonstrate that a risk-adjusted return on their R&D investment had not yet been achieved. This approach would be consistent with the "national treatment" requirements of TRIPS.

The net cost of patent systems was considerably increased by removing local working requirements \textit{without also streamlining privileges}. The preferred approach of limiting the patent privilege to sale would require an amendment to TRIPS. Developing economies – and economies with strongly negative balances on intangibles trade – would do well to flag the desire to amend Article 28 of TRIPS (perhaps under the auspices of WIPO’s Committee on Development and Intellectual Property). The goal would be a system where:

\textsuperscript{38} Australia, for example runs a negative balance on its trade in "intellectual property". IP receipts over the past decade have been of the order of 0.25% to 0.5% of the current account and payments have been two to eight times larger at 1.0% to 1.5% (IP Australia 2013: 22 sourcing data to Australian Bureau of Statistics (2012) Account 5302.0 balance of payments and international investment position).

\textsuperscript{39} This issue was considered in depth by the 2012-13 Australian Pharmaceutical Patents Review (the website for this review was taken down during the 2013 caretaker government period and has not yet been replaced. Please email hazel.moir@anu.edu.au for copies of the issues paper, the draft report and all submissions.)
The sole privilege granted by a patent is the right to prevent sale into the market. There is no right to prevent the import and sale of goods produced legitimately elsewhere, unless the product is locally produced and the patentee can demonstrate that a risk-adjusted return to the R&D investment has not yet been achieved.

7. Incentives, penalties and strategic gaming

A range of incentives and disincentives are embedded in the patent system. These are rarely discussed. For example, it is widely known that the incentive to challenge an invalidly granted patent is far lower than the incentive to sue for infringement. This is due to the fact that if a patent-holder sues for infringement and wins s/he gains all the consequent benefits (damages, costs, payment of license fees and a greater ease in obtaining license fees from other parties). But where an innovating firm finds their business path blocked by a seemingly invalid patent, s/he would bear all the costs and risks of the legal action yet instantly share all the benefits of clearer market access with all other companies competing in that field. There is one exception. The US Hatch-Waxman Act provides an incentive to companies which successfully challenge an invalid pharmaceutical patent – they gain a period of 180 days of market exclusivity for their generic version.40

Another perverse incentive is that while a firm with an invalid patent will be forced to pay legal costs and damages, there is no requirement for firms with invalid patents to repay the profits they have made from these patents unless each party sues individually. This is both inefficient and unfair. As the recent example of the patents over BRACA1 and BRACA2 genes shows, patents can be used for most of their market life before they are found fully or partially invalid. In contrast, where a firm is found to infringe a valid patent, one form of compensation is the payment of all profits derived from this infringement. These clearly asymmetrical penalty structures lead to a situation where there is no disincentive to seeking patents for trivial inventions.

A. Penalties for infringement

Penalties for infringement are well developed in patent systems. Over recent decades there have been changes in the basis on which patent-holders are compensated for infringement, principally in the USA. A major change was access to injunctions shutting down infringing operations rather than requiring payment of an appropriate royalty (Jaffe and Lerner 2004: 111-115). Another is much increased damages payments. Hall and Ziedonis, in interviewing firms in the US semi-conductor industry, found that the demonstration effect of the Kodak-Polaroid case in 1986 and the Texas Instruments case in 1985-86 had made firms very much more aware of patents and their economic impacts (Hall and Ziedonis 2001: 109).

Several decades after it became common in the USA there has been a shift towards prohibiting infringing action as a penalty for patent infringement. Patent policy involves a tension between the economic goal of disseminating new knowledge and technology and the supposed need of a competitive restraint to provide an incentive for its creation. Because of this tension the general approach had been to provide for royalty payments where there was infringing use of a patented technology. This simultaneously ensured a proper incentive for the inventor and the more widespread use of the technology. The precedent-setting penalties in the Kodak-Polaroid case involved an extremely high cost to many innocent parties, particularly those who lost their jobs.

Patent policy is economic policy, designed to encourage investment in R&D that would not otherwise occur. It operates by granting the patentee the right to prevent others from operating in the claimed technological space. Patent policy – like copyright policy – is specified in legislation which gives the authority for parties whose privileges have been breached to take legal action to enforce their rights. It is clear that these laws are civil laws. Any action which undermines the granted rights can cause an economic loss to the privilege-holder – but this is not a criminal matter, it is a matter that should be

40 This privilege is limited to the first generic entrant (see Holovac 2004).
pursued through civil courts. The introduction of criminal penalties into copyright law was an accident of history.\textsuperscript{41} Unfortunately it has spread globally and patent privilege-holders are now seeking its extension to patent policy. There is no sound reason for this. Because of the damage patents can cause to other innovating firms, it is important that infringement penalties be as parsimonious as the privileges granted. They need to be focused on compensation for lost earnings and must avoid damage to innocent third parties (such as employees).

\begin{center}
Patent law is civil law and all penalties should be civil.
As the damage done by infringement is hurt of profits, penalties should focus on ameliorating this hurt. Patent infringement penalties should, to the maximum extent possible, avoid doing harm to innocent parties.
Normal rules should apply, with alleged infringers being assumed innocent until proven guilty.\textsuperscript{42}
\end{center}

B Incentives to maintain patent standards

In contrast to penalties for infringement, little consideration has been given to penalties for attempting to undermine the patent system. In the USA there are penalties for deliberately misleading the Patent Office. More generally "fair basis" rules attempt to limit unfair use of divisionals and amendments. But there are limited penalties for reaping profits from an invalidly granted patent, although this can substantially harm many consumers as well as other innovative firms. Nor are there penalties for undermining the system itself and substituting semantics for technology, pretending software is not software, or pretending that discoveries can be classed as inventions (e.g. DNA).

The lack of penalties for exploiting an invalid patent encourages a form of moral hazard – it creates strong incentives for firms to try to gain patents for "inventions" that fall far short of delivering any benefit. While a firm successfully challenging a patent will be awarded damages, other parties have no cheap or simple avenue to seek compensation. In Australia, for example, a secondary pharmaceutical patent over clopidogrel delayed generic entry by 3 years. A 5-year term extension on the patent was simultaneously invalidated. It has been estimated that the total cost to the Australian taxpayer of use of this invalid patent was some $A540 to 660 million.\textsuperscript{43} There are no mechanisms for the government to seek repayment of this unjustified subsidy beyond the $A60 million accruing during the injunction period (Moir and Palombi 2013: 25).

There is considerable "doctrinal incoherence" (silly outcomes) in the patent system. Thambisetty points to a UK case where the failed challenger of a patent's validity had to pay damages for infringement even after the patent had been revoked after a successful subsequent challenge.\textsuperscript{44} This is economic policy gone mad.

When tax is erroneously under-estimated there are well-established mechanisms for this to be repaid (including with penalties depending on the circumstances). When social security payments are made in error, these are recouped from the recipient. Providing a parallel mechanism for ensuring that patent-holders do not benefit from unjustified monopolies would substantially change the incentive for firms to seek more and more patents for trivial "inventions". It would also ensure any unjustified profits would be repaid.

\textsuperscript{41} See Boldrin and Levine (2008, chapter 2, pp32-33) for an account of the disruptions caused by private actions to enforce new copyright privileges in respect of sheet music. This led to a new copyright law in 1902 which for the first time made copyright violation a criminal offence.
\textsuperscript{42} Unfortunately the TRIPS Agreement includes a reverse onus of proof in respect of pharmaceutical process patents (Article 34).
\textsuperscript{44} Coflexip v Stolt Comex [2004] FSR 7 (Ch (Pat Ct)) and [2004] FSR 34 (CA) see Thambisetty 2009: 23.
Patent statutes should specify clear mechanisms to fully recover profits earned from products based on invalidated patents.

Jensen and Webster (2004) analyse the systems-wide effects of how administrative errors can impact on patent systems. They identify as Type I errors those cases where a "desirable" application is rejected and as Type II errors those cases where a "bad" application is accepted. A "bad" patent is one which would happen anyway or where there are insufficient spillover benefits to offset costs. A "good" patent is one contributing new knowledge from which other firms and inventors can benefit. Type II errors are far more likely when the inventive step is low. An important related issue is who bears the cost of correcting administrative errors?

With Type I errors – most likely when the inventive step is high – a "good" patent is rejected. In this circumstance it is the applicant who bears the cost of seeking a review. All jurisdictions provide substantial opportunities for rejected patent applicants to challenge an unfavourable decision. With Type I errors it is the party seeking the monopoly privilege who bears all costs and risks of seeking a second opinion and who will gain the full return if successful.

In contrast, where the inventive step is low and Type II errors are more likely, it is innocent third parties who bear the costs of dealing with incorrect decisions. As noted above a firm affected by a dubious patent faces a poor risk-return trade-off for the option of challenging patent validity. It makes sense for such a firm to "fly under the radar" with respect to dubious patents, arguing these out-of-court, or counter-suing for invalidity if formal infringement proceedings are brought. With current incentive structures public policy cannot rely on affected third parties challenging invalid patents and so maintaining high standards in the patent system. There is nothing in the system to prevent the standard from falling and falling.

This situation could be radically changed if patent holders were required to repay all profits ever earned from any patent declared invalid. After reimbursing the challenging firm for legal and other costs in mounting the challenge, the balance could be shared between the challenging firm and agencies representing competition and consumer interests. It is, after all, consumers and competitors who bear the costs of the patent system.

Introduce clear mechanisms for patent holders to repay all profits made from products underpinned by patents which are subsequently found invalid: Share these repaid profits between the successful challenger and consumer and competition advocacy bodies.

Outside of pharmaceutical patents, the incentive to challenge bad patents has been particularly low in the USA where granted patents have a presumption of validity. This adds substantially to the costs and risks of a third party challenger. The Australian patent statute expressly states that there is no presumption of validity in the fact that a patent has been granted. Despite this a Federal Court judge has recently qualified this express disclaimer stating that “[r]egistration of the patent is, of itself, prima facie evidence of validity.” Again this indicates that (some) judges have little hesitation in changing the law, regardless of the express wording of the statute. As Quillen noted in relation to judicially determined extensions to patentable subject matter in the USA such judicial policy-making occurs "without any inquiry into the facts" or the public policy implications (Quillen Jr. 2008: 71). When policy is made in this manner it is no wonder it creates unbalanced sub-optimal outcomes. A reminder from the responsible Minister that this misreads parliamentary intent would be appropriate.

In the USA a granted patent is presumed valid, while there is no such presumption about a claim to infringement. This means that the standard of proof required for the alleged infringing party is higher

45 “Nothing done under this Act or the PCT guarantees the granting of a patent, or that a patent is valid, in Australia or anywhere else.” Patents Act 1990, Section 20(1).

"clear and convincing evidence") than it is for the patent-holder ("preponderance of the evidence"). History shows that patent offices tend to grant many patents which courts subsequently find invalid. Quillen (2006) reports on a 1980 study – prior to the shift to presumed validity – by Koenig (1980) which calculated that US appeal courts found nearly two-thirds of patents challenged for validity were in fact invalid. This is an extremely high error rate. Patent offices work closely with those who seek patents and those who assist would-be patent-holders. But they have little contact with innovating firms which are harmed by the grant of invalid patents. These factors probably underlie problematic outcomes such as "Swiss medical claims" where the Swiss Patent Office designed a set of words which could be used to undermine the clear intent of the EPC (see next section). As noted above the system is biased against the challenge of trivial patents. Given these factors, it is not surprising that patent offices tend to err towards the grant of invalid patents rather than the protection of the public from trivial patents. Given the high likelihood that patent offices will inappropriately grant patents for trivial inventions, it is important that the standard of proof required to demonstrate that an "invention" is neither novel nor inventive be set at a sensible level.

No granted patent can be presumed valid.

C Strategic games playing: semantics

The lack of clearly thought through incentives and disincentives in the patent system combines with the (possibly deliberate) lack of policy-oriented data to ensure substantial strategic games playing. Such games range through the deliberate flouting of authorising legislation (for example "Swiss medical claims") through evergreening to frequent but low-level games where semantic inventiveness replaces technological inventiveness.

When one starts studying the patent system one of the first striking aspects is its peculiarly archaic language. "Art" is used to mean technology, though "prior art" means allowable existing knowledge. If judges used modern language – such as technology for technology – might they have been more circumspect in extending patent privileges to fields such as business methods? Certainly business is an art, but it is not a technology in any normal sense of the word. Members of the patent community strongly resist attempts to modernise the language. It appears that continued use of archaic language is integral to the complexity which puts outsiders off enquiring too closely into the costs and benefits of the patent system. For example using the phrase "prior art" for "allowable existing knowledge" hides the limits placed on existing knowledge before the novelty and inventiveness tests are applied. Indeed in a recent Australian case the judge discounted evidence by experts for the infringing party on the basis that they did not understand the meaning of the word obvious as it is used in patent law.

All patent terminology should be current commonly used language and all words should take their ordinary meanings.

While semantic problems bedevil rules and procedures, arguments about shades of meaning in words are also frequently found during the examination process. Such complaints are not new, but remain unaddressed. Edwards, for example, comments that: "[a]s it reaches the patent office the application combines technological and legal invention, and the latter, if of superior quality, may do much to offset deficiencies in the former" (Edwards 1949: 218). My own empirical work has focused on business method patents, which not being a technology might be more subject to such linguistic arguments. Nonetheless the examples found there are startling. In three out of four cases where the European Patent Office (EPO) granted a patent for the proposed business "invention" the application was initially rejected as not technically inventive. But when specific words were moved from dependent to independent claims suddenly a patent was granted (Moir 2013a). Unfortunately EPO examiners do not have to give any reason for grant of a patent, so one cannot interrogate the underlying thinking.

Certainly from a policy viewpoint there can be no benefit to the public in the grant of a patent where "inventiveness" is based on narrow shades of linguistic meaning, or which claim they are in, rather than genuine technological invention. Recommendations have been made above (Section 5) to prevent semantics replacing technology and knowledge as a basis for patentability.

Some types of semantic inventiveness are used at a strategic level and have system-wide impacts. For example the EPC limits the patentability of methods of medical treatment. But the EPO grant patents for the first medical use of a known substance. This seems at odds with the wording of Article 53:

"European patents shall not be granted in respect of: ...
(c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods."

Clearly Article 53 allows pharmaceutical products to be patented, but equally clearly, at least to the non-lawyer, it excludes patents for specific medical uses of pharmaceutical products, as these are prescribed for therapeutic treatment. Setting aside this conundrum on patenting first medical uses, Thambisetty indicates that "as a response to pressure from the pharmaceutical industry the EPO was interested in extending patent product protection to second medical use of known products" (Thambisetty 2009: 17). She provides an example of the minor variation in wording designed by the Swiss Patent Office to overcome this exclusion (a technique known as "Swiss medical claims"). This comes very close to those who are supposed to uphold the law taking action to undermine it. It is possible in large part because the patent system's deliberate complexity hides it from proper accountability and evaluation mechanisms (see next section).

Some of the decisions of the quasi courts of the EPO (the Technical Boards of Appeal) involve at least substantial mental gymnastics – though some consider the EPO "outright violates the European Patent Convention" (Bakels 2012: 2). Such semantic games have been roundly criticised by UK courts. In the most strongly worded of these admonitions, Prescott J stated that "[y]ou are not allowed to get round the objection – that you are attempting to patent a computer program – by claiming it as a physical artefact, a mere change of form."

Stepping back from the patent system one is reminded of the "creative accounting" of the late 1970s and early 1980s that allowed payment of tax liabilities to be discretionary for many of those with highly trained tax lawyers. The public revulsion over the existence of choice in the payment of tax led to a substantial degree of reform with overarching principles trumping specific rules. Thus "anti-avoidance" principles deem specific financial arrangements void for tax purposes if their principle purpose is to avoid payment of tax. The semantic games in the patenting industry seem designed to obtain patent monopolies for trivial "inventions". They could be addressed with similar approaches.

Anti-avoidance principles developed to reduce taxation liabilities should be investigated and adapted for use in patent systems. In particular the technique where over-arching principles trump specific rules could usefully be investigated.

8. Transparency, evaluation and audit

One reason economists are so reluctant to endorse regulatory interventions in markets is that such interventions create the opportunity to benefit financially from how the rules are shaped. This encourages beneficiaries to lobby to change the rules even further in their favour. Classes of agents (such as patent attorneys) grow up to argue which side of the regulatory boundary their client should be on. These agents also develop vested interests. In the USA they persuaded Congress to drop a proposal

49 In the matter of Patent Applications GB 0226884.3 and 0419317.3 by CFPH L.L.C, [2005] EWHC 1589 (Pat) at 36.
50 Important rules for preventing abuse of complex systems where there are substantial pecuniary awards from undermining the system are discussed by Braithwaite (2005: 144-155).
to investigate the real-world impact of granting patents for business methods. The consequent risk of regulatory capture creates a vicious cycle favouring sectional interests rather than the public good. The patent system is an excellent example of this. The patent system has developed into a complex legalistic system where even those meant to uphold the law openly undermine it. "Swiss medical claims" are named after the patent office which designed them (Thambisetty 2009: 16-17).

There is no tradition of proper oversight of the activities of patent offices from a competition perspective. Patent offices are usually located in industry portfolios making them particularly susceptible to regulatory capture. Formal statements from patent offices suggest they do not see consumers or non-patenting innovators among their "stakeholders". Several well-informed students of the patent system suggest that patent offices have become part of an in-grown self-reinforcing community impervious to (and generally unaware of) the evidence as to possible negative impacts from the current "strong" system (Thambisetty 2009; Drahos 2010). To offset these continuing pressures patent systems need clear built-in systems for effective oversight, including audit and evaluation.

Introducing clear stated objectives into patent statutes (Section 3) will assist in improving transparency and accountability, provided these are properly designed and make clear the goals and balances needed to achieve positive economic outcomes. Without these it is not surprising that an inward-focussed community can head in an economically dysfunctional direction.

Complexity needs to be substantially reduced. This would open the system to proper democratic oversight and minimise room for strategic games. The patent bargain is simple – a patent should only be granted for a technological invention which has substantial spillover benefits and where R&D costs are large and lumpy. Eliminating the current complex obviousness rules – and replacing these with the right question, "is it inventive?" – will go along way towards implementing this (Section 5). So too will use of simple modern words such as technology and allowable existing knowledge. At a system level it would be useful to return to the original language used to describe the privileges granted by a patent. They are not rights. Nor are they property. They are privileges designed to induce a higher level of investment in genuine R&D.

**Collect data on the impact of patents**

An entirely unacceptable aspect of patent systems, given that they have been a tool of economic policy for several hundred years, is the lack of appropriate data on patent use and patent costs for improving the design of patent policy. There have been recommendations to collect such data but these have rarely been implemented. Indeed there are suggestions that well-organised beneficiaries of a "stronger" patent system have actively undermined such proposals. It seems quite extraordinary that governments hand out thousands of monopolies yet collect no data on their use.

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51 The American patent bar lobbied successfully to prevent the US Government Accountability Office (a highly respected research body) from undertaking a study of business method patenting. This had been part of the penultimate draft of the *American Inventors Protection Act 1999* but was removed in the final statute (Kahin 2003).

52 "Strong" in this context means strong rights for patent-holders and very weak protection for consumers and competitors.

53 Machlup and Penrose (1950: 16-17) demonstrate that the term "property" replaced "privilege" during the French revolution. Those drafting the declaration of the rights of man wished to retain their patent and copyright privileges and were conscious that the existing "privilege" terminology did not sit well with the new human rights agenda.

54 For example collection of use data at the time of patent renewal was recommended in 1984 in Australia (IPAC 1984: 10). This recommendation has never been implemented. Yet in his speech at the first Pacific Rim Innovation Conference (January 2010), the Director General of IP Australia (the body within which the Australian patent Office lies) went on the public record regretting the lack of data on patent use.

55 Examples cited by Kahin (2003) have been provided above. Bessen and Meurer (2008, p.293-4) comment that the Federal Trade Commission (FTC) recommendation most prominently rejected by the Intellectual Property Owners Association (dominated by patent lawyers from large firms) was recommendation 10 "expand consideration of economic learning and competition policy concerns in patent law decisionmaking."

56 And never have, except for a brief period in Canada following the Firestone (1971) review.
Little of the reams of data on patent applications provided by patent offices is useful for policy purposes. None give any insight into how the granted monopolies are used.\(^{57}\) It would be a very simple administrative procedure – virtually tick-a-box – to require at least some data on use as patents are renewed. While this might be onerous for companies who own many thousands of patents,\(^{58}\) if the system is to be based on evidence rather than myth, then such data are essential. An alternative which would be cheaper for frequent patenters, though it might disclose more information, would be to require advice to the patent office before any legal action was taken to enforce a patent.

The leaked IP chapter requires, in Article 12(2), promotion of "the collection and analysis of statistical data and other relevant information concerning intellectual property rights infringements as well as the collection of information on best practices to prevent and combat infringements."\(^{59}\) This is very one-sided and again points directly to the authorship of this text – although it was presented by a government it was clearly drafted by patent-holders and shows none of the balance one expects from government text. What we desperately need are proper data on patent use and the costs of this use. Infringement is a minor issue in comparison.

Despite the lack of policy-relevant data from the patent system, there are substantial data from surveys of industrial innovation and these throw considerable light on the role and importance (or lack therefore) of the patent system. These are well reviewed elsewhere (López 2009). What is surprising is that National Innovation Surveys do not fully replicate the questions asked in the Yale and Carnegie-Mellon surveys. Nor do they thoroughly build on that body of work. One critically important omission is data on how innovating firms are affected by the patents that other people own. The issues of blocking and hold-up patents are widely understood to be important policy questions. Yet we collect no data. And although we know a tiny percentage of patents provide the vast bulk of returns we do not, for example, have good empirical data on the costs and returns from pharmaceutical patents.\(^{60}\) Another important omission is data on the cost of copying. Mansfield and colleagues (1981) did the initial empirical work on this issue and it was replicated in the Yale survey (Levin, Kleverick, Nelson and Winter 1987). Since then there has been no new empirical work despite the importance of the cost and speed of copying as a motivating factor for the patent intervention. This is unfortunate as new technologies (such as computer-aided manufacture, computer-aided design, "maker" technology and 3-D printing) and new economic players (China, India) may have changed the time and price of copying.

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\(^{57}\) Indeed in Europe (certainly using the UK and EPO search systems) it is not possible for an innovator to search a particular technology area (whether by technology class or keywords) and obtain a list of all patents currently valid in that country. The esp@cenet database will not return more than 500 entries and does not allow searching by grant status. The European Patent Register will return all hits, but also does not allow limitation by grant status – each returned case has to be searched individually by legal status to find which have been granted and are in force. This seems an extraordinary abrogation of the implicit duty of patent offices towards innovating firms.

\(^{58}\) IBM, for example has acquired more than 67,000 patents in the last 20 years (Frier 2013). However about half these have ceased and many of the remainder are simply the same "invention" patented in a number of countries. A relatively small number of companies own a relatively large proportion of all granted patents. The 300 most frequent patenting companies owned 45 percent of patent grants in the period 1990 to 2001 in each of Australia and the USA – on average 206 patents in Australia and 2190 in the USA (calculated from Moir 2008: Table 2).


\(^{60}\) Though the recent European Commission study into the pharmaceutical industry places some rather large numbers on the losses to taxpayers of the strategic games that "Big Pharma" plays with regulatory bodies, including patent offices (European Commission 2009).

Develop new questions for National (Community) Innovation Surveys to directly address issues relevant to the role of patents in promoting technological innovation. In particular address issues of technological hold-up or diversion, the costs of defensive patenting and the speed and cost of imitation.

Regular audit and periodic evaluation

The patent system seems to have had a remarkable ability to escape review, evaluation or audit since the US Senate enquiry of 1958. This is despite the trend towards greater evaluation of government programs across all beneficiary groups. One reason for this is that it is not an budget-funded (outlay s) program. Like tariff barriers, the costs are distributed across the economy. But unlike tariffs, the costs are not readily amenable to quantification, and relevant data are difficult to obtain.

The development from the mid-1980s of a "stakeholder" culture was intended to increase the sensitivity and responsiveness of government agencies to the groups affected by their actions. Unfortunately this reform has simply embedded regulatory capture, with revolving doors between patent offices, patent attorney firms and frequent users of the patent system. The patent community – patent offices, patent attorneys and frequent patenters – has developed into an isolated cultural community unaware of the broader research and findings on industrial innovation. But governments have a responsibility to the whole nation. Breaking this inward-looking culture could readily be achieved by moving patent offices from industry or legal portfolios to agencies charged with promoting competition. This would ensure that the "stakeholder" definition was broadened to include, at a minimum, consumer interests and competitive voices (for example the generics medicine industry).

In countries new to patenting, where the bulk of the applications are for pharmaceutical products or processes, relevant competition and public interest issues will most likely be handled by the health ministry. In such situations the objectives of ensuring balance between the incentive and competition elements of patent systems might best be achieved by locating patent offices in the ministry of health.

Regular economic evaluation would further strengthen a more balanced approach to the grant of patent privileges. This would need to be undertaken by economists independent of the patent system and its beneficiaries. Organisations such as the US Government Accountability Office (GAO) are precisely the kind of independent bodies that should be charged with such evaluations. It was however precisely this independence – phrased as "they are not properly qualified" – which led to the American patent bar lobbying to prevent the GAO from being mandated to undertake a study of business method patenting.

Any attempt to set up an independent evaluation of any part of the patent system immediately leads to cries of lack of representativeness. For example the Australian Federation of Intellectual Property Attorneys of Australia (FICPI) took issue with balance of the independent panel established to review the pharmaceutical patent system in Australia in late 2012, as "there is no representative on the panel who is representative of the interests of the innovation based pharmaceutical industry." Yet when

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62 In Australia the patent office (IP Australia) is part of the Department of Industry and Innovation. In January 2008 their Minister commissioned a major review of Australia’s National Innovation System (Cutler et al. 2008). In 2008 IP Australia’s advisory body was charged with reviewing what subject matter should be patentable and their issues paper was released in September 2009 (ACIP 2008). Members of the National Innovation System (NIS) review team were unaware of the ACIP review and the ACIP review team was ignorant of the NIS review – until I took action to cross-inform them. This shows how isolated the patent community can be, even from the innovation community.

63 Personal conversation with a senior representative of the American patent bar, March 2011. See footnote 51.

determining regulatory policy a fundamental issue is that "one must look further afield than those involved in and regulating an industry when canvassing opinions regarding changes in public policy" (Beggs 1981, p.44). It is precisely this requirement for independence that the "stakeholder" groups do not understand.

There is a place for sectional interests to lobby elected governments, but it should not extend to preventing the type of independent review and evaluation that forms the basis for sound public debate.

As well as regular evaluation there should also be a system for independently auditing the inventiveness standard being implemented by the patent office. As discussed above the incentives to ensure independent review of possibly erroneous decisions are weak. Further, in at least some countries, judges have shown themselves to be poor defendants of the public interest in patent systems. Periodic independent review of applications in specific fields (including both grants and borderline rejections) by experts would do much to ensure that the new higher standards were maintained.

| Undertake periodic independent economic evaluation of patent policy outcomes and the net impact on the economy; |
| Undertake a regular program of review of patent office decisions by experts in particular technology fields |

9. Conclusions

These proposals are put forward as policy standards designed to ensure that patent systems do what they are intended to do – encourage technological invention that would not otherwise take place. They are also designed to ensure that patent systems provide benefits to users of technology and discourage rent-seeking behaviours. They are placed on the table to encourage debate and discussion about the fundamental principles needed to ensure patent systems enhance rather than reduce national economic welfare.

Since their earliest days international treaties on patents have been largely drafted with the interests of large business in mind. This has been most obvious with TRIPS and the later TRIPS-Plus treaties. These treaties have created substantial problems for civil society and indeed for sovereign governments. Particular concerns have been raised by the health sector.

The objective in this paper has been to identify a set of minimum standards which more closely reflect the interests of technology-importing economies, many of which are also developing economies. In such countries the imbalance of TRIPS and TRIPS-Plus rules are clear. There are few protections against rorting the patent system. Where national innovation capacity is low, this simply leads to transfers from consumers to foreign companies with no offsetting benefits. Foreign companies are able to acquire domestic monopolies without there being any commensurate spillovers benefits to domestically-located firms. These revenues assist in transfer pricing allowing local subsidiaries of such companies to avoid paying a fair share of domestic taxation.

Some one hundred years ago, when today’s high income countries were developing, patents were far less frequently granted, were limited to genuine technological inventions and required more substantial inventiveness. They had a far less deadening effect on local innovation. It is ironic that as the pace of innovation has increased, and innovation has become a normal part of commercial life, the standards required to obtain a monopoly for such innovation have fallen to very low levels. Apart from the injustice of forcing this neo-colonial set of regulatory rules on others, the TRIPS deal also appears to have been a Faustian bargain. In exchange for agreeing to these regulatory interventions to reduce competition and restrain trade developing nations expected to achieve better market access in agriculture and textiles.

and an end to "punitive measures under the U.S. Trade Act Section 301" (Scherer 2006: 39). The former were very slow in coming and the latter has still not occurred.

The proposals set out in this paper are made from an economic perspective. They are based on the view that patents form an important part of innovation policy, being designed to draw resources into technological innovation. A further major assumption is that only where the induced innovation creates spillover benefits larger than the costs of the reduced competition should a patent be granted. Unless a patent system delivers on these two criteria it will act to reduce economic welfare in any economy. As most patents in technology-exporting nations are held by overseas entities (for example some 92 per cent of patents granted annually in Australia) such a patent system will be a major impost on the current account balance and is unlikely to contribute anything to the development of domestic industrial capacity. Patent grants in Vietnam, Malaysia, Singapore and Thailand are largely owned by non-resident entities (see Figure 1).

![Figure 1: Proportion of granted patents owned by non-residents, 1997 to 2011](image)

In the immediate post-TRIPS environment the EPO has played a large role in assisting economies new to the patenting world to establish patent offices. In doing this they have transferred mental models appropriate to European economies. Drahos considers that overseas aid in establishing local patent offices has integrated them "into a system of international patent administration in which the grant of low-quality patents by major patent offices is a daily occurrence" (Drahos 2007b: 4). Drahos queries whether this model serves the interests of developing economies. But there is no off-the-shelf patent model that does serve the interests of developing economies – or even of technology-importing developed economies such as Australia, New Zealand or Singapore. This paper is a first step in doing this.

In summary the suggested position on patent policy for a developing economy is that the first-best option is that restraints on competition and trade should not be included in "free trade" negotiations. Unfortunately this preferred option is now precluded by the outcome of the Uruguay Round. Subsequent post-TRIPS "trade" treaties have further reduced national sovereignty in managing domestic policy to support innovation.

As a second-best approach the set of principles outlined here would protect developing economies from the worst effects of importing the dysfunctional patent systems currently in use in jurisdictions such as the USA, Australia and Europe. While the principal need for reform is in the critical areas of inventiveness and technology, no reform package will succeed unless it also addresses the substantial gaming behaviour encouraged by the current system. If the focus on semantics rather than substance is not addressed then other reforms will fail, for the very reasons the current system has become so unbalanced. Because patent policy is delivered through courts and quasi-courts it may become necessary to introduce additional elements to monitor court compliance with parliamentary objectives.
The following components are designed to achieve a targeted, balanced system which maximises the incentive to invest in genuine R&D while minimising the negative effects on innovation, competition and public welfare:

- A clear objectives statement that focuses solely on the economic goals and balances;
- Limitation to areas of technology (to proxy large lumpy development costs);
- Countries should be free to set a high inventiveness requirement → no patents for new combinations or uses of known elements;
- Presumptions should favour the public interest, with applicants being required to demonstrate why a patent should be granted;
- System-wide processes to reduce complexity and strategic gaming to ensure patent policy cannot be undermined (including abandoning archaic language);
- Infringement penalties to align with policy goals → minimise collateral damage; no criminal penalties;
- Recovery of all profits where patents are found invalid;
- Collection of data that will assist in evaluating patent policy; and
- General oversight, audit and evaluation provisions.

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