

Patent policy principles for the Trans Pacific Partnership Agreement

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A balanced patent system is designed to encourage those inventions *which would not otherwise occur and where the social benefits exceed the social costs*. "Strong" IP means strong barriers to competition. The goal should be minimal disruption of competition consistent with achieving the policy goals. That is, patent policy must be consistent with Article 5 of the Competition Principles Agreement. This can be achieved with a patent system with the following elements:

- A clear objectives statement that focuses on the economic goals;
- Limitation to **technology** (to proxy large lumpy development costs);
- A requirement for a **significant** contribution of new knowledge (inventive step);
- Presumptions in favour of the public interest, with the onus resting on the applicant to demonstrate the benefit which would justify a patent grant;
- Improvements to remove complexity and strategic games playing – reducing the extent to which patent policy goals are undermined by rights-holders;
- Infringement penalties aligned with patent policy goals;
- Simple procedures for the recovery of all profits where patents are found invalid; and
- General oversight, audit and evaluation provisions, including collection of data that will assist in evaluating patent policy.

A more detailed statement of these principles is at page 8.

Disclaimer: These views are my own and do not represent the views of any other body or institution.

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Patent policy principles for the Trans Pacific Partnership Agreement

"Free" trade and restraints on competition: the background

It is a marvel of spin-doctoring that government restraints on competition are included in, and indeed made worse through, "free trade" negotiations.

Since the Uruguay Round most "free trade" agreements have included "intellectual property rights". These cover patents, copyrights, trademarks and a variety of other restraints on competition. It is well known that the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was drafted by large global businesses (Drahoš 2002; Sell 2003). More recent "trade" agreements usually include a TRIPS-plus agenda. No substantial evidence has ever been put forward that patent or copyright systems (let alone global trade marks) improve overall economic performance.

These "trade" 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.¹ 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.²

This secrecy makes it essential that civil society and democratic governments develop their own agenda for such legislated monopolies and debate these publicly. This paper sets out an alternative agenda for a patent system that would operate to benefit any nation, but particularly nations such as Australia (and many of our trading partners) who are technology importers.

One of the great authorities on innovation, Ove Granstrand, has concluded from decades of research and study that "the patent system ... has been neither necessary nor sufficient for technical and/or economic progress at country and company level historically" (Granstrand 1999: 44). Encaoua and colleagues suggest that if the policy interest is the incentive to invest in research and development (R&D), then patents should not be the default policy choice (Encaoua, Guellec and Martínez 2006). Boldrin and Levine (2004) suggest patents should be used only when the R&D investment is large and indivisible. Dutton (1984) and Mandeville (1996) both concluded that the most balanced (welfare-enhancing) patent policy was a "weak" patent system. Winter has demonstrated that both R&D investment and total surplus would be higher without patents (Winter 1993). More recently, in analysing situations where governments subsidise R&D and where imitation takes time, Bonatti and Comino (2011) also find that economic outcomes are improved by the absence of patents.

The first-best option would be to exclude any form of artificial restraint on competition, whatever the supposed benefit, from this treaty. That is, the preferred outcome of these negotiations is no IP chapter. This is consistent with the recommendations of the Productivity Commission (2010: 264).

Based on past evidence – the AUSFTA – Australia is unlikely to take such an evidence-based position. A set of second-best proposals are put forward here. They take as a given that there will be an IP chapter, and seek to minimise the damage such a chapter could cause. Such damage principally lies in tying the hands of this and all future governments with respect to policy reform in the domestic arena.

¹ 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.

² 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." The focus on efficacy indicates the origin as the pharmaceutical industry. For a copy of the leaked intellectual property chapter see <http://keepthewebopen.com/assets/pdfs/TPP%20IP%20Chapter%20Proposal.pdf>.

Objective of these proposals

These proposals draw on the substantial empirical evidence that can be used to inform patent policy. They are designed to encourage domestic innovating firms without incurring the large deadweight losses of the current system. The proposals cover 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. These are put forward as policy principles rather than negotiating text.

The proposals also stand firmly on the well-known empirical finding that the major benefits of trade treaties derive from what you give away, not from what you gain (Armstrong 2012: 1641). That is, it is domestic reform, particularly reductions in restraints on competition, that generate the largest gains to the economy – these gains flow through the cost-structures of many firms. Gains from such reform are wider and larger than the gains to the few exporting firms who may obtain increased access to overseas markets. Similarly with patent policy. Reforms to patent policy which insure that it aligns with Article 5 of the Competition Principles Agreement will maximise the consequent economic benefits.

The major gains from trade are from what you give away.

It is the consequent domestic reform and increase in competition which leads to improved economic outcomes from trade negotiations.

The direct objective of patent policy is to induce *technological* invention **that would not otherwise take place**. Further, the induced invention **must have spillover benefits** (benefits not capturable by the producer) **such that total benefits (private benefits plus spillovers) exceed the cost of the restraint of competition**. If this occurs then the dynamic efficiency gains from patents will exceed the static efficiency losses.

There is, however, a complication for technology importing nations. In such nations most patents are held by overseas entities (92% in the case of Australia). The requirement that patented inventions should be produced in the domestic economy (local working) was eliminated through TRIPS. But if patented goods are imported, there are no pathways through which spillovers of new knowledge can flow to other firms. Unless there is some other kind of benefit – the most important of which would be a substantial improvement in health outcomes – then the grant of a patent for a good produced overseas will never be in the granting country's interest. Patent grant will simply cause a flow of funds from citizens and taxpayers to foreign corporate entities. Further many of these corporates use high royalty and licensing payments to overseas affiliates to minimise their taxable income. There is thus a further loss to citizens, an unjustifiably low taxation contribution from such corporates.³

Agreeing to bind our current extremely low standards forever would prevent essential future reform. **This is a very high price to pay for improved market access for selected goods**. Indeed it appears that market access issues have yet to be seriously discussed, though agreed text is reported to have been completed for 18 of 21 chapters – all presumably dealing with non-trade issues. This appears to be a regulations treaty not a trade treaty.

If this agreement is about regulation rather than trade, it is unsurprising that members of civil society are highly dubious about any benefits. Proceeding with such a treaty will add to distrust between citizens and our government. Non-trade chapters bind future governments in ways that run directly counter to domestic economic reform, including the regular review of anti-competitive legislation and regulations required under the Competition Principles Agreement. They could thus prevent the kind of domestic reform that lies at the heart of the benefits that can be derived from genuine trade agreements.

Because patent policy is riddled with "spun" language – where technology is referred to as art and a restraint on competition is called "protection" one must anchor discussions in a clear understanding of the

³ This effect is also particularly noticeable with respect to copyright and trade marks, with enterprises such as Amazon, Starbucks, Google and Microsoft paying very little tax in many jurisdictions.

objectives of patent policy. Advocates of the type of text previously put forward to the TPPA call their proposals "strong IP protection". But when one analyses the details the proposals are for even lower hurdles for firms to pass before they get the government's backing to eliminate their competitors. Article 8(1) of the leaked draft is a prime example.

"Strong" IP means strong barriers to competition.

Artificial deadlines are a strategy used by stronger parties to maximise their gains. We should resist them.

Negotiating fatigue is a real phenomenon and overwhelms smaller parties to international negotiations (Drahos 2007). It is used as a strategy by well-resourced parties – particularly the USA and the European Union – to the detriment of smaller nations. As a relatively well-resourced smaller nation, Australia should stand up against such unfriendly tactics and should clearly resist the pressure imposed by the USA to reach agreement by the end of 2013. This artificial deadline is quite unnecessary and is designed only to force smaller nations to pay too high a price for limited market access gains.

Maximising innovation and minimising harm: patent policy for treaties

Patent objectives

These proposals are based on the view that patents form an important part of innovation policy, being **designed to draw additional resources into domestic technological innovation**. In general it is not economically sensible to intervene in markets to change the allocation of resources – well-functioning markets are better able to do this. Further, such interventions often only benefit sectional interests. This is why Article 5 of the Competition Principles Agreement is so important.⁴ Interventions should not take place unless it can be demonstrated that this will lead to a general improvement in outcomes, and there is no more efficient way of doing this.

However it is generally agreed that technological intervention differs from intervention in other markets. This is because it is widely thought that technological invention has substantial spillover benefits, principally through new knowledge and know-how that flows to other firms in the economy. These spillovers give rise to dynamic efficiency benefits. If these are substantial they will outweigh the costs of the reduced competition and it will make sense to have a patent system.

But there must be sufficient spillover benefits so that the dynamic efficiency gains exceed the static efficiency losses. Otherwise the net effect of a patent system will be negative.

The objective of a patent system is to encourage technological innovation that would not otherwise occur; and which provide social benefits greater than the cost of the restrained competition.

Patentable subject matter

The first-best option for a focused and efficient patent system would be to limit patent grant to highly codified inventions with large lumpy R&D costs. It is in such conditions that there may actually be a need for, and national benefit from, the grant of a patent. This first-best option is denied by TRIPS which mandates no discrimination between fields of technology. This is perhaps the single most damaging aspect of the TRIPS treaty. It runs counter to every sane principle of industry and innovation policy. A second-best option is that *patents should be limited to technological innovations*.

Recent patenting activity in Australia, the USA and Europe has shown that judges have pushed out this subject matter limitation while determining individual cases. This judge-made policy is not based on any assessment of the evidence as to the costs and benefits of such changes to the nation. In all three jurisdictions courts or patent offices have approved the patenting of discoveries (in the form of genes, gene

⁴ Article 5.1 of the Agreement provides that "legislation ... should not restrict competition unless it can be demonstrated that: (a) the benefits of the restriction to the community as a whole outweigh the costs; and (b) the objectives of the legislation can only be achieved by restricting competition." See <http://www.coag.gov.au/node/52> (accessed 6 August 2012).

fragments and proteins). Recently the US Supreme Court has ruled that this is not lawful.⁵ Judges in Australia and the USA and quasi-judges at the European Patent Office have extended patents to software despite the clear intent of executive government and legislatures that software not be patentable.⁶ Software is an important enabling science/art, but is not technology and does not incur the large lumpy R&D costs of genuine technological invention. In Australia judges have overturned the long-standing tradition that methods of medical treatment are not patentable,⁷ and the Swiss Patent Office has developed wording to undermine this exclusion in Europe.⁸ None of these changes were based on any evidence. They take the patent system far beyond agreed technology boundaries and should be wound back.

Patents are only for technological inventions and specifically exclude patentability for:

- anything not markedly different from what is found in nature (i.e discoveries);
- all inventions based on mathematical algorithms and all software inventions in any form;
- all methods of medical treatment (including, but not limited to diagnostic, therapeutic or surgical treatments) within a broad exclusion for inventions 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" in pharmaceutical marketing approval. The industry has thus succeeded in an overall extension in patent term for all technologies, on the basis of argument about their own industry,⁹ 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.

Spillover benefits and "how inventive"

As noted above a critical aspect of patent policy is designing a system that will ensure a high level of social benefits from each and every granted patent. Only if this is achieved will a patent system deliver a positive economic outcome for a nation. How do we ensure this? TRIPS restrains the design of national policy systems by mandating that patents must be granted if an invention is novel, inventive and capable of industrial application. If the inventiveness requirement is set at a high level – perhaps the level advised to the Australian parliament in the Explanatory Memorandum to the Raising the Bar Bill 2011¹⁰ – then the system will likely deliver positive outcomes. With such a standard only a fraction of the current volume of

⁵ *Association for Molecular Pathology v. Myriad Genetics, Inc.* 569 U.S. 12-398 (2013).

⁶ In both the USA (see Samuelson et al. 1994) and Australia (IPAC 1984) review committees recommended that patent systems not be extended to software and these decisions were accepted by executive government. In the case of Australia this had bi-partisan support. The exclusion of software is written into the European Patent Convention. Miceli (2005) suggests that despite this clear exclusion the EPO had granted at least 40,000 software patents by 2005.

⁷ See discussion in ALRC 2004: 172, citing *Joos v Commissioner of Patents* (1972) 126 CLR 611, 619 where Barwick CJ decided that a process for cosmetic treatment could be patentable, but distinguished this from medical treatments which were not patentable. This tradition was overturned in *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1; *Bristol-Myers Squibb Co v FH Faulding & Co Ltd* (2000) 170 ALR 439.

⁸ See discussion in Thambisetty 2009: 16-17.

⁹ 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.

¹⁰ "It is a fundamental requirement that a patented invention possess an 'inventive step' (in the sense that the new invention adds significantly to what was previously known)" (p.40); "A key principle of the patent system is that protection is only given for things that are a significant advance over what was known and what was available to the public at the priority date of the patent. A granted patent can be a powerful exclusive right: as such, it is appropriate that the inventive step requirement be sufficiently stringent" (at p. 42). The Explanatory Memorandum is available at <http://www.comlaw.gov.au/Details/C2011B00114/Explanatory%20Memorandum/Text> (11 October 2013).

17,700 patents would be granted each year. This is because of the chasm between the standard advised to parliament and the standard used in our courts – a scintilla. A shift to the significant advance standard would not impede genuinely inventive firms such as CSL, Cochlear and ResMed.

The very low standard arises from asking the wrong question (Moir 2013; and forthcoming). Is it obvious? If "obvious" inventions are excluded, then that does not mean that the remainder are sufficiently inventive to merit grant of a patent. Just as ruling out the ugly in a population does not mean that the rest would qualify as beauty finalists (or even runners-up).

A further issue is that every step in the process of seeking a patent is weighted towards the interests of would-be patent-holders and against the interests of other innovating firms, consumers and the general public. In the USA the Federal Trade Commission (FTC) found a "plethora of presumptions and procedures [that] tip the scales in favor of the ultimate issuance of a patent, once an application is filed" (FTC 2003: 8). In Australia a patent application is assumed inventive unless the patent office can show that it is not. Such rules run directly counter to Article 5 of the Competition Principles Agreement.

Countries must be free to set the inventive step at a high level. There must be flexibility to move away from the dysfunctionally low "is it obvious" approach¹¹ towards a positive approach designed to ensure sufficient inventiveness to produce spillovers of value.

Those applying for patents should be required to demonstrate that they meet patentability standards. In particular applications should not be presumed either novel or inventive. The appropriate threshold questions for patent grant are:

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

All exclusions from existing knowledge for the novelty and inventiveness tests must be removed.

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

- **new uses of known things or processes (including use of known things in new environments);**
 - **specifically excluding new therapeutic treatments using known compounds unless the new treatment provides a substantial improvement in health outcomes and substantial investment was required**
- **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 a publicly available document, to clearly specify the benefit which will pass to the public in authorising the patent grant. 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.

Patent privileges

TRIPS made a local working requirement unlawful, but did not simultaneously review the privileges granted by a patent. Local working was the mechanism through which knowledge spillovers flowed to the domestic economy.¹² When patented goods are produced overseas most of the spillover benefits will occur overseas and the nation will be left with only costs. Unless there are net consumer benefits,¹³ such as substantially improved health outcomes, grant of any such patent involves only costs. Despite removing this public benefit safeguard, TRIPS did not – as it should have done to be even-handed – review the range of privileges granted in a patent. This should now be done as a matter of urgency.

¹¹ Which the leaked IP chapter draft would have mandated – see Article 8(1), footnote 15.

¹² Not reading patent specifications. These are written in legalese, often omit key words and inventors do not even recognize their own inventions when drafted as a patent (Mandeville, Lamberton and Bishop 1981). Data from National Innovation Surveys show how infrequently patent data are used by those undertaking industrial innovation.

¹³ An extraordinarily difficult measurement task as the relevant concept is the **net** consumer benefit from the invention minus the goods displaced by the invention.

In the absence of a local working requirement, the only privilege granted by a patent should be to prevent sale in the domestic market. This, of course would require an amendment to TRIPS Article 28. The patent privilege should not extend to prohibition of the import and sale of goods made with the patent-owner's authorisation in an overseas market (i.e. parallel importing should be allowed). The one exception in regard to parallel importing would be if the product is locally made **and** the patent-holder can demonstrate that a risk-adjusted return to the investment has not yet been achieved.

The *only* privilege granted by a patent should be the right to prevent sale in the domestic market.

The right to prohibit manufacture should not extend to manufacture for export or for entry to the market immediately on patent expiry.

The patent right to prohibit the manufacture of goods should not extend to any prohibition on making goods for export to countries where there is no valid patent. Further, the right to prohibit manufacture should cease some months before patent expiry to allow competing firms to tool up. Without this limitation the already lengthy patent period is de facto extended.

Penalties, incentives and a self-reinforcing standard that benefits the nation

The current patent system has a very poor incentive structure. As noted above almost every element of the patent system is tipped in favour of patent holders or would-be patent holders. One exception is that, in Australia, a granted patent is not presumed valid. Under no circumstances should this important anchor be given away – in the US innovating firms face a harder hurdle in challenging trivial patents because of the presumption that a granted patent is valid.

While there are clear procedures for recompensing firms for patent infringement there are no parallel systems for ready compensation where firms have taken out trivial patents to impede other firms. Aspects of infringement penalties need to be clarified; new procedures are needed to recover profits from sales supported by invalidated patents and normal legal rules should apply, including the presumption of innocence. Given that patent law is public law, the outcomes of its application must be public.

Patent law is civil law and all penalties should be civil.

The damage done by patent infringement is hurt of profits – penalties should reimburse lost profits and should not extend to closing businesses. They should, to the maximum extent possible, avoid doing harm to innocent parties such as employees.

In any case that reaches at least a first Directions Hearing, detailed information on costs and damages should be made publicly available.

Patent offices could link these data to their patent grant databases.

Normal legal rules should apply, with alleged infringers being assumed innocent until proven guilty. This would require TRIPS Article 34 to be revoked.

Complexity is a deliberate ploy used to hide rent-seeking behaviour and outcomes (Braithwaite 2005). The patent bargain is simple – the spillover benefits of inventions are exchanged for a temporary restraint on competition. Unnecessary complexities need to be removed from patent law. Some – such as removing limitations on existing knowledge before tests of novelty and inventiveness are applied – have been suggested above. A range of other improvements are suggested here, which together could provide systemic robustness and ensure high standards for patent grant.

Ensuring patent systems self-reinforce high standards for patent grant:

- no granted patent can be presumed valid;
- all words used in the patent system must have their ordinary meanings, using current language;
- clear mechanisms should be established to recoup profits arising from invalidated patents; these should be shared between the party who successfully challenged the invalid patent and bodies tasked with upholding competition or consumer rights;
- anti-avoidance principles should be imported from taxation law to ensure that overarching principles/objectives trump specific rules where there is a conflict; and
- there should be severe financial penalties for attempting to undermine patent system objectives, e.g. by using semantics to patent inventions that have no technological merit.

Data, evaluation and oversight

Despite an increased emphasis on evidence as the only basis for sound policy in a democracy, patent systems have managed to avoid scrutiny. Most "reviews" have been based on opinion rather than fact. There is no evidence of any cost-benefit or other evaluations. Indeed interested parties have actively succeeded in suppressing the collection of relevant data. For example IPAC's 1984 recommendation that data on patent use be collected at the time of renewal has never been actioned. Yet in early 2010 the Director-General of IP Australia publicly pointed to the gap in evidence because no data on patent use are available. In the USA FTC recommendation 10 for increased evidence based analysis of the patent system was strongly rejected by the Intellectual Property Owners Association.¹⁴

Patent Offices should require data on how patents are being used as a condition of renewal.

This should include any formal legal use including solicitor's letters;

Patent Offices should maintain a public database of any fines or legal costs incurred by any party to a patent validity or infringement case;

National (Community) Innovation Surveys should include questions to address key issues relevant to the role of patents. In particular data are needed on technological hold-up or diversion, the costs of defensive patenting and the speed and cost of imitation;

Periodic independent economic evaluation of patent policy outcomes and the net impact on the economy;

A regular program of expert review of patent office decisions in particular technology fields.

¹⁴ Bessen and Meurer 2008: 293-4. Kahin (2003) reports that, subsequent to the *State Street* case the White House Office of Science and Technology Policy commissioned the Science and Technology Policy Institute at RAND to undertake a study on software patent quality and business effects. He notes that "it was suspended at the request of a U.S. multinational company concerned that the study would undercut efforts to secure greater international acceptance of software patents". The American patent bar successfully lobbied to remove a US Government Accountability Office (GAO) study of business method patents from the *American Inventors Protection Act* of 1999.

Patent policy principles for the Trans Pacific Partnership Agreement

"Strong" IP means strong barriers to competition. What we need is a balanced patent system.

Artificial deadlines are a strategy used by stronger parties to maximise their gains. Resist them.

Summary of patent policy principles

The **objective** is to encourage **technological innovation** that would not otherwise occur; and which provide **social benefits** greater than the cost of the restrained competition.

Patents are only for **technological inventions** and should specifically exclude:

- anything not markedly different from what is found in nature (i.e. discoveries);
- all inventions where the inventiveness lies in mathematical algorithms or software;
- all methods of medical treatment (within a broad exclusion for inventions required to protect life, health and the environment).

Patent **term extensions** should be resisted. Any extension should be conditional on proof that a risk-adjusted return on the R&D investment has not yet been achieved.

Countries must be free to **set the inventive step at a high level**. Those applying for patents should be required to demonstrate that they meet patentability standards. Applications should not be presumed either novel or inventive. The appropriate inventiveness questions for patent grant are:

- "what new knowledge is contributed?" or "what social benefit is contributed?" **and**
- "is this sufficient to provide spillover benefits to outweigh the costs in reduced competition?"

All exclusions from existing knowledge for the novelty and inventiveness tests must be removed.

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

- new uses of known things or processes; and
- combinations of known elements or processes

Examiners should clearly specify the benefit which will pass to the public when they authorise a patent grant. This grant authority document should be public.

The *only* **privilege granted by a patent** should be the right to prevent sale in the domestic market (requires amendment of TRIPS Article 28). The right to prohibit manufacture should not extend to manufacture for export or for entry to the market immediately on patent expiry.

A range of features are required to stop to the gaming behaviour that currently characterises patent policy. The following are particularly important:

- Patent law is civil law and all penalties should be civil. The only infringement penalty should be reimbursement of profits. Penalties must not harm innocent parties such as employees or taxpayers.
- For all cases that reach at least a first Directions Hearing, detailed information on costs and damages should be made public. (Patent Office to ensure consolidated publication).
- Normal legal rules should apply, with alleged infringers being assumed innocent until proven guilty. This requires TRIPS Article 34 to be revoked.
- No granted patent should be presumed valid.
- All words used in the patent system must have their ordinary meanings, using current language.
- Straightforward procedures to recoup all profits from invalidated patents.
- Anti-avoidance principles should be imported from taxation law to end strategic games.

Proper audit and evaluation systems must be added:

- Patent Offices should collect data on how patents are being used as a condition of renewal.
- National (Community) Innovation Surveys should include questions to address key issues relevant to the role of patents. In particular data are needed on technological hold-up or diversion, the costs of defensive patenting and the speed and cost of imitation.
- Periodic independent economic evaluations of patent outcomes and the net impact on the economy.
- A regular program of review of patent office decisions by experts in particular technology fields.

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