

Harmonisation and net technology importers

Posted on 18/03/2009 by [Tim Jackson](#), and [Harriet Wilson](#)

How developing countries deal with patent protections on life-saving medicines in a global world.

There is increasing pressure, particularly from developed countries and multinational companies, for harmonisation of the patent system. The five biggest patent offices (those of the US, Japan, Europe, China and South Korea) met in South Korea recently to discuss, among other things, common examination standards and data sharing. The drivers for this are relatively clear. All patent offices are suffering from examination pressures and the cost of repeated examination is becoming an increasing burden for users of the system. This is particularly so where examination timing issues result in the need for continued review of related applications across multiple countries.

Programmes such as the Patent Prosecution Highway (PPH) have been discussed to alleviate this burden. The PPH provides for accelerated patent prosecution by sharing information between some patent offices. It is intended to reduce duplication by each office and thereby reduce backlogs while still maintaining higher patent quality. [\(1\)](#)

A further expansion of the PPH could see worldwide patenting become a simpler and less expensive process for applicants. But, would all countries benefit from this?

JUSTIFICATION

Patent law is generally justified on four grounds: a contract between the state and the inventor to disclose the invention for the public good; a reward for invention; a means of protecting inventor's rights; and an incentive to invention and innovation.⁽²⁾

In a developed country that is a net exporter of technology, where the focus is industrial development, investment, research, commercialisation and exporting or licensing products, the justification for patents generally is reasonable. Harmonisation of the patent system and reducing the cost burden of obtaining patent protection worldwide will have benefit for such countries. However, as applicants from other countries will also find the cost of obtaining patent protection in those countries easier, it may result in more patents being applied for and obtained. This may not be too much of an issue for net exporting countries (or regions) as they tend to be the targets for most applications anyway and the reduction in administrative burden for both the patent offices concerned and applicants from those countries may far outweigh any downsides.

In a developed country that is a net importer of technology, the focus of the country can again be on industrial development, investment, research, commercialisation and exporting or licensing products. Again, the justification for patents is reasonable, and again, harmonisation of the patent system and reducing the cost burden of obtaining

patent protection worldwide should benefit such countries. Simpler and cheaper access to patent protection worldwide will be of great benefit, particularly due to the inherent problem of having to fund the worldwide applications for protection from a relatively small local market base. As a net importer of technology, however, the benefit to the country as a whole can be impeded by the patent protection obtained by applicants from other countries, usually those from countries that are net exporters of technology.

One of the benefits of being a smaller country is that patent protection is not always applied for as part of a multi-country filing program. Often this is based on cost, as the expense of applying for and obtaining patent protection is not justified on the basis of the market size. That distributed knowledge then becomes available for general use. If that country is also a developed country then the industrial development, investment, research, and commercialisation infrastructure may also be present to allow that knowledge to be used to commercial advantage. From that perspective, simpler and cheaper access to patent protection in that smaller developed country may have downsides that outweigh the benefits of a reduced administrative burden.

In developing countries where the main concerns are food, health and education, the patent system may not necessarily be so easily justified.

“[Patents and] medicine are inextricably inter-linked. Patents are a monopoly. Drug companies possess separate monopolies over many life-saving and other drugs, including those that treat HIV-AIDS. As monopolists, these companies have no compunctions about fixing high prices for essential drugs. High prices create a clear divide between the rich who can afford the medicine and the poor who cannot”. (3)

The enforcement of patents in developing countries can sometimes be difficult to justify.

It has been reported that eight thousand people die from AIDS in the developing world every day due to lack of access to essential medicines.⁽⁴⁾ This lack of access to essential medicines can be affected by high drug prices. The price of medicines can in part be attributed to global patent rules, which can be used to restrict the availability of the patented medicine or of affordable generic versions. ⁽⁵⁾

GLOBAL APPROACH

The current global approach to intellectual property rights, and in particular the patent system, is governed by the World Trade Organisation's (WTO) Trade Related Aspects of Intellectual Property Law (TRIPS) Agreement. WTO member countries are required, under the TRIPS agreement, to enforce intellectual property rights, including patents. Thus the requirement to provide adequate intellectual property right protection is inextricably linked to trade issues. This is can easily be justified on the basis that development of inventions that have the ability to benefit the public (medicines being a prime example) are expensive to develop and easy to copy. If adequate return on the investment required to develop the product is not achieved then, eventually, the incentive to develop new products will decline. That decline in development would clearly be to the future detriment of all countries, including developing countries.

Under art 8 of the TRIPS agreement, however, member countries "may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development".⁽⁶⁾ Further Article 31 ⁽⁷⁾ allows a country to override a patent by authorizing a compulsory license for production of a

drug.⁽⁸⁾ The compulsory license may be issued on public health grounds to authorise production of patented drugs without the consent of patent holders, subject to adequate compensation. Countries can also issue compulsory licenses in response to national health emergencies.

On this basis, the Thai government, for example, issued a number of compulsory licenses. The first of these was issued in 2006 for Efavirenz, which is a treatment for HIV/AIDS patented by Merck Sharp & Dohme. Since then, Thailand has extended its compulsory licensing to include anti-AIDS drugs, heart medication and anti-cancer drugs. The US has expressed its disapproval of these activities.⁽⁹⁾

TENSIONS

There are clearly tensions that arise between the demands of those countries (or regions) that have the ability to invest in the development and production of medicines, and those who do not have the ability to meet the cost of accessing those medicines.

This is particularly so for developing countries but it is also an issue for many developed countries where the cost of providing access to new medicines is an increasing burden. Compulsory licences and Bolar type exceptions to infringement, for example, are available in most countries and are designed to provide some balance to this. Imposition of restrictions on patent rights must also be balanced against the provision of incentives for foreign companies to invest in the country concerned, thus transferring knowledge and skills to the local community. On that basis, targeted extensions of monopoly periods for pharmaceuticals, such as Supplementary Protection Certificates, can be considered.

For countries that are net importers of technology, the ability to control the grant of monopoly rights within the local business and social environment, once a monopoly right, such as a patent right, has been applied for, is critical. Such countries may be those that are considered to be “developed” but also those considered to be “developing”. The key to addressing many of the concerns of these countries is the national patent office. It is the patent office that has the responsibility of administering the grant of most registered intellectual property rights, including patent rights. The national patent office is effectively the gateway through which a patent applicant, foreign or local, must pass if monopoly rights are to be obtained.

There is clearly a temptation to allow the administration of the patent offices to be run by the patent office of another, usually larger, country that may have greater resources. However, this approach may have the result that the smaller country will then be faced with increased applications for patent protection based not on the importance of the smaller country to the international business community but rather on the importance of the larger country. Inclusion in the PPH may also be a temptation as this could also lower the administrative burden. Again, however, this may result in increased applications for patent protection due to the inclusion of that country on the list of participating PPH countries. The effect may be a cumulative one for a smaller country if administration of the patent office is run by a larger country and that larger country is then included in the PPH. Regional patent offices, such as the EPO, may be very successful, but only following the creation of a regional trading block, in that case the EU, which it services.

The issue of increased numbers of monopoly rights hindering innovation has recently been recognised in a recent review of the Australian national innovation system that was commissioned by the Australian Minister for Innovation, Industry, Science and Research. This review noted in Chapter 7 at pages 83 and 84:

“The development of intellectual property is cumulative. In the words of Sir Isaac Newton, we stand on the shoulders of giants. Because new knowledge always builds on old knowledge, the property rights we have erected to encourage innovation can actually obstruct it.

This is particularly so where intellectual property rights are too easily granted, and where they are ambiguously defined, so that innovators are uncertain as to what innovations might be subject to the prior claims of patent holders. There have been some worrying trends in this regard in recent years. In the last three decades judges have overturned important ‘gatekeeping’ principles of the patent system that existed until the early 1980s. Thus it had been held that software and business methods could not be the subject of patents. But this has been overturned. Likewise the tests of non-obviousness and ‘analogous use’ have become much less stringent – as some have argued, to the point of vacuity.

There is mounting evidence that this is impeding rather than stimulating innovation” [\(10\)](#)

TRIPS

The starting point for addressing some of these issues from an administrative perspective is the TRIPS agreement. The ability to trade without sanction is critical to most countries so meeting the basic requirements outlined in the TRIPS agreement is essential.

Article 27 of TRIPS allows the grant of patents for “any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application”.[\(11\)](#) WTO countries that are signatory to the TRIPS agreement may also “exclude from patentability inventions, the prevention

within their territory of the commercial exploitation of which is necessary to protect order public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law". Further, Article 27 allows for the exclusion from patentability of (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; and (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.⁽¹²⁾

ROLE FOR NATIONAL PATENT OFFICES

From a monopoly restriction perspective, it is clearly better for an application for that monopoly not to be filed rather than its effect being restricted during processing through that country's patent office. However, there is scope within the TRIPS agreement for countries to allow national patent offices to legitimately restrict the impact of monopolies applied for by having a strict approach to patentability. For instance, methods of medical treatment can be excluded, a high threshold of inventiveness can be required, strict approaches to software, business methods and microbiological patents can be taken.

From a practical perspective, the national patent system can also impose procedural requirements, such as requiring applicants to request examination, limiting time periods for responses, restricting amendment options, imposing maintenance fees, excess page and claim fees, and extension of time fees, to name a few possibilities. Patents also have an inherent public notice role. Therefore countries can require certified translations of the specification, or at least the claims, into the main business

language(s) spoken in the country concerned.

These imposed conditions and fees will, of course, also affect the local patent applicants. This is always a balance of priorities. One must remember however, that it is a monopoly right that is being requested. There is no actual requirement for anyone to request a monopoly. While the imposition of fees and conditions will be a cost to local business, it is optional and the benefits of the monopoly obtained should readily justify that cost.

The grant of a monopoly such as a patent right can result in smaller businesses being encouraged to innovate and develop inventive products. As a result, growth of “knowledge based” business and the move toward an economy based on adding value to products and the resultant technology transfer can be stimulated. In addition, information about that invention will then be disseminated into the wider business community by publication through the patent system. There is an incentive therefore to encourage local businesses to obtain patent protection to provide the basis for growth. But if the barrier to obtain such a monopoly is set too low then the overall effect can be one of impedance rather than stimulation.

To address the impact on local applicants, a tiered fee schedule that is dependent on the size of the company concerned (eg small and large entities) can be used. Further, options such as the Australian innovation patent system, which requires only an innovative step but has a balancing 8 year term, can be available. Consideration of such options must also take into account that they will be available to foreign applicants

as well. They could result in a plethora of short term monopoly rights having a narrow focus and whose validity may be difficult to attack.⁽¹³⁾ The shorter term monopoly right could also be backed up by broader, longer term, rights available through the standard patent system.

The introduction of a fee component for various procedural steps would obviously have the capability to provide benefits to the national patent office beyond that of perhaps discouraging the filing of applications in the first place. The financial gains may be used to make the patent office self-sufficient, as opposed to relying on government funds. Further, this could allow for the employment of an increased number of examiners, and improved examiner training, resulting in a higher quality of examination. In countries that do not have a tradition of intellectual property rights, the financial gains could also be used by patent offices to run education programmes to increase awareness of intellectual property rights and the benefits that can be gained from educated use of such rights.

The intention of this article was to focus on countries that are net importers of technology and to explore issues and options that may be available within the current international patent system. It is clear that most of those countries will benefit from access to more efficient patent processing systems, such as may be provided by the PPH. It is also clear that globalisation and harmonisation of procedures have their dangers and how those countries use their national patent offices within that international environment will be critical to the ability to incentivise growth and innovation.

This article was published in *Pharmaceutical law Insight*, November 2008.

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- 2 - "Balancing IP Rights with Public Policy", Federation Internationale Des Conseils En Propriete Industrielle
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- 5 - See note 4
- 6 - TRIPS Agreement, Article. 8
- 7 - TRIPS Agreement, Article 31
- 8 - See note 4
- 9 - Noonan, Kevin E., "Thailand Continues Its Compulsory Licensing Practices", Patent Docs, March 11, 2008
- 10 - Venturous Australia Report, Review of the National Innovation System, Panel headed by Terry Cutler (can be found at http://www.innovation.gov.au/innovationreview/Documents/NIS_review_Web3.pdf)
- 11 - TRIPS Agreement, Article 27
- 12 - See note 7
- 13 - Delnorth Pty Ltd v Dura-Post (Aust) Pty Ltd [2008] FCA 1225 (13 August 2008)