Patents in the Global Economy

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Foreword

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Contents

1 INTRODUCTION

A multi-faceted debate: the role of patents in the global economy

Until relatively recently the notion that patents promote the inventive process, innovation and development remained largely uncontested. Policy making in the field of patents focused almost entirely on ensuring that patent regimes provided strong protection for rights-holders, with the presumption that benefits would then accrue for developed, developing and least-developed countries.[1] For the global economy these benefits would include increased foreign direct investment (FDI), and higher levels of technology transfer or licensing leading to the transfer of know-how and expertise that would contribute to local economic growth and higher levels of domestic innovation (Matthews 2002: 108).

The economic rationale for these anticipated benefits was that, by preventing competitors from imitating an invention, a free-rider problem could be avoided whereby a new entrant imitated (i.e. copied) the technology and the inventor could not then generate sufficient returns on their investment to cover costs associated with the inventive process. The concern was that, even if the social benefits of free-riding were significant, the potential innovator without patent protection could well decide subsequently against innovating altogether or could under-invest in the future (Bessen and Maskin 1999: 2; Mukherjee and Pennings 2004: 715).

Following implementation of the World Trade Organisation (WTO) Agreement on Trade Related Intellectual Property Rights (TRIPS) it has more recently become widely recognised that, while patents can stimulate the inventive process by avoiding the free-rider problem, promoting investment in research and development (R&D) and encouraging diffusion of knowledge, patents can also hinder development if a balance between rewarding inventors and safeguarding the public domain for a wider public good is not achieved.

[1] Although there is no established definition of what constitutes a developing country, the following are defined as least-developed countries by the United Nations: Afghanistan, Angola, Bangladesh, Benin, Bhutan, Burkina Faso, Burundi, Cambodia, Cape Verde, Central African Republic, Chad, Comoros, Democratic Republic of the Congo, Djibouti, Equatorial Guinea, Eritrea, Ethiopia, Gambia, Guinea, Guinea-Bissau, Haiti, Kiribati, Lao People's Democratic Republic, Lesotho, Liberia, Madagascar, Malawi, Maldives, Mali, Mauritania, Mozambique, Myanmar, Nepal, Niger, Rwanda, Samoa, São Tomé and Principe, Senegal, Sierra Leone, Solomon Islands, Somalia, Sudan, Timor-Lesté, Togo, Tuvalu, Uganda, United Republic of Tanzania, Vanuatu, Yemen, Zambia.

While developed countries have well-established and longstanding patent regimes, designed to encourage inventive activity and promote investment R&D, many low income developing and least-developed countries are unable to realise the prices for goods derived from patented inventions to the same extent as can be done in the developed world. There is therefore a trade-off that needs to be made between the impact of weaker patent regimes and the potential for increased technological diffusion in recipient developing and least-developed countries if foreign partners are more willing to undertake FDI and enter into licensing agreements in the knowledge that stronger patent protection is available (World Bank 2008).

This debate about the role of patents in the global economy has become part of a much wider discourse on global justice and equity, trade rules and economic development strategies, and the negative consequences of an unbalanced patent regime.

Yet, although theoretical studies (Lai 1998; Taylor 1994) have stressed the importance of patents for technological diffusion through FDI and licensing agreements, empirical evidence is ambiguous overall (World Bank 2008). Some studies find no relationship between the level of patent protection and FDI or licensing (Primo Braga and Fink 2000; Branstetter, Fisman and Foley 2005; Maskus and Konan 1994) while other studies show a positive effect of strong patent regimes on FDI both in influencing location decisions by multilateral corporations and in inducing foreign firms to invest in production rather than in distribution activities (Javorcik 2004; Lee and Mansfield 1996; Mansfield 1994; Maskus 1998).

In addition, while some evidence suggests that a stronger patent regime is associated with a rise in flows of knowledge and FDI into middle-income and large developing countries (World Bank 2008), this is not the case with poorer and lower income or least-developed nations (Fink 2005; Hoekman, Maskus and Saggi 2005; Smith 2001).

So it is in the context of this wider debate about the role of patents in the global economy that this chapter examines in greater detail the following issues: (i) whether patents can be used as a stimulus for invention and innovation; (ii) the role of patents in recently industrialised countries; (iii) the impact of patents on development; (iv) the role of licensing and technology transfer; (v) the impact of the TRIPS Agreement; (vi) public health issues: given that concerns about the appropriateness of the present patent system have focused, in particular, on

health and access to medicines in developing countries, alternatives to the present patent system will then be considered in relation to current initiatives to address public health imperatives; and (vii) prospects for the future, particularly in terms of the potential of using patent information to stimulate invention and innovation.

2 PATENTS AS A STIMULUS FOR INVENTION AND INNOVATION

It is often said that patents stimulate invention and innovation. The distinction between the two concepts is key to understanding why this might be the case. While the invention of new things can be protected by patents, innovation refers to the development of marketable products from that invention. Innovation can be protected only indirectly through whatever patent protection the related invention is able to obtain and the extent of protection granted therefore depends on the invention-innovation link. In the case of pharmaceutical inventions, for instance, what is worked on in the laboratory, described in the patent specification, manufactured and ultimately prescribed by the medical practitioner and administered to the patient, are all absolutely identical. In contrast, in the case of engineering, the actual link between a patented invention and the related innovation process is nothing like as close as there will almost certainly be a number of incremental changes between the start of development work on such an invention and the time a product is finally put on the market (Fink and Maskus 2005).

The recent record of countries in nurturing a culture of invention and innovation carries mixed messages for developing and least-developed nations seeking to progress along a path of economic development. Inadequate patent protection can stifle both the invention and innovation process even in countries with low levels of economic development (Maskus 2000a: 299). This is because, since pioneering inventive breakthroughs are extremely rare, in the vast majority of cases invention is a relatively mundane process involving minor adaptations to existing technologies, with cumulatively powerful effects on growth. As such, it is important for firms to adopt new management and organisational systems and new product and quality control mechanisms to identify new technologies. This is difficult in an environment of weak patent protection as it is not always possible to foster attitudes of creativity, invention and risk-taking in such an environment, a culture of imitation leading instead to economic stagnation (Maskus 2000a: 299).

There is no single iconic, fail-safe way of achieving successful catch-up with developed country economies that every country can or should emulate (Fagerberg 2006: 17). Instead, every country needs to develop its own approach based on an understanding of: firstly, the contemporary global technological, institutional and economic dynamics; secondly, the behaviour

and needs of the relevant agents (of which the firm is arguably the most important); and, thirdly, the specific context in which the catch-up takes place and the broader factors that influence it.

Fink and Maskus (2005: 5) have also pointed out that developing and least-developed countries differ from their industrial counterparts in their innovative potential, the education of their workforce, the structure and funding of research and development (R&D), the management of technological assets, and the existence of complementary intellectual property institutions, such as technology transfer offices (TTOs).

Defining innovation is also extremely difficult in the context of a developing or least-developed country. The innovative process in these types of country can involve many forms of adaptation, absorption and even creative imitation (Maskus 2000a: 325). But, while the poorest countries allocate virtually no resources to invention or innovation and have little intellectual property to protect, as incomes and technical capabilities grow to moderate levels, some inventive capacity emerges, particularly of the adaptive kind, incorporating modifications into existing technologies. The primary economic activity at this stage of development is still likely to be based on imitation (not innovation) and the majority of economic and political actors will consequently prefer weak patent protection in order to facilitate this. As an economy develops further, additional inventive capacity and demands for high-quality products begin to emerge. At this stage, more domestic firms begin to see the benefits of effective patent protection, as do foreign firms interested in servicing growing markets. Finally, demand for patent protection increases sharply as incomes reach the higher levels found in developed countries (Maskus 2000a: 298).

Alongside demand for patent protection through increased patent filing activity, the strength of enforcement efforts also differ as economic development occurs. On the part of low-income developing and least-developed countries, this may involve costly administrative expenses and the necessity to train human capital in the complex technical and judicial issues associated with patent protection and enforcement that have not previously been encountered at the domestic level (Maskus 2000a: 298).

In fact, developed and developing countries respond differently to reforms related to patent protection and enforcement. Park (2008: 322-3), for instance, argues that patent protection and enforcement in developing countries need to reach a threshold level before R&D becomes responsive to reforms of the

patent system. Similarly Allred and Park (2007) find that, although a relationship between patent strength and R&D can be identified in developed countries, this is not so evident in developing nations.

For some developing or least-developed countries shifting from initially weaker patent regimes and introducing stronger patent protection, levels of R&D may actually decrease. This can occur because these types of economies, with weaker patent regimes, are largely conducting incremental, adaptive innovation. In such circumstances the increased costs of R&D associated with the introduction of higher levels of patent protection may bring about a greater detrimental effect in the short-term, instead of a positive impact brought about by enhanced opportunities for investment in R&D in a stronger patent environment (Park 2008: 312). As a result, Allred and Park conclude that patent protection has a statistically insignificant effect on R&D, Park (2005) also finding that patent protection has largely negligible impacts on developing country R&D expenditures.

In part, this is because a larger market for patented products or a larger R&D sector is required before stronger patent protection provides sufficient incentives for increasing R&D expenditures. Strengthening patent regimes from an initially low level to a somewhat higher level may not therefore be sufficient to provide the necessary incentives or the wherewithal to provide a legal infrastructure to support research and innovation (such as research facilities, a court system, patent administration, specialised professions, or a market for licensed technologies (Park 2008: 312-3).

Allred and Park (2007) even found that stronger patent protection can have a negative effect on domestic patenting activity in developing countries because patent reforms attract foreign patents which are filed first, have priority rights and which cover diverse fields and claims so that some domestic patenting in developing countries is crowded out, displaced or pre-empted by foreign patents.

These transformative difficulties, as developing countries seek to move from imitation to innovation in a strong regime of patent protection and enforcement, can in part be addressed through effective systems of utility model protection which require lower levels of novelty than patents but grant more limited periods of protection. A study of Japan's system of utility model protection (Maskus and McDaniel 1999), for instance, demonstrated that this contributed positively and significantly to Japan's post-war productivity increases. The study's findings

indicate that patents play a positive role in stimulating enterprise development and innovation in developing countries. At the same time, they also make clear that a reformed legal regime is likely to be a necessary but not sufficient condition for local technology development.

3 THE ROLE OF PATENTS IN RECENTLY INDUSTRIALISED COUNTRIES

So, on one hand it is argued that patent rights promote innovation because the patent system allows for returns on the inventive process. On the other hand, concerns have been raised that the patent system increases the costs of innovation and technology transfer because technological inputs will be more expensive when protected by proprietary rights (Park 2008: 297).

Moreover, while the primary objective of a stronger system of patent protection and enforcement is to maximise the competitive gains from additional innovation and technology acquisition over time, with particular emphasis on raising innovative activity by domestic entrepreneurs and enterprises, upgrading patent protection alone is an insufficient condition to achieve this. Instead, the patent system needs to be strengthened within a comprehensive and coherent set of policy initiatives that optimise the effectiveness of patents. Such initiatives include: further structural reform of enterprises; trade and investment liberalisation; promotion of financial and innovation systems to commercialise new technologies; expansion of educational opportunities to build human capital for absorbing and developing technology; and specification rules for maintaining effective competition in developing country markets (Maskus, Dougherty and Mertha 2005: 297).

As noted earlier, innovation in developing countries tends to be more imitative, adaptive and incremental in nature than in developed nations, with recent empirical work by Park (2008) demonstrating that different environments and innovative capacities mean that the optimal level and impact of patents varies depending on the stage of economic development domestically (Park 2008: 297). This leads to concerns that, if developing countries were obliged to adopt developed country standards of patent protection, the resulting standards would exceed optimal levels for their economies. Instead, Park (2008: 298) has suggested that developing country patent regimes should take into account market size and the imitative, adaptive nature of developing country R&D. If standards of patent protection are too high in developing countries, Park argues, there is a risk that innovation could be adversely affected.

Conventional thinking is that the imitation phase is an essential first step of development whereby domestic firms can internalise the ‘global’ state of the art in any given field – in other words, before one can innovate, one must know

what the most advanced thinking is around the world. After that, developing country firms can engage in low-level innovation in terms of developing incremental improvements to pioneering technologies and obtain patent protection on these incremental changes to known technologies. Of course, in order to do so, developing country innovators must have the necessary intellectual, technical and material tools to access and process this global state of the art before improvements or adaptations can be envisaged. For Gervais (2007: 43) this explains the strong emphasis on education in technical assistance analyses.

However, recent developments in China, India and other countries such as Brazil and Russia beg the question whether imitation is a necessary phase of industrial development.[2] For fast growing developing countries, particularly Brazil, Russia, India and China (BRICs) inward technology transfer remains the primary source of new information for effecting technological change and structural transformation (Fink and Maskus 2005: 6).

In practice, the innovation pattern varies between industry sectors and does not accord with the conventional thinking that the imitation phase is an essential first step in every case. In an industry where imitation is challenging and costly, the innovation sequences may well not include imitation. By way of illustration, the aerospace industry is a common example of a sector where patents are relatively unimportant. In this respect, it is important to differentiate between industries when considering the impact of the patent system on invention and innovation.

A related question is whether technological innovation can be woven into different social and economic fabrics or whether, conversely, Western economic institutions and capitalism are a prerequisite for that patent system driving invention and innovation. In this respect, Gervais (2007: 43) notes that China appears to have done better over the past ten years than, for instance, India, while being further removed from the free market economy approach of the developed world.

Maskus (2000a: 300) reports that higher standards of patent protection and enforcement stimulate innovation in developing countries, citing evidence that was presented in the results of a survey of 377 Brazilian firms, conducted jointly by the Brazilian Ministry of Industrial Development and Commerce and the

[2] Defined as a movement towards Western-style capitalism with a strong emphasis on innovation.

American Chamber of Commerce. The survey found that 80 per cent of firms in the cohort would invest more in internal R&D and training if better patent protection were available.

In China, while the regime for patent protection appears to have been improving in recent years, there are still significant problems associated with inadequate enforcement of those rights. Regional income differences, insufficient incentives for commercialisation of the results of R&D and relatively low levels of research effort are also significant factors that could hinder the likely impact of the patent system in that country (Maskus 2000a: 308).

Nonetheless, the use of patents is rising rapidly in China for a number of reasons: firstly, the laws have improved and application fees are lower, inviting more applications; secondly, as patent infringement increases, both domestic and foreign enterprises recognise the importance of establishing a more rigorous patent enforcement regime; thirdly, as income levels grow, patents become more important in Chinese markets; and, fourthly, Chinese research organisations and enterprises are engaged in higher levels of invention, with Chinese firms also undertaking more innovative activity.

However, although bringing new products to market is a critical issue for technology development in China, with research managers often facing inadequate incentives to convert the results of their inventive work into marketable products and services, there is a lack of clarity on who owns technologies. There are also insufficient links between state owned enterprises and distribution networks, and there is a capital market that does not sufficiently finance private risk-taking.

Patents can play an important and constructive role in overcoming these difficulties by providing a well-defined asset, and participants in the research process can see clearly see the benefits of patent ownership (Maskus 2000a: 323). Such rights generate incentives for commercialising patented technologies and make the risk-taking associated with invention and commercialisation more attractive to potential investors such as banks and venture capitalists.

4 THE IMPACT OF PATENTS ON DEVELOPMENT

In practice the impact of patents on economic development is complicated by the fact that the potential gains in innovation must be offset against the short-term costs associated with patent protection, particularly the likelihood that relatively high prices will be charged for patented products, such as pharmaceuticals, in the absence of imitative products circulating in the market (Maskus 2000a: 169). Furthermore, in reality the extent to which patents will contribute to innovation and economic development will depend on local conditions and must be assessed on a case-by-case basis. Recent studies have considered this question in econometric terms.

Gould and Gruben (1996) related economic growth rates across countries to a simple index of patent strength and other variables. They found no strong direct effects of patents on growth but noted a significantly positive effect when the index was interacted with a measure of openness to trade. In particular they found that strengthening the patent regime in open economies was likely to raise growth rates by 0.6 per cent on average. For Gould and Gruben, therefore, trade liberalisation in combination with stronger patent protection and enforcement enhances growth because it improves the competitive nature of markets and increases access to foreign technologies.

Park and Ginarte (1997) focused on the extent that patents affect investment in capital and R&D, as well as economic growth. As with Gould and Gruben's study, they found no direct correlation between patent strength and economic growth. However, Park and Ginarte did generate empirical evidence to suggest that patents can have a powerful and positive effect on investment and R&D spending, which in turn can have indirect positive effects on economic growth.

For Maskus (2000a: 306) the empirical evidence thus supports three major conclusions. Firstly, while the relationship between patents and economic development is complex and difficult to unpack, on balance the evidence suggests that patents can indirectly have a positive effect on development. Secondly, the extent to which patents facilitate economic growth and technology development depends heavily on local conditions and the specific context in which the patent regime is operating. In this regard, policy-makers can maximise the benefits of the patent system by promoting an active technology infrastructure, including building human capital and skills, developing an

innovation system that helps move technologies from laboratories to the market, and establishing a transparent set of patent policy instruments.

Other important complementary factors include: structural reform to increase entrepreneurship and flexibility of enterprises; expanded liberalisation of restrictions on trade, investment and technology agreements; and additional steps to ensure competition in domestic markets among firms and across regions. Thirdly, there remains a role for restricting patents in order to achieve social goals such as ensuring access to affordable medicines and ensuring an adequate balance of benefits in technology transfer. Achieving social goals through restrictions on patents must, however, be achieved in a way that does not unduly limit the competitive incentives that are intended to be generated by the patent system as a whole (Maskus 2000a: 306). In this respect, a balanced patent system is defined as one where social benefits exceed social costs, and the system therefore contributes to a nation's economic wellbeing. Achieving balance in the system should therefore be the key objective of patent policy (Moir 2009).

So patents are capable of encouraging innovation under certain conditions, but can also hinder innovation under others and, given the complexity of the relationship between patents, innovation and economic performance, fine-tuning of the patent system is crucial to ensure that patents become an effective policy instrument for innovation (OECD 2004: 9). The risk is that patent protection may hinder innovation when it limits access to essential knowledge, as may be the case in emerging technological areas when innovation has a particularly pronounced cumulative character and patents protect foundational inventions. In this context, patent protection that is too broad can discourage follow-on inventors if the holder of a patent for an essential technology refuses others access under reasonable conditions (Merges and Nelson 1992: 187).

Furthermore, although patents are invariably thought of as the characteristic means of making it rational to invest in innovation, in fact they rank in importance far behind large-scale investments in terms of their ability to stimulate and facilitate innovation. This assertion is supported by empirical evidence on how firms capture the rewards from the results of their R&D in the US, Europe and Japan. These studies are generally in agreement that, with the exception of the strong role played by patents in the chemical and pharmaceutical industries, patents are unambiguously the least central of the major mechanisms for facilitating innovation (Kingston 2009: 12). Nonetheless, in technologies where the time and cost of imitation are relatively low, such as

in pharmaceuticals, there is a risk that innovation would not take place in the absence of a strong patent regime (Moir 2009: 33). In such instances, the crucial role played by the patent system as a stimulus for innovation needs to be recognised (Moir 2009: 38).

Yet the relationship between patents and innovation will still depend on the stage of economic development of the country in question and the initial strength of patent protection before stronger protection is introduced (Park 2008: 296). As we have seen, depending on the initial level of patent protection, the rate of innovation can vary significantly in response to higher standards of patent protection.

Park (2008: 297) suggests that stronger patent rights may negatively effect innovation because stronger rights increase the incentives to file patent applications. As a result, if more patents are subsequently issued, more second-comer innovators will need to obtain more permissions in order to access and build on previous technologies. These so-called 'patent thickets' increase the transaction costs of licensing and cross-licensing negotiations (Shapiro 2001). They also increase the likelihood of blocking patents, namely where the holder of a patent refuses to grant permissions in order to stave off competitive market entry. The increased transaction costs associated with blocking patents can consequently have a negative effect on R&D and innovation (Park 2008: 297).

A further variable to take into account is the fact that innovation is not only about developing new products – it is also about establishing marketing and distribution networks that support expansion and scale economies. It is therefore widely thought that it is difficult to do this in an environment of weak patent protection because rights-holders cannot readily protect their marketing channels (Maskus 2000a: 301).

For Maskus (2000a: 325) while higher standards of patent protection may make imitation more costly, real productivity benefits are likely to be realised through higher quality and increased levels of foreign technology inflows, either via technology transfer or FDI. These inflows, in turn, are critical to the success of domestic innovation efforts, with the key challenge being the identification of an appropriate patent regime that can attract foreign technology inflows at the same time as enhancing and protecting domestic incremental innovation.

Yet higher standards of patent protection do not in themselves establish the effective conditions under which technology development and growth will occur. Rather, these higher standards must be part of a broader toolkit of policy instruments that include an active technology innovation system, strengthened development in human capital through education in science and technology, and measures to encourage lifelong learning through training within enterprises, as well as through the formal education system (Maskus 2000a: 327).

5 LICENSING AND TECHNOLOGY TRANSFER

Licensing can also be used as a valuable policy tool to substitute for FDI and to overcome uncertainty about the policy environment, and may be a more viable route for multinationals seeking to exploit their patented inventions than exploiting the technology through foreign investment. This may be even more likely to be the case since domestic firms may have more information or be better placed than foreigners to deal with a poor policy environment (World Bank 2008). Maskus (2002) suggests that both FDI and licensing respond to an adequate business environment, and factors such as patent protection may shift incentives for investors from FDI toward licensing.

In practice, where patent protection is weak, multinationals may be less willing to license technology for fear of it being copied by domestic firms or, alternatively, they may only license out-of-date technologies (Maskus 2000b). Data on U.S. multinationals show that the likelihood of entering into licensing agreements increases as developing countries raise the standard of patent protection available (Antras, Desai and Foley 2007).

Yet, for the poorest countries in particular, technology transfer to least-developed countries has in recent years been hampered by factors including the fact that technology is mainly in the private sector, with a limited role from governments, and also because least-developed countries' absorptive capacity needs to be increased, with greater emphasis on education and training.

6 THE IMPACT OF THE TRIPS AGREEMENT

Reconciling TRIPS implementation in developing and least-developed countries with national patent policies to promote invention and innovation is therefore a significant challenge. Discussion has focused in part on utilising to the full extent measures to protect and promote the public interest as set out in flexibilities allowed by the TRIPS Agreement, such as Article 7 on technology transfer and dissemination, Article 8.1 on measures to promote the public interest in sectors of vital importance to their socio-economic and technological development or Article 29 on disclosure in patent applications.

Article 7 of the TRIPS Agreement sets out the objectives that WTO member countries should be able to reach through the protection and enforcement of such rights.[3] As Article 7 makes clear, intellectual property rights are not an end in themselves, so the protection of intellectual property rights will not automatically lead to the promotion of technological innovation and to the transfer and dissemination of technology (UNCTAD-ICTSD 2005: 126).

Article 8.1 of the TRIPS Agreement provides the opportunity for WTO member countries, when formulating or amending their laws and regulations, to promote the public interest, including those in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the TRIPS Agreement.[4] Although 'public interest' is not defined in the TRIPS Agreement, this suggests that measures adopted by WTO members should be presumed consistent with TRIPS unless another member seeking to challenge the exercise of discretion is able to prove inconsistency (UNCTAD-ICTSD 2005: 127). In this way, by mandating measures to promote the public interest in sectors of vital importance to their socio-economic and technological development, Article 8.1 provides an important flexibility in limiting

[3] Article 7, TRIPS Agreement: '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.'

[4] Article 8.1, TRIPS Agreement: 'Members 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, provided that such measures are consistent with the provisions of this Agreement.'

the potential range of non-violation nullification or impairment causes of action that might be pursued under TRIPS (UNCTAD-ICTSD 2005: 127).[5]

The relationship between patents, health and access to medicines has been a critical issue with regard to the public interest in developing and least-developed countries in recent years, with many medicines that could save or extend lives unavailable, inaccessible, or unaffordable to those who need them most. There is a pressing need for measures to ensure access to existing medicines and the development of new medicines that effectively address the global disease burden. In the context of these concerns, the obligations of developing and least-developed countries to implement the TRIPS Agreement have come under close scrutiny, and criticism from development-orientated public health non-governmental organisations (NGOs) and public health experts has been commonplace.

These criticisms have arisen because the TRIPS Agreement requires WTO members to grant patents for pharmaceutical products. Patented medicines generally cost more than the equivalent, unpatented, 'generic' versions but the TRIPS Agreement limits the extent to which countries can produce, import and export cheaper generic versions of medicines. With the prospect of rising prices for patented medicines, the link between patents and access to medicines has become more widely recognised.

In the immediate post-TRIPS period the initial challenge related to the scope and interpretation of the TRIPS Agreement - to the constraints on the use of in-built TRIPS flexibilities designed to ensure access to medicines. TRIPS flexibilities include provisions with regard to compulsory licensing, exceptions to rights granted by patents and parallel importation. Under Article 31 of the TRIPS Agreement a compulsory licence can be granted by a government to allow a third party to produce a generic version of a patented pharmaceutical product without the authorisation of the patent holder, in so doing allowing low-price generic pharmaceuticals to be produced locally (Matthews 2004: 77). The TRIPS Agreement provides a further public health-related flexibility with possible exceptions to rights conferred by a patent, including research and

[5] On 6 November 2009 WTO members reached agreement on a two-year recommended extension of a moratorium on challenging other WTO members under intellectual property rules for actions not in violation of the WTO, according to a WTO official. The recommended extension would go before the WTO General Council and then to ministers at the 30 November to 2 December 2009 WTO ministerial in Geneva.

experimentation, prior use, early working, and the export of medicines to non-producing countries.

Parallel trade refers to instances where products produced under protection of a patent (or trade mark or copyright) in one market are subsequently exported to a second market and placed on that market without the authorisation of the local owner of the patent, with the practical effect that a patented product becomes available locally from multiple sources, in doing so enhancing market competition between sources of the same products which tends to drive down prices (Matthews and Munoz-Tellez 2007: 1429). Under the TRIPS Agreement, countries are free to determine how they approach exhaustion of rights, with the effect that developing countries can adopt in their national regimes an international exhaustion principle to permit parallel importation which, under certain conditions, would allow for a patented medicine to be imported and sold in the market at a lower price than that for which the patent holder sells it in that market (Matthews and Munoz-Tellez 2007: 1429).

However, developing countries have faced a number of problems in utilising available TRIPS flexibilities to protect public health and to promote access to medicines. One of the main problems for developing countries attempting to utilise TRIPS flexibilities is that, although the provisions on compulsory licensing permit generic drug companies to manufacture a patented product without the authorisation of the right holder, in doing so creating a mechanism for cheap generic medicines to be made available at a lower cost than the equivalent patented products, the TRIPS Agreement also requires that medicines produced under compulsory licence conditions should be predominantly for the supply of the domestic market of the WTO member authorising such use. This constitutes a major problem for WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector, these countries being unable to make effective use of compulsory licensing under the TRIPS Agreement (Matthews 2004: 78). On 6 December 2005 an amendment to the TRIPS Agreement was agreed, making permanent a waiver of the requirement that compulsory licences be predominantly for the supply of the domestic market (Matthews 2006). However, two principle problems persist in relation to patents, health and access to medicines: firstly, perceived restrictions on the use of TRIPS flexibilities due to bilateral trade pressures; and secondly the relative inability of the patent system to provide adequate incentives for R&D into neglected diseases.

The use of compulsory licensing provisions and other TRIPS flexibilities has been problematic because the procedural requirements for implementing the appropriate national legal provisions are complex and burdensome, particularly for developing and least-developed countries that lack the necessary technical and legal expertise and administrative capacity (Matthews 2005: 423). In addition, free trade agreements (FTAs) often include measures, commonly referred to as 'TRIPS-plus' provisions, that prevent developing countries from using TRIPS flexibilities and often even exceed the obligations under the TRIPS Agreement and limit the capacity of developing countries to issue compulsory licenses effectively or allow parallel importation (Musungu, Villanueva and Blasetti 2004: 30).

7 ALTERNATIVES TO THE PRESENT PATENT SYSTEM

Given that concerns about the appropriateness of the present patent system have focused, in particular, on health and access to medicines in developing countries, it is in this context that alternatives to the present system have come to the fore with greatest prominence.

Although fewer than 5 per cent of medicines on the WHO Model List of Essential Medicines are patented (World Health Organisation 2002: 4) many new drugs, particularly those designed to deal with the most pressing public health crisis of modern times, the HIV/AIDS virus, are subject to patent control (Bourgeois and Burns 2002: 839). Many commentators fear that the problem of obtaining access to the medicines needed to deal with the HIV/AIDS pandemic in developing countries will be further hindered by the patent provisions of the TRIPS Agreement. The concern has been that, due to the TRIPS Agreement, the extension of patent protection for pharmaceuticals in developing and least-developed countries will lead to unacceptably high prices for medicines in the developing world (see also Ismail 2003: 395; Rozek 2000: 896; Rozek and Rainey 2001: 471).

This concern was affirmed in the UK Commission on Intellectual Property Rights report, which suggested that if patents were absent in developing countries more patients would be able to afford treatment since there is considerable evidence that consumption of medicines is sensitive to price (Commission on Intellectual Property Rights 2002: 37; see also Department for International Development 2003: 5; and criticisms of the CIPR Report by Crespi 2003). But, conversely, in the absence of patent protection for pharmaceuticals in developing countries, the Commission's report also demonstrated that there may be insufficient incentive structures, with the result that investment in private sector pharmaceutical R&D for diseases that predominantly affect developing countries remains low.

Less than 5 per cent of the estimated $44 billion spent on R&D is directed towards developing country diseases, while only 13 of the 1,393 new drugs approved between 1975 and 1999 are concerned with tropical diseases (Commission on Intellectual Property Rights 2002: 32). The HIV/AIDS pandemic is particularly problematic in this respect since the majority of HIV vaccines are being developed for genetic profiles of subtype B, prevalent in developed

countries, while most AIDS sufferers in developing countries are types A and C, for which far less research is being carried out (Commission on Intellectual Property Rights 2002: 33).

Yet the overall situation remains complex with factors other than patents (such as health care provision, research and political commitment in developing countries) also constituting significant barriers to access to essential medicines in developing countries. Attaran and Gillespie-White (2001), for instance, have argued that patents are not a significant barrier to the treatment of HIV/AIDS in Africa, with a variety of other factors, such as poverty, tariffs and sales taxes, and a lack of sufficient international financial aid to fund anti-retroviral treatment, being of greater significance.

Since 2003 the World Health Organization (WHO) has been addressing the need to support biomedical R&D and released a report by the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) in April 2006.

The subsequent WHO Intergovernmental Working Group (IGWG) on Public Health, Innovation and Intellectual Property was established in 2006 by WHA Resolution 59.24 and was tasked with producing a "global strategy and plan of action" with the goal of "securing an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries, proposing clear objectives and priorities for research and development, and estimating funding needs in this area." A Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property was adopted in May 2008 by WHA Resolution 61.21. In November 2008, a results-orientated and time-limited Expert Working Group (EWG) on R&D Financing was established.

The EWG has the mandate to examine current financing and coordination of research and development, as well as proposals for new and innovative sources of funding to stimulate research and development related to Type II and Type III diseases and the specific R&D needs of developing countries in relation to Type I diseases. The EWG has a one-year mandate to examine current financing and coordination of research and development, as well as proposals for new and innovative sources of funding to stimulate research and development related to Type II and Type III diseases and the specific R&D needs of developing countries in relation to Type I diseases. The members of the group are 24 internationally recognized policy-makers and technical experts

that participate in their personal capacity. Amongst the proposals under review by the EWG are prize funds and patent pools.

In addressing the need for a new global framework for supporting the funding of medical R&D, the EWG has considered the extent that prize funds can be used as mechanisms for stimulating R&D into diseases that disproportionately affect the developing world. Prizes are funds that create rewards for successful development of new products, to be paid in a lump sum once a product obtains the necessary marketing approval. The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) has argued that prizes should be structured to complement and not undermine current patent systems.[6] Knowledge Ecology International (KEI) has argued that innovation inducement prizes with proportional reward systems should replace marketing monopolies as the primary incentive mechanism for stimulating R&D.[7]

Another initiative relates to the use of patent pools. A patent pool is an agreement between two or more patent owners to licence one or more of their patented inventions as a package (Kaplan 2007). This agreement can take many different forms (Serafino, 2007). In one common form, patents are cross-licensed to each of the other patent owners. In another form, a third party administers one or more packages of patent licences to third party manufacturers (e.g. makers of generic antiretrovirals - ARVs). This patent package would be offered to third party licensees who would be authorised to use the bundle of patented inventions to exploit the technology encompassed by the patent pool. The third parties would typically pay royalties to the patent holders or to the organisation administering the pool. The organisation allocates royalties back to the patent owners.

This form of collective patent management has been around for over 100 years in a variety of industries (Bekkers, Iversen and Blind 2006). Theoretical and practical reasons to create collective management structures include the possibility of lower prices, improved economies of scale, lower transaction costs of negotiating and administering licensing programmes, increased innovation, removing blocking patents and managing or eliminating litigation risks (Grassler and Capria 2003).

[6] IFPMA Submission to the Public Hearing on Proposals for R&D Financing. Available at: http://www.who.int/phi/IFPMA.pdf.

[7] Comments of Knowledge Ecology International (KEI) to the WHO public hearing for proposals for new and innovative sources of funding to stimulate R&D, 15 April 2009. Available at: http://www.who.int/phi/KEI.pdf.

Operationalising these collective management structures for ARVs is complicated by the fact that market-driven and public health-driven views of innovation and IP in the pharmaceutical value chain are often at odds. This factor is manifested as continued debate over patents and access to medicines. The OECD countries have technology buyers and sellers (Evenson, 2001) while, with some exceptions (South Africa, Brazil, India, China, Indonesia), developing countries are buyers of technology.

Recent examples of patent pools have arisen in relation to UNITAID and GSK. On 2-3 July 2008, UNITAID's Executive Board approved a proposal to establish a patent pool for medicines with the aim of providing patients in low-income and middle-income countries with increased access to more appropriate and affordable medicines,[8] with an initial focus on paediatric antiretroviral medicines and new combinations.[9] Since then, on 13 February 2009, GSK announced its intention to create a least-developed country (LDC) patent pool to promote R&D into medicines for neglected diseases,[10] contributing over 800 granted or pending GSK patents to the collaborative pool.[11] However, the GSK announcement has been criticised as failing to provide a sustainable model for innovation and access for all[12]. It failed to include HIV in its definition of a neglected disease, apparently because GSK is separating middle-income developing countries from least-developed countries, offering a promise of benefits only to the least-developed, and little more.[13]

[8] UNITAID Press Release: 'UNITAID moves towards a patent pool for medicines'. Available at: http://www.unitaid.eu/en/20080709113/News/UNITAID-moves-towards-a-patent-pool-for-medicines.html.

[9] This move was supported, in July 2009, by the UK All-Parliamentary Group on AIDS in its published report The Treatment Timebomb which called for patent pools for HIV drugs.

[10] The diseases targeted by GSK's patent pool are the 16 diseases identified by the US Food and Drug Administration in its own neglected tropical diseases initiative. These are tuberculosis, malaria, blinding trachoma, buruli ulcer, cholera, dengue/dengue haemorrhagic fever, racunculiasis, fascioliasis, human African trypanosomiasis, leishmaniasis, leprosy, lymphatic filariasis, onchocerciasis, schistosomiasis, soil transmitted helminthiasis and yaws.

[11] *GSK's contribution to the patent pool*. Available at: http://www.gsk.com/collaborations/contribution.htm.

[12] *KEI reaction to GSK announcement on patent pool for neglected diseases*. Available at: http://keionline.org/blogs/2009/02/19/gsk-patent-pool.

[13] MSF Access to Medicines Campaign Press Release, 16 February 2009, *A Welcome First Step - but HIV is also a neglected disease*. Available at: http://www.msfaccess.org/media-room/press-releases/press-release-detail/?tx_ttnews%5Btt_news%5D=1532&cHash=f8c0eca3b4.

8 PROSPECTS FOR THE FUTURE: USING PATENT INFORMATION TO STIMULATE INVENTION AND INNOVATION

Although the evidence that patents encourage invention and innovation in developing and least-developed countries is ambiguous overall, one policy option available to developing and least-developed countries that could assist further with stimulating invention and innovation is greater use of patent information. Patent information comprises technical, legal, business-relevant and public policy-relevant information which is generally publicly available, free of charge. In this regard, Article 29 of the TRIPS Agreement sets out the obligation to disclose a patented invention in a manner sufficiently clear and complete for others to be able to recreate the invention and improve upon it (UNCTAD-ICTSD 2005: 448). The expectation is that, while the inventor is given a limited monopoly on the use of his invention in exchange for allowing it to be published, others can build on it, even though they cannot use it during the term of patent protection without the patentee's agreement. As a result of this requirement, national and regional patent offices provide a vast repository of technical information that can be accessed free of charge.

So there is great potential for patent information focusing on a particular technology – known as patent landscapes – to contribute to the development needs of developing countries by identifying essential technologies, know-how, processes and methods that are potentially of use to them.

However, even though patent information is easily accessible via the internet, this resource is used to only a small fraction of its potential for stimulating invention and innovation. In building their economic success, Japanese firms used the publication provisions of the international patent system as a valuable source of information, even in pre-electronic information days, far more effectively than firms in any other country have done.[14] The use of patent disclosure information remains limited in developing and least-developed countries, despite the existence of a number of free patent database services such as WIPO's Patentscope®[15] or Cambia's Patent Lens.[16] General knowledge and techniques in searching patent information, including the extraction of

[14] Source: William Kingston, *correspondence with the author.*
[15] http://www.wipo.int/patentscope/en/.
[16] http://www.patentlens.net/daisy/patentlens/patentlens.html.

relevant information from patent databases, are not at present readily known and therefore it is fundamentally important to support these through technical assistance initiatives in favour of developing and least-developed countries in the future.

9 CONCLUSIONS

This chapter has re-examined the premise that the absence of an effective patent system in developing and least-developed countries is important because unfettered imitation is a prerequisite for invention and innovation. The absence of patents, it is argued, is the essential first step to economic and technological development that allows firms in these countries to learn freely about, and to internalise, technological advancements in any given field before starting to invent and innovate themselves.

For firms in developing or least-developed countries that are engaged in imitating or adapting technologies in this way, it is thought that introducing stronger patent protection could actually inhibit the process that helps them to learn about technologies and to build an effective knowledge base for subsequent R&D-orientated activity. According to this model, only when additional inventive capacity has been developed in this way will stronger patent systems stimulate innovation and invention in the manner anticipated in the developed world.

However, recent successes in terms of building invention and innovation in China, India and other countries such as Brazil and Russia challenge the view that imitation should be considered a necessary phase of industrial development for emerging economies. These countries are building domestic infrastructure and R&D capacity by using other ways of learning about new technologies rather than relying on imitation. These new approaches include opportunity to access information available online, the use of open access scientific journals and patent databases.

The fact that patent information in particular is not widely known or used in low-income developing or least-developed countries in this way supports the view that it is fundamentally important to develop further technical assistance initiatives in favour of explaining how patents can stimulate and support invention and innovation in developing and least-developed countries in the future.

In practice there can be no one-size-fits all approach to prescribing how patents can play a positive role in the global economy. The extent to which patents will contribute to invention, innovation and economic development will depend much on local conditions. Education, the structure and funding of R&D, the management of technological assets, and the existence of technology transfer

offices (TTOs) will all play a part, as will patent enforcement mechanisms. The extent to which patents can stimulate invention and innovation must also be assessed on a case-by-case basis, and responsiveness to a patent system will vary depending on the industrial sectors and the countries concerned.

The impact of pharmaceutical patents on health and access to medicines, where a number of alternative models for new drug development are now being articulated, is just one aspect of how the social value of invention and innovation needs to be balanced against the enclosures created by intellectual property rights (the traditional knowledge of indigenous communities being another notable example).

Patents have the potential to stimulate invention and innovation, but they can also have unintended consequences and must be utilised as part of a wider set of policy instruments. The issue is consequently more complicated than simply saying whether or not patents will lead to development. The challenge for the future will be how best to incorporate these nuances into a complex web of policy imperatives that best define the role of patents in the global economy.

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