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# Designing patent policies suited to developing countries needs\*

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**Abstract:** Despite the internationalization of the patent system that started more than one century ago and, particularly, the establishment of minimum standards of protection under the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS), States still enjoy a certain degree of discretion to determine key substantive aspects relating to the grant of patents. Initiatives for further harmonization of the system have not materialized yet. Recent trends in some developed countries point to a drastic relaxation of the standards of patentability, particularly in connection with the inventive step. Developing countries need not follow the same approach; they may apply strict standards of patentability compatible with their innovation systems and reward incremental innovations by means of utility models rather than patents. They may also develop rules to deal with the specificities of traditional knowledge.

**Key words:** patent harmonization, novelty, inventive step, grace period, traditional knowledge, innovation systems, utility models, TRIPS Agreement.

**JEL:** O34, O38.

## 1. Introduction

The patent system was devised in order to reward inventiveness, encourage technical progress and foster the dissemination of innovations. The restriction to the free movement of ideas that the granting of a patent entails has been justified under different theories, namely natural rights, moral reward, incentive to invention, encouragement to

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innovation. The idea that patents are necessary to allow the investor to recoup its investment in R&D dominates in current debates and the case law of many countries (Gutterman, 1997).

Though the development and exploitation of numerous contributions to technology have been closely linked to, although not necessarily determined by, the possibility of obtaining exclusive rights to exploit inventions (Archibugi and Malaman, 1991), the patenting system is far today from fulfilling its intended objectives. The expansion of the subject matter of patentability from inanimate to living forms, the admission of broad claims encompassing vast fields of technology, the dilution of the patentability requirements, and shortcomings in the examination process, have led to a profound distortion of the system (Jaffe and Lerner, 2004). There is a proliferation of patent applications<sup>1</sup> and grants, in great part motivated by a variety of defensive and offensive patenting strategies (Granstrand, 1999).

One increasingly widespread view is that the patents system is in crisis (Foray, 1995), and that its role in promoting innovation is less substantial than usually claimed (Landes and Posner, 2003; Levin et al., 1987). Patents may even stifle the very innovation they are supposed to foster. The National Academies of the United States have taken up the criticism leveled by many academics and sectors of industry and have expressed their concern about the lax application of the patentability standards (National Academies of Science, 2003), especially as regards non-obviousness and usefulness, in the examination and granting of patents, resulting in many over-broad (Mazzoleni and Nelson, 1998) or “low quality” patents (Cooper, 2004).

According to Deputy Director F. Gurry of the World Intellectual Property Organization (WIPO), there is only a ‘functional stress’ in the patent system, ‘due to an explosion in demand, an explosion in counterfeiting and piracy, and radical new technologies and economic changes affecting delivery and the ability to copy or imitate protected material. In addition, the growing recognition of the enormous value of intellectual property rights has led to more political attention being paid to it’.<sup>2</sup>

However, even the users and main beneficiaries of the patent system have become growingly critical. A survey conducted among large com-

panies<sup>3</sup> by the Intellectual Property Owners Association (IPO) in August 2005 showed that its corporate members perceive the quality of patents granted by the U.S. Patent and Trademark Office to be less than satisfactory. Over half of respondents, 51.3 percent, rated the quality of patents issued in the U.S. today as less than satisfactory or poor (47.5 percent less than satisfactory and 3.8 percent poor). Those rating quality more than satisfactory or outstanding were 8.8 percent of all respondents (8.8 percent more than satisfactory and 0 percent outstanding). Respondents' prognosis for the future was not encouraging. Over two-thirds of respondents said they would be spending more, not less, on patent litigation over the coming years.<sup>4</sup>

The efficacy of the patent system for ensuring a satisfactory rate of innovation at the lowest social cost is under serious doubt. A basic question in developed countries is how to ensure that patents actually encourage, rather than unduly limit competition and hold back innovation (Federal Trade Commission, 2003; Samuelson, 2004). As incremental innovations prevail in most sectors (including biomedicine), the patent system has increasingly moved away from its objective of stimulating genuine 'invention' towards a system for the protection of investment in incremental innovation, whether truly inventive or not. For some analysts, "the time has come not for marginal changes but for wide-open thinking about designing a new system from the ground up" (Thurow, 1997).

This paper discusses, first, different dimensions of the globalization of the patent system. Second, it examines the policy space left for the design of national patent policies, including the harmonization process conducted under the auspices of WIPO and the TRIPS-plus provisions in free trade agreements, the room to adapt such policies to the characteristics of the innovation process, and the application of patents to indigenous/traditional knowledge.

## 2. Globalization of the patent system

The internationalization of the patent system started more than one century ago with the adoption of the Paris Convention for the Protection

of Industrial Property in 1883. The Convention reflected the interests of the emerging industrialized countries at that time,<sup>5</sup> but left considerable flexibility for contracting parties to design their patent systems. While in successive revisions of the Convention, such flexibility was somehow limited (for instance in relation to the revocation of patents for lack of local working), the Convention left space for exclusions to patentability, the determination of what exclusive rights would be enjoyed, how long patents would last, among other matters. During the 1970's developing countries attempted to further expand such flexibilities, in parallel with the development of international rules for the transfer of technology and for the conduct of multinational corporations, but such attempts found an insuperable resistance from developed countries and finally failed.

Developed countries have increasingly promoted, since the 1980's, the adoption of their own standards of patent protection in developing countries (Correa, 2002a). This has been made via different mechanisms:

First, bilateral and multilateral technical assistance has significantly contributed to shape the patent systems in many developing countries in line with those adopted in developed countries, generally with little consideration of the particular situation and needs of the recipient country (Pengelly, 2005).

Second, the TRIPS Agreement adopted in 1994 incorporated a detailed set of substantive and procedural minimum standards applicable to patent law. Although the Agreement allowed developing countries and LDCs to apply transitional periods, it did not permit any form of differential treatment. The Agreement essentially followed a 'one size fits all' approach, though it left room for maneuver in many areas (CIPR, 2002; World Bank, 2001:147).

Third, WIPO launched an initiative to further harmonize the patent system through the so-called 'WIPO Patent Agenda'.<sup>6</sup> This initiative was envisaged as a process of worldwide discussions with the aim of preparing the platform for the development of a more uniform international patent system. One of the main components of this Agenda was to resuscitate the negotiations on a Substantive Patent Law Treaty (SPLT), which had collapsed in the 1980's as developed countries strategically moved to

GATT in the face of WIPO's failure to push forward a draft treaty for the harmonization of patent law.

Finally, developed countries, notably the United States, have multiplied its efforts to export key features of its own patent system through specific provisions in free trade agreements (FTAs). Such provisions include, in the case of US FTAs, the definition of patentability and disclosure requirements, extension of patent term, limitations to exceptions to exclusive rights (including, in some FTAs, compulsory licenses), and new modalities (not even in force in the USA) for linking patent protection to the registration of pharmaceutical products (Correa, 2004b).

In this context, rethinking what the patent system does, who benefits from it, and how can it be applied with a minimum cost, has become an urgent task for developing countries. The critical issue is how to design the domestic patent system in a way that fits the national level of development and the socio-economic needs of the country. Adopting a national approach to the patent system – as opposed to a 'global' approach – assumes that despite the international trends mentioned above, countries still have space to establish their own patent policies. It also postulates that such a solution is superior, in terms of socio-economic benefits, to the uniformity prescribed by a global approach based on the patterns conceived by and applied in developed countries.

### 3. Designing patent laws

Despite the intense efforts to further harmonize, at a global scale, the patent system, developing countries retain the capacity to pursue the development of systems that are better adapted to their own needs. A number of considerations need to be made in this regard.

#### Space remaining for the design of patent laws

The limitations that the TRIPS Agreement has imposed on WTO Members to develop their own intellectual property systems have been extensively examined (UNCTAD-ICTSD, 2005). In the area of substantive

patent law they include: (i) criteria for patent protection; (ii) determination of eligible subject matter; (iii) specification of exclusive rights, subject to compulsory licenses and exceptions; (iv) term of protection; and, (v) reversal of burden of proof for process patents.

Notwithstanding that the patent section is more detailed than other sections of Part II of the TRIPS Agreement (with the exception of geographical indications), it leaves a large number of issues at the discretion of national governments. Some of these issues are critical for the design of a patent regime, such as the definition of what an ‘invention’ is, the patentability requirements, what is deemed to belong to the prior art, the grounds of compulsory licenses and exceptions.

As mentioned above, the space left by the TRIPS Agreement is being eroded, in some countries, by the TRIPS-plus provisions contained in FTAs. Countries signing such treaties are giving away a good deal of their capacity to shape their patent policies. In some FTAs the faculty to establish exceptions to patentability has been limited, and the obligation to grant patents has been extended beyond TRIPS so as to cover *uses* of known products, such as the second indication of existing medicines.

Another threat to the policy space retained by countries under the TRIPS Agreement has been the WIPO initiative to develop a SPLT with a number of specific provisions on key issues of patent law (Correa and Munsungu, 2002; Correa, 2004a). As the result of the considerable resistance from developing countries, and of the persistent disagreement among developed countries on some provisions, developed countries opted to narrow down their ambitious proposal. Following the advice of the Association Internationale pour la Protection de la Propriété Intellectuelle (AIPPI)<sup>7</sup> – one of the major “users organizations” – the USA, Japan and the European Patent Office (EPO) elaborated a proposal (known as the ‘trilateral proposal’) to develop a gradual approach to the adoption of the SPLT. They suggested to limit immediate discussions to a narrow but important set of issues: (1) Definition of prior art; (2) Grace Period; (3) Novelty; (4) Non-obviousness/Incentive step. The issues suggested for this initial phase of harmonization are crucial. If agreed upon, they would provide a uniform definition to key aspects determining the scope of patentability.

‘Prior art’ is all of the pertinent and applicable knowledge in the public domain at the time a patent application is filed.<sup>8</sup> A narrow definition of this concept may lead to the expansion of the room for appropriation that is and should remain in the public domain and available to all. Important issues are, among others, whether the secret prior commercial use or the offer for sale without disclosure puts an invention into the prior art, the extent that information disclosed in previous patent applications are to be considered, and for what purposes,<sup>9</sup> and the determination of the date of availability to the public.

Another important issue for developing countries is the extent to which indigenous/traditional knowledge may be considered part of ‘prior art’. Can knowledge that has been available within an indigenous/traditional community be deemed to have been made available to the public? If so, neither the holders of such knowledge nor any other person might validly seek and obtain patent protection. If dissemination within a community is not regarded, however, as making the invention available to the public, the subject matter might still be patentable. Of course, the holders of such knowledge would be the only legitimized parties to apply for patent protection, although they are unlikely to often do so for lack of awareness, cultural, financial or technical reasons.

The application of a grace period (admitted in the USA and in many other countries) has raised a significant controversy between the USA and the European countries, where such period is not provided for. It expands the scope for patenting, as inventions disclosed during that period would be eligible for protection, despite that they would have been deemed in the prior art in accordance with the general rule on novelty.

The definition of ‘novelty’ is also crucial. The TRIPS Agreement does allow Members to adopt their own definitions. This has permitted, for instance, the USA to maintain its double standard depending on whether the disclosure of the inventions has taken place within or outside the territory of the USA. In practice, the concept of novelty is narrowly construed by patent offices, requiring an almost ‘photographic’ disclosure of the invention in a single prior document in order to consider that novelty does not exist. For experienced patent applicants, overcoming novelty barriers is just a matter of clever design of patent applications. Important

issues are raised, among others, in cases where an invention is not found *expressis verbis* in a document but may be derived therefrom, and where an invention is selected from a family of products already disclosed (the so called ‘selection inventions’) (Grubb, 1999).

Finally, defining ‘non-obviousness/inventive step’ is one of the most critical aspects of a patent regime, as it determines the level of technical contribution required to obtain a patent. As the TRIPS Agreement does not define this concept, Member countries are so far free to determine whether they want a system under which a myriad of minor, incremental, developments are patentable,<sup>10</sup> or one aimed at rewarding substantive departures from the prior art. The original proposal of the SPLT clearly opted for the first approach. The draft Regulations proposed a broad definition that imposes a very low standard for determining inventive step.<sup>11</sup> The claimed invention would be assessed against the general knowledge of an ordinary skilled person, and not against specialized knowledge in a particular field of technology.

This analysis suggests that despite its apparent narrowness, the ‘trilateral proposal’, if pursued, would impose important constraints on the countries’ ability to drawing the dividing line between knowledge that remains in the public domain and that is subject to private rights. Many developing countries have rightly adopted a critical view on that proposal, and recent developments in WIPO showed that it will not be an easy task for their proponents to move it any further.

It is argued, however, that more uniformity in respect of the building blocks of the patent system would facilitate the tasks of patent offices<sup>12</sup> and increase foreign patenting, including by nationals from developing countries. This may be partially true, but the eventual benefits for developing countries that such uniformity might brought about do not justify the price to be paid in terms loss of the capacity to design their patent laws in a way that serves national interests.

### Adapting patent law to innovation systems

Patents are granted to promote innovation. The formulation of a patent law, hence, should not be dissociated (as is generally the case)



from the characteristics of the innovation system<sup>13</sup> of the relevant country. These considerations have been generally absent in the programs of technical assistance provided through bilateral or multilateral means.

Interestingly, there is only one provision in the TRIPS Agreement where the relationship between the protection of intellectual property and technological capacity is mentioned. Paragraph 1 of article 66 ('Least-Developed Country Members') provides that;

“In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period”.

The wording of this provision suggests<sup>14</sup> that in order to develop a 'viable technological base' LDCs need a flexible intellectual property system, that is, less protection than that required under the Agreement. This is in sharp contrast with the main argument of the proponents of the TRIPS Agreement, in the sense that more intellectual property protection would lead to more innovation, and is rather in tune with developing countries' demand for more flexibility and policy space to develop their own technological capacities.

In most developing countries the innovation systems are fragmented and weak, and they overwhelmingly depend on innovations made abroad. In many countries, which followed the 'linear model' of scientific and technological development, the public sector modestly invest in scientific activities – generally focused on subjects of research of interest to developed countries- while domestic firms largely generate “minor” or “incremental” innovations<sup>15</sup> derived from the routine exploitation of existing technologies. Domestic firms generally follow “imitative” or “dependent” technological strategies, usually relying on external sources of innovation, such as suppliers, customers and competitors.

However, there are growing differences among developing countries. Some developing countries (such as China, Brazil and India) that are more scientifically advanced than others, are starting to reap benefits from decades of investments in education, research infrastructure, and manufacturing capacity. These countries – which have been called in recent literature as ‘innovative developing countries’ (IDCs) (Morel et al., 2005:401), invest in R&D relatively more than other developing countries, there is a greater involvement of the private sector, and the interactions between public institutions and private companies and with innovation agents in developed countries are more frequent

Adapting the patent system to these various situations is not a simple task. The considerations relevant to an IDC may well be different from those relevant to less technologically advanced countries. These differences, however, should not be overstated since, on the one hand, developing countries, including IDCs are equally vulnerable to patent strategies of large companies from developed countries and, on the other, a large portion of the population in those countries live in poverty, and will equally bear the costs of tight patent systems in terms of reduced access to essential goods, such as medicines and chemical products for agriculture.

An example of adaptation of the patent law to local conditions is provided by the recent reform (2005) of the Indian Patent Law. In order to prevent the so-called ‘evergreening’ of pharmaceutical patents,<sup>16</sup> which delay or impede competition of generic products, the law introduced a specific provision tightening the inventive step requirement as applied to new forms or modifications of existing products. Section 3(d) stipulates that the following shall not be treated as an invention within the meaning of the Act:

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

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

Although this is an important example, the broader question is how to frame the patent system where the innovations prevailing in the country relate to minor/incremental technical changes. At first sight, such innovations may be regarded as outside the patent system, and a different set of measures to promote them would seem to be called for.

Contrary to the ordinary belief, however, patents are not granted only when a significant technical development has been achieved. In fact, the largest part of R&D undertaken (by large and small firms) is devoted to the improvement on and further refinement and patenting of existing technologies.<sup>17</sup> Though not all types of incremental innovations may be eligible for patent protection, many actually do.

Inventions marked with considerable originality (Merges and Nelson, 1996:128) do not occur frequently, even in highly intensive R&D industries. For instance, while in the pharmaceutical sector, only a small number of “new chemical entities” (i.e. not pre-existing molecules) are developed and patented each year,<sup>18</sup> thousands of patents are applied for and obtained covering processes of manufacture, different crystal forms or formulations, new indications, and other aspects of or modifications to existing pharmaceutical products. There is also a great deal of emulation of successful drugs by rival companies (Casadio Tarabusi and Graham, 1998, p. 78), leading to the development of “me-too drugs”. Nearly half of the new drugs approved for use in the USA in the 1990s did not offer important clinical improvements (Oxfam, 2000, p.26). A study made in Canada on 1147 newly patented drugs, including derivatives of existing medicines between 1990 and 2003, revealed that 1005 of such drugs did not provide a “substantial improvement over existing drug products” (Morgan *et alli*; 2005).

The application of low standards of patentability may, in practice, subject to private control both genuine inventions and minor/incremental innovations that occur in different sectors. Although patents

may only capture a subset of such innovations, it might be argued that a patent regime based on a low inventive threshold could be functional to the innovation path prevailing in developing countries, as patents might encourage both major and minor innovations.

In some countries, such as UK, it has been deemed preferable to include provisions in the ordinary patent law that allow the patent office a great degree of flexibility in applying the patentability standards, rather than establishing a separate title for small inventions (Llewelyn, 1996, p. 195). This is also, *de facto*, the case in the USA, where a large number of patents with low, if any, inventive step are granted.

This expansive approach on patentability, however, may have negative consequences. On the one hand, as exemplified by the case of pharmaceuticals, large firms with experienced patent lawyers are much better prepared, financially and technically, to exploit a patent regime with a low patentability threshold than domestic firms, and there is a risk of blocking innovation and competition, rather than promoting it. In addition, the public will be bound to pay monopoly prices for access to knowledge and product that should be, and remain, in the public domain.

On the other, the cost of acquisition and, particularly, exercise of patent rights is too high for most local innovators, generally small and medium enterprises (SMEs). While SMEs could opt in many cases to seek patent protection, they must bear the costs of filing, registration and maintenance. If there is litigation, (either to enforce the patent against infringers or to defend it from validity challenges), victory in courts is not assured, damage claims by counterparts may be high and litigation costs may be prohibitive.

A second approach, adopted by some countries, for the promotion of innovation that may not meet a high standard of inventive step is to provide for the registration of utility models, also known as “petty patents”.<sup>19</sup> These titles may be useful to protect minor or incremental innovations, particularly in the mechanical field. The main differences with patents, as described by WIPO, are the following:<sup>20</sup>

- The requirements for acquiring a utility model are less stringent than for patents. While the requirement of “novelty” is always to be met, that of “inventive step” or “non-obviousness” may be much

lower or absent altogether. In practice, protection for utility models is often sought for innovations of a rather incremental character which may not meet the patentability criteria.

- The term of protection for utility models is shorter than for patents and varies from country to country (usually between 7 and 10 years without the possibility of extension or renewal).
- In most countries where utility model protection is available, patent offices do not examine applications as to substance prior to registration. This means that the registration process is often significantly simpler and faster, taking, on average, six months.
- Utility models are much cheaper to obtain and to maintain.
- In some countries, utility model protection can only be obtained for certain fields of technology and only for products but not for processes.<sup>21</sup>

Utility model protection<sup>22</sup> is simpler and may be more accessible to domestic companies than patents. The enforcement of the rights conferred may raise, however, the same problems as patents, since litigation is costly and of uncertain outcome. The lack of substantive examination might be an advantage, but the risk of exercising the exclusive rights against third parties without a prior scrutiny of compliance with the eligibility requirements, is also highly risky.

In Australia, petty patents, which were introduced in 1979 mainly to protect functional designs were replaced in 2000 by ‘innovation patents’.<sup>23</sup> The new law weakened the requirement of ‘inventive step’ and replaced it with an ‘innovative step’, defined as follows:

“an invention is to be taken to involve an innovative step when compared with the prior art base unless the invention would, to a person skilled in the relevant art, in the light of the common general knowledge as it existed in the patent area before the priority date of the relevant claim, only vary from the kinds of information set out in subsection (5) in ways that make no substantial contribution to the working of the invention”. (Section 7(4) of the Australian Patents Act).

The subject matter covered by the innovation patents is the same as under conventional patents, except for plants and animals, or biological processes for the generation of plants and animals.<sup>24</sup> It is too early to say whether the ‘innovation patents’ may have a significant impact as a stimulus to incremental innovation.

Finally, a third approach –not yet implemented in national laws- to encourage incremental innovations, but without the grant of exclusive rights, has been proposed by Professor J. Reichman of Duke University. According to his proposal, a Compensatory Liability Regime (CLR) might be introduced to protect innovations which do not meet a strict inventive-step standard:

“... liability rules conjure up a regime built on a “take and pay” principle. Under such a regime, second comers can access and use the protected subjected matter for specific purposes without permission, but they must compensate the first comer for the uses in one manner or another”. This will also motivate second users to try for follow-on innovations or incremental innovations. (Lewis and Reichman, 2003)

The proposed CLR aims at promoting innovation by providing a lead time over competitors and a royalty payment (around 3 – 9% of the sales value). The proposed protection would allow the title holder to prevent slavish copies but not follow-on innovations on the protected subject matter. The rights would be granted for a short period (e.g. five years) The second innovator might rely on the original innovation and modify it further; he would also be illegible for some payment.

A CLR may be superior, in terms of both static and economic efficiency, to regimes based on exclusionary rights. The practicalities of a CLR have not been worked out yet. Many of the problems posed by the enforcement of rights, which are common to patents and utility models, are also likely to arise in the case of a CLR. This is, however, an approach worth of being further refined and tested.

## Indigenous/traditional knowledge<sup>25</sup>

In many developing countries there is a diverse and rich set of indigenous/traditional knowledge (hereinafter ‘TK’), which seldom generate, however, marketable products or services. It has been argued that the patent system may play a role in promoting the translation of such knowledge into innovations. There are, however, several major obstacles to affording patent protection to existing TK. Some of such obstacles stem from the legal standards established to acquire patent rights in national laws, as examined below. Other obstacles, not examined here, arise from the difficulties that TK holders are likely to face for acquiring and enforcing rights.

## Novelty

The novelty requirement will normally impede the patenting of TK that has been published or openly used before the filing date of the patent application.<sup>26</sup> Hence, a large portion of TK used by local/indigenous communities, as well as codified TK, is likely to be deemed not to be novel and therefore not patentable.

In order to destroy novelty, however, the knowledge must have been ‘available to the public’, and prior use must generally be such that access to the information should have allowed a third party to execute the invention, without significant further experimentation or research. Thus, there may be situations in which novelty may not be lost, despite the relevant TK having been previously known and used, even for long periods. An example would be the case of TK used in a small community, when the information has not diffused beyond the community’s members. Cases in which the traditional healers have kept confidential<sup>27</sup> certain aspects of their treatment and associated medicines may be another example. In short, it would be incorrect to assume that all TK, because it may have been previously used, has necessarily lost its novelty for the purposes of patent law.

Disclosure in a non-written form may not be an obstacle to obtain patents on TK in countries where a *relative* novelty standard is applied, such as in the United States.<sup>28</sup> This means that TK that has been pub-

lished in a written form in the United States or in any other country is not patentable. However, if such knowledge was publicly used but not documented in a foreign country, novelty is not lost and patenting remains a possibility.

As it is well known, as a result of the relative novelty requirement of the US patent law, however, several patents relating to or consisting of genetic materials or traditional knowledge acquired in developing countries, have been granted to researchers or firms by the US Patent and Trademark Office.

### Inventive step

When the novelty of TK has been preserved – the existence of “inventive-step” (or “non-obviousness”) must be established in order to obtain patent protection. This standard requires that the claimed invention be non-obvious for a person with ordinary skills in a given technical field.

“A person with ordinary skills” is a legal fiction. Patent offices and courts may apply different notions of a skilled person, according to their own policies and the technical fields concerned. Thus, something that may be obvious to a healer or professional trained in Ayurveda traditional medicine may not be so for somebody trained in the Western medical tradition (the reverse may also be true, of course), thereby allowing for the granting of a patent. It is likely that patents and courts tend to assess the inventive step under the crystal of Western knowledge, as long as they do not recognize TK as a valid system of knowledge. Hence, uses of plants and other knowledge that may be obvious within a TK system may be deemed “inventive” and patentable. This increases the possibility of TK holders obtaining patents but, given their limited resources and lack of familiarity with the patent system, it is likely that others (researchers and companies) will benefit the most from this limitation in the examination process.

Given the low standards of patentability applied in some countries, the patentability of TK, or minor variants around it, may be more likely than expected by many, as illustrated by several questionable patents based on TK. As a general matter of policy, the patenting of minor



advancements, if any, in relation to previously available information, is undesirable. The preservation of the freedom to use knowledge within the public domain should be a basic principle in any intellectual property system. There would be little society's gain in extending legal monopolies to holders of TK, or to those that obtained knowledge from them, where no genuine invention can be claimed. This does not mean to exclude measures to compensate indigenous/traditional communities for their contributions, such as through sharing in the benefits derived from the commercial exploitation of the knowledge they held, as prescribed under the Convention on Biological Diversity.<sup>29</sup>

China is perhaps the only country to offer a specific type of patent protection for traditional medicinal knowledge. The patent law -promulgated in 1984 and amended in 1992 and in 2000- provides protection for product, methods and use of medicine. Article 3 of the Provisional Provisions on Patent Administration of Chinese Medicines inventions include preparations (including effective chemical monomers, effective elements and effective parts extracted from plants, animals and minerals) of Chinese medicine and methods and processes for their production, machines and equipment for Chinese medical treatment and their production processes, health care medicines, cosmetics, foods, soft drinks and seasonings containing traditional medicine, testing preparations and hygienic materials, designs and patterns for packaging and containers of Chinese medicines and other inventions and creations related to Chinese medicines.

#### 4. Conclusions

Developing countries enjoy considerable room to determine some basic aspects of their patent regimes subject to the rules of the TRIPS Agreement. While such countries have, as a group, resisted the pressures for patent harmonization sponsored by WIPO, they have individually accepted, in some cases, important constraints in the context of FTAs. If these developments continue, developing countries' stand in multilateral fora may be substantially eroded.

In order to adapt the patent systems to local needs in developing countries, the nature and characteristics of the local innovative process must be carefully considered.<sup>30</sup> While in some developed countries –notably the USA– the patentability standards have been relaxed in order to capture a growing number of incremental innovations, developing countries may get little benefit from this approach. Given the public policy implications of granting patent rights and the asymmetries in the capacity of foreign and local companies to claim such rights, even under lax patentability standards, developing countries’ needs may be best served by a two-tiered system under which patent rights are confined to inventions that meet a strict inventiveness standard, while other modes of incentives are provided (with or without exclusive rights) in relation to incremental innovations.

## Notes

- <sup>1</sup> Applications under the Patent Cooperation Treaty reached approximately 130,000 in 2005, a rise of 6 to 8 percent. An annual growth rate of around the 5 percent is predicted. See ‘Failure of Patent Harmonisation Not Critical For WIPO, Official Says’, *Intellectual Property Watch*, 7/9/2005.
- <sup>2</sup> ‘Failure Of Patent Harmonisation Not Critical For WIPO, Official Says’, *Intellectual Property Watch*, 7/9/2005.
- <sup>3</sup> With annual revenues exceeding \$10 billion.
- <sup>4</sup> “Patent Litigation Costing More”, PR Newswire (press release), New York - Sep 13, 2005.
- <sup>5</sup> For a lucid analysis of the history of the Paris Convention, see Penrose (1974).
- <sup>6</sup> The initiative was presented by WIPO’s Director General to, and was approved by the WIPO Assembly, the Paris Union Assembly and the Patent Cooperation Treaty (PCT) Assembly, in September 2001. See WIPO document A/36/14: Memorandum of the Director General titled ‘Agenda for Development of the International Patent System’ 6 August 2001, Geneva.
- <sup>7</sup> See Annex to document WO/GA/31/9 dated 23 July 2004, available at <http://www.wipo.int/documents/en/document/govbody/index04.htm>.
- <sup>8</sup> According to the SPLT proposal, ‘prior art with respect to a claimed invention shall consist of all information which has been made available to the public anywhere in the world in any form, as prescribed in the Regulations, before the priority date of the claimed invention’.

- <sup>9</sup> For instance, under European law such information is only considered for the evaluation of novelty. The same limitation was included in the proposal for a SPLT. See, however, SCP/8/9/Prov. Paragraph 17 and SCP/9/8/Prov. Paragraph 172 (noting the US position favorable to the application of the concept of prior art to both novelty and inventive step).
- <sup>10</sup> Scherer noted almost two decades ago: ‘As the bleary-eyed reviewer of some 15,000 patent abstracts in connection with research... I was struck by how narrowly incremental (adaptive?) most “inventions” are’ (Scherer, 1987:124).
- <sup>11</sup> See SCP/9/8 Prov. paragraph 102.
- <sup>12</sup> It is to be recalled that a treaty on *procedural* aspects of patent law has already been negotiated in WIPO (Patent Law Treaty).
- <sup>13</sup> See, e.g, on this concept, Lundvall, 1992; OECD, 1997; Patel and Pavitt, 1994.
- <sup>14</sup> See also the Preamble of the TRIPS Agreement.
- <sup>15</sup> These are successive improvements upon existing products and processes which bring out increases in technical efficiency or/and improvements in quality (Galhardi, 1994:49).
- <sup>16</sup> ‘Evergreening’ consists in the patenting of minor changes to or versions of existing products (e.g. formulations, dosage forms, polymorphs, salts, etc.) in order to indirectly extend the life of the original patent over an active ingredient.
- <sup>17</sup> According to a Guide of the Canadian Intellectual Property Office, for instance, 90% of all patented inventions were minor improvements on existing patented devices (Canadian Intellectual Property Office, 1994).
- <sup>18</sup> Between 1975 and 1996 only 1.223 new chemical entities were developed (WHO, 2001).
- <sup>19</sup> Utility model protection is granted in Argentina, Armenia, Austria, Belarus, Belgium, Bulgaria, China, Colombia, Costa Rica, Czech Republic, Denmark, Estonia, Ethiopia, Finland, France, Georgia, Germany, Greece, Guatemala, Hungary, Ireland, Italy, Japan, Kazakhstan, Kenya, Kyrgyzstan, Malaysia, Mexico, Netherlands, members of the African Organization of Intellectual Property (OAPI), Peru, Philippines, Poland, Portugal, Republic of Korea, Republic of Moldova, Russian Federation, Slovakia, Spain, Tajikistan, Trinidad & Tobago, Turkey, Ukraine, Uruguay and Uzbekistan.
- <sup>20</sup> WIPO at [www.wipo.org/sme/en/ip\\_business/utility\\_models/](http://www.wipo.org/sme/en/ip_business/utility_models/).
- <sup>21</sup> Utility models generally apply to mechanical innovations. In Germany, however, they can also be acquired with regard to chemical and pharmaceutical products.
- <sup>22</sup> The analysis contained in the remainder of this sub-section is largely based on the studies undertaken with S. Mukherjee in the context of the South Centres’s Project on Intellectual Property, Innovation and Development.
- <sup>23</sup> See ‘The Innovation Patent Bill’ of 29 June, 2000 effective on 24 May, 2001.
- <sup>24</sup> This exclusion does not apply if the invention is a microbiological process or a product of such a process.

- <sup>25</sup> This sub-section is substantially based on the author's analysis as contained in Correa (2002b).
- <sup>26</sup> In the *Delgamuukw* case (December 1997) the Supreme Court of Canada rejected the court's usual approach of attributing little if any weight to the oral evidence of elders. That is, oral testimony was given status as legal evidence. Presumably, in Canada at least, this precedent provides an argument for non-written knowledge (oral history) to invalidate novelty on a patent claim (personal communication from K. Bannister, 22.8.01).
- <sup>27</sup> In the *Mobil* case, for instance, the Enlarged Board of Appeal of the European Patent Office decided that the word "available" carries with it the idea that, for lack of novelty to be found, all the technical features of the claimed invention in combination must have been communicated to the public, or laid open for inspection. Under the European Patent Convention, a hidden or secret use, because it has not been made available to the public, is not a ground for objection to validity of a European patent (*Mobil/Friction-Reducing Additive*, 1990).
- <sup>28</sup> According to article 102 of the Patent Law (35 United States Code), 'A person shall be entitled to a patent unless the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States...?'
- <sup>29</sup> See, in particular, articles 15 and 16.
- <sup>30</sup> Another dimension, which has not been examined in this paper is, of course, the *costs* that patents create to competitors and consumers.

## O desenho das políticas de patentes sujeitos às necessidades dos países em desenvolvimento

**Resumo:** Apesar da internacionalização do sistema de patentes que começou há mais de um século e, particularmente, do estabelecimento de padrões mínimos de proteção sob o Acordo sobre Aspectos Relacionados com o Comércio de Direitos de Propriedade intelectual (TRIPS), os estados ainda desfrutam de um certo grau de discricionariedade para determinar os aspectos chave relativos às concessões de patentes. Ainda não se tem materializado iniciativas para maiores harmonizações do sistema. As recentes tendências em alguns países desenvolvidos apontam para um drástico relaxamento dos modelos de patentabilidade, particularmente os relacionados com diferentes estágios inventivos. Os países em desenvolvimento não precisam seguir a mesma abordagem; eles podem aplicar padrões estritos de patentabilidade compatíveis com seus sistemas de inovação

e recompensar inovações incrementais mediante modelos de utilidade mais do que através de patentes. Eles também podem desenvolver regras para tratar com as especificidades do conhecimento tradicional.

**Palavras-chave:** harmonização de patente, novidade, etapas inventivas, período de carência, conhecimento tradicional, sistemas de inovação, modelos de utilidade, acordo TRIPS.

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