AN AGENDA FOR PATENT REFORM AND HARMONIZATION FOR DEVELOPING COUNTRIES[1]

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Introduction

The international harmonization of substantive and enforcement rules on intellectual property rights (IPRs) is actively pursued by developed countries in the World Intellectual Property Organization (WIPO) and other fora. The establishment of the same or comparable standards of IPRs protection is one of the platforms on which economic globalization is built upon. The availability of such standards facilitates the global protection of intellectual assets, as it simplifies their management and reduces the costs of acquiring and enforcing rights. Naturally, such harmonization is essentially functional to companies with large international operations and with interest in seeking and enforcing IPRs protection on a global scale.

Different degrees and types of harmonization may be distinguished. On the one hand, in some cases in which parties are obliged to apply *minimum* standards, but not necessarily provide for the same rights and obligations. Although parties may confer broader rights, the minimum requirements impose the respect of a set of common rules. The TRIPS Agreement, for example, has had a significant harmonizing effect, despite that WTO Member countries can grant rights *in addition* to what the minimum standards require. In other cases, harmonization requires more uniformity, as it aims to define the standards to be applied by all parties concerned, with little or no room for deviation. Thus, the Patent Law Treaty (PLT) provides *common* and, as a general rule, *maximum* requirements for many of the formalities involved in the procedures before national/regional patent offices.

On the other hand, some harmonization processes involve *substantive* rules, that is, rules on the type, extent and scope of rights conferred, while in others they address *procedural* aspects, such as those relating to the acquisition and enforcement of rights. The TRIPS Agreement is an outstanding example of an agreement involving both types of rules. Of course, the impact of substantive harmonization on the parties' capacity to design the IPRs system is much greater than in cases where only procedural issues are involved.

This paper addresses the attempts under WIPO auspices to establish a set of uniform substantive rules of on key aspects of patent law, which would lead, if successful, to a deep harmonization in this field.

The patent harmonization process

The Paris Convention on the Protection of Industrial Property provided a rather flexible framework for the protection of industrial property, including patents. Although it introduced certain common standards (e.g. independence of patents, priority right, conditions for revocation of patents and compulsory licenses) it left the determination of most aspects of patent law (including patentable subject matter, duration, rights conferred) to national laws.

A first important attempt to harmonize substantive patent law was initiated by WIPO in 1984, with the ambitious objective of adopting a 'Treaty Supplementing the Paris Convention as far as Patents

[1] Paper prepared for the Bellagio Dialogue on "Intellectual Property and Sustainable Development: Revising the agenda in a new context" , 24 – 28 September 2005, Bellagio, Italy.

are concerned', which would have dealt with issues ranging from the right to obtain a patent to modalities for claim interpretation[2].

This first failed as a result of many North-South divergences as well as of some key disagreements among developed countries. While developing countries were reluctant to accept treaty rules that would erode their capacity to design national patent regimes, the United States also decisively contributed to the collapse of negotiations. United States was under pressure to give up its 'first to file' system. It considered, however, that the negotiating package offered little in exchange for the abandonment of such system. In its view, a 'balanced package' would have to include, inter alia, a grace period, generally opposed in Europe. The head of the US delegation argued at the First Part of the Diplomatic Conference (The Hague, June 19, 1991) that

> based on the direction of negotiations…, the interested circles in the United States might never get to the point of approving first-to-file because they might well lose interest and enthusiasm while evaluating the many changes the Treaty would presently require in the law of the United States of America, coupled with the loss of the strengthening improvements sought by the Delegation of the United States of America in the basic proposal. If the United States had to make major changes in its law, and obtain no improvements in the laws of others, it was not realistic to think that a treaty along such lines could be approved in the United States[3].

The failure of the 1980's WIPO's substantive harmonization attempt, however, turned out soon into a resonant success for the proponents of higher and more uniform standards of patent law. Several of the key provisions contained in the WIPO draft treaty (such as on patentable subject matter, rights conferred, term of protection and reversal of burden of proof) were incorporated into the TRIPS Agreement.

Moreover, soon after the failure of the substantive Treaty initiative, WIPO revived the patent harmonization process, albeit limited to procedures and formalities for patent applications. On June 2, 2000, the Patent Law Treaty (PLT) was signed by 43 countries, with the support of the United States and the European Patent Office. The PLT does not contain substantive provisions[4]. It rather harmonizes procedural requirements and steps: what may be required to obtain a filing date (Article 5), what may be required relating to the form and content of an application (Article 6), representation before a patent office (Article 7), various issues regarding communications (Article 8), what constitutes sufficient notification (Article 9), validity of patents if not in compliance with certain formal requirements (Article 10), relief in respect of time limits (Article 11), reinstatement of rights (Article 12), correction or addition of priority rights (Article 13). The PLT provisions should help to reduce the risk of errors by patent offices, and the time and costs of procedures for patent applicants, thereby facilitating the acquisition of patent rights internationally. The PLT also provides a clear linkage to the PCT for current and any future patent law harmonization (Article 16).

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[2] See, eg., WIPO, 'Suggestions for the further development of international patent law', WIPO Standing Committee on the Law of Patents (Fourth Session, Geneva, November 6-10,2000 WIPO Document No. SCP/4/2 September 25, 2000.

[3] Intervention of H. Manbeck (Head, United States delegation), Records of the First Part of the Diplomatic Conference for the Conclusion of a Treaty Supplementing The Paris Convention as Far as Patents Are Concerned, Nineteenth Meeting, Main Committee I, The Hague (June 19, 1991)

[4] Article 2 states that "[n]othing in the Treaty or in the Regulation is intended to be construed as prescribing anything that would limit the freedom of a Contracting State to the PLT to prescribe such requirements of the applicable substantive law relating to patents as it desires".

In 2001, WIPO's Director General went a step forward and launched a 'Patent Agenda' in response to the perceived main users' concerns of the patent system about the burdensome, complex and costly procedures for obtaining patents internationally, due to the current territorial nature of the system.[5] The main emphasis of the proposal has been to facilitate the acquisition of patent protection in foreign countries by making the system more user-friendly, cost effective and secure. The Patent Agenda is aimed at addressing the alleged failure of the system to adequately respond to the international nature of business activities, the high costs of obtaining patents, the workload crisis in patent offices[6].

The main purpose of the Patent Agenda, as set out by the WIPO Director General is, therefore, to create mechanisms whereby inventors and industry have access to national, regional and internationally patent protection systems that enable them to obtain, maintain and enforce their patents globally[7]. Development objectives are completely absent from the initiative. No assessment was provided about the benefits and costs of the proposed harmonization, particularly as it would eliminate the room that countries have retained to decide what an 'invention' is and how the patentability standards are determined. The proposed Agenda failed to acknowledge the major problems that the patent system currently face, as a result of the application of lax patentability criteria[8], the asymmetries in the ability to use it due to high enforcement costs[9], and the disadvantages of patent policy harmonization for different levels of economic and technological development[10].

One component of the Patent Agenda involved the streamlining of the procedures for international applications under the Patent Cooperation Treaty (PCT), and the granting of additional facilities (such as an extended term for initiating the national phase and the adoption of an "international preliminary report on patentability'). It is to be noted, however, that the PCT was not designed as a harmonizing instrument[11].

Another component of the Patent Agenda is the development of a Substantive Patent Law Treaty (SPLT). In November 2000, the Standing Committee on Patents (SCP), agreed that first draft provisions for a future legal instrument should focus initially on a number of issues of direct relevance to the grant of patents, in particular, the definition of prior art, novelty, inventive step/non-obviousness, industrial applicability/utility, the drafting and interpretation of claims and the requirement of sufficient disclosure of the invention. The SCP further agreed that other issues related to substantive patent law harmonization, such as first-to-file versus first-to-

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[5] See the Memorandum of the Director General, WIPO document A/36/14, *'Agenda for Development of the International Patent System'*, 6 August 2001, Geneva, para 3.
[6] Idem, para. 17 – 28.
[7] Idem, para 38-39.
[8] See, e.g., Jaffe, Adam B. and Lerner, Josh (2004), Innovation and Its Discontents : How Our Broken Patent System is Endangering Innovation and Progress, and What to Do About It, Princeton University Press; Federal Trade Commission (FTC) (2003), To promote innovation: the proper balance of competition and patent law policy, available at htpp://www.ftc.gov .
[9] See, e.g., Carlos Correa (2002), Internationalization of the patent system and new technologies**,** Wisconsin International Law Journal, vol. 20. No.3.
[10] The need for tailoring patent systems to different levels of development has been broadly recognized. See, e.g., World Bank (2001) Global Economic Prospects and the Developing Countries 2002, Washington D.C., p. 129; UK Commission on Intellectual Property Rights, Integrating intellectual property rights and development policy, London, 2002 (available at www.iprcommission.org);.

[11] According to Article 27(5) of the PCT, "Nothing in this Treaty and the Regulations is intended to be constructed as prescribing anything that would limit the freedom of each Contracting State to prescribe such substantive conditions of patentability as it desires. In particular, any provisions in this Treaty and the Regulations concerning the definition of prior art is exclusively for the purposes of the international procedure and, consequently, and Contracting State is free to apply, when determining the patentability of an invention claimed in an international application, the criteria of its national law in respect of prior art and other conditions of patentability not constituting requirements as to form and contents of applications".

invent systems, 18-month publication of applications and a post-grant opposition system, would be considered at a later stage.

As a 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 Intellectuele (AIPPI)[12] -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 more 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/Inventive Step

The issues suggested for this initial phase of harmonization are crucial[13]. If agreed upon, they would provide a uniform definition to key aspects determining the scope of patentability. In order to push forward this proposal, WIPO's Director General convened 'informal consultations' concerning future sessions of the SCP in Casablanca, Morocco, on February 16, 2005. Widely criticized for the lack of transparency and the attempt to give undue weight to the outcome of the meeting, this process was unable to move the negotiations further[14]. At the WIPO Assemblies held in September 2005, a compromise was reached to continue work at the SCP[15].

The trilateral proposal

As mentioned, the 'Trilateral proposal' aims as at addressing key issues concerning the patentability standards. These concepts determine the extent of knowledge that may be detracted from the public domain and subject to exclusive rights for a minimum twenty years period. The TRIPS Agreement does allow Members to adopt their own definitions on *all* these concepts, thereby providing Members flexibility to design their patent regimes.

[12] See Annex to document WO/GA/31/9 dated 23 July 2004, available at http://www.wipo.int/documents/en/document/govbody/index04.htm.

[13] It is somehow surprising –having in view the aim of the harmonization exercise- that the criterion of industrial applicability/utility was not included in this short list. This may reflect major differences between United States and Europe with regard to whether a 'technical effect' should be required.

[14] The Casablanca statement proposed that only four issues (prior art, grace period, novelty and inventive step) advocated by developed countries be taken up by the SCP. It also proposed that two other issues (sufficiency of disclosure and genetic resources), which the developing countries have been advocating for, be taken up instead in the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC).

[15] According to the agreement, a meeting will be held and report be made to the 2006 General Assembly. The SCP meeting will be preceded by an informal open forum in the first quarter of 2006 on all issues related to the draft SPLT. Contributions to the forum will reflect a "balance of geographical representation and perspectives, and technical expertise". Then an informal session of the SCP will follow to agree on a work programme for the committee, taking into account the discussions of the open forum. See Intellectual Property Watch, 'New Committee For WIPO Development Agenda; Patents Reinvigorated', 3/10/2005, available at http://www.ip-watch.org/weblog/index.php?p=97&res=1024&print=0.

Prior art

According to the draft SPLT , 'the 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' (article 8.1)[16]. This concept is broader than the corresponding concept in Rule 64 (1)(a) of the PCT, which only considers 'means of written disclosure (including drawings and other illustrations)' as prior art.

The eventual harmonization of the concept of 'prior art' would require agreement on a number of issues on which national laws differ, notably:

Non-written disclosures. Some national laws exclude non-written disclosures from the prior art. In the case of the United States, a mixed standard is applied, since non-written disclosures are only taken into account when they occurred within the United States. 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...

The viability of adopting in the USA a concept of 'prior art' including non-written disclosures anywhere in the world was questioned by the US delegation during the failed harmonization attempt of the mid 1980's [17].

Secret prior commercial use or the offer for sale without disclosure. According to the law and practice of some countries, the prior art includes disclosures by prior commercial use of the invention[18], but this is not a generalized approach.

Disclosures in prior patent applications. The extent to which prior art may include disclosures in previous patent applications is also controversial. For instance, under European law such information is considered, under certain circumstances, for the evaluation of novelty but not inventive step. The same limitation was included in the proposal for a SPLT (article 8.2), but the United States and others advocated for a broader effect[19].

Determination of the date of availability to the public. In some cases the available information allows the determination of only the month or the year, but not the specific date of

[16] See WIPO document SCP/10/4, available at www.wipo.int

[17] '…[I]t would be particularly difficult for its various interest groups to understand and agree to a provision in the treaty which would require the United States to consider oral disclosures anywhere in the world as prior art' (Intervention of H. Manbeck (Head, United States delegation), Records of the First Part of the Diplomatic Conference for the Conclusion of a Treaty Supplementing The Paris Convention as Far as Patents Are Concerned, Nineteenth Meeting, Main Committee I, The Hague, June 19, 1991).

[18] See e.g. SCP/8/9/Prov. para. 171, and SCP/9/8 Prov. para. 163 (indicating the support by USA, Australia, Argentina, and others to the establishment of such a limitation to the concept of prior art).

[19] See, however, SCP/8/9/Prov. para. 17, and SCP/9/8 Prov. para. 172 (noting the US position favorable to the application of the concept of prior art to both novelty and inventive step). This divergence was one of the issues highlighted by the United States as preventing an agreement on harmonization in 1991: the Head of the United States delegation did not believe that 'his Delegation could explain satisfactorily to its Congress that it would be required to issue patents on inventions which differed only in obvious details from the disclosures contained in earlier-filed United States patent applications-imposing confusion on the U.S. public in the name of reducing so-called secret prior art' (Intervention of H. Manbeck, Head, United States delegation, Records of the First Part of the Diplomatic Conference for the Conclusion of a Treaty Supplementing The Paris Convention as Far as Patents Are Concerned, Nineteenth Meeting, Main Committee I, The Hague, June 19, 1991).

availability to the public. The issue is therefore what date is to be considered and who has the burden of proof. This issue was addressed in draft Rule 8 of the SPLT in a way that privileged the patent applicant's interest [20].

Availability to the public. While certain patent systems require concrete disclosure for complying with the standard of "availability to the public," others provide that the possibility of having access to the information is sufficient (e.g. availability of a thesis at an university library). Of course, the latter approach is more functional to a system that aims at rewarding genuine innovations.

Indigenous/traditional knowledge. An important issue for developing countries is the extent to which indigenous/traditional knowledge may be considered part of 'prior art'. The key point is whether knowledge that has been available within an indigenous/traditional community would be deemed to have been made available to the public and, hence, considered as part of the prior art. If not, misappropriation of such knowledge may occur and patents may be granted to those who are not 'inventors' and entitled to patent protection. Under US law, for instance, inventorship is a requirement for entitlement to a patent [21].

Grace period

The application of a grace period (admitted in the USA and in many other countries) has raised a significant controversy between the USA and European countries[22], where such period is not provided for. It expands the scope for patenting, as inventions disclosed during that period would be eligible for protection, notwithstanding that they would have been deemed in the prior art in accordance with the general rule on novelty. During the harmonization process in the mid 1980's, the resistance to recognize a grace period was one of the main reasons for the US withdrawal of support to the process, and a key trade-off sought by the United States for changing its 'first to invent' rule[23].

Novelty

The definition of 'novelty' is crucial. Since the TRIPS Agreement allows Members to adopt their own concept, United States, for instance, has been able to maintain its relative novelty standard with regard to the place where disclosures have taken place.

Novelty results from the comparison between the existing prior art at the date of filing (or the date of priority) and the claimed invention. The issues mentioned before with regard to the prior art have, hence, a bearing on the concept of novelty.

In practice, the concept of novelty is narrowly construed by patent offices, requiring in some cases an almost 'photographic' disclosure of the invention in a single prior document in order to consider that novelty does not exist. 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') [24].

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[20] See the proposal made by the Delegation of Argentina, supported by the Delegations of Brazil, India, Pakistan, Peru, Spain and Sudan (SCP/9/8 Prov. para. 183). More generally, on proposals for reviewing, from a developing countries' perspective the SPLT, see Carlos Correa (2004), The WIPO draft Substantive Patent Law Treaty: a review of selected provisions, Working Paper 17, South Centre, Geneva.

[21] See 35 USC 102(f): "A person shall be entitled to a patent unless he did not himself invent the subject matter sought to be patented".

[22] Despite the opinion of inventors' communities in some European countries. See G Dinwoodie, W. Hennessey and S. Perlmutter, International Intellectual Property Law and Policy (2001:Newark; Lexis Nexis), p. 424.

[23] Ibidem.

[24] 'Selection inventions' are deemed patentable in some countries, but found unpatentable where a strict novelty requirement is applied, such as in Germany. See, e.g. Grubb, Philip, (1999), Patents for chemicals,

Non-obviousness/Inventive Step

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 protection. As the TRIPS Agreement does not define this concept, Member countries are free to determine whether they want a system under which a myriad of minor, incremental, developments are patentable[25], or one aimed at rewarding substantive departures from the prior art. The draft SPLT Regulations proposed a low standard for determining inventive step[26]. 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.

Developing countries will be made a great disservice if they were induced, through the WIPO patent harmonization process, technical assistance or other means, to import features of a patent regime that is growingly seen as malfunctioning in developed countries, and often stifling rather than promoting innovation[27]. The decline in the patentability standards is one of the factors behind the 'intense pathology of the current [patent] system' in the United States[28]. The best policy for developing countries would rather be to establish high standards of inventive step[29], in order to avoid 'evergreening'[30] and other patenting strategies aimed at blocking genuine competition and follow on innovation[31]. For instance, the recent reform (2005) of the Indian Patent Law has incorporated an anti-evergreening provision, which tightens the inventive step requirement as applied to new forms or modifications of existing pharmaceutical products[32].

It may be argued that a low inventive step may be a wise policy as it might allow domestic companies to acquire patents. However, there is no justification for detracting knowledge from the public domain whether patents are applied for by domestic or foreign companies. Moreover, while domestic companies may seldom resort to patent protection due, *inter alia*, to high enforcement costs, large foreign companies (e.g, in the pharmaceutical sector) are well prepared not only to patent inventions but eventually to invent patents. Such companies often apply for a large number of patents merely to discourage or prevent competition.

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pharmaceuticals and biotechnology. Fundamentals of global law, practice and strategy, Clarendon Press, Oxford, 196-199.

[25] 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, p 124).

[26] See SCP/9/8 Prov. para. 102

[27] See, e.g., Jaffe, Adam B. and Lerner, Josh (2004), Innovation and Its Discontents : How Our Broken Patent System is Endangering Innovation and Progress, and What to Do About It, Princeton University Press.

[28] Idem, p. 19.

[29] See See, e.g., World Bank (2001) Global Economic Prospects and the Developing Countries 2002, Washington D.C., p. 129.

[30] '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 extend the life of the original patent over an active ingredient.

[31] See Carlos Correa, Internationalization of the patent system and new technologies**,** Wisconsin International Law Journal, vol. 20. No.3, 2002.

[32] 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'.

Policy issues of concern to developing countries

Developed countries are likely to pursue negotiations on a 'light' SPLT on the basis of the trilateral proposal. This approach would avoid tensions within the group of developed countries themselves, as controversial issues such as the 'first to invent' vs. the 'first to file' approach and the technical nature of inventions would remain out of discussion. Quite clearly, it is not in the interest of developing countries to seek neither a 'light' SPLT nor a more comprehensive SPLT, since they have little to gain from a broader harmonization of substantive patent law.

In this scenario, however, developing countries should resist any attempt to limit their capacity to prevent the patenting of developments that do not constitute a real technical contribution to the state of the art. If such countries wished to promote 'minor' innovations, the appropriate policy would not be to lower the patentability requirements, as it is often argued, but to establish utility models (or 'petty patents') that confer less extensive rights than patents or to explore other options, such as the recognition of a remuneration right rather than exclusionary rights. In brief, developing countries should endeavour to keep the existing policy space to determine the level of the 'inventive step'.

If negotiations on the prior art and novelty concepts were pursued, developing countries should aim at the recognition of a *universal* novelty standard that does not discriminate on the basis of the place where non-written disclosures took place. Such a standard could prevent a significant part of the misappropriation of genetic resources and indigenous/traditional knowledge that currently occurs. However, the change of the novelty standard may not be sufficient to prevent bio-piracy if the evidentiary requirements for non-written disclosures made abroad are too complex or stringent, thus making the proof of the existence of prior too difficult or impossible . If this were the case, there would be little gain for developing countries.

In addition, the circumstances under which traditional knowledge may be deemed or not part of the prior art[33] should be explored systematically and incorporated into the discussion.

Developing countries should also incorporate into any possible negotiating text an *obligation to disclose the origin* of genetic materials and associated indigenous/traditional knowledge claimed in patent applications, as demanded by such countries within both WTO and WIPO[34]. Developing countries have elaborated the arguments justifying the disclosure of origin obligation within the patent system as follows:

> …a legally binding obligation to disclose the source and country of origin of biological resources and/or traditional knowledge used in inventions will guide the patent examiners in ensuring that all relevant prior art information is available to the patent examiners. Disclosure will also be relevant in helping patent examiners determine whether the claimed invention constitutes an invention that is excluded from patentability under Article 27 paragraphs 2 and 3 of the TRIPS Agreement. Further, disclosure would serve as part of a process to systematise available information of biological resources and traditional knowledge that will continuously build the prior art information available to patent examiners and the general public[35].

[33] See, e.g., Manuel Ruiz, The International Debate on Traditional Knowledge as Prior Art in the Patent System: Issues and Options for Developing Countries, South Centre, T.R.A.D.E. Series Occasional Paper 9, October 2002.

[34] See, e.g., Carlos Correa (2005) The politics and practicalities of a disclosure of origin obligation, Occasional Paper 16, QUNO, Geneva.

[35] See, e.g., 'Elements of the obligation to disclose the source and country of origin of biological resources

In addition to the disclosure of origin obligation, developing countries may seek to incorporate safeguards and other provisions that ensure sufficient flexibilities and a pro-development approach. In fact, those countries had already suggested in the SPLT process some of such provisions:

> *Exception:* Nothing in this Treaty and the Regulations shall limit the freedom of a Contracting Party to take any action it deems necessary for the preservation of essential security interests or to comply with international obligations, including those relating to the protection of genetic resources, biological diversities, traditional knowledge and the environment.
>
> *Public Interest Exceptions*: Nothing in this Treaty and the Regulations shall limit the freedom of a Contracting Party to protect public health, nutrition and the environment or to take any action it deems necessary to promote the public interest in sectors of vital importance to its socio-economic, scientific and technological development
>
> *Compliance With Applicable Law on Other Matters*: A Contracting Party may also require compliance with the applicable law on public health, nutrition, ethics in scientific research, environment, access to genetic resources, protection of traditional knowledge and other areas of public interest in sectors of vital importance for their social, economic and technological development. [36]

The extent to which and how these provisions would fit into a 'light' SPLT is to be considered in the context of any future text, if the negotiating process is continued. Other provisions that may be worked on include:

-requirement of industrial applicability (as opposed to utility) based on a distinct technical effect of the invention;

-best mode as a uniform requirement;

-principles and objectives;

-transfer of technology;

-measures against anti-competitive practices .

Conclusions

A deep reexamination of the patent system and how it operates in different contexts is called for. The system presents a number of serious distortions that affect its potential role in promoting innovation, particularly in developing countries. The harmonization process conducted for now almost two decades under WIPO's auspices overlooks the problems and asymmetries of the system, and essentially aims at reducing the operational costs for users at a global scale. That process is certainly not intended to address the system's current shortcomings, nor adapting it to the needs of developing countries.

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and/or traditional knowledge used in an invention¡, submission from Brazil, India, Pakistan, Peru, Thailand, and Venezuela, IP/C/W/429 of September 21, 2004, para. 4-5.

[36] See WIPO, Draft Substantive Patent Law Treaty, SCP/9/2, March 3, 2003.

The harmonization process poses a significant challenge and creates a number of risks for developing countries[37]. While there are no convincing reasons for such countries to support the process, if it proceeds further on the basis of the trilateral or other proposals, the following issues should be considered:

- What objectives developing countries should pursue in responding to the harmonization demands of developed countries?

Developing countries should aim at the recognition of a universal novelty requirement and of a disclosure of origin obligation. They should also seek, inter alia, to clarify the treatment of indigenous/traditional knowledge as part of prior art. The ability to determine the required level of inventive step should not be negotiable; in particular, no proposals should be admitted that allow for a low inventive step standard for the granting of patents. Developing countries should consider means alternative to patents to promote minor innovations, if suitable to their developments needs.

- How feasible and practical do these proposals have to be in order to gain support from other stakeholders and to be successfully carried forward in international fora?

Although developing countries should seek the elaboration of a scientifically-based development assessment on the general implications of the proposed harmonization process, they should also elaborate concrete proposals on the issues put on the table by developed countries, as well as those that are of interest to developing countries, such as those mentioned above.

- Which could be the areas of the respective reform processes where coalitions could be built between developing and developed partners?

There are, finally, specific areas in which agreements with some developed countries may be reached. Thus, European countries are likely to support demands for a truly universal novelty requirement, while the USA may support the consideration of prior patent applications as part of the prior art for both novelty and inventive step. Developing countries negotiating strategies should try to ably capitalize on the divergences that exist between developed countries in order to advance their own agenda in the process.

[37] See generally Carlos Correa and Sisule Musungu (2002)**,** The WIPO Patent Agenda: the risks for developing countries **,** Working Paper No. 12, South Centre, Geneva.