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12

THE WIPO PATENT AGENDA: THE RISKS FOR DEVELOPING COUNTRIES

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THE SOUTH CENTRE

In August 1995, the South Centre became a permanent intergovernmental organization of developing countries. In pursuing its objectives of promoting South solidarity, South-South co-operation, and coordinated participation by developing countries in international forums, the South Centre has full intellectual independence. It prepares, publishes and distributes information, strategic analyses and recommendations on international economic, social and political matters of concern to the South.

The South Centre enjoys support and co-operation from the governments of the countries of the South and is in regular working contact with the Non-Aligned Movement and the Group of 77. The Centre's studies and position papers are prepared by drawing on the technical and intellectual capacities existing within South governments and institutions and among individuals of the South. Through working group sessions and wide consultations which involve experts from different parts of the South, and sometimes from the North, common problems of the South are studied and experience and knowledge are shared.

PREFACE

The South Centre, with funding support from the TCDC Unit of the UNDP, initiated in 1998 a project to monitor and analyse the work of WTO from the perspective of developing countries. Recognizing the limited human and financial resources available to the project, it focuses on selected issues in the WTO identified by a number of developing countries as deserving of priority attention. As hoped, the project has helped in establishing a medium-term work programme by the South Centre on issues related to international trade and development, which includes several sub-projects on specific WTO Agreements/issues.

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It is hoped that the T.R.A.D.E. working paper series will be found useful by developing country officials involved in WTO discussions and negotiations, in Geneva as well as in the capitals.

South Centre, November 2002

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ABBREVIATIONS

CIPR	Commission on Intellectual Property Rights
ESTs	Expressed Sequence Tags
FDI	Foreign Direct Investment
GATT	General Agreement on Tariffs and Trade
IPEA	International Preliminary Examining Authority
IPRs	Intellectual Property Rights
IPRP	International Preliminary Report on Patentability
ISA	International Searching Authority
MFN	Most-Favoured Nation treatment
NGO	Non-Governmental Organization
PCT	Patent Cooperation Treaty
PLT	Patent Law Treaty
R & D	Research and Development
SCP	Standing Committee on the Law of Patents
SPLT	Substantive Patent Law Treaty
TRIPS	Trade-Related Aspects of Intellectual Property Rights

Organizations

AIPLA	American Intellectual Property Law Association
ARIPO	African Regional Intellectual Property Organization
BIO	Biotechnology Industry Organization
EAPO	Eurasian Patent Office
EPO	European Patent Office
EU	European Union
IIPS	International Intellectual Property Society
OAPI	African Intellectual Property Organization
U.N.	United Nations
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

EXECUTIVE SUMMARY

The 36th series of meetings of the Assemblies of the Member States of the World Intellectual Property Organization (WIPO) in September 2001 endorsed an initiative by the Director-General of the organization aimed at the further harmonization of patent law worldwide. The initiative, called the 'WIPO Patent Agenda' was envisaged as a process that would lead to the preparation of a blueprint for the future development and harmonization of the patent system. The Patent Agenda initiative has therefore placed the further harmonization of patent law as a top priority in WIPO's activities. The main activities under the Patent Agenda relate to the efforts to promote the ratification of the Patent Law Treaty (PLT); the reform of the Patent Cooperation Treaty (PCT); and, the ongoing negotiations on a Substantive Patent Law Treaty (SPLT). These separate, but interlinked, activities are ultimately oriented to set up an international legal framework for a global patent with the result that the limited policy space left in the hands of national governments under the World Trade Organization's (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS) will be further eroded.

This paper is aimed at assessing some of the implications of the Patent Agenda, in the context of the ongoing debates on the benefits and costs of intellectual property protection for developing and least developed countries. The main aim of the paper is to provide an overview of the processes under the WIPO Patent Agenda, to identify and examine the main issues that are under discussion and to underscore the importance of these issues for developing and least-developed countries.

Following a brief introduction to the interlinkages between the intellectual property standard setting at WIPO and at the WTO in section I the paper, in section II, provides a historical perspective of the trends in international intellectual property standard setting. The paper explores the strategy that the United States and other developed countries used in the 1980s, to shift the intellectual property regulatory focus from WIPO to the General Agreement on Tariffs and Trade (GATT) framework, where the developing countries' capacity to set the agenda was limited, and then back to WIPO after establishing minimum standards under the TRIPS Agreement. This section therefore provides a basis for appreciating the challenges posed by the WIPO Patent Agenda for developing countries in their efforts to ensure the development of a more balanced intellectual property regime at the multilateral level.

In section III, the paper presents a brief background to the Patent Agenda including an overview of the three main pillars underlying the process. While the TRIPS Agreement established binding standards in many areas of patent law, it left considerable room in others, such as with regard to the crucial issues of what is patentable and how the requirements for patentability are defined. As currently conceived, the process is intended to be complementary to the achievements in the Uruguay Round and, if successful, will further erode the room for manoeuvre that developing countries were able to retain from that Round's negotiations.

In this context, the first part of section III examines some implications of the PLT which harmonizes the procedures for applying for, obtaining and maintaining patents. In particular, this paper discusses the relaxation of the conditions for admission of a patent application and the determination of the application date, which is crucial for the assessment of novelty and inventive step, as well as the establishment of the right to a patent grant in case of rival claims by different inventors. The relaxation of standards may permit the deliberate submission of applications prior to the actual conception of an invention, as well as raising the possibility of applicants subsequently introducing new, different or

additional subject matter and claims while benefiting from an earlier filing date. The lax requirements may also create uncertainty about who the applicant is and open the door for manipulation and fraud.

The second part of section III examines the reform of the PCT, in particular, the issues that arise with amendments to the treaty to simplify and streamline procedures while at the same time aligning it to the new PLT standards. Apart from reviewing the changes anticipated in relation to coordination of international searches and international preliminary examination, and time limits for entering the national phase, the paper also briefly examines the implications of the proposals, by the United States and other developed countries, for a more fundamental overhaul of the PCT system in order to facilitate global patenting. If this latter goal is achieved, it would not only mean that most national patent offices would become superfluous but, more importantly for developing countries, the current flexibilities permitted by the TRIPS Agreement with regard to rules on patentability and exceptions thereto would be eliminated.

The third part of section III covers the negotiations and discussions taking place in the WIPO Standing Committee on the Law of Patents (SCP) on the SPLT. The paper in this part discusses the implications of the work on the SPLT aimed at creating uniform substantive patent law standards on issues such as prior art, novelty, utility and inventive step, disclosure, drafting and interpretation of claims, grounds for refusal of an application, and issues relating to revocation and invalidation of patents. Unlike the PLT and the PCT, the SPLT is meant to prescribe substantive standards on what an invention is, how patentability is to be established, and what the scope of patent protection should be. The main issues discussed therefore include those relating to patentability requirements, the technical character of inventions, exclusions from patentability, infringement and the doctrine of equivalents and the prohibition on the imposition of further conditions at the national or regional level.

The last part of section III then examines some of the main concerns, from the perspective of developing countries, with the SPLT negotiations as well as the other processes under the WIPO Patent Agenda. This part covers concerns relating to the adaptation of patent law to local conditions and needs, the practice of harmonizing at the highest level of protection and the impact of the harmonization in developing countries. The question as to who benefits from the Patent Agenda process is also explored.

In the fourth and final section, the paper addresses some strategic considerations for the future participation of developing countries in the Patent Agenda process within the context of WIPO - WTO intellectual property standard setting. The paper concludes that the Patent Agenda has been launched without any analysis of its impact on development. The Patent Agenda has been conceived and is executed with the goal of benefiting those companies with large-scale international patenting activity, and to support the proliferation of patents on incremental developments, which are often used to erect market barriers. The further harmonization of patent law does not therefore seem to be in the best interest of developing countries. Given the objectives of the Patent Agenda, there is little that developing countries could gain through this far-reaching exercise in international intellectual property standard setting. To counter this lopsided approach to the development of international patent law what is needed is better coordinated and sustained efforts by developing countries aimed at preserving the currently available flexibility to fashion national laws.

In this regard, the paper concurs with the recommendation by the Commission on Intellectual Property Rights (CIPR) that, the WIPO harmonization process should be rejected by developing countries if it appears that the outcome will not be in their interests. The paper also stresses the importance of developing country representatives in both WIPO and WTO appreciating intellectual property as a tool for development policy, and not merely as a contentious area to be designed and redesigned in response to developed countries' demands or political pressures. While it may take some time to significantly influence the course of such complex processes as the Patent Agenda, developing

countries need to initiate a debate within WIPO about the effects of intellectual property standard raising and harmonization on their development prospects.

I. INTRODUCTION

In August 2001, the Director-General of the World Intellectual Property Organization (WIPO) announced a new initiative christened the 'WIPO Patent Agenda'.[1] The initiative was envisaged as a process of worldwide discussions with the aim of preparing a strategic blueprint that would underlie the future development of the international patent system. The initiative was presented to and approved by the WIPO Assembly, the Paris Union Assembly and the Patent Cooperation Treaty (PCT) Assembly in September 2001.

The Patent Agenda process has placed the issue of further development and harmonization of patent law as a top priority in WIPO's activities for several years to come. The Patent Agenda activities are taking place under three main processes in WIPO. First, the move to promote the ratification of the Patent Law Treaty (PLT). Second, the effort to reform the PCT. Third, the ongoing negotiations on the draft Substantive Patent Law Treaty (SPLT). These processes are ultimately oriented to create an international legal framework for a universal patent.

Prior to the entry into force of the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), most intellectual property negotiations and standard setting took place at WIPO. The situation changed significantly when the TRIPS Agreement introduced the concept of minimum standards for intellectual property rights (IPRs) in diverse areas covered by WIPO administered treaties.

Following the coming into existence of the TRIPS Agreement, while the 'politics' of intellectual property have mainly taken place at the WTO, new intellectual property standards continue to be set under the auspices of WIPO.[2] In this context, the activities at WIPO such as the Patent Agenda process may greatly influence the shape of the international intellectual property system. In particular, "new developments" in WIPO may provide the basis, under article 71 of TRIPS, for further increases in intellectual property standards for all WTO Members.

Intellectual property negotiations and discussions at WIPO are therefore particularly important for developing countries, as they set the agenda for the development and harmonization of intellectual property standards at the multilateral level. A clear understanding and appreciation of the challenges posed by the WIPO Patent Agenda is hence a critical strategic issue for developing countries in their efforts to ensure the development of a more balanced intellectual property regime at the multilateral level. By identifying and defining the issues and the fora in which each of the issues need to be addressed, developing countries will move closer to achieving the objective of attaining a development-oriented patent system.

This paper is aimed at assessing some implications of the Patent Agenda process, in the context of the ongoing debates on the benefits and costs of intellectual property protection for developing and least developed countries. It provides in section II a historical perspective of the trends in international intellectual property standard setting. In section III it presents a brief background to the Patent Agenda including an overview of the three main pillars underlying the process. Section IV, finally, suggests some considerations for the future participation of developing countries in the context of WIPO - WTO standard setting processes.

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[1] See WIPO document A/36/14: Memorandum of the Director-General *'Agenda for Development of the International Patent System'* 6 August 2001: Geneva.

[2] As illustrated by the adoption, in 1996, of the WIPO "Copyright Treaty" and the "Performances and Phonograms Treaty" in 1996.

II. PATENT LAW STANDARD SETTING IN WIPO

WIPO, which was preceded by the International Bureau that administered the Paris and Berne Conventions, came into being in 1970 when the 1967 Stockholm WIPO Convention came into force. Under a 1974 agreement, WIPO became a specialized agency of the United Nations (U.N.) its main mandate being the promotion of the use and protection of intellectual property. WIPO's current membership is 179 States, a majority being developing countries.[3] While the WIPO Convention provides the umbrella framework for the organization, it is an administrative treaty only.[4] The substantive intellectual property standards are established by separate treaties, each of which has different contracting States. WIPO currently administers 23 such international treaties relating to various types and aspects of intellectual property rights.

The WIPO patent system has been based on two main treaties, namely, the Paris Convention for the Protection of Industrial Property (Paris Convention)[5] and the PCT. The Paris Convention established substantive standards in various areas of intellectual property including patents while the PCT established procedural standards. Indeed, the Paris Convention can be said to be the corner stone of today's international patent system. In addition to these two treaties, the Budapest Treaty on the Deposit of Micro-organisms establishes a system for the international recognition of deposits of micro-organisms in specified institutions for the purposes of patent disclosure. With the adoption, in June 2000, of the PLT a new component has been added to the WIPO patent system. When it comes into force, the PLT will facilitate compliance with patent formalities internationally and compliment the PCT system.

Under the Paris Convention, countries were able to adopt different standards especially in areas of technology relating to public interests, such as public health. While WIPO was considered an important international forum during the 1980s, the feeling in the United States emerged that the WIPO administered treaties provided rights without remedies.[6] Due to the lack of uniform standards and of an enforcement mechanism in WIPO, key industry players in the United States, persuaded their government that WIPO had failed to secure the appropriate levels of intellectual property protection,[7] and lobbied to initiate an IPR standardization process within the General Agreement on Tariffs and Trade (GATT) system.

An obvious advantage of GATT vis-à-vis WIPO was the possibility of applying trade sanctions to countries found as non-compliant under the settlement of disputes mechanism and, equally important, the possibility of negotiating higher standards of IPRs protection in exchange for concessions in other trade areas, such as textiles and agriculture. GATT offered developed countries an alternative to WIPO where webs of coercion could work better. According to one industry leader in the United States, their experience with WIPO in those times was the last straw in their attempt to operate by

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[3] See *http://www.wipo.int*

[4] Abbott, F., T. Cottier and F. Gurry (eds.), *The International Intellectual Property System: Commentary and Materials*, Kluwer Law International, The Hague/London/Boston, 1999, p. 303.

[5] The Convention, adopted in 1883, has since then been revised six times in 1900, 1911, 1925, 1934, 1958 and 1967 and amended once in 1979.

[6] Drahos, P., "Developing Countries and International Intellectual Property Standard Setting", CIPR Study Paper 8, 2002, p. 25.

[7] The increasing participation of developing countries in WIPO in the 1980s had defeated developed country proposals, while at the same time allowing some progress in advancing developing countries' agenda for the reform of the Paris Convention.

persuasion.[8] The overall objective of the United States strategy in the 1980s was to shift the IPRs regulatory focus from WIPO to GATT where the capacity of developing countries to set the agenda was limited.

It is no surprise that when the United States began to push for the inclusion of intellectual property in the Uruguay Round; developing countries resisted the proposal arguing that issues relating to such rights fell within the brief of WIPO. In parallel to this process, the United States and the European Communities exercised the art of ramming down intellectual property standards through bilateral dealings and the use of unilateral retaliatory power, such as under Section 301 of the U.S. Trade and Tariffs Act. As a consequence, the promise of multilateralism in intellectual property standard setting under GATT was in some ways appealing to developing countries.

With the adoption of the TRIPS Agreement, WTO Members were obliged to comply with a new set of detailed standards on patents, as well as with articles 1 through 12 and article 19 of the Paris Convention. The TRIPS Agreement, Part I, Section 5, substantially supplemented the Paris Convention's provisions on patents, and significantly contributed to increasing the levels of protection and to harmonizing certain key aspects, such as the patentability in all fields of technology. In the view of the United States;,

> *"Although many might question whether there is a single international patent system, there can be no question that the foundation for an international system exists in the Patent Cooperation Treaty (PCT) and the Patent Law Treaty (PLT), (…), and in the Agreement on Trade Related Aspects of Intellectual Property (TRIPS Agreement)".*[9]

However, the TRIPS Agreement does not cover all areas in patent law and, as examined elsewhere[10] and confirmed by the Doha Declaration on the TRIPS Agreement and Public Health,[11] there are some "flexibilities" for the design and implementation of the patent regime at the national level. Many such flexibilities now face the possibility of being eroded or suppressed under the new WIPO Patent Agenda.

Of course, the task of filling the gaps in the TRIPS Agreement could have been promoted at the WTO itself, under the review and amendments clause contained in article 71. However, developed countries -- actively supported by intellectual property lawyers' and businesses' associations that participate in WIPO as non-governmental organizations (NGOs) -- came back to WIPO for further developing patent law standards.

Having experienced the sour taste of forum shifting strategies in the 1980s, WIPO learned how to live in the world of TRIPS. In quick succession, the WIPO Assembly passed two resolutions, one in 1994 mandating the International Bureau to provide technical assistance to WIPO members on TRIPS-related issues, and a second one in 1995 to enter into a cooperation Agreement with the WTO for WIPO to provide technical assistance to developing country Members of the WTO irrespective of their membership of WIPO. Furthermore, with the adoption of the WIPO Copyright Treaty and the

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[8] Lou Clemente, Pfizer's General Counsel quoted in Drahos, op. cit., p. 7.

[9] Rogan J.E, "The Global Recognition of Patent Rights: An Agenda for the 21st Century" (presentation made at the WIPO Conference on the International Patent system in Geneva on 26 March 2002).

[10] See, e.g. South Centre, *The TRIPS Agreement. A Guide to the South. The Uruguay Round Agreement on Trade-Related Intellectual Property Rights*, South Centre, Geneva 1997.

[11] See WTO document WT/MIN(01)/DEC/2, 14 November, 2001.

Performances and Phonograms Treaty in 1996, and of the PLT in 2000, WIPO showed its ability to respond to developed countries' demands.

In many ways, these developments indicated that WIPO had found a niche in the TRIPS world. Though it was seen as lacking in enforcement, the technical expertise that had developed over the years was perceived by developed countries as indispensable in promoting the TRIPS standards, as in fact WIPO did, through extensive technical assistance to developing countries. Indeed, WIPO has consistently sought to reinforce the perception that it is a highly technical body to keep away most of the political and economic debate about IPRs.

This would not have been possible; however, had developing countries tackled intellectual property issues more consistently in WIPO and WTO. The WIPO has clearly offered a friendlier forum to the IPR system than WTO. Developing countries' views are generally represented in WIPO through their industrial property offices, whose officials lack a global perspective on the economic and social implications of IPRs, and often share the same objectives about the patent system that inspire developed countries' representatives. Developing countries have not been effectively engaged within WIPO in questioning the orthodoxy that more and more intellectual property rights are better for developing countries.[12] This is in stark contrast with the level of engagement that such countries have exhibited in the WTO's Council for TRIPS, where they have questioned -- through their trade representatives -- the implications of the IPR system, particularly in the area of public health.[13] WIPO has therefore successfully avoided dealing with development concerns raised by developing countries, and has safely watched as the 'intellectual property and development debate' rages a few blocks away at the Centre William Rappard housing the WTO headquarters.

[12] Drahos, op. cit., p. 32.

[13] A notable expression of this critical view was the adoption of the Doha Declaration on the TRIPS Agreement and Public Health, op. cit.

III. THE WIPO PATENT AGENDA: ANALYSIS ASSESSMENT AND ALTERNATIVES

III.1 Objectives

Apart from the basic GATT principles of National Treatment and Most-Favoured-Nation treatment (MFN), the TRIPS Agreement introduced the principle of minimum intellectual property standards. This principle has played and will continue to play a critical role in the overall strategy of developed countries to attain higher standards of intellectual property protection in areas of their interest. The net effect of this principle is that each subsequent bilateral or multilateral intellectual property agreement can only create higher standards but not derogate from the existing minimum standards. With the TRIPS standards firmly entrenched, the Patent Agenda can only aim at higher standards and more harmonization.[14]

While the TRIPS Agreement established binding standards in many areas of patent law, it left considerable room in others, such as with regard to the crucial issues of what is patentable and how the requirements for patentability are defined. The Patent Agenda, in essence, aims at introducing new standards that would exclude the flexibility available under the TRIPS Agreement. As conceived, it is a complementary effort to the achievements in the Uruguay Round that will substantially erode, if successful, the room for manoeuvre that WTO members were able to retain from that Round's negotiations.

The main users of the current patent system complain about the burdensome, complex and costly procedures for obtaining patents internationally, due to the current territorial nature of the patent system.[15] The main emphasis in the so-called "improvement of the patent system" is to facilitate acquiring patent protection in foreign countries by making the system more user-friendly, cost-effective and secure. The Patent Agenda is supposed to address the 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 and time consuming procedures.[16] The main purpose of the Patent Agenda, as set out by the WIPO Director-General is, therefore, to create mechanisms and programmes whereby inventors and industry have access to national, regional and internationally effective patent protection systems which enable them to obtain, maintain and enforce their patents globally.[17]

III.2 The Pillars of the Patent Agenda

The three main pillars of the Patent Agenda are the PLT, the PCT reform process, and the draft SPLT,[18] which are briefly described in this section.[19]

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[14] See, for example, article 2 of the PLT on more favourable requirements.

[15] See the memorandum of the Director-General para. 3.

[16] See the memorandum of the Director-General paras. 17 – 28.

[17] See the memorandum of the Director-General paras. 38 & 39.

[18] However, the Director-General of WIPO emphasized in his memorandum to the WIPO Assemblies introducing the Patent Agenda initiative, that the process he envisaged was broader than just the legal system and encompassed supporting infrastructure for administration, maintenance, exploitation and enforcement.

[19] The process may include other elements, for example, the revision of the Budapest Treaty on the Deposit of Micro-organisms for the purpose of patent protection. There is no obligation under the TRIPS Agreement to sign the Budapest Treaty, as Members have considerable freedom to establish the disclosure requirements. Accession to that treaty, however, has been promoted by the United States and the European Union (EU) through their

III.2.1 The Patent Law Treaty

The PLT was adopted in Geneva on 1 June 2000.[20] Its main aim is to harmonize the procedures for applying for, obtaining and maintaining patents. For that purpose, the treaty includes a set of standardized formal requirements for national and regional patent offices to apply when dealing with patent applications.

> The PLT does not contain any substantive provisions. Its article 2 states that
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> *"[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".*

The Treaty 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 provides a clear linkage to the PCT for current and any future patent law harmonisation (Article 16).[21]

One questioned aspect of the PLT[22] is the relaxation of the conditions for admission of a patent application and the determination of the application date, which is crucial for the assessment of novelty and inventive step, as well as to establish the right to a patent grant in case of rival claims by different inventors. Article 5(1) of the PLT innovates with regard to most national laws and the PCT procedures as it allows the applicant to submit minimal information: "an express or implicit indication to the effect that the elements [received by the patent office] are *intended* to be an application" and "a part which on the face of it *appears* to be a description" (article 5(1) (i) and (iii)).[23] This provision may permit the deliberate submission of an application prior to the actual conception of an invention (for instance when an inventor has a hypothesis but not an experimental verification thereof),[24] as well as to subsequently introduce new, different or additional subject matter and claims while benefiting from an earlier filing date. In addition, the lax requirements contained in article 5(1)(ii) ("indications allowing the identity of the applicant to be established or allowing the applicant to be contacted by the patent office") create uncertainty about who the applicant is and might lead to manipulation and fraud.[25]

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bilateral trade agreements with developing countries. According to WIPO, there is a need to expand this treaty to the registration of DNA sequences in a central database, that would probably boost gene patenting worldwide (GRAIN, "WIPO moves towards 'world" patent system", 2002).

[20] See WIPO document PT/DC/47.

[21] See, e.g., Nolff, M., *TRIPS, PCT and Global Patent Procurement*, Kluwer Law International, London/The Hague/Boston, 2001.

[22] The following analysis is based on Zaveri, N., *Patent Law Treaty. An Open Invitation to Mischief*, Mumbai (mimeo), 2000.

[23] Emphasis added.

[24] In the area of biotechnology, for instance, *in vitro* experimentation results may not be confirmed when tested *in vivo*. Many patents are invalidated because the inventor had not actually realized the invention at the time of the application.

[25] Ibid.

Moreover, applications may be kept pending almost indefinitely. The patent office has the burden of inviting the applicant (without any fixed term) to provide the elements missing in the application. Even if the requirements were deemed at one point as not complied with and the application deemed as not filed, patent offices are obliged to provide for "continued processing" and, if necessary, *reinstatement* of the application. Finally, non-compliance with formal requirements will not be a ground for revocation, unless fraudulent intention is proven. The burden of proof is thereby shifted to any complaining party.

The described rules ostensibly benefit patent applicants, while they are likely to increase uncertainty and litigation. In contrast to the proclaimed goal of the Patent Agenda, they are also likely to increase rather than reduce patent offices work in dealing with applications at the initial phase of procedures.

The PLT is not yet in force and as of 15 October 2002 only four countries had ratified and/or acceded to it, while 53 others and the European Patent Organization (EPO) had signed the treaty.[26] The PLT only requires ten ratifications and/or accessions in order to come into force.[27]

III.2.2 The Patent Cooperation Treaty (PCT)

Purpose and object of the PCT

The PCT was adopted in 1970 with the aim of providing a single system under which patent applicants could file one international application (see *Box 1*) that would be valid in all the Contracting States designated by the applicant. While certain stages are still reserved for national and/or regional patent offices, the system allows for international publication, an international prior art search and even an international preliminary examination if the applicant so desires. Although the results are not given full recognition by national and regional patent offices, the PCT system is seen as a great success upon which a truly international patent system can evolve.[28]

The PCT, as noted, is essentially a patent filing procedure with some elements of a patent examination procedure. It has been built upon and has respected differences in substantive patent law.[29] There are only three mandatory PCT obligations:[30]

(1) a regularly filed PCT application must have the effect of a regularly filed national application;

(2) a PCT application cannot be processed by national authorities before the expiry of a certain time limit, unless expressly requested by the PCT applicant;

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[26] See current status of ratification and/or accession to the PLT at: *http://www.wipo.int/treaties/documents/english/word/u-page33.doc*

[27] See article 21 of the PLT.

[28] See the Memorandum of the Director-General, para. 8.

[29] At the Washington Diplomatic Conference on the PCT, it was observed that "it was a fundamental principle invoked frequently both during the preparatory work of the PCT and in the present Conference that the PCT should not require major or significant changes in the national laws of Contracting States" (Record of the Washington Diplomatic Conference on the Patent Cooperation Treaty, WIPO Publication, No. 313 (E), note 760.1 at 554, quoted by Nolff, M., op. cit., p. 46).

[30] See Nolff, op. cit., p. 41-42.

(3) a PCT Contracting State cannot require, subject to certain exceptions, compliance relating to the form or contents of a PCT application, which differs from the requirement provided by the PCT.

Box 1
The International Applications under the PCT

The PCT was concluded in 1970, amended in 1979 and further modified in 1984. It is open to all States party to the Paris Convention for the Protection of Industrial Property (1883). The Treaty makes it possible to seek patent protection for an invention simultaneously in each of a large number of countries by filing an "international" patent application. Such an application may be filed by anyone who is a national or resident of a Contracting State. It may generally be filed with the national patent office of the Contracting State of which the applicant is a national or resident or, at the applicant's option, with the International Bureau of WIPO in Geneva. If the applicant is a national or resident of a Contracting State which is party to the European Patent Convention, the Harare Protocol on Patents and Industrial Designs (Harare Protocol) or the Eurasian Patent Convention, the international application may also be filed with the European Patent Office (EPO), the African Regional Industrial Property Organization (ARIPO) or the Eurasian Patent Office (EAPO), respectively.

The Treaty regulates in detail the formal requirements that any international application must comply with.

Among all the Contracting States, the applicant indicates those in which he wishes his international application to have effect ("designated States"). The effect of the international application in each designated State is the same as if a national patent application had been filed with the national patent office of that State. Where a designated State is party to the EPO, the applicant may, and in the case of Belgium, Cyprus, France, Greece, Ireland, Italy, Monaco and the Netherlands, must opt for the effect of a European (rather than a national) patent application. Where a designated State is party to the EAPO, the applicant may opt for the effect of a Eurasian (rather than a national) patent. Where a designated State is party to the Harare Protocol, the applicant may, and in the case of Swaziland, must opt for the effect of an ARIPO (rather than a national) patent application. Where a designated State is a member of the African Intellectual Property Organization (OAPI), the effect is that of a regional application filed with OAPI.

The international application is then subjected to what is called an "international search." That search is carried out by one of the major patent offices.[1] The said search results in an "international search report," that is, a listing of the citations of such published documents that might affect the patentability of the invention claimed in the international application.

The international search report is communicated to the applicant who may decide to withdraw his application, in particular, where the said report makes the granting of a patent unlikely.

If the international application is not withdrawn, it is, together with the international search report, published by the International Bureau and communicated to each designated Office.

If the applicant decides to continue with the international application with a view to obtaining national (or regional) patents, he can wait until the end of the 20th month after the filing of the international application or, where that application claims the priority of an earlier application, until the end of the 20th month after the filing of that earlier application, to commence the national procedure before each designated Office by furnishing a translation (where necessary) of the application into the official language of that Office and paying to it the usual fees. This 20-month period is extended by a further 10 months where the applicant chooses to ask for an "international preliminary examination report," a report which is prepared by one of the major patent offices mentioned above and which gives a preliminary and non-binding opinion on the patentability of the claimed invention. The applicant is entitled to amend the international application during the international preliminary examination.

The international preliminary examination report shall not contain any statement on the question whether the claimed invention is or seems to be patentable or unpatentable according to any national law. It shall state, subject to the provisions of paragraph 3, in relation to each claim, whether the claim appears to satisfy the criteria

of novelty, inventive step (non obviousness), and industrial applicability, as defined for the purposes of the international preliminary examination in Article 33(1) to (4).

Source: Based on WIPO web page, *www.wipo.int* and Nolff, 2001.

[1] The Patent Offices of Australia, Austria, China, Japan, the Russian Federation, Spain, Sweden, the United States of America and the European Patent Office.

The PCT was therefore not originally designed as a harmonizing instrument. According to its Article 27(5),

> *"Nothing in this Treaty and the Regulations is intended to be construed 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, any 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".*

The procedure under the PCT has great advantages for the applicant and the patent offices:

(i) the applicant has eight or 18 months more than he has in a procedure outside the PCT to reflect on the desirability of seeking protection in foreign countries, to appoint local patent agents in each foreign country, to prepare the necessary translations and to pay the national fees; he is assured that, if his international application is in the form prescribed by the PCT, it cannot be rejected on formal grounds by any designated Office during the national phase of the processing of the application; on the basis of the international search report, he can evaluate with reasonable probability the chances of his invention being patented; on the basis of the international preliminary examination report, that probability is even stronger; and the applicant has the possibility during the international preliminary examination to amend the international application to put it in order before processing by the designated Offices;

(ii) the search and examination work of the patent offices of designated States can be considerably reduced or virtually eliminated thanks to the international search report and, where applicable, the international preliminary examination report that accompanies the international application;

The PCT reform

The process of reforming the PCT started in 2000.[31] The reform of the PCT is geared towards introducing amendments to the treaty to simplify and streamline procedures while at the same time aligning it to the new PLT standards. The changes anticipated relate to coordination of international searches and international preliminary examination, and time limits for entering the national phase. In

[31] See the memorandum of the Director-General para. 33. In September 2001, at the PCT Assembly, the Committee on the Reform of the PCT -- which had been created by the PCT Assembly in 2000 -- recommended the establishment of a Working Group in order to speed up negotiations.

addition, the United States and other developed countries want to see a more fundamental overhaul of the PCT system in order to facilitate global patenting.

The initiative to reform the PCT has been championed by the United States, which made an initial proposal to change the Treaty in two stages. The first stage would include "modest, simplifying and PLT-based changes that would be targeted for implementation in about five years", while the second stage would constitute "a radical departure from today's PCT system" and could include "a much more comprehensive overhauling of the entire PCT system that would result in a system bearing little resemblance to the PCT system of today".[32]

The short-term objectives of the reform, as presented by its proponents, include:

- to streamline and simplify procedures for patent applicants;[33]
- to reduce the duplication of examination tasks[34] and remedy the overload of patent offices due to the growth in patent applications;[35]
- to reduce the cost of filing for patent applicants and facilitate the acquisition of the same patent in a large number of countries.[36]

However, the objective of the PCT reform, according to the United States, should not only be to make the PCT system "fully cost-competitive, or even less costly, when compared to the costs associated with direct national filings" but to make "the great leap" to the grant of substantive rights for PCT

[32] See PCT/R/1/2.

[33] In its proposal, the United States stated that "from the perspective of potential users, the PCT is often criticized as being overly complex and unforgiving. Many inventors and patent applicants in the United States do not use the PCT system because of these concerns." See, (PCT/R/1/2).

[34] According to the United States "there is much duplication of patent application processing among the International Bureau of WIPO, the receiving offices and International Searching and Examining Authorities and the national patent offices throughout the world" (PCT/R/1/2) "With about 45% of patent applications filed in the United States of America being of foreign origin, and about one half of US-origin applications being also filed abroad, about three quarters of what was done in the examination process in the United States of America was repeated elsewhere at some point in time. This state of affairs made no sense" (PCT/R/1/26, para. 17). According to Australia, only about 20% of the processing work of the major offices is not duplicated (PCT/R/1/26, para. 27).

[35] The United States Delegation observed that "some national and regional Offices were being overwhelmed by filings. To cope with increasing workload, additional examiners needed to be hired…In 1980, the United States Patent and Trademark Office had about 900 examiners; now it had 3000 examiners. Nevertheless, the pendency time continued to grow" (PCT/R/126, para. 17). Japan, moreover, indicated that, "in its view, the PCT system was in a crisis. Patent applications in the world had increased rapidly from about 1.7 million in 1990 to about 5.8 million in 1998. This rapid increase was mostly due to the rise in the number of applications filed by foreign residents, mainly as a result of an increase in the number of countries for which each application was filed". According to Japan, "purely domestic applications," which were never filed in foreign countries only totalled 550,000, while the rest represented "internationally-oriented domestic applications," that is, applications that were subsequently filed in foreign countries through the PCT and/or under the Paris Convention.

[36] In its proposal the United States held that "under the present system, today's inventors and patent applicants are placed in the untenable position of having to make worldwide business decisions based, in large part, on the costs of obtaining and maintaining patents. A more desirable state of affairs would be one in which patenting costs played little or no role in these business decisions" (PCT/R/1/2). The same delegation also indicated that "users of all patent systems were pleading for relief. It was necessary to strive for a situation where the costs of patent protection became negligible, so that the resources of individuals and companies could be focused on what they did best. Those groups had been calling for cost reductions, streamlining and simplification" (PCT/R/1/26, para. 17).

applications. Thus, "the system could move away from its current, non-binding patentability opinions and adopt procedures where substantive rights could eventually be granted via the PCT".[37]

Hence, while the immediate objective of the United States and other proponents of the PCT reform is to streamline procedures and reduce duplication and costs, the final objective is to be able to grant a *global patent.* The harmonization of substantive patent law becomes a central piece in the new proposed architecture.[38] The adoption of such a patent would not only mean that most national patent offices would become superfluous but, more importantly, that the current flexibilities permitted by the TRIPS Agreement with regard to rules on patentability and exceptions thereto would be eliminated, as discussed below.

During the first session of the Committee on Reform of the Patent Cooperation Treaty (hereinafter "the Committee") held in Geneva on May 21 to 25, 2001, it was agreed that the reform of the PCT system, which would involve changing both Articles and Rules, should be based on the general objectives indicated in *Box 2*.

The initiative to reform the PCT has found substantial support from both developed and developing countries,[39] but there is no consensus on several aspects of the reform, including its scope[40]. Colombia, in particular, is opposed to the grand objective of the reform, that is, the grant of "international patents".[41]

During the first session of the Committee some delegations indicated that the reform should not only take into account the interests of applicants but also those of third parties. Netherlands, in particular, observed that "there was little room for third parties to intervene in the international phase". It recalled that, "in 1964, the Netherlands had introduced a deferred examination system under which both the applicant and third parties could file a request for search and/or examination" (para. 15).[42] The United Kingdom opposed the United States proposal to grant at least one deferral of six months from the 30th month available from the priority date to initiate the national phase, because "…it could lead to anti-competitive abuse". This Delegation mentioned that at present it could take more than two and a half years for third parties to know whether an application would be pursued in any particular

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[37] The "second phase" of the reform should ensure, according to the United States, that "positive examination results in certain PCT authorities bind Contracting States" (PCT/R/1/2). For the Netherlands, the final goal is "that the procedures under the Treaty would result in the applicant obtaining a patent accepted by all the cooperating Contracting States" (PCT/R/1/26, para. 14).

[38] United States emphasized the "need to coordinate PCT reform with other reform efforts that had been completed or were under way", namely, " further convergence of national and international practices, substantive patent law harmonization through the work of the SCP, work sharing, and a "global patent" (however that might eventually manifest itself)" (para. 18). Hungary also noted that "a global patent system… could be achieved only in close coordination with international moves towards substantive harmonization of patent laws" (PCT/R/1/26, para. 22). See also the declarations by Germany (para. 32), Morocco (para. 34) and ARIPO (para. 53), supportive of a substantive harmonization process (PCT/R/1/26).

[39] See, e.g., the interventions at the first session by China, Republic of Korea, Egypt, Kenya, Niger, Sudan, OAPI and ARIPO (PCT/R/1/26).

[40] Spain, for example, noted that the reform "should not encompass changes of a substantive nature" (PCT/R/1/26, para. 30). Some countries expressed agreement only with regard to streamlining and simplifying the current system (see, e.g., South Korea's intervention, para. 35).

[41] The Colombian delegation noted that "the PCT harmonized formalities but did not prescribe the requirements for patentability". In its view, providing for the grant of patents under the PCT would be contrary to PCT Articles 1(2) and 27(5), as well as Article 4 of the Paris Convention. However, the Delegation was in favour of proposals for the harmonization and simplification of procedures under the PCT (para. 43).

[42] Norway indicated that an important objective of the reform would be to secure "a proper balance between the rights of applicants and those of third parties" (PCT/R/1/26, para. 37). See also, the interventions by China, United Kingdom, Spain, Russian Federation and Sweden in PCT/R/1/26.

State. No further delay was justified. Furthermore, this Delegation did not favour a mechanism by which commercial advantage over competitors would be dependent on one's ability to pay a fee. That would be against the interests of small and medium-sized enterprises (SMEs) and individual applicants who would be less able to afford such a fee" (PCT/R/1/26, para. 149).[43]

It is interesting to note that the need to ensure the *quality* of the examination process and of patents granted (a key issue for third parties) was mentioned by some delegations (Austria, para. 39; EPO, para. 110), but no specific proposal was made to attain that objective.

Box 2
Agreed Objectives of the PCT reform

The general objectives (not necessarily in order of priority) of the PCT reform are as follows:

(i) simplification of the system and streamlining of procedures, noting also that many PCT requirements and procedures will become more widely applicable by virtue of the Patent Law Treaty;

(ii) reduction of costs for applicants, bearing in mind the differing needs of applicants in industrialized and developing countries, including individual inventors and small and medium-sized enterprises as well as larger corporate applicants;

(iii) ensuring that PCT Authorities can meet their workload while maintaining the quality of the services provided;

(iv) avoiding unnecessary duplication in the work carried out by PCT Authorities and by national and regional industrial property Offices;

(v) ensuring that the system works to the advantage of all Offices, irrespective of their size;

(vi) maintaining an appropriate balance between the interests of applicants and third parties, and also taking into account the interests of States;

(vii) expanding programs for technical assistance to developing countries, especially in the area of information technology;

(viii) alignment of the PCT, to the maximum extent possible, with the provisions of the PLT;

(ix) coordination of PCT reform with the ongoing substantive harmonization work being carried out by WIPO's Standing Committee on the Law of Patents;

(x) taking maximum advantage of modern information and communications technology, including the establishment of common technical and software standards for electronic filing and processing of PCT applications;

(xi) simplifying, clarifying and, where possible, shortening the wording of the provisions of the Treaty and the Regulations;

(xii) streamlining the distribution of provisions between the Treaty and the Regulations in order, in particular, to gain increased flexibility.

Source: Report of the first session of the Committee on Reform of the Patent Cooperation Treaty,

[43] The proposal was also rejected by Mexico, Austria, Cuba, China, Brazil, Norway, Denmark, Turkey, Switzerland, Sudan and OAPI (see, PCT/1/26), in some cases noting concerns about the protection of third parties' interests.

para. 66. Available at *http://www.wipo.int*

Some of the few developing countries that participated in the debates of the first session of the Committee advocated, *inter alia,* for the reduction of fees and simplification of procedures (Kenya), the need to take into account the interests of developing countries applicants (Niger) and States (OAPI and ARIPO).[44] While most participating countries objected to the United States proposal for elimination of all residency and nationality requirements (thus allowing persons and companies not domiciled in a PCT member to invoke the PCT), Brazil supported the proposal. It argued that "Brazil, as a PCT Contracting State in South America, was surrounded by several countries that were not members of the PCT. Inventors from those non-member States presently find ways of filing PCT applications with the Brazilian Office" (para. 90). Egypt was also supportive of this proposal (para. 105).

Though the separate procedures under Chapters I and II would be retained,[45] the proposed "enhanced international search and preliminary examination system" would include the establishment of an examiner's opinion, which would be advanced and incorporated into the Chapter I procedure. Under the new system, the International Searching Authority (ISA) would be responsible for establishing a preliminary and non-binding written opinion, called the "international preliminary report on patentability ("IPRP (Chapter I)") on the questions whether the claimed invention appears to be novel, to involve an inventive step and to be industrially applicable. That written opinion of the ISA would be used for the purposes of Chapter I and, if the applicant files a demand for international preliminary examination under Chapter II, the IPRP (Chapter I) issued by the ISA would, unless the International Preliminary Examining Authority (IPEA) specifically opts otherwise, take the place of the first written opinion established, under the present system, by the IPEA during the international preliminary examination procedure. International preliminary examination would be carried out on the basis of the international search report and the written opinion of the ISA, and would be concluded with the international preliminary examination report which, in order to stress the similarities between the report established under Chapter I and that established under Chapter II, is proposed to bear the title "international preliminary report on patentability" ("IPRP (Chapter II)") .[46]

The flow chart on the following page illustrates the main features of the proposed enhanced international search and preliminary examination system.

Thus, under the proposed reform, the international search and international preliminary examination procedures will be combined to a much greater extent than is the case at present[47]. This means a significant departure from current PCT procedures. The main distinction between the IPRP (Chapter I) and the IPRP (Chapter II) would be that the former would be established on the basis of the international application as filed whereas the latter would be established following a dialogue between the applicant and the examiner, often on the basis of the international application as amended, in response to the international search report and the written opinion of the ISA.[48]

Another corollary of the proposed change would be that any future appointment by the PCT Assembly of an Office or organization as an ISA and an IPEA would need to be simultaneous and on

[44] See PCT/R/1/26, paras. 48, 49 and 52.

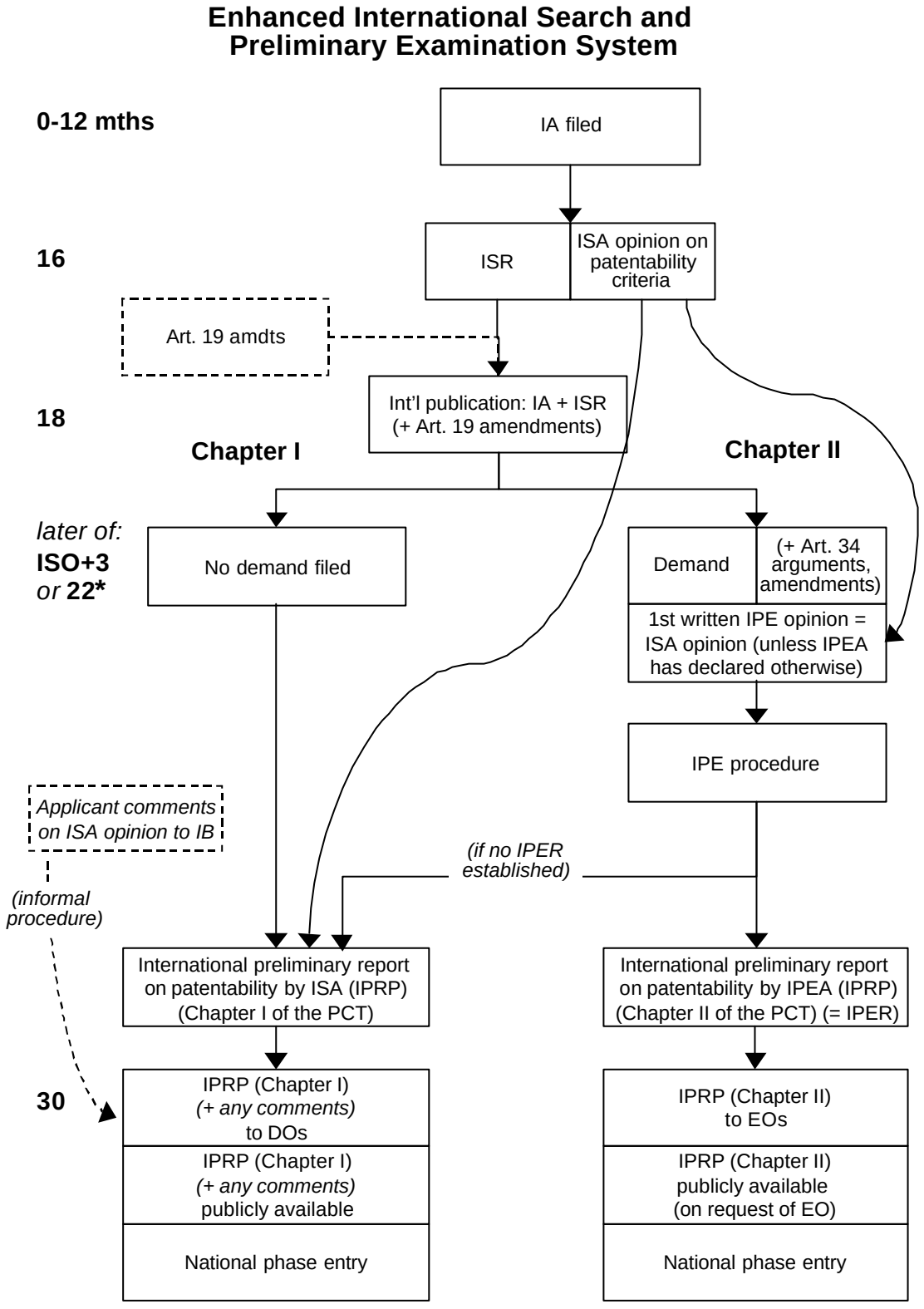
[45] During the discussions in the Working Group and the Committee on how to improve coordination of international search (Chapter I of the Treaty) and international preliminary examination (Chapter II of the Treaty), it was recognized that a possible merger of the procedures under Chapters I and II would only be considered in the context of long-term reform of the PCT (PCT/R/WG/2/12, para. 33).

[46] Ibid, paras. 15 and 16.

[47] See PCT/A/31/6, para. 13.

[48] Ibid.

the basis of the same qualifications. The expansion of the Chapter I procedures to include a written



** must in practice file demand by 19 months for Article 22 transitional reservation countries*

[49] Nolff, op. cit., p. 112.

The reform, as proposed by the major countries, however, does not entail establishing a PCT Search Report which is regarded as conclusive. This is a positive element, since it will preserve the room for national patent offices to disagree with the conclusion reached in such report. It is also indicative, however, that despite the fact that a binding report would bring a significant reduction in duplicative tasks (one of the main objectives of the Patent Agenda), developed countries are not prepared to lose their autonomy in the examination of patent applications. They rather prefer and do not hesitate to push for the harmonization of substantive patent law, on the obvious assumption that they will be able to impose their *own* standards of patentability on the rest of the world, as examined below.

III.2.3 The draft Substantive Patent Law Treaty

The negotiations and discussions on the SPLT are taking place in the WIPO Standing Committee on the Law of Patents (SCP). This work is aimed at initially creating uniform substantive patent law standards relating to issues of prior art, novelty, utility and inventiveness, requirements relating to sufficient disclosure, drafting and interpretation of claims, grounds for refusal of an application, and for revocation and invalidation of a patent.[50]

After this first phase of work, further harmonization is envisaged -- in areas where the main players, the United States and the European Union, do not agree so far -- such as the first to file versus first to invent principles and post-grant opposition proceedings.[51] At its seventh session in May 2002 the SCP discussed the draft articles of the SPLT together with the corresponding draft rules and practice guidelines.[52] The SCP then gave the International Bureau the mandate to redraft the provisions based on the SCP discussions and to submit the revisions to the next meeting of the SCP scheduled for November 2002.

In fact, the initiative to develop a treaty on substantive patent law is not new. A failed attempt was made in the 1980s, when significant progress was achieved in drafting a potentially binding treaty. A Diplomatic Conference was convened which discussed several important aspects of patent law. The draft treaty (as prepared by the WIPO Secretariat) covered the substantive issues indicated in *Box 3*.[53] Some of the issues in the Box were dealt with by the TRIPS Agreement, notably the rights conferred by the patent, term of patents and the reversal of the burden of proof. Many of the remaining issues are now part of the agenda of the SCP on its work on the SPLT.

While it is often suggested that this early harmonization process collapsed due to the United States refusal to give up the "first-to-invent" rule[54] for determining who has the right to a patent, there were probably other strategic motivations behind developed countries' loss of interest in that exercise. At the time the WIPO negotiations were pursued, the United States and other developed countries had been able to lay down the basic elements of a comprehensive agreement on intellectual property in the framework of GATT, later adopted as the TRIPS Agreement. Developed countries were aiming in GATT at the universal recognition of pharmaceutical product patents and at other objectives important to their industries, and were confident that such objectives could be achievable in the framework of a "package" that would offer concessions attractive to developing countries in other trade areas. In addition, as mentioned, GATT was seen as "having teeth", in the sense that the dispute settlement

[50] SCP/4/6, SCP/7/3 and SCP/7/4.

[51] See the Memorandum of the Director-General para 31.

[52] See WIPO document SCP/7/7.

[53] See "Record of the Diplomatic Conference for the Conclusion of a Treaty Supplementing the Paris Convention as far as Patents are Concerned", WIPO, Geneva, 1991.

[54] Most of the rest of the world applies a "first-to-file" rule, that is, the patent is granted to the first to file for the patent, even when somebody else could demonstrate that he had first reached the invention.

machinery would allow the application of trade retaliations in case of non-compliance with the adopted standards by another WTO Member.

Box 3
Substantive Issues under Consideration by the 1991 Diplomatic Conference on Harmonization of Patent Law

⇒ Disclosure and Description
⇒ Claims
⇒ Unity of Invention
⇒ Identification and Mention of inventor; Declaration Concerning the entitlements of an Applicant
⇒ Claiming of Priority
⇒ Filing Date
⇒ Right to a Patent
⇒ Fields of Technology
⇒ Conditions of patentability
⇒ Disclosures Not Affecting Patentability (grace period)
⇒ Prior art effect of Certain Applications
⇒ Amendment or Correction of Application
⇒ Publication of Application
⇒ Time Limit for Search and Substantive Examination
⇒ Change in Patents
⇒ Administrative Revocation
⇒ Rights conferred by the Patent
⇒ Prior User
⇒ Extent of Protection and Interpretation of Claims
⇒ Terms of Patents
⇒ Enforcement of Rights
⇒ Reversal of Burden of Proof
⇒ Obligations of the Right Holder
⇒ Remedial Measures Under National Legislation

Unlike the PLT and the PCT, the SPLT would prescribe substantive standards to determine what an invention is, how the patentability is to be established, and what the scope of patent protection will be. The proposed treaty will also go well beyond TRIPS, which only indicates what the requirements of patentability are (novelty, inventive step or non-obviousness, and industrial applicability or usefulness),[55] but it neither defines such concepts nor what an "invention" is. TRIPS, moreover, does not contain rules on the scope and interpretation of patent claims, which are essential to establish the scope of protection.

The SPLT is potentially, as discussed below, the most troublesome building-block of the proposed international patent system from the perspective of developing and least developed countries. If adopted, it would establish new binding international standards in critical areas of patent law, so far left to the discretion of national legislation. Strong pressures to adopt such standards both bilaterally and multilaterally (through, for example, the review and amendment procedures of article 71 of TRIPS) can be anticipated.

[55] See article 27.1 of TRIPS.

The SPLT negotiating process

The negotiation process at the SCP shows a substantial asymmetry in the preparation and participation of developing countries vis-à-vis developed countries and many NGOs representing corporations' and patent lawyers' interests. Thus, the interventions by developing countries at the Sixth Session of the SCP (Geneva, 5-9 November 2001)[56] were a small proportion of those by developed countries,[57] and were even outnumbered by those of the referred to NGOs.[58] China and South Korea were responsible for most interventions by developing countries, with less frequent observations or questions made by Argentina, Brazil, Dominican Republic, Egypt, Kenya, Morocco and Sudan.

Curiously, despite their "observer capacity", the referred to NGOs participated in the debates on the same footing as governments, making proposals or "reservations",[59] supporting the positions of some governments[60] or being opposed to government positions.[61] There were no NGOs representing the views of consumers or developing countries.

The process of negotiation at the SCP raises the recurring question as to the extent to which developing countries can effectively influence the outcomes of international intellectual property standard setting. In a recent study, Drahos concluded that due to the continued use of webs of coercion by the United States and the European Union, developing countries still have comparatively little influence in international intellectual property standard setting.[62] As noted by the CIPR, it is necessary to improve the quality of participation by developing countries whose representatives often lack expertise and experience in international intellectual property standard setting and in the examination of

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[56] See SCP/6/9.

[57] The following States members of WIPO and/or the Paris Union were represented at the meeting: Albania, Argentina, Australia, Austria, Bangladesh, Barbados, Belgium, Belize, Benin, Brazil, Bulgaria, Cambodia, Cameroon, Canada, China, Costa Rica, Croatia, Czech Republic, Denmark, Dominican Republic, Ecuador, Egypt, Estonia, Finland, France, Germany, Ghana, Greece, Guatemala, Honduras, Hungary, India, Indonesia, Iraq, Ireland, Italy, Japan, Jordan, Kazakhstan, Kenya, Latvia, Lesotho, Lithuania, Malaysia, Mexico, Morocco, Mozambique, Netherlands, New Zealand, Nigeria, Norway, Oman, Peru, Philippines, Poland, Portugal, Republic of Korea, Romania, Russian Federation, Seychelles, Slovakia, South Africa, Spain, Sudan, Sweden, Switzerland, Thailand, The former Yugoslav Republic of Macedonia, Tunisia, Turkey, Ukraine, United Kingdom, United States of America, Venezuela, Viet Nam and Yugoslavia.

[58] Representatives of the following non-governmental organizations took part in the meeting in an observer capacity: American Bar Association (ABA), American Intellectual Property Law Association (AIPLA), Asian Patent Attorneys Association (APAA), Biotechnology Industry Organization (BIO), Chartered Institute of Patent Agents (CIPA), Committee of National Institutes of Patent Agents (CNIPA), Institute of Professional Representatives before the European Patent Office (EPI), Intellectual Property Institute of Canada (IPIC), Intellectual Property Owners Association (IPO), International Association for the Protection of Industrial Property (AIPPI), International Federation of Industrial Property Attorneys (FICPI), International Intellectual Property Society (IIPS), Max-Planck-Institute for Foreign and International Patent, Copyright and Competition Law (MPI), Trade Marks, Patents and Designs Federation (TMPDF), Union of European Practitioners in Industrial Property (UEPIP) and Union of Industrial and Employers' Confederations of Europe (UNICE).

[59] See, e.g., para. 28, SCP/6/9.

[60] See, e.g., paragraphs 167, 170, 185, and 186, SCP/6/9.

[61] See, e.g., the opposition of BIO to the inclusion of the exceptions contained in article 27.3 (b) (para. 186).

[62] "The simple truth is that on intellectual property issues that really matter to it the United States has been able to utilize webs of coercion whereas on the issues that matter to them developing countries have had to work through webs of dialogue", Drahos, op. cit., p. 26. For a detailed discussion of regulatory webs see, Braithwaite, J. & P. Drahos, *Global Business Regulation*, 2000, Cambridge University Press: Cambridge.

the relationship between intellectual property and national interests, and who may be unfamiliar with some of the technical subjects being discussed in WIPO. [63]

The main issues in the SPLT negotiations

Though discussions on the SPLT are still in an initial phase and, as mentioned, the participation of developing countries has been quite limited, some controversies have already arisen and others are foreseeable, to the extent that developing countries get better prepared and aware of the negative implications of the process on their freedom to design patent laws and integrate them into their development policies.

Defining patentability requirements

The draft SPLT contains specific definitions on what is eligible for protection, on the requirements of patentability (article 12) and on the concept of "prior art" (article 7). The latter is particularly important. Though the concepts of novelty and, in particular, of inventive step (or non-obviousness) have been standardized to some extent in national laws, differences with regard to the concept of prior art may lead to different conclusions in a particular case as regards patentability. Therefore, the draft SPLT would create the basis for a universal concept of patentability.

Neither the Paris Convention nor the TRIPS Agreement defines what an "invention" is, thus allowing for different solutions at the national level. One of the implications of the proposed SPLT rules would probably be, *inter alia*, the elimination of the available freedom to determine the room of patentability for biological materials, including genes. For instance, in the United States an isolated and purified form of a natural product is patentable. The concept of "new" under the novelty requirement does not mean "pre-existing" but "novel", in a prior art sense, so that the unknown but natural existence of a product cannot preclude the product from the category of statutory subject matter[64]. In contrast, the Brazilian patent law (1996) stipulates that no patents shall be granted with respect to living beings or "biological materials found in nature", even if isolated, including the "genome or germplasm" of any living being.

If the draft SPLT were adopted and became an international standard, the room currently used, for example, by the Brazilian legislation to limit the patenting of biological materials may disappear.

Technical character of inventions

One of the most significant issues on which some developing countries expressed their position at the SCP Sixth Session was whether an invention should show a "technical character" in order to be patentable.[65] The United States argued -supported by the Representatives of AIPLA, BIO and IIPS- that "requiring a technical character was unnecessarily limiting the innovations in new fields of endeavour, such as information technology and biotechnology, and that the term "in all fields of technology" which appeared in Article 27.1 of the TRIPS Agreement was not mandating any requirement relating to technical character. This Delegation added that the standard for patentability

[63] CIPR, *Integrating Intellectual Property Rights and Development Policy*, London, 2002, p. 164.

[64] Similarly, under the rules of the EPO, a patent can be granted when a substance found in nature can be characterized by its structure, the process by which it is obtained, or by other criteria, if it is new, in the sense that it was not previously available to the public.

[65] See SCP/6/9, para. 184.

should be that an invention need only provide for a practical application having a useful, concrete and tangible result".[66]

An ostensible objective of the United States proposal -- which entails a clear "TRIPS-plus" obligation, is to export to the rest of the world its policy of patentability of software, "business methods" and research tools.

Software is patentable as such in the United States. In *Diamond v. Diehr* and *Diamond v. Bradley* (both decided in 1981), the U.S. Supreme Court applied a liberal rule that permitted the patenting of software algorithms *per se*. The U.S. Patent and Trademark Office followed suit by issuing software patenting guidelines that have expanded the definition of patentable software subject matter. In *State Street Bank v. Signature Financial Group* (1998) the definition of protectable software was further expanded, and a software patent awarded on a data-processing system used in financial transactions was validated.[67] As a result, in the United States patents are routinely granted in cases where there is no transformation of physical substances into a different physical state, and only manipulation of data is involved. However, in European and in many other countries, software as such is not deemed an "invention" due to lack of industrial applicability.[68]

"Business methods" include methods applied to business activities such as buying and selling, marketing techniques, financial schemes and strategies, generally supported on computer software and networks. In the United States, the *State Street Bank v. Signature Financial Group* case opened the way for the controversial patenting of "business methods". This was later confirmed in *AT&T Corp. v. Excel Communications, Inc.* (1999) in relation to a patent that protected a message record used by a long distance carrier in providing a differential billing treatment for subscribers. On appeal, the Federal Circuit Court found again that no "physical transformation" was necessary for a mathematical algorithm to be patentable subject matter.[69]

The broad definition of "invention" leading to the patentability of business methods is highly controversial even within the United States.[70] Because of their low inventive standard (if any) and broad coverage, "business method patenting raise the spectre of an explosion of litigation focused on technical methods long in use, but patented only recently".[71]

"Research tools" are methods or substances (such as Expressed Sequence Tags - ESTs) used to undertake research in specific fields. Patents on genes, for instance, restrict their use as tools to identify possible therapeutic molecules or therapies. Access to these tools, and hence the progress of

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[66] See SCP/6/9, para. 185.

[67] U.S. Patent No. 5,193,056 protects a computerized accounting system used to manage a particular type of mutual fund investment structure, specifically the "hub and spoke" structure for mutual funds that simultaneously invest in stocks in different national stock exchanges, priced in different currencies. The court held that the transformation of data, representing discrete dollar amounts, by a machine through a series of mathematical calculations into a final share price, constitutes a practical application of a mathematical algorithm, formula, or calculation, because it produces "a useful, concrete, and tangible result".

[68] It is to be noted that the Diplomatic Conference for the Revision of the European Patent Convention (Munich 20-29 November 2000) rejected (by 16 of 20 votes) the proposal to delete the prohibition to grant patents for computer programs from article 52(2)(c) of the Convention. See, Nack R. and B. Phélip, "Report. Diplomatic Conference for the Revision of the European Patent Convention". Munich 20 - 29 November 2000", 2001, IIC, vol 32, No.2.

[69] Glazier, S., *E-Patent Strategies for Software, e-Commerce, the Internet, Telecom Services, Financial Services, and Business Methods (With Case Studies and Forecasts)*, 2000, LBI Institute, Washington D.C, p. 40.

[70] See e.g., Glazier, op. cit., p. 28-31-32.

[71] Steil, B., D. Victor and R. Nelson, *Technological Innovation & Economic Performance*, 2002, A Council on Foreign Relations Book; Princeton University Press, Princeton and Oxford, p. 22.

science, may be slowed down, particularly in developing countries and in public research institutions, due to the need to obtain multiple licences and the escalation of research costs from license fees[72].

The limitations imposed on research by the patenting of "research tools" are illustrated by the patent on the merozoite surface protein 1 ("MSP-1") of plasmodium, which provides one of the best candidates for the development of a malaria vaccine. The patent landscape of MSP-1 includes 39 patent families describing the antigen, processing fragments, constructs, production, delivery, etc. belonging to different title-holders. This complex landscape requires the lengthy negotiation of multiple licenses, at an unpredictable cost.[73]

In sum, dropping the requirement of "technical character" of inventions would substantially expand the scope of the patent system, beyond its basic intent of promoting technical progress. Such a step will go well beyond the TRIPS Agreement (which only prescribes patenting in "fields of technology") and the current PCT, according to which the invention must be of "technical character" (it must relate to a technical field, be concerned with a technical problem, and have technical features in terms of which the subject matter for which protection is sought can be defined in the claim).[74]

It is to be noted that the European Communities and its Member States, Argentina, Brazil, the Dominican Republic, Guatemala, Japan, Mexico, Norway, Romania, the Russian Federation, Switzerland and the Representative of the EPO, have objected to the proposal of ignoring the technical effect of inventions, wanting to keep the concept of industrial applicability as a separate requirement.[75]

Exclusions from patentability

Another important issue raised by some developing countries (Brazil, Argentina, and Guatemala, supported by the Russian Federation and the Representative of the EAPO) was the need to incorporate in the draft treaty Articles 27.2 and 27.3 of the TRIPS Agreement,[76] and to include a general provision allowing exceptions to patentability which would be necessary for the protection of public health and environment. This proposal was opposed by the United States and the biotechnology industry, in particular in relation to plants and animals, with the argument that the TRIPS Agreement "provides for minimum requirements under the WTO" and that the SPLT, in contrast, would aim at establishing best practices at the international level".[77] Clearly, some countries seek to suppress the right of WTO Members to provide for exceptions legitimate under the TRIPS Agreement, thereby introducing "TRIPS-plus" standards in the SPLT.

If this approach succeeded, the SPLT "could make the World Trade Organization's Trade-Related Intellectual Property Rights (TRIPS) Agreement obsolete. TRIPS "only" spells out the minimum required elements of national patent laws. SPLT, by contrast, will spell out the top and the bottom line. It is a fixed set of rules on what can be patented and under what conditions: the political substance of a potential world patent system".[78]

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[72] See Heller M. and R. Eisenberg, "Can Patents Deter Innovation? The anticommons in biomedical research", *Science*, vol 280, 1998, pp. 698-699.

[73] CIPR, op. cit., p. 12.

[74] PCT Preliminary Examination Guidelines, IV-1.2.a (October 1998).

[75] SPC/6/9, para. 189.

[76] These articles allow Members to exclude from patentability those inventions the commercialization of which may offend morality or public order, and to exclude plants and animals as well as essentially biological process to obtain them, respectively.

[77] See SCP/6/9, para. 186.

[78] GRAIN, op. cit.

Infringement and the doctrine of equivalents

The depth of the harmonization sought by some countries at the SCP is illustrated by the debate on the possible inclusion of rules on patent infringement. Thus, the Delegation of Canada stated at the Sixth Session that it was premature to exclude all infringement issues from the scope of the SPLT in view of the objective of harmonization, which was to provide a framework allowing one application to be prepared and accepted by the Offices of all Contracting Parties. Therefore, in its view, it was not sufficient to deal with the issue concerning claim interpretation in the pre-grant phase only, since applications would have to be drafted differently, depending on whether a particular country applied the doctrine of equivalents or not.

Stressing the importance of international harmonization on the drafting of claims as well as claim interpretation, the Delegation of the United States, supported by the Delegation of the United Kingdom, noted that, even if harmonization on the drafting of claims were achieved, a different interpretation of claims might defeat the objective of the SPLT. The Delegation of Germany, supported by the Delegation of France, underlined the importance of patents after grant, and pointed out that some provisions under the current draft, for example draft Rule 12(2)(b) and the use of the term "limitation," were also applicable in the context of infringement.[79]

These issues raise questions about the "theory of equivalence" to be applied,[80] an issue that so far has been outside the TRIPS Agreement standards and entirely left to national law. It is a matter of national legislation to define when products or processes that are not *literally* described in a claim may be deemed "equivalent" and therefore considered as infringing on the patent rights.

There are different approaches to deal with the equivalence doctrine.[81] Under one approach, equivalence may be found if the allegedly infringing variant of a process or product performs substantially the same function in substantially the same way to obtain the same result. Another approach relies not on a functional analysis, but on an objective comparison of the elements that constitute the variant and the invention, and particularly on the extent to which the variant introduced by the potential infringer may be deemed obvious by the skilled person in the light of the claimed invention.[82] This latter approach may permit an adequate protection of the inventor's interests, while leaving more room for third parties' innovations in the field covered by the patent. Of course, for developing countries it is crucial to leave as much room as possible for inventing around patented inventions, a perception that many also share in developed countries, where some experts think that a narrow doctrine of equivalents is required to promote innovation.[83]

No further conditions allowed

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[79] See SCP/6/9 para. 53. In contrast, the Delegation of Japan stated that infringement issues went beyond the objective of the SPLT, which was to provide the same examination results for the same applications. Although the Delegation was afraid of a delay in the conclusion of the SPLT due to the inclusion of infringement issues, it did not object to exploring any links between elements which were applicable throughout examination, grant and infringement procedures.

[80] This doctrine provides a conceptual framework to determine if a violation exists when there is no *literal* infringement of patent claims.

[81] See, e.g., Franzosi, M., *Il Brevetto: Quale Tutela?*, Quaderni di Giurisprudenza Comerciale. No. 169,1996, Milano; Schuster, R., *Germany Doctrine of Equivalents: Managing Intellectual Propertry*, 1996; Anzalone, S., "Infringement under the doctrine of equivalents. The search for certainity", *Patent World*, September 1996.

[82] The date at which the equivalence is considered may be the filing date of the application or the date of infringement.

[83] See, e.g., Merges, R., *Patent Law and Policy. Cases and Materials*, Contemporary Legal Educational Series, Boston, 1992, p. 705.

One of the most controversial provisions of the draft is a provision that would prohibit Contracting Parties from imposing any further conditions to obtain a patent other than those specifically provided for in the treaty. This is a very sensitive issue, since many developing countries have argued in WIPO and WTO for the need to establish an obligation on the patent applicant to disclose the origin of any biological materials claimed. As widely examined elsewhere,[84] such an obligation may help to limit or remedy the misappropriation of genetic resources and traditional knowledge, since it would permit patent offices to obtain more complete information on the "prior art", and may also facilitate to put in practice effective mechanisms for benefit sharing.

Though it has been argued that the disclosure obligation would create an *additional* patentability requirement, it would rather be aimed at obtaining information regarding inventorship. As a matter of principle, a patent should not be granted to a person who has not made an "inventive contribution". Applicants may be required to summarily show, in the case of inventions relating to the use of plants, etc., whether they have effectively reached the invention. This would not add a new requirement of patentability, since inventorship is a basic element in patent law and there are no limitations under the TRIPS Agreement with regard to the means to determine it.

III.3 The Main Development-related Concerns with the SPLT and the other Components of the Patent Agenda

The draft SPLT covers fundamental areas of patent law on which there are so far no international standards. This means that, if adopted, this new treaty will eliminate the flexibility that WTO Members enjoy to legislate in such areas. Preserving flexibility in framing national patent laws is not an end in itself. It is a necessary (but not sufficient) condition to allow countries to adapt, as far as permitted under existing international obligations, patent standards to their own needs and circumstances. In this context, the proposed harmonization raises, from the perspective of developing countries, several concerns.

III.3.1 Adaptation of patent law to local conditions and needs

There is growing recognition that the regulation of patents and other IPRs cannot be reasonably made with a unique, universal standard. Different socio-economic conditions and levels of development require different intellectual property systems. A recent report by the World Bank shows that the patent system may entail considerable short-term costs for developing countries, mainly due to administrative costs and problems with higher prices for medicines and key technological inputs, while "long term benefits seem uncertain and costly to achieve in many nations, particularly for the poorest countries".[85] The said report concludes that "one size does not fit all" and that countries should be left the flexibility to adapt the levels of intellectual property protection as their economies grow. It argues that "it should be recognized that developing countries need to have lower and more flexible IPRs standards than do their developed counterparts. TRIPS provides such flexibility in many areas and the

[84] See, e.g., Correa, C., "Intellectual Property Rights and Foreign Direct Investment", *International Journal of Technology Management*, vol.10, No. 2/3, 1995, London.

[85] World Bank, *Global Economic Prospects and Developing Countries*, 2001, World Bank, Washington D.C, p.129.

developing countries should be afforded the opportunity to operate at the lower limits if it is in their development interests to do so.[86]

The CIPR has also stated that,

> *"Developing countries should not be deprived of the flexibility to design their IP systems that industrialized countries enjoyed in earlier stages of their own development, and higher IP standards should not be pressed on them without a serious and objective assessment of their development impact. We need to ensure that the global IP system evolves so that it may fulfil its original goals, and most importantly contribute to the development of developing countries, by stimulating innovation and technology transfer relevant to them, while also making available the products of technology at the most competitive prices possible. We need to make sure that the IP system facilitates, rather than hinders, the application of the rapid advances in science and technology for the benefit of developing countries".* [87]

History shows that the patent system evolved over time in industrialized countries according to different perceptions and taking into account the competitive strength of their industries. Thus, in the United States copyright protection was restricted to United States citizens until 1891. Pharmaceutical product patents were recognized in France, Germany, Japan and Switzerland only in the 1960s and 1970s, when their industries had significantly developed.

But the opportunity that industrialized countries had to adjust their IPRs systems as they developed, is now largely denied to developing countries under the TRIPS Agreement, and will be more so if the SPLT were adopted.

III.3.2 Harmonization at the highest level of protection

As history also shows, the process of harmonization of IPRs has always meant standardization at the *highest level* practiced in the countries participating in the process:

> *"Harmonization means that developing countries negotiate new standards and rules without necessarily having had the benefit of experience in that area. In general, harmonization exerts an upward force on national laws and policies; …intellectual property harmonization has consistently (if gradually) resulted in stronger and more expansive rights for owners. Correspondingly, the scope of limitations or exceptions tends to be narrower… Where developing countries are concerned, harmonization has been a means of introducing higher standards of intellectual property into the domestic economy".* [88]

The feasibility, costs, and benefits of a further harmonization should be viewed from an economic perspective as well as a legal one. Very few economic studies are available on the matter. The

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[86] World Bank, op. cit., p. 147. For a deeper analysis of the development strategies of industrialized countries during their earlier stages of development see Chang, H., *Kicking Away the Ladder: Development Strategy in Historical Perspective,* Anthem Press, London, 2002.

[87] CIPR, op. cit., p. 8.

[88] Okediji, R., "Setting an Agenda for Intellectual Property Negotiations in the Next Five years", 2002, Bellagio (mimeo), p. 1.

analyses to date are derived from recent models examining the welfare economics of patent protection in North/ South contexts, and do not suggest that global welfare would be increased by a uniform system, except in the case where the welfare of all countries is valued equally, and distribution issues are moot. Moreover, initiatives for harmonization presume that a move towards greater uniformity based on protection parameters inspired by the more advanced countries would be superior in terms of "making all countries better off and no country worse off after a suitable redistribution of income or endowments. Yet, that itself is questionable. The links between [intellectual property] protection and innovation have yet to be shown to be on a scale that would justify such social engineering efforts in the name of global welfare maximization".[89]

III.3.3 Impact of harmonization in developing countries

The agenda for development of the "international patent system" launched by WIPO is premised on the assumption that "a robust and dynamic industrial property system, and particularly the patent system, supports and encourages technological innovation, brings more and better products onto the market for the benefit of people, and promotes investment and technology transfer".[90] There is no evidence, however, to support these assumptions in developing countries.

The new international framework on patents established by the TRIPS Agreement has affected the conditions for access to and use of technology in developing countries. Reverse engineering and other methods of imitative innovation have been restricted, thereby making technological catching-up more difficult. Strengthened patents improve the negotiating position of right-holders to determine the royalties to be paid and other conditions for the transfer of needed technologies, in case they agree to part with them at all.

Higher standards of patent protection are unlikely to have a positive effect on local innovation, except in those few countries (and sectors) that have reached a certain level of technological development and have the capacity to finance substantial research and development (R&D). Developing countries account for a small proportion of all patents granted in the world, and despite the increase in PCT applications, nothing indicates that they will be able substantially to increase their participation in the system.

Moreover, there is no conclusive evidence suggesting a direct link between increased level of IPRs and the magnitude and[91] quality of foreign direct investment (FDI).[92] FDI is critically dependent on various factors such as market size, growth prospects, resource endowment and political conditions, which normally have an overriding impact on investment decisions. Moreover, to the extent that all WTO Member countries are bound by the TRIPS Agreement, the differences among various national IPRs systems will be considerably reduced and the existence of IPRs protection is not likely to constitute a country-specific advantage to attract FDI.

Indeed, stronger protection allows title-holders to safely supply local markets through imports. Under secure IPRs, in effect, technology owners may prefer to promote the diffusion of their innovations through trade rather than by the transfer of technology or the establishment of subsidiaries

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[89] Frischtak, C., "Harmonization versus Differentiation in Intellectual Property Rights Regimes", *International Journal of Technology Management*, vol. 10., No. 2/3, 1995.

[90] WIPO, op. cit.

[91] Paradoxically, "higher" standards would mean in this context the obligation to apply *low* inventive activity standard thereby expanding the scope of patentable subject matter, as currently done in the United States.

[92] See, e.g. Correa, op. cit.; Maskus, K., *Intellectual Property Rights in the Global Economy*, Institute for International Economics, Washington, D.C., 2000.

in a foreign country. In fact, it was the expansion of trade that ultimately explained the reform of the intellectual property system prompted by developed countries through the TRIPS Agreement.[93]

III.3.4 Who will benefit?

The main objectives of the Patent Agenda include reducing the costs of patenting internationally for "international industries", individual inventors and SMEs, reducing the workload of patent offices by avoiding duplicative work, and speeding up the process of patent grant.[94]

It is no secret that the multinational companies, supported by the United States, are the main proponents and will be the main beneficiaries of higher, uniform and harmonized intellectual property standards worldwide. While substantive harmonization may facilitate compliance with laws in different countries by any applicant, SMEs and individual inventors will not be the main beneficiaries of such harmonization. Patents have been important for some highly innovative SMEs, such as biotechnological start-ups in the United States, but overall, the functioning of the patent system is too complex and, particularly, costly for SMEs and individual inventors. The Patent Agenda does not include any specific component aiming at reducing the barriers for the use of the patent system by SMEs and individuals, such as reduction of registration fees and, particularly, of the substantial litigation costs required to defend their rights or protect them against infringement.

Serious questions also arise about the opportunity of further harmonizing the patent system at a time when there are growing concerns about its functioning and impact on competition and innovation. Thousands of patents are granted each year in some jurisdictions, notably the United States, for minor, purely trivial developments, or for substances (including genes) that already exist in nature and which have merely been *discovered* but not *invented* by their would-be "owner". In 2000, the U.S. Patent and Trademark Office granted over 160,000 patents, twice the number granted ten years before.

This is the fruit of a variety of corporate patenting strategies,[95] of the application of loose criteria for patentability,[96] of the excessive flexibility of the Patent Offices in assessing the degree of inventiveness, and of shortcomings in the examination procedure.[97] Many of the patents granted cover minor developments, and are astounding not so much for their inventiveness but for their triviality. The fact that the income of patent offices (through registration and maintenance fees) depends on patents granted also favours a pro-patent atmosphere, under which the applicant is treated as the "client", ignoring that a basic responsibility of such offices is to preserve knowledge in the public domain and protect society from the grant of unwarranted legal monopolies rather than satisfy private "clients".

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[93] See, United States position in GATT, in *Patent & Licensing*, vol.17, No.6, December 1987, p.11.

[94] WIPO, op. cit.

[95] Granstrand, O., *The Economics and Management of Intellectual Property: Towards Intellectual Capitalism*, Edward Elgar, Cheltenham, 1999, p. 221-222.

[96] The adoption of a standard of *local* innovation for knowledge disseminated by media other than publication outside the United States has led, for example, to the patenting of plants and knowledge already widely used in the developing countries.

[97] For example, less than 50% of the examinations conducted by the U.S. Patent and Trademark Office refer to relevant background bibliography; the examination is by and large limited to analyzing previous patents. See, Aharonian, G., "Patent Examination System is Intellectually Corrupt", *Patnews*, (electronic journal) 1 May 2000. In the United States, moreover, patent examiners are encouraged to grant patents in the shortest possible time: their bonuses (up to 10% of salaries) depend on maintaining their production schedule in accordance with the limited time allotted for each application. 60% of all patent applications result in the issuance of a patent (even though they may differ from the original application). See, *U.S. Patent Statistics, 1963-2001, at www.uspto.gov/ web/offices/ac/ ido/oeip/taf/us_stat.pdf*

In addition, new areas have emerged, such as software and "methods of doing businesses", for which the number of patents has surged, increasingly overloading patent offices. As a result, developed countries (notably the United States) are pushing internationally for a cure to a problem that their own lax patentability policies have created. While the (patent) system in developed countries is under great strain, for reasons unconnected with developing countries, and there is much duplication of effort in the system, this does not mean that the appropriate solution is to harmonize standards globally, or regard an "international patent" as the overriding objective towards which the system is moving.

IV. CONCLUSIONS: INTEGRATING DEVELOPMENT IN IPR STANDARDS SETTING

IPRs are but one tool of national policy. IPRs rules should promote development by facilitating the transfer and diffusion of technology, and be consistent with basic public policies (such as food nutrition and public health).

Like the negotiations leading to the TRIPS Agreement -which was not designed to respond to development concerns but to satisfy developed countries' industries demands- the Patent Agenda has been launched without any analysis of its development impact. While it remains difficult to isolate the impact of patents on development, it is quite clear that the benefits and costs of patents significantly vary according to the levels of economic and technological development. The costs for developing countries of introducing or increasing the levels of IPRs protection are higher than the benefits that they can extract from such protection.

A further substantive harmonization of patent law is not in the best interest of developing countries. The WIPO Patent Agenda has been conceived and is executed with the clear goal of benefiting those companies with large-scale international patenting activity, and to support the proliferation of patents on incremental (often trivial) developments that can be used by large companies to erect market barriers. It does not contain any elements to improve the quality of patent grants. Given the design and objectives of the Patent Agenda, there is little that developing countries could gain with this new and far-reaching exercise of international standard setting. As noted by Barton,

> *"[a] harmonized treaty would probably leave significantly less flexibility than does TRIPS. This is a problem if the harmonized structure ends up, as is likely, as a compromise between the U.S. and the European systems, for such a compromise is likely to include a low inventive step standard and a very broad subject matter standard, standards that are not in the interest of developing nations (nor, in the judgment of many, of the developed nations either)".*[98]

In the WTO developing countries have followed a reactive strategy to deal with what are considered the negative elements in the TRIPS Agreement, but have been able to articulate their arguments and concerns and to force the international community to recognize the flexibilities and safeguards that the Agreement allows, particularly to protect public health. Paradoxically, the same approach has not been followed in WIPO, where developing countries seem to have consented, to a large extent, to a process that is likely to further reduce their freedom to design patent laws according to their own conditions and interests.[99] Coordinated and sustained efforts by developing countries should aim at preserving the currently available flexibility to determine what constitutes an invention and how patentability is to be

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[98] Barton, J., "Integrating IPR policies in development strategies", Background paper for Bellagio Meeting, 30 October - 2 November 2002.

[99] During the 37th series of Meetings of the Assemblies of the Member States of WIPO, however, some developing countries indicated reservations about the Patent Agenda and, in particular, about the work of the SCP. Thus, the delegation of Egypt noted that "we do not concur with the appropriateness of establishing new technical and procedural standardization measures whose implementation would require further efforts and resources beyond our limited means, in particular, in the absence of precise data and specific studies regarding their costs and expected benefits …S]ome countries expect that this process will result in the harmonization of the rules and procedures of a wide majority of countries with the practices and legislation of a small number of countries. This could represent, in reality, a step-backwards from the limited aspects of flexibility stipulated in the TRIPS Agreement".

established. As recommended by the CIPR, the WIPO process should be rejected "if it appears that the outcome will not be in the interests of developing countries".[100]

Developing countries will therefore have to pay greater attention to the Patent Agenda process and seek to influence it on the understanding that, so far, the Agenda is substantially designed to suit the economic interest of large countries, notably the United States and the European Union. Developing countries should critically reconsider the pros and cons of the Patent Agenda in the light of a development-oriented framework, and should elaborate options that preserve their freedom to operate under existing international rules. For instance, a number of options are available to address many of the problems identified by WIPO as grounds for the harmonization process in the PCT Reform.[101]

The inherent tension between the activities and processes in WIPO, an international organization that exists to promote intellectual property, and the development interests of developing countries, which require safeguards and technology transfer obligations, should also be considered. Developing countries, which form the majority of WIPO's membership, would therefore do well to start reconsidering the role of WIPO in development.[102]

The Patent Agenda raises, in sum, a major challenge for developing countries. While the United States and other developed countries see the bipolar structure of international intellectual property embodied in WIPO and WTO as a continuum, and see each of the organizations as providing them with an opportunity to achieve higher intellectual property standards, this complex reality does not yet seem to have dawned on developing countries.[103] Developing countries need to face up to this reality and formulate strategies to manage it.

Developing country representatives in both WIPO and WTO should appreciate intellectual property as a tool for development policy, and not merely as a contentious area to be designed and redesigned in response to developed countries' demands or political pressures. While it may take some time to significantly influence the course of such complex processes as the Patent Agenda, such countries need to undertake a debate within WIPO about the effects of intellectual property standard raising and harmonization on their development prospects. The key to such constructive influence in WIPO clearly lies in higher levels of engagement and coordination than currently exists.

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[100] CIPR, op. cit.

[101] Such options include:

1) To offer applicants the option of being able to request a "PCT-type search" for national applications to be made by an ISA, as permitted by PCT Article 15 (5);
2) To effectively apply PCT Rule 69(b) which allows for a concurrent PCT search and PCT examination;
3) To supplement the PCT procedure by providing the possibility for applicants to request a *supplementary* international search report from an ISA different from the one that carries out the usual international search that is required by Article 15 (option suggested by the PCT Committee for Administrative and Legal Matter).
4) To conclude the international phase, for those countries that wish to accept it, with a "PCT Certificate of Patentability" for any claims which appear to be patentable.
5) To better define, *for the purposes of the PCT applications*, what constitutes prior art, so that treatment of PCT applications could be harmonized (see, Nolff, M., op.cit., Chapter 8).

[102] See CIPR, op. cit.

[103] As one commentator has observed, 'international intellectual property norm making in an age in which intellectual capital has assumed increasing importance promises to be far more complex than it has been in the past'.(Gurry, F., "The Evolution of Technology and Markets and the Management of Intellectual Property Rights" in Abbott, Cottier and Gurry, op. cit., p.311).

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