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STANDING COMMITTEE ON THE LAW OF PATENTS

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REPORT ON THE INTERNATIONAL PATENT SYSTEM

prepared by the Secretariat

BACKGROUND

The Standing Committee on the Law of Patents (SCP), at its twelfth session held from June 23 to 27, 2008 in Geneva, agreed that document SCP/12/3 [Report on the International Patent System] would remain open for further discussion at the next session of the SCP and be open for written comments to the WIPO Secretariat until the end of October 2008, which would reflect those comments in footnotes or annexes to document SCP/12/3. Accordingly, Circular C.7646 inviting comments regarding document SCP/12/3 was sent to members and observers of the SCP. As mandated by the Committee, the Secretariat prepared this document for the thirteenth session of the SCP, to be held from March 23 to 27, 2009[*]. It incorporates the comments in the following manner as agreed by the SCP: (i) Annex II contains updated information regarding national laws; and (ii) comments on the text of document SCP/12/3 are contained in Annex III. Annex I was updated in order to reflect the latest membership of the Treaties. The text of document SCP/12/3 has not been changed, except for obvious errors, such as spelling mistakes and typos.

[*] At the twelfth session of the SCP, document SCP/12/3 Rev. was issued in the English and Spanish versions in which some paragraph numbers had to be corrected. Consequently, this document bears the document number SCP/12/3 Rev.2 in all three language versions.

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EXECUTIVE SUMMARY

1. Pursuant to the decision by the 34th WIPO General Assembly held in September/October 2007 to submit a Report on the International Patent System to the Standing Committee on the Law of Patents (SCP), the present document is submitted by the Secretariat as a working document for the twelfth session of the SCP, to be held from June 23 to 27, 2008. It contextualizes the existing situation of the international patent system, and attempts to cover the different needs and interests of all Member States. The Report covers three broad issues: Chapters II to IV address the economic rationale of the patent system and its role in innovation and technology dissemination, Chapters V to VIII address legal and organizational aspects relating to the patent system and Chapters IX and X focus on issues that are particularly relevant to broader policy considerations and development concerns.

Economic Rationale for Patents and Different Interests and Needs in the International Patent System (Chapter II)

2. The fundamental role of the patent system from an economist's perspective is to address market failure and restore the incentives to invest in production of knowledge. The patent system is intended to correct market failure and under-provision of innovative activities by providing innovators with exclusive rights to prevent others from exploiting their inventions without the patentee's consent. To correct the potential inefficiencies of the market power which may be created through exclusive rights, the patent system provides for, among other mechanisms embedded in the system, public disclosure of the patented matter. The disclosure of the technical details of the invention through the patent system expands the public stocks of technical knowledge and creates competition among innovators. A third function of the patent system is to encourage technology transfer by creating tradable property rights to improve the efficiency of knowledge flows.

3. Inconclusive empirical evidence on the role of the patent system to encourage research and development (R&D) and technology transfer makes it difficult to draw any clear-cut conclusion about the effectiveness of the patent system for economic development. Nevertheless, since the mid-1990s, demand for patents has been increasing at a rapid rate in the majority of countries under both national systems and the PCT international system. There has also been an increase in the share of non-resident filings, reflecting the increasing level of internationalization. The usage of the patent system varies significantly from one country to another. In recent years, however, the number of patent filing originating from emerging economies has been rapidly increasing.

Technology Disclosure through the Patent System (Chapter III)

4. The technical information derived from patent information serves various functions and user groups. It is widely used in business in formulating a firm's R&D activities, analyzing technology and competitors' trends and facilitating licensing and technology transactions. Further, patent information can be used by policy makers as an industrial policy tool, such as monitoring national technology performance, and as an input into R&D policy. In recent years, patent information is increasingly available via the Internet, free of charge. The expansion of industrial activities around the world results in increasing number of patent documents published in non-European languages. Although technical information derived from patent information is widely available on the Internet, information concerning the legal status of granted patents is more difficult to obtain through an on-line service.

Technology Diffusion and the Patent System (Chapter IV)

5. Transfer of technology may be achieved through different means, such as publications, cooperative research and development agreements, joint venture arrangements or foreign direct investments. In many cases, patent and know-how (trade secret) licensing agreements play an important role for successful technology transfer. In this Chapter, the international dimension of technology transfer is discussed in conjunction with the increasing transnational trade flows and globalization. A further dimension of technology transfer is the transfer of basic research results from research institutions to the industry that is capable of developing the research results to tangible products for the market.

6. From the viewpoint of competition policy, in general, technology diffusion through licensing agreements promotes competition in the market. However, where any provision in a licensing agreement conflicts with the prohibition of anti-competitive practices, the agreement is usually considered null and void. Many national competition authorities issue guidelines that clarify licensing practices that are considered to restrict or distort competition. Another issue relating to competition law and patent law relates to the effect of patent pooling agreements on competition.

7. Technological standards play an important role for interoperability of different technological components and for diffusion of technology. A number of questions have been raised with respect to balancing the interests of patent holders whose inventions are essential for the implementation of standards, other producers who need access to the patented invention and the public which seeks a wide choice of interoperable products.

8. Against the backdrop of increasing R&D costs, particularly in the area of complex, and often newly emerging, technologies, various initiatives to support collaborative research that could attract a wide range of researchers and investors have been developed in the recent past. In this Report, some of those collaborative research projects, namely, open source, a proposal for a Medical Research and Development Treaty and public-private collaboration, are summarized.

Current Multilateral Framework (Chapter V)

9. In the field of patents, currently, five multilateral treaties, namely, the Paris Convention for the Protection of Industrial Property (Paris Convention), the Patent Cooperation Treaty (PCT), the Strasbourg Agreement Concerning the International Patent Classification (Strasbourg Agreement), the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (Budapest Treaty) and the Patent Law Treaty (PLT), are administered by WIPO, and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), which is an Annex to the Agreement Establishing the World Trade Organization (WTO), is administered by the WTO. The coverage, scope and objectives of those treaties vary significantly, ranging from general principles to an international patent classification standard. In Chapter V, the current international legal framework is briefly described from five different angles: framework principles, substantive norms, formalities, administrative cooperation and an international filing and processing system. Further, recent discussions on substantive patent law harmonization, i.e., the draft Substantive Patent Law Treaty (SPLT) are summarized.

Patent Systems and Existing Forms of Cooperation (Chapter VI)

10. Although a number of international treaties have brought national legal frameworks closer together, there are differences in the architecture of national and regional patent systems, accommodating different national interests and needs. Chapter VI focuses on some key elements of the patent system and describes how those elements are implemented in the national patent systems. Further, it describes existing forms of direct and indirect cooperation among Member States.

11. The first set of elements relates to the patenting procedure before a national/regional patent office. It starts from filing an application, processing the application by the office (this may include searching prior art and substantive examination of patentability) and deciding on the grant/refusal of a patent. In certain countries, administrative opposition proceedings are available before the patent office. The second set of elements concerns substantive requirements under the patent law. In this Report, issues such as prior art, novelty, inventive step, grace period, sufficiency of disclosure, patentable subject matter and exclusions from patentability and exceptions and limitations to the patent rights are highlighted. Although patent laws have been constantly reviewed in the face of new technological developments, patents in the fields of biotechnology and information technology, in particular, raise a number of concerns. Therefore, challenges in the field of emerging technologies are addressed in this Chapter. Chapter VI also touches upon one management issue that is important for the functional patent system, i.e., patent quality management.

Support Structures for the Patent System (Chapter VII)

12. It is generally recognized that the patent system should be viewed in the context of national economic and development policies and strategies in order to truly empower the patent system as a tool for technological development and economic growth. While the patent law provides the legal framework, a number of other features need to be in place, including human resource development, education and effective and efficient administration, and judicial systems. As a specialized professional, patent attorneys (patent agents) provide an important service for the “checks and balances” of the national patent system. Their qualification and functions, however, are different from one country to another. In particular, differences with respect to the recognition of a professional privilege with respect to the communications between a patent attorney and his clients cause concerns at the international level.

13. In order to foster the transaction of technology supported by the patent system, measures have been taken by a number of Member States to create a marketplace for technology transfer and to support the funding and transferring of technology. Some of those initiatives are described in Chapter VII.

Perceived Threats to the Effectiveness of Patents as Incentives to Innovation (Chapter VIII)

14. In Chapter VIII, two issues, namely, litigation and patent thickets are considered as to their effects on the functioning of the patent system. With respect to litigation, accessibility to court procedures, legal certainty and timely judgments play an important role for the well-functioning of the patent system. This becomes increasingly important considering the greater than ever international dimension of litigation. Further, with the ever-increasing complexity of technology and the development of patent-based business models, the question as to whether the current level of trade-off between exclusive patent rights and the obligation

to disclose the invention is an effective incentive to boost future innovation has been raised. Certain business strategies, such as patent trolls, and phenomena of patent thickets in particular fields of technology, are seen by many as contributing to unjustifiable increases in the transaction costs, and thus as obstacles to a functioning patent system and to further innovation and research.

The Innovation Incentive in the Context of Public Policy Objectives (Chapter IX)

15. As a policy tool, the patent system was established to grant exclusive rights that would harness private interest sufficiently to create public goods, i.e., produce new technologies effectively made available to the public. On the other hand, in the fields where the public interest is most significant, such as the life sciences and technologies that provide for basic human needs, market-oriented incentives created by the patent system are considered to be not always effective. In this Chapter, the innovation effect of the patent system in the context of public policy is analyzed in three distinct areas: impacts of the patent system on public health; synergy and mutual supportiveness between the patent system and the conservation, sustainable use of biological resources and traditional knowledge and equitable sharing of benefits arising from such use; and ethical concerns relating to, in particular, life science research.

Development Related Concerns (Chapter X)

16. Although many issues that have a bearing on the development dimension are addressed in the preceding Chapters, Chapter X specifically reviews some of the major concerns raised by member States in different fora. Development is one of the most urgent challenges that the international community is facing today. In the context of the WIPO Development Agenda, a Committee on Development and Intellectual Property (CDIP) held its inaugural session in March 2008. In view of the innovation capacity gap not only between developed and developing countries but also among developing countries, questions have been raised as to whether, and to what extent, the international patent system is supportive of national efforts for development. Such concerns include the costs for utilizing and benefiting from the international patent system, the costs for fully benefiting from the disclosure mechanism under the patent system and from access to patent information, and those for tailoring a national patent system in such a way that it responds to national policy objectives and, at the same time, meets international obligations and facilitates international procurement of technology. Many of those concerns have already been expressed in past sessions of the SCP.

I. INTRODUCTION

17. The WIPO General Assembly, at its 34th session held in September/October 2006, requested its Chair to conduct informal consultations for the purpose of discussing and recommending a work program for the SCP to the WIPO General Assembly in September/October 2007. The consultations held by the Chair of the General Assembly were not able, in terms of the substantive contents of a working program for the SCP, to overcome all differences among the various positions, but nevertheless resulted in the following recommendation which was submitted by the Chair to the WIPO General Assembly in September/October 2007.

18. The recommendation stated that the WIPO Secretariat should establish a report on issues relating to the international patent system covering the different needs and interests of all Member States, which would constitute a working document for the next session of the SCP. The Report would contextualize the existing situation of the international patent system, including reference to the WIPO Development Agenda process, and would contain no conclusions. The Report would be made available to all members and observers of the SCP by the end of March 2008. The WIPO General Assembly in September-October 2007 unanimously adopted the recommendation by the Chair of the General Assembly.

19. Accordingly, this report is submitted by the Secretariat as a working document for the twelfth session of the SCP, to be held from June 23 to 27, 2008. As mandated by the WIPO General Assembly, it follows closely the indicative draft outline adopted by the WIPO General Assembly in September-October 2007. The order of the Chapters, however, was revised with a view to provide a better structure of the report into three main areas: Chapters II to IV address the economic rationale of the patent system and its role in technology disclosure and dissemination, Chapters V to VIII address legal and organizational aspects relating to the patent system and Chapters IX and X focus on issues that are particularly relevant for broader policy considerations and development concerns. A considerable number of issues relating to the international patent system have a bearing on development, and many of those are addressed in the various chapters of this document. Chapter X, however, more specifically reviews some of the major concerns raised by member States in different fora, including in WIPO. Since the issue of costs associated with the international patent system relate to a number of aspects of the patent system, that issue is addressed under various topics covered by this document.

20. As the title suggests, the Report covers the so-called “international aspects” of the patent system. The content of the Report, however, is not limited to the international instruments or the international norms. It attempts to cover various issues relating to the patent system that have been debated at the international level or that appear relevant to international discussion and consideration. In order to limit the size of the main Report, additional information has been included in the Annexes.

21. The statistics in this document, where not otherwise indicated, are taken from the WIPO Statistics Database, which is based on information supplied to WIPO by Patent Offices in annual surveys. Each year, WIPO request statistics from national patent offices, including the number of patent applications filed and patent granted and enforced, broken down by country of origin, date and a number of other criteria. Further sources of statistics and indicators used for this report are referenced in the relevant parts of the document itself.

II. ECONOMIC RATIONALE FOR PATENTS AND DIFFERENT INTERESTS AND NEEDS IN THE INTERNATIONAL PATENT SYSTEM

22. Over the past two decades, intellectual property rights have been high on the policy agenda. Important changes in the patent system have taken place across the world and the general view is that the world has moved towards strengthening and harmonization of the patent system.

23. With the move towards a knowledge-based economy,[1] intangible assets (such as trade secrets, patents, trademarks, etc.) have become important resources of businesses. It is common for businesses to treat intangible assets as a strategic business issue.

24. Both developed and developing countries are investing heavily in knowledge production activities. For example, the latest available data shows R&D expenditure of the countries which are members of the Organisation for Economic Co-operation and Development (OECD) amounted to around 772 billion US dollars. China's R&D expenditure amounted to 115 billion US dollars, making it the third largest country in terms of R&D expenditure.[2] Patent data provides a similar picture about the worldwide innovative activities and these figures show the increasing importance of knowledge assets to modern economies.

25. Changes to the patent system, and a considerable increase in patent activity, national and international patent systems have come under close scrutiny. The discussions have focused on three broad issues: functioning of the patent system,[3] effectiveness of patents as a policy instrument to promote economic development, and the use of the patent system by developed and developing countries. This chapter will focus on the latter two issues.

26. The first section will highlight the economic basis of the patent system. It should be noted that the debate surrounding the economic rationale for patents is not a new one – economists have been debating this issue for more than one hundred years. The aim of the chapter is not to provide a detailed analysis and critique of the economics of the patent system, but to outline briefly the main theory behind the patent system.

27. The second section will provide statistical evidence on the use of the national and international patent system. It will provide an overview of patenting activity at the national and international level for both developed and developing countries.

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[1] For example, in recent years expenditure on intangible assets has been increasing at a faster rate than expenditure on physical assets in the OECD countries. Investment in intangible assets amount to around 10% of GDP in the OECD region. Recent estimates in the United States revealed that investment in intellectual assets by US business in the 1990s was around 800 billion US$, which is similar in magnitude to the amount invested in tangible assets.

[2] Developing countries R&D expenditure has been increasing at a faster rate than the increase observed for the major developed countries. China's R&D expenditure increased by 18%, a year since 2000 and South Africa's R&D expenditure increased by around 8.5%, a year since 1997 (R&D expenditure of the OECD countries increased by 2.2% since 2001). Non-OECD economies account for a growing share of the world's R&D expenditure.

[3] There has been a considerable amount of discussion on the impact of increase in patent applications on the patent offices. With the increase in workload, questions have been raised about the ability of patent offices to process applications in a timely manner and maintain high quality level.

(a) Economic Rationale for the Patent System

(i) Incentives to Innovate

28. Technology and knowledge are classified by economists as public goods. Public goods are those that are "non-rival" (they can be used simultaneously by many people) and "non-excludable" (people cannot be excluded from freely using the public good). Public goods distort the normal cost-benefit dynamics that regulate the efficient production and use of goods in a competitive market, and are prone to under-provision (e.g. public radio) or to over-use (e.g. roads, fishing resources). This is known as market failure.

29. The fundamental role of the patent system from an economist's perspective is to address market failure and restore the incentives to invest in production of knowledge. In the absence of a patent system, competitive markets will fail to provide sufficient incentives to innovators to undertake costly and risky investments in innovation because of market failure (Arrow, 1962).[4]

30. In the case of intellectual property rights, the public good nature of knowledge means that, once an invention has been created, it can be freely used by others at no additional cost. This means that the inventor, who must invest to create a new invention, cannot capture the full benefits of the invention by selling it in the market and so incentives to invent are diminished. Free riders can copy or imitate the invention and undersell the original inventor because they do not bear the cost of development. This would reduce the expected returns of the original inventor and would result, in theory, in under-provision of new inventions.

31. The patent system is intended to correct the market failure that would result in under-provision of innovative activities, by providing innovators with exclusive rights to prevent others from exploiting their invention and thereby enabling the innovators to appropriate the returns of their innovation. Patents provide the owner with an exclusive right for a limited time period, which would increase his/her incentive to innovate. However, where the exclusive right allows the firms to establish a monopoly position, it may lead to market distortions. A monopoly typically results in overall loss of efficiency in a market because of higher prices and under-provision of the final goods. In the case of patents, the potential inefficiencies of monopoly are higher prices for the finished goods and under provision of the finished goods, but not of the inventive activity. The monopolistic market situation means that overall social benefits may not be maximized.[5] This loss of efficiency compared to competitive markets is known as a static deadweight loss.

32. To correct for the potential inefficiencies of the monopoly market power, the patent system provides for, among other mechanisms embedded in the system, public disclosure of the knowledge, thus ensuring that society can, eventually, fully benefit from the inventive activity. The disclosure function of the patent system is discussed in the next section.

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[4] Arrow, K. "Economic Welfare and the Allocation of Resources for Inventions." In The Rate and Direction on Inventive Activity: Economic and Social Factors. Edited by R. R. Nelson. Princeton, NJ: Princeton University Press.

[5] Social welfare is not maximized because the marginal cost of production and dissemination of knowledge is near zero after the invention. Resources are allocated efficiently if prices are equal to marginal cost. However by allowing the inventors to charge a price above the marginal cost resources are not allocated efficiently.

33. To summarize, the patent system involves a trade-off between providing incentives to private agents to invest in innovative activities on one hand and the potential inefficiencies of short-lived monopoly power. An unreasonably weak protection of inventors' work may lead to underinvestment in innovative activities, whereas an inappropriately strong patent protection may lead to excessive monopoly distortion. The challenge for the policy makers is to design an optimal protection that will provide enough incentives to investment in innovative activities and at the same time minimizes the deadweight loss caused by the monopoly situation. The patent system is the second best solution that corrects the market failure by restoring the incentives to innovate. The first best solution – providing incentives to undertake socially desirable level of R&D investment without monopoly distortion – is unattainable.

Empirical evidence

34. At an aggregate level Kanwar and Evenson (2003)[6] analyzed the impact of stronger intellectual property rights (IPR) on R&D expenditure for 32 countries. They report that stronger IPR has a positive and significant impact on R&D investment. Chen and Puttitanun (2005)[7] analyzed the impact of IPR on innovation for 64 developing countries and report a positive impact of IPR on innovation and suggest a U-shaped relationship between IPR and economic growth, i.e., there may be an optimal level of IP protection beyond which the costs exceed the benefits in terms of economic growth. (Mansfield 1986)[8] provides empirical evidence in support of the view that patents are quite effective in encouraging innovation in pharmaceuticals and chemical industries.

35. There is also ample evidence on the limitations of the patent system in encouraging innovation activities. Sakakibara and Branstetter (2001)[9] analyzed the impact of the 1988 patent reform in Japan and concluded that R&D effort and innovative output in Japan was unresponsive to the change in patent scope. Hall and Ziedonis (2001)[10] studied the semiconductor industry of the United States of America and concluded that stronger patent protection did not drive the innovative effort of firms.

36. Inconclusive empirical evidence on patent strength and innovation relationship makes it difficult to draw any conclusion about the effectiveness of patent system to encourage R&D investments. For example, a recent study concluded that stronger patent protection provided for in "patent laws by itself do not promptly stimulate domestic innovation". However,

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6 Kanwar, S.and R. Evenson (2003), "Does intellectual property protection spur technological change?", Oxford Economic Papers, 55(2), pp. 235-264.

7 Chen, Y. and T. Puttitanum (2005), "Intellectual property rights and innovation in developing countries.", Journal of Development Economics, 78, pp.474-493.

8 Mansfield, E. (1986), "Patents and innovation: an empirical study.", Management Science, 32(2), pp. 173–181.

9 Sakakibara, M, and L. Branstetter (2001), "Do stronger patents induce more innovation? evidence from the 1988 Japanese patent law reforms.", Rand Journal of Economics, 32(1), pp.77-100.

10 Hall, B. and R. Ziedonis (2001), "The patent paradox revisited: an empirical study of patenting in the U.S. semiconductor industry, 1979-1995.", RAND Journal of Economics, 32(1), pp. 101-128.

implementation of patent laws will stimulate innovation in countries with high level of economic development, education and economic freedom (Qian, 2007).[11]

(ii) Disclosure of Knowledge in the Public Domain

37. Patent holders are given exclusive rights to prevent others from exploiting the patented inventions and, in return for the exclusive rights, patent holders are required to disclose information relating to the invention. The disclosure of information is an essential element of the patent system. It is the basis of the balance between inventor's interests and those of society.

38. For each patent, applicants are required to provide technical details of the invention, which are made publicly available after 18 months.[12] At the end of the patent term, others may use the claimed invention. Even during the term of the patent, others are free to incorporate the information into new inventions as long as it does not infringe the granted patent. Granted patents may also encourage others to invent around the patent. For example, others can use the disclosed information to develop new technologies that fall outside the exclusive rights of the issued patent. In this respect, the patent system creates competition which benefits consumers in the long-run.

39. In the absence of a patent system, or in the absence of the public disclosure function of the patent system, inventions would tend to remain secret and the information regarding the invention would not reach the public domain. The patent system facilitates the disclosure and dissemination of information and access to knowledge. This results in the expansion of public stocks of technical knowledge and an increase in the overall social benefits. Since the mid-1980s, on average, more than a million patent applications were filed and published each year across the world. This makes patent information one of the most important resources for information about technological knowledge.

40. The patent system also has the potential to reduce duplication of R&D: the availability of information in patented technology provides innovators with an indication about a competitor's research activities and the evolution of technology. Companies can target their research efforts accordingly. They will also clearly not undertake R&D to duplicate something that has already been invented.

(iii) Technology Transfer, Commercialization, and Diffusion of Knowledge

41. A third important function of the patent system is to encourage technology transfer, nationally and internationally, by creating tradable property rights. In the absence of a patent system, firms will be reluctant to share technology know-how when there is a high risk of imitation by the prospective buyer or a third party. An effective deterrence of imitation will reduce the costs of enforcing contracts and at the same time increase the expected returns on foreign direct investment (FDI) and licensing, which will have a positive effect on technology transfer. Patent rights encourage technology transfer by providing owners with legal

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[11] Qian, Y. (2007), "Do national patent laws stimulate domestic innovation in a global patenting environment? a cross-country analysis of pharmaceutical patent protection, 1978–2002.", Review of Economics and Statistics, 89(3), pp. 436-453.

[12] Public disclosure after 18 months is the norm in most jurisdictions. However, some conditions may apply in certain countries.

certainty. Technology transfer takes place through different channels: trade, FDI, licensing, and joint ventures (Maskus, 2000).[13]

42. The patent system contributes to the creation of markets for technology that facilitate transfer of technology by improving the efficiency of knowledge flows[14] (Arora, et. al., 2005).[15] By creating transferable property rights, patents can help to structure a complex transaction that also includes unpatented knowledge, such as know-how (Foray, 2004).[16]

43. There is evidence of a growing international technology market (Arora, et. al. 2001)[17] estimated the size of the global technology market to be around US$ 35 billion in the mid-1990s. A recent survey by the Economist (2005)[18] estimated that technology licensing generates around US$ 45 billion (annually) in the United States of America and US$ 100 billion worldwide. Athreye and Cantwell (2007)[19] estimated the size of the technology market to be of a similar magnitude.[20]

44. At the national level, the patent system also plays a crucial role in technology transfer between public (e.g. university) and private sectors. In recent year, there has been an increase in the level of patenting by universities, especially in the United States of America. This issue has received a considerable amount of attention from both researchers and policy makers. In addition to the commonly used argument for patent system (incentives to innovate), university patenting encourages knowledge transfer between university and companies and facilitates the commercialization of knowledge by creating a market for technologies.

Empirical evidence

45. Technology transfer via trade: The results from various empirical studies support the view that stronger IPR protection can lead to higher trade flows between countries. Maskus and Penubarti (1997)[21] analyzed the exports from 22 OECD countries to a sample of 25 developing countries. They conclude that stronger patent laws in developing countries

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[13] Maskus, K. (2000), "Intellectual Property Rights in the Global Economy", Institute for International Economics, Washington D.C.

[14] The patent system can improve the efficiency of knowledge flows in several ways. Direct cost of knowledge transfer is lowered when knowledge is codified and organized in a systematic way. The patent system provides incentives to codify knowledge. Know-how is costly and contracts for know-how are inefficient which increases transfer costs. The patent system improves the efficiency of the licensing contract and the tacit knowledge component of the technology is included in the licensing contract.

[15] Arora, A., A. Fosfuri, and A. Gambardella (2001), "Markets for technology and their implications for corporate strategy.", Industrial and Corporate Change, 10(2), pp. 419–451.

[16] Foray, D. (2004), "The economics of knowledge.", MIT Press, Cambridge.

[17] Arora, A., A. Fosfuri, and A. Gambardella (2001). o*p. cit.*

[18] The Economist (2005), "A market for ideas: a survey of patents and technology.", The Economist, October 22nd, 2005.

[19] Athreye, S. and J. Cantwell (2007), "Creating competition?: globalisation and the emergence of new technology producers.", Research Policy, 36(2), pp. 209-226.

[20] It should be noted that the figures on revenue generated by technology licensing include patent licensing, royalty receipts, copyrights, know-how, and other types of intellectual assets.

[21] Maskus, K. and M. Penubarti (1997), "Patents and international trade: an empirical study.", Edited by K. Maskus, P. Hooper, E. Leamer, and J. Richardson, Quiet pioneering: The international economic legacy of Robert Stern (Ann Arbor: University of Michigan Press), pp. 95-118.

have a positive impact on bilateral imports into both small and large developing countries. Smith (1999)[22] examined the exports of United States of America (at state level) to 96 countries and found that the effect of IPR depends on the ability of local firms to imitate the exporter's technology. Smith's finding suggests that weak IPR system is a barrier to the United States exports for those countries that pose a strong threat of imitation.

46. Technology transfer via FDI: A number of empirical studies found a positive relationship between IPRs and flows of FDI.[23] Branstetter et al. (2006)[24] examined whether technology transfer behavior of US multinational firms changes in response to IPR reforms. They found evidence that changes in the IPR regime abroad lead to increase in technology transfer by US multinationals to IPR reforming countries.[25] In a firm level study, Smarzynska-Javorcik (2004)[26] found that a weak IPR regime deters foreign investors in technology intensive sectors that depend heavily on IPRs. An OECD (2002)[27] study reported a positive association between patent rights and FDI. The effects of IPRs on FDI vary by country's level of economic development and by industry.

(b) Use of the Patent System

(i) Worldwide Patent Activity

47. Figure 1 represents the recent trends in worldwide patent filings. From the mid-1980s to mid-1990s, the number of worldwide patent filings was relatively stable (averaging around one million per year). However, since 1995, patent filings have grown at a rapid rate. In 2005, the total number of worldwide patent filings exceeded 1.6 million, a substantial increase from the 1995 level (1 million). Approximately half of the worldwide filings originated from Japan and the United States of America.[28] The share of worldwide patent filings originating from Japan decreased from 38.3% to 31.4% between 1995 and 2005. In contrast, the shares of China, the Republic of Korea and the United States of America increased over the same period.

48. The distribution of worldwide patent filings by residents and non-residents applicants shows that the share of non-resident patent filings has been increasing. In 2005, non-resident

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[22] Smith, P. (1999), "Are weak patent rights a barrier to U.S. exports?", Journal of International Economics, 48, pp. 151-177.

[23] Ferrantino (1993), Mansfield (1993), and Maskus and Eby-Konan (1994) find no effect of IPR on FDI. However, Maskus (2000) questions the validity of these studies and points out that they suffered from limited specification of models and employed poor measurement of IPRs.

[24] Branstetter, L., R. Fishman, and C. Foley (2006), "Do stronger intellectual property rights increase international technology transfer? empirical evidence from U.S. firm-level panel data.", Quarterly Journal of Economics, 121 (1), pp. 321-349.

[25] They analyze the effects of IPR reform on the royalty payments, R&D expenditures of US multinational affiliates and the level and growth rate of patent filings by non-residents.

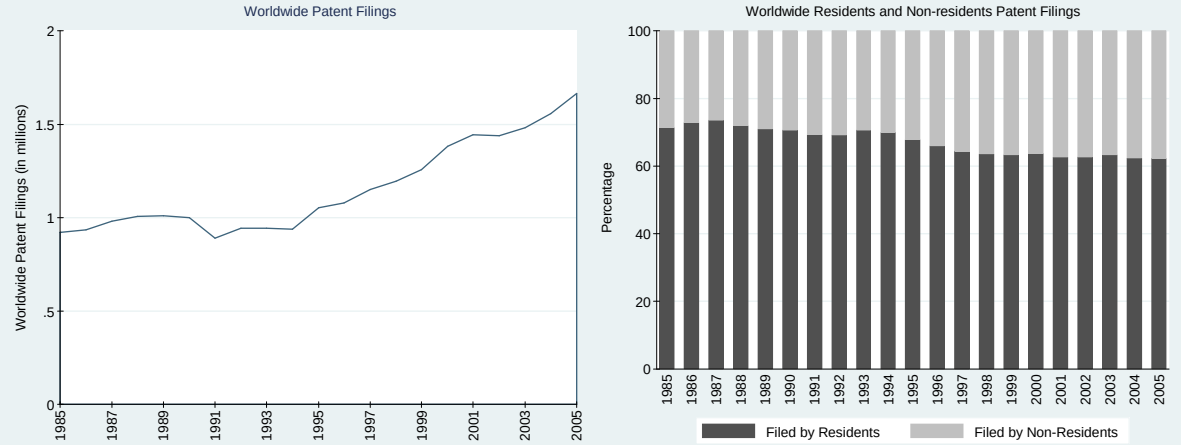
[26] Smarzynska-Javorcik, B. (2004), "The composition of foreign direct investment and protection of intellectual property rights: evidence from transition economies.", European Economic Review, 48(1), pp. 39-62.

[27] OECD (2002), "The impact of trade-related intellectual property rights on trade and foreign direct investment in developing countries.", OECD Trade Directorate, Trade Committee Discussion Paper, TD/TC/WP(2002)42/FINAL.

[28] Those two countries also account for roughly 60% of OECD-wide R&D expenditure.

patent filings accounted for 37.8% of the worldwide patent filings, which represents a 5.6 percentage point increase from the 1995 figure.

Figure 1: Trends in Worldwide Patent Filings: 1985-2005



Source: WIPO Statistics Database

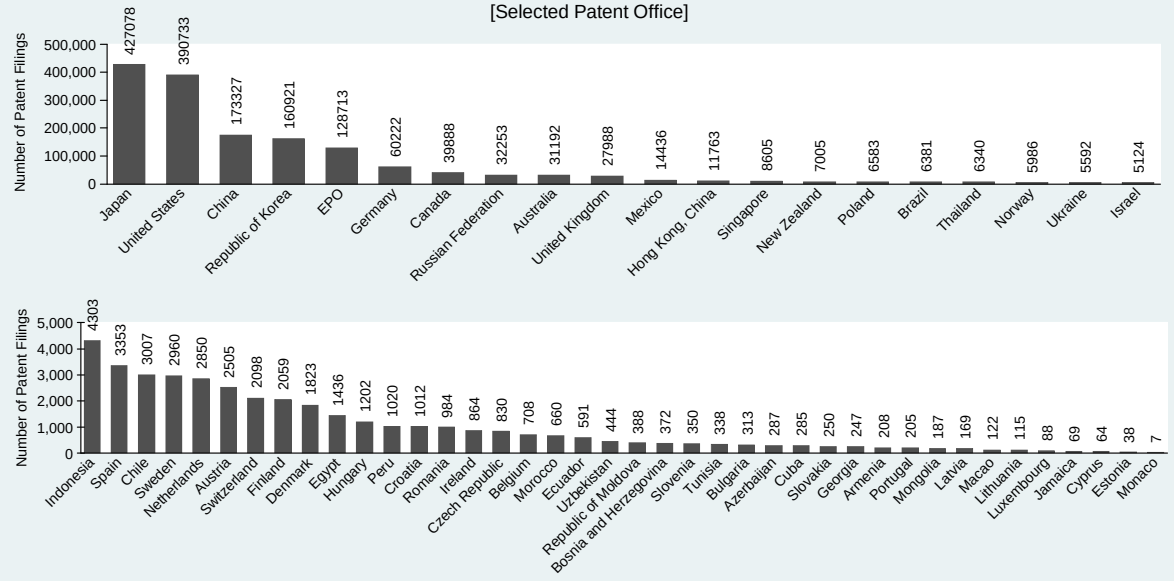
49. There is a significant variation in the volume of patent filings received by national and regional patent offices (see figure 2). The patent offices of Japan and the United States of America[29] received the highest number of filings in 2005. Since the mid-1990s, the majority of patent offices have experienced an increase in the level of patent filings. This has caused an increase in the workload of the patent offices. Patent offices face a major challenge with regard to processing filings in an efficient and timely manner, while maintaining a high quality level. For example, in 2005, the backlog of applications awaiting a first review by an examiner at the USPTO was around 600,000 and this figure is expected to increase to above 1,000,000 by 2010.[30]

[29] The volume of filings received by patent offices depends on factors such as market size, R&D investment, economic development, etc. The large number of patent filings in China, Japan, and the United States of America is due to their market size and R&D expenditure.

[30] www.uspto.gov/web/offices/com/speeches/2005sep08.pdf.

Figure 2: Patent Filings by Patent Office: 2005

[Selected Patent Office]

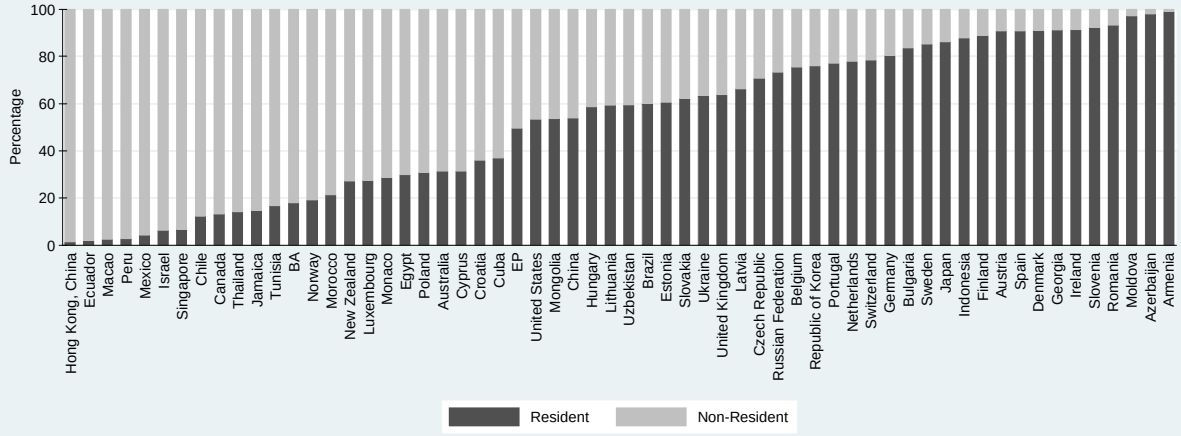


Source: WIPO Statistics Database

50. There has been an increase in the level of internationalization of patent filings. Applicants are increasingly filing for patent rights in foreign markets. The share of resident and non-resident patent filings varies across patent offices (see figure 3). In 2005, non-resident patent filings accounted for 98% of total filings in Hong Kong SAR, China. In contrast, non-resident filings accounted for less than 1% in Armenia. Hong Kong SAR, China, Ecuador, Macau, Peru, and Mexico have a high share of non-resident filings: more than 95%. Non-resident patent filings share is low in Central/Eastern European countries, Nordic countries, Austria, Spain and Japan: non-resident filings in those countries accounted for less than 15% of the total filings.[31] In most patent offices, the share of non-resident filings was higher in 2005 compared to mid-1990s.

[31] Low share of non-resident filing with the Offices in European countries may be explained by the existence of parallel patent system in Europe – i.e., existence of national patent office and European Patent Office.

Figure 3: Resident and Non-Resident Patent Filings by Patent Office: 2005



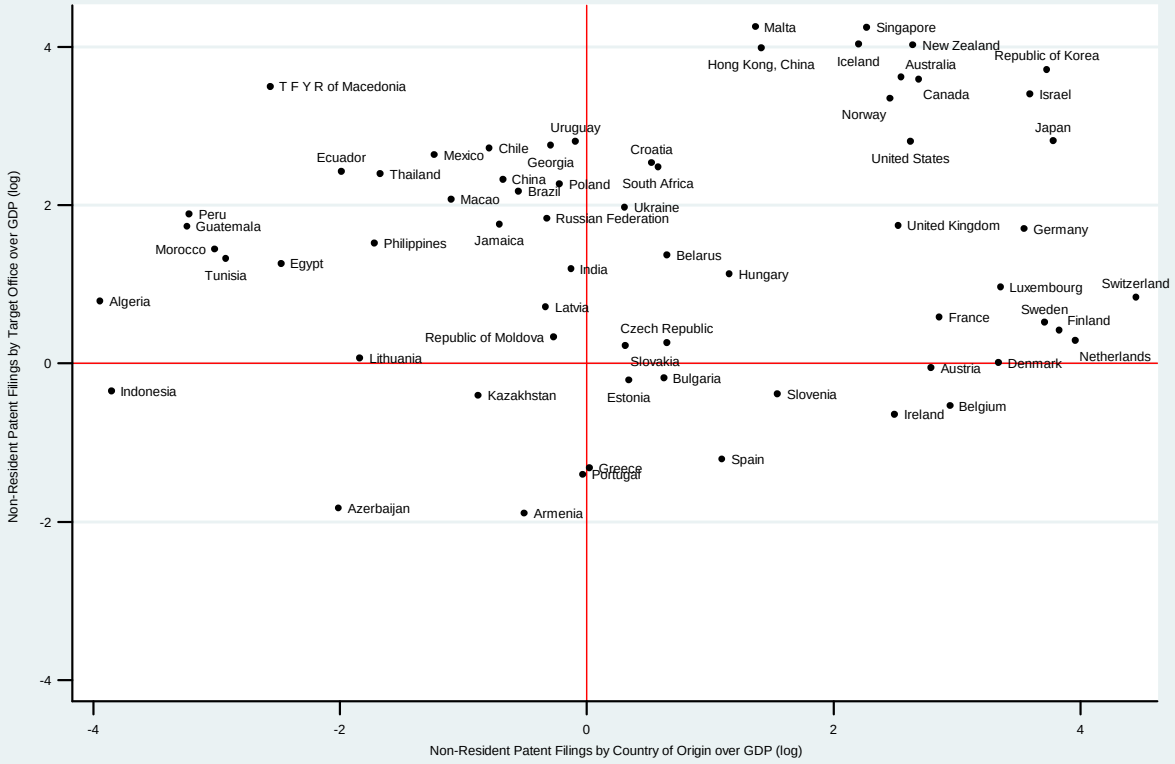
Source: WIPO Statistics Database

Note: BA (Bosnia and Herzegovina) and EP (European Patent Office).

51. Figure 4 presents non-resident patent filings by country of origin and target office (patent filings normalized by GDP). The country of origin is the source of patent filings and the target office is the patent office where protection is being sought. Countries such as Australia, Canada, Japan, the Republic of Korea and the United States of America, have a high non-resident filing to GDP ratio, both as a country of origin and as a target office. This indicates that they are heavy users of the patent system (with regard to filing abroad) and attractive target countries (with regard to receiving demand for patent rights from non-residents). A group of national offices in the European countries (EPO member countries) has a high ratio of non-resident filing to GDP, as an origin country, but low non-resident filing to GDP ratio, as a target office. This could be due to the existence of a parallel patent system in Europe – i.e. existence of national patent office and European Patent Office (for European countries, figure 4 includes only direct filings to the national patent office). In contrast, emerging and developing countries such as Brazil, China, and South Africa are high target countries (i.e., attracts high numbers of non-resident filing), but they are not heavy users of the patent system.

52. These differences in usage patterns reflect different needs in different parts of the world. Those patent offices that receive relatively large numbers of non-resident patent filings have different needs from those that tend to receive more filings from their own residents, or from those that have relatively low levels of patent filing activity. For example, solutions to the problem of increasing workloads may be different for countries that tend to receive non-resident patent filings (that are often duplicated in other offices) compared to those that are receiving a high proportion of first filings.

Figure 4: Patent Filings by Patent Office and Country of Origin

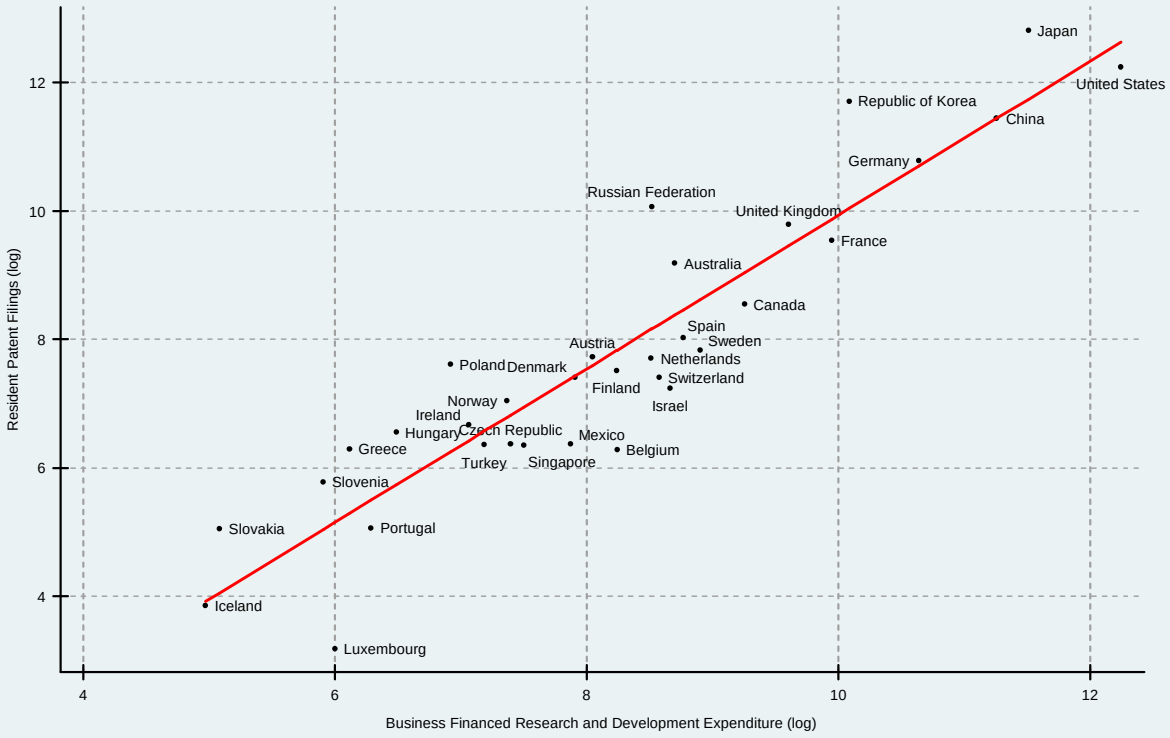


Source: WIPO Statistics Database

(ii) Patent Activities and Research and Development

53. Traditionally, patents are considered to be an output measure on innovative activity. Expenditure on R&D and innovation is considered to be an input measure. The relationship between patents as an intermediate output resulting from R&D inputs has been investigated extensively. Figure 5 shows that there exists a strong correlation between business financed R&D and resident patent filings (R2=0.85). Countries with a high level of business financed R&D expenditure (such as China, Japan, the Republic of Korea and the United States of America) also have a large number of patent filings. In contrast, Iceland, Luxembourg, Portugal and Slovakia have low levels of business financed R&D expenditure and resident patent filings.

Figure 5: Resident Patent Filings and Business Financed R&D: 2005



Source: WIPO Statistics Database, Eurostat and OECD

Note: Business financed research and development expenditure (R&D) is lagged by 1 year.

(iii) Non-Resident Patent Filings and Foreign Direct Investment

54. As mentioned above, one of the main arguments in favor of the patent system is that it facilitates transfer of technology across countries. A number of empirical studies report a positive relationship between IPRs and FDI. Figure 6 shows a positive correlation between inward foreign direct investment and non-resident patent filings (note that Figure 6 plots FDI with non-resident patents instead of IPRs). Countries with high level of inward foreign-direct investment receive a large number of non-resident patent filings. Developing economies such as Brazil, China, Mexico, Poland and the Russian Federation have attracted a significant amount of foreign direct investment as well as a large number of non-resident patent filings.

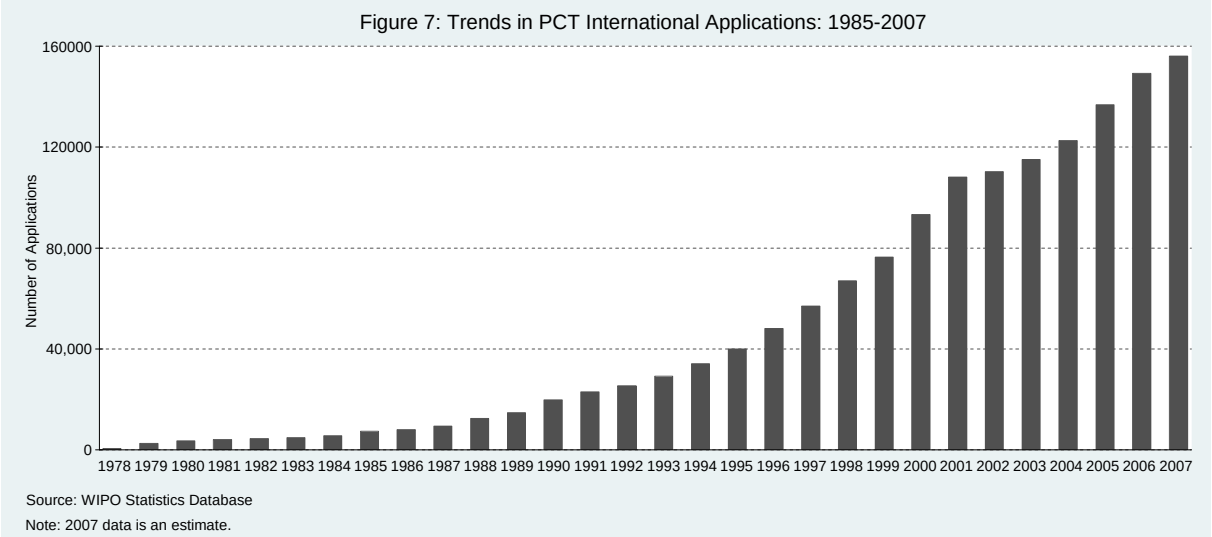
Figure 6: FDI Inflows and Non-Resident Patent Filings: 2000-2005 Average

Source: WIPO Statistics Database and UNCTAD

(iv) International Applications Filed under the Patent Cooperation Treaty (PCT)

55. The PCT procedure makes it possible to seek patent protection for an invention simultaneously in a large numbers of countries by filing a single “international” patent application. The PCT procedure has become a popular method for filing international patent applications. The latest available data shows that around 156,100 international applications were filed in 2007,[32] representing a substantial increase from the mid-1980s level (see figure 7).

[32] 2007 data is WIPO estimate.



56. Although there are 139 member states of the PCT (as of April 10, 2008), there is a significant heterogeneity across the countries with regards to their use of the PCT system (Table 1). In 2006, 18 countries, classified as intensive users, accounted for 94.8% of total PCT filings (see figure 8). In contrast, medium and low users consist of 102 countries, but they accounted for 5% of total filings. Between 1995 and 2006, medium and low users had a higher growth rate than the intensive users, and increased their share in total PCT filings. In 2007, the largest number of PCT filings originated from the United States of America (33.3%), Japan (17.8%) and Germany (11.5%). Between 1995 and 2006, the share of the United States of America decreased by 9.5 percentage points, while Japan increased its share by 10.9 percentage points.

Table 1: Distribution of PCT Filings by User Type, 2006

	"Intensive" User[1]	"Medium" User[2]	"Low" User[3]
Number of Countries	18	26	76
Number of PCT Filings	141 369	6 812	656
Average Annual Growth Rate (1995-2006, %)	12.6	14.4	18.8
Share in Total PCT Filings (%)	94.8	4.6	0.4
Change in Share of Total PCT Filings (1995-2006)[4]	-0.9	0.7	0.2

1. Intensive users: more than 1000 PCT Filings in 2006.
2. Medium users: between 50 and 1000 PCT Filings in 2006.
3. Low users: less than 50 PCT Filings in 2006.
4. Percentage points.

57. The Republic of Korea and China are increasingly using the PCT system to file for foreign patent rights. Between 1995 and 2007,[33] the number of PCT filings originated from the Republic of Korea and China increased by 34.9%, and 38.9%, a year, respectively. The

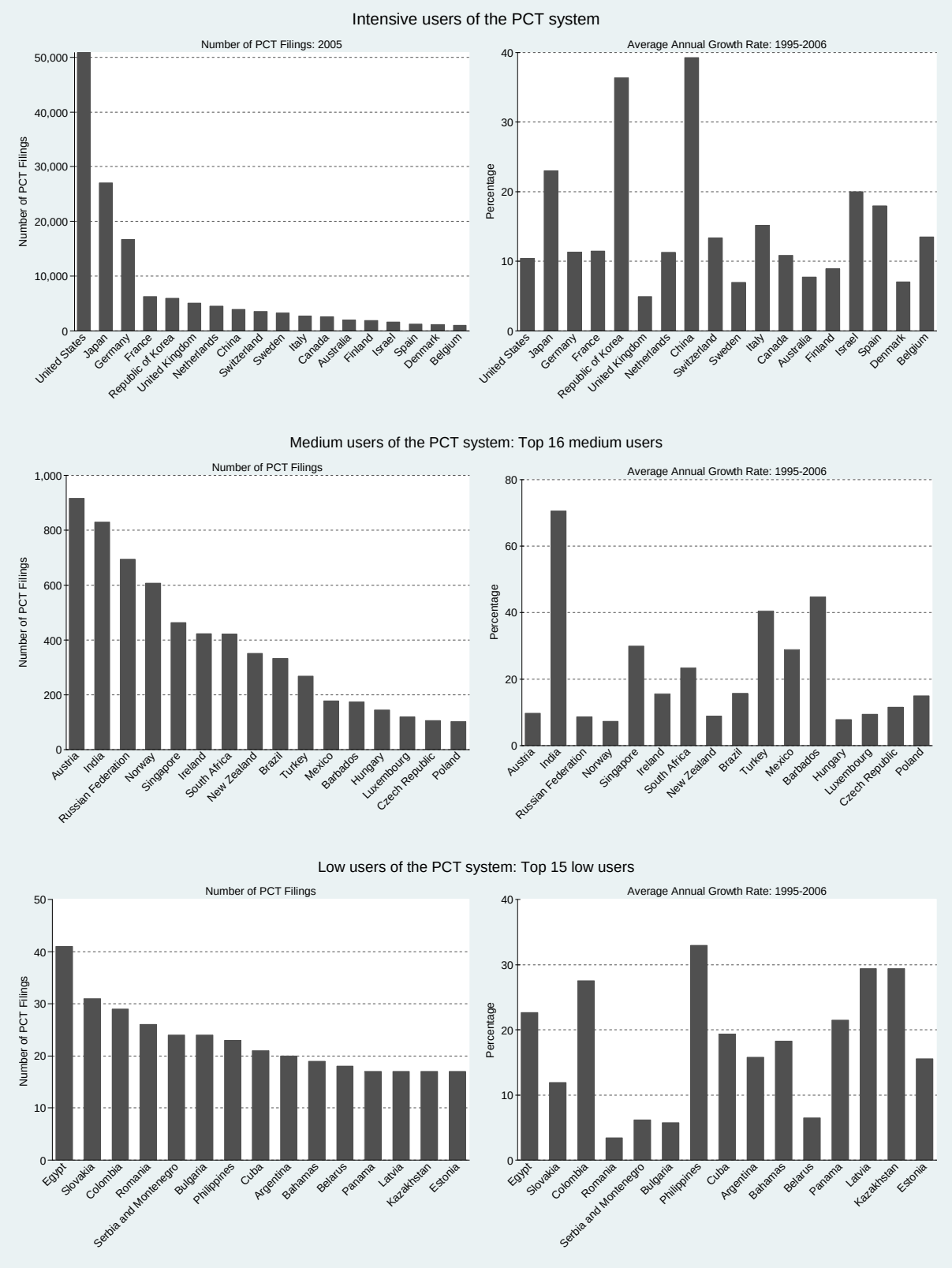
[33] 2007 data is WIPO estimate.

average annual growth rate of those two countries is far above that of the other “intensive users” countries. In 2007, the Republic of Korea and China are ranked fourth and sixth, respectively.

58. The medium user group consists of 26 economies, which are mostly small open economies (such as Austria, Ireland, Norway and Singapore), and emerging economies (such as Brazil, India, the Russian Federation and South Africa). Although starting from a low base, most of the countries from this group recorded a high growth rate between 1995 and 2006.

59. Although the number of PCT filings originating from the low user group has been increasing at a faster rate than the other groups, the total number of PCT applications originating from the low user group is relatively small. In 2006, their combined share in total PCT filings was around 0.4%, a slight increase from the 1995 share.

Figure 8: Different Types of Users of the PCT System: 2006



Source: WIPO Statistics Database

(v) Need for Further Investigation

60. Economists have analyzed the rationale for a patent system quite extensively. However, the majority of the studies have focused on developed countries. The effect of a stronger patent system on stimulating innovation, especially in developing countries, is open to debate. Therefore, further work in this area will enhance the existing literature and contribute to our understanding of the role of a patent system in the context of developing countries.

61. Over the last two decades, the patent system has evolved towards a more inclusive system. Data presented in this report shows that the usage rate of the patent system differs across countries. There is a lack of empirical studies on the usage of the patent system and the effectiveness of the existing international patent system to meet different user needs. Further work in this area could contribute to the debate on the effectiveness of the patent system in knowledge transfer. Those issues may include: extensive literature review on the economics of the patent system; empirical study on the relationship between IP and innovation, with specific focus on developing countries; interaction between patents and other forms of IP, including trademarks, copyrights, and trade secrets; develop more detailed indicators at industry and country level on the use and value of the patent system from the developing countries perspective; empirical study on international collaboration and knowledge flows between developed and developing countries.

III. TECHNOLOGY DISCLOSURE THROUGH THE PATENT SYSTEM

(a) Background

62. The patent system is based on the fundamental principle of society granting an inventor a temporary exclusive right in return for the inventor’s disclosure of his invention to society. This balances the provision of a temporary exclusive right which, although it rewards the inventor for his ingenuity and creativity, nevertheless may impose restrictions on the free use of the invention, and the public disclosure of the invention which aims to stimulate further innovation and economic growth. In recent years, because of the increasing ease in accessing and retrieving patent information via the Internet, this balance has shifted in favor of the positive benefits derived from such disclosure.

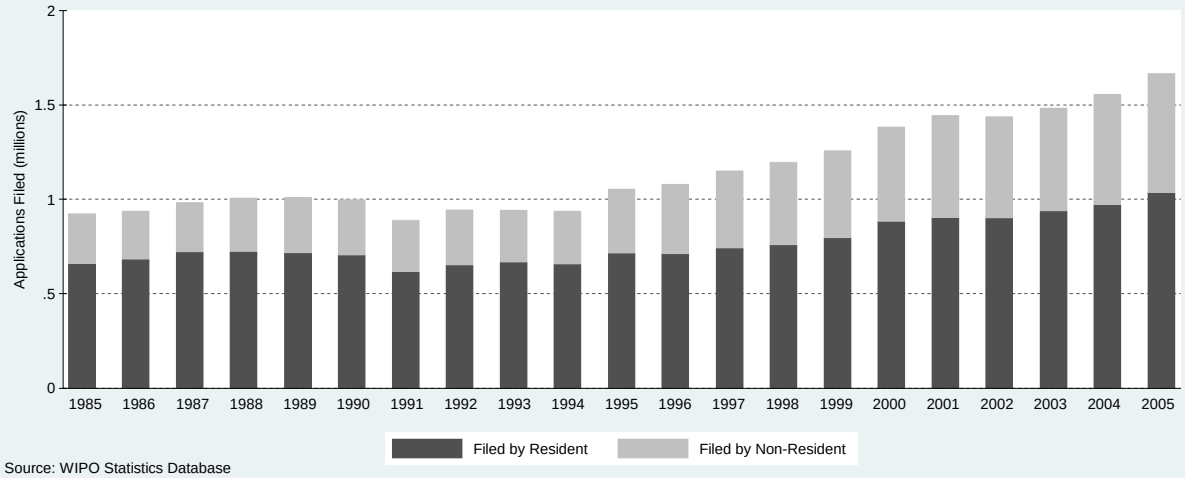
63. The balance between protection and disclosure is further differentiated in that protection is territorial and refers to one country or region, whereas disclosure is global. This means that manufacture and marketing are restricted within the territorial and legal scope of protection but the information disclosed may be freely used by anyone. The patent system also allows the legal use of technology and knowledge when the patent has expired or been abandoned and the knowledge enters the public domain, useable by everyone.

64. In recent years, the generation and dissemination of knowledge, led by the development of communication and information networks such as the Internet, has become more important in industrialized economies. The patent system plays a key role in the knowledge-based economy, not only in providing protection for the underlying inventions by encouraging investment, the availability of venture capital and making products marketable, but also in disseminating technical information and knowledge.

65. The recent increase of the number of patent applications filed reflects the continued importance of innovation in modern economies. It also reflects an increasing volume of

technical knowledge that is disclosed worldwide. Figure 9 represents total patent application numbers filed worldwide per year.

Figure 9: Number of Patent Applications Filed Worldwide (millions)

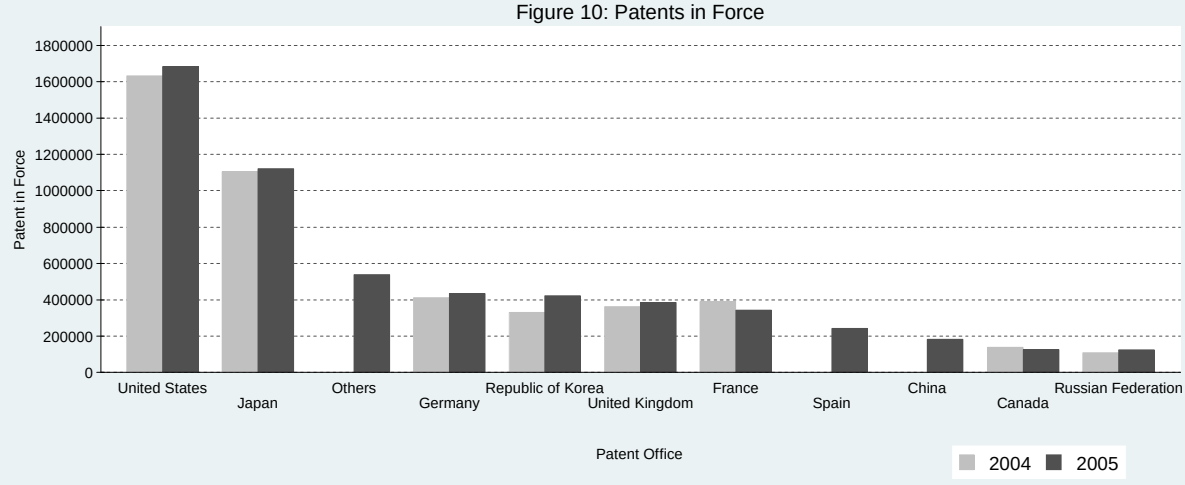


Source: WIPO Statistics Database

66. Given that at the end of the year 2005, more than 4.9 million patents were in force (see figure 10), a very substantial proportion of patent documentation is now in the public domain.

67. In 2005, approximately 5.6 million patents were in force worldwide. The majority of the total patents in force were granted by the patent office of the United States, Japan, Germany, the United Kingdom and France. However, their share in total patents in force has been following a downward trend over the past five years. In contrast, the share of patent in force for patent granted by other patent offices, most notably China and the Republic of Korea, has been increasing over the same period.

Figure 10: Patents in Force



Source: WIPO Statistics Database

(b) The Role of Patent Information in Business

68. The technical information derived from patent information serves various functions and user groups. It is widely used in business in formulating a firm's IP strategy, as an input into research and development processes, to facilitate licensing and technology transactions, for technology transfer and for analysis of markets and competitors.

69. Patent information is indispensable for formulating IP policy at the company level. A company must decide what to patent, how to draft patent applications effectively, the extent of geographical coverage for patent applications, how long a patent should be maintained in force in each jurisdiction, and must monitor potential infringement or freedom-to-operate issues. These decisions are driven by the need to use resources efficiently so as to obtain maximum benefit from expenditure on IP. In this respect, patent information is a critical part of the decision-making process.

70. Patent information also plays an important role as an input into research and development activity from the outset of planning, when it assists in forecasting market trends and needs in specific technical fields, as well as indicating problems and solutions in a particular technology. Patent information is important when assessing the current state of the prior art in a specific technical field in order to realize what has been invented to date and make sure that time and energy is not squandered on inventions already invented. The availability of this knowledge avoids "reinventing the wheel" and duplicating R&D which results in the waste of resources. It is also important in the evaluation of developments in a specific technical field, where patents directly reflect the output of research and development and indicate whether a technology is growing, in a mature state or in decline.

71. Once this information is known, it stimulates further innovation by helping to develop technology which surpasses the known technology (also known as "leapfrogging"), encourages alternative solutions for the same problem, or it may indicate how to solve comparable problems in other technical fields. In all these cases, the availability of technical information through patents is a stimulus for further innovation.

72. By creating a legally enforceable property right, the patent system also makes the invention an intangible asset which can be traded, such that the invention becomes part of the economic process itself, creating new "goods" and value in the economic process. Patent information is, therefore, an important contribution to market information regarding technology licensing and technology transfer. It provides more information to buyers and sellers and helps to make technology markets more efficient.

73. The technical information contained in the description of a patent document is a source of inspiration for inventors and engineers. But patent information is also valuable for analysis and monitoring of markets and competitors. The fact that patent owners and inventors are disclosed in a patent document means that the information can be used to analyze firms and industries, especially when combined with other sources of information. A company's patenting behavior can reveal its activity in certain technological fields and the level of development achieved. Similarly, the future direction of a company's technology can be derived from its present patenting activity. This information can be valuable for competitors, financial analysts, financial institutions and others wishing to assess the current and future value of a company.

74. Research and Development departments and financial institutions or government officials, for example, require a sound analysis of patent information before deciding on important issues such as investment and research strategies, strategic planning, technology transfers, joint-ventures, licensing or financing an industrial project or industrial polices.

(c) The Role of Patent Information in Industrial Policy

75. At the national level, patent information can be used as a part of industrial policy in several ways. It can be used to monitor national technology performance, as an input into R&D policy and to encourage the use of information to make technology dissemination more efficient. Moreover, detailed empirical information can be used to validate theoretical models in various fields including companies' strategic behavior, competition policy, etc.

76. Patent information can be used in monitoring national technology performance in specific technical fields, in particular to highlight strengths or weaknesses. Moreover, patent activity can be used as an indicator of knowledge production, acquisition and for cross-country comparisons.

77. Patent information can also serve as input into a national industrial policy strategy in general or into R&D policy more specifically. Often patent analysis is also required before state funding is approved for public projects.

78. A national industrial policy should in return promote the dissemination of patent information in order to encourage national technology markets, in particular technology transfer from public institutions to private companies or cross-licensing between private firms for a more efficient use of national technology resources.

79. The role of patent information in economic development is especially important for emerging economies, which benefit not only from the available knowledge derived from prior art, but can identify potential licensing and technology transfer partners. The role of patent information in development is reflected in the recently adopted WIPO Development Agenda, which includes several proposals for increasing the availability of patent information in developing countries.

(d) Development of Patent Databases – Access to Patent Information

80. Patent information is increasingly available via easily-accessible services that are delivered over the Internet. There are two main categories of database service available: free services, typically provided by patent offices and other public sector institutions, and fee-based services provided by the private sector.

81. The availability of a wide selection of free databases provides for the basic needs of patent searches carried out by non-professionals, particularly individual inventors, students and small and medium enterprises (SMEs). Such services are provided mostly by national and regional patent offices, by WIPO and by academic institutions.[34] Even if these free-of-charge databases are initially intended only to provide very basic functionality, the

[34] WIPO provides the PATENTSCOPE® Search Service http://www.wipo.int/patentscope]. The URLs of other databases are available at: http://www.wipo.int/ipdl/en/resources/links.jsp.

decreasing cost of information technologies has enabled the free public sector database services to develop rapidly and to provide more powerful search functionalities for users.

82. Commercial patent information providers tend to provide more sophisticated and value-added services. Such services may be tailored to specialist user groups, and they often match patent data with other technological and commercial information, as well as providing more sophisticated analysis, monitoring and reporting tools.

83. The success of searchable patent databases to identify relevant technical knowledge has been greatly assisted by the fact that all patents are classified according to specific patent classification systems, allowing a far more effective retrieval of such documents. Many technical and scientific papers, articles and documentation, the so-called non-patent literature (NPL), is now also being systematically classified according to technology-specific classification and, in some cases, patent classification as well.

84. Patent information is also playing a role in making the patent system more efficient. Given the growing number of patent applications across the globe, many patent offices are currently experiencing difficulties in mastering their workload. By searching the state of the art in patent information databases prior to drafting and filing patent applications, thereby providing a better indication of prior art, applicants increase the likelihood of obtaining patents on their inventions, and at the same time, assist patent office examination procedures. Moreover, this is also the case when third parties or peers provide examiners during a patent granting procedure with prior art relevant in deciding whether to grant or refuse a patent application.

(e) Non-Patent Literature

85. The accessibility and retrieval of non-patent literature is rapidly developing, expanding and complementing the existing search possibilities of technical information in general, which until recently could only be searched using classified patent databases. Moreover, in certain technical fields, such as biotechnology, medical technology and computing, NPL provides the most important contribution within the available prior art. However, unlike basic patent documentation, which is made available free of charge by patent offices around the world, access to NPL is not always available free of charge and is often only available via subscription.

(f) Patent Information Dissemination Policies

86. In providing patent information, every patent office follows a patent information dissemination policy which can differ from country to country. The policy normally takes into consideration the role of the public sector, principally the patent offices which are subsidized by patent fees, and the private sector, which takes the raw information from the patent offices and develops it into value-added services and products.

87. In some countries, a strong private patent information industry is encouraged, sometimes by direct funding of public or semi-public enterprises, or by contracts with patent information providers that guarantee a certain level of patent information dissemination within the country. In these cases, the patent office itself typically provides minimal services directly. In other countries, the patent offices support free and wide distribution of patent data and this can spawn a very active private sector with very sophisticated uses of patent information, although the office itself may not actively participate in creating the private

sector except by making data easy to access. While other offices in some countries only provide basic information in paper-form in gazettes with no electronic documents, in which case wider dissemination of patent information is more difficult.

88. Patent offices, policymakers and international bodies should encourage the availability of more reliable and timely information from patent offices. Today, it is difficult to easily access information concerning the legal status of patents granted all over the world (for example, on the Internet), which creates uncertainty and hinders efficient decision-making by companies and by policymakers. Such legal status information includes, for example, information as to whether a patent is still in force, abandoned or expired, any correction made to a patent and any change in ownership of a patent.

(g) Current Issues in Patent Information

89. The changing nature and importance of the patent system, demands of users and availability of new information technologies, combined together, pose new challenges for the effective use of patent information. This section briefly outlines some of the current issues.

(i) Coverage of Patent Data and Status Information

90. Although there are currently 184 member states of WIPO, patent data is only available in electronic format for around 80 patent authorities. Much of that data is simple bibliographic data records, often without a title or an abstract for search and retrieval purposes. Full text of patent documents is only available for a minority of patent authorities. Similarly, detailed status information, regarding the ownership and legal status of patents, is only available in electronic format for a small number of patent authorities. This means that it can be very difficult to obtain reliable information about the geographical coverage and legal status of patents in different parts of the world, particularly in developing countries.

91. In many cases, patent authorities devote their limited resources to processing and examining patent applications rather than dissemination of patent information. Such offices need technical assistance for the digitization and dissemination of their patent data, in order to improve the accessibility of information nationally and internationally.

(ii) Linguistic Diversity of the Prior Art

92. Since the industrial revolution, most of the world’s technology has been documented in European languages, the majority in English, German and French, and more recently in Japanese. However, the dramatic growth of new users of the patent system means that there is now a very large volume of technical information which is only available in Asian languages, especially Japanese, Chinese and Korean (see Table 2). The expansion of industrial activity around the world can be expected to add more languages to this base in the future.

Table 2: Number of PCT International Patent Applications by the Language of Filing

Languages of Filing	2007	2007 Share
English	91'114	58.4%
Japanese	27'106	17.4%
German	18'336	11.7%
Chinese	5'009	3.2%
Korean	4'931	3.2%
French	4'540	2.9%
Italian	1'288	0.8%
Spanish	1'175	0.8%
Russian	587	0.4%
Finnish	526	0.3%
Swedish	515	0.3%
Dutch	512	0.3%
Norwegian	179	0.1%
Danish	136	0.1%
Hungarian	46	<0.1%
Slovenian	21	<0.1%
Czech	20	<0.1%
Portuguese	19	<0.1%
Turkish	17	<0.1%
Slovak	11	<0.1%
Croatian	10	<0.1%
All Others	2	<0.1%
Total	156'100	100%

Source: WIPO Statistics Database
Note: 2007 data is an estimate.

93. This increasing linguistic diversity makes it more difficult for patent offices to conduct extensive prior art searches, which affects the legal certainty of the patenting process. The diversity of languages also makes it more difficult for users of patent information to access the full range of available information.

94. Several solutions are being proposed to increase the accessibility of information in different languages. Because manual human translation is very expensive given the volume of information, most work is being conducted in the area of machine translation and cross-language tools. Human translation is still the basis for legally-authentic translations, and will probably continue to be so for the foreseeable future.

95. The development of machine translation has greatly assisted these efforts and constitutes the basis of understanding different language documents. However, languages with certain scripts and structural differences create difficulties for machine translation systems, e.g. between Chinese and English. Patent documents also tend to contain very specialized language forms and terminology which are difficult for commercial machine translation systems to work with effectively. Patent offices are investing in specialized patent translation systems and terminology databases in order to improve the reliability of machine translation.

(iii) Role of the Public and Private Sectors

96. The primary role of the public sector, i.e. of patent offices, should be to ensure that reliable information is available in a usable format. Some patent offices may need assistance to achieve this goal. In general, the public sector should encourage dissemination and

effective use of patent information, either by providing such services itself, or by encouraging the private sector to do so.

97. The wider national and international dissemination of patent information can result in a loss of control over the information by the authority that created it. Patent information dissemination policies should take into account the right of patent offices to maintain rights on the use and re-distribution of their data, in particular the right to receive income from the commercial use of the information.

(iv) Effective Use of Patent Information

98. Patent information is currently under-used in developing countries and in SMEs around the world. Effective use of patent information should be further encouraged by patent offices by providing information materials, training and online services.

IV. TECHNOLOGY DIFFUSION AND THE PATENT SYSTEM

(a) Licensing and the Transfer of Technology

99. Although there is not much hard evidence on the subject, research generally suggests that a functioning patent system, including adequate enforcement measures, does rather encourage technology transfer and foreign investment,[35] but that it is only one among many other factors influencing such a transfer, which include the size of the market, the faculty to absorb the technology, financial incentives and the existing infrastructure, among others. At the same time, it is recognized that too strong a protection of patent rights, in particular, in the early stage of industrialization when learning takes place through reverse engineering and duplicative imitation, or an abusive use of such rights, may also hinder a transfer of technology,[36] and increase the cost of licenses. As to how the owner of a patent can exploit his invention, he can either do it himself (through his enterprise or by creating a business for manufacturing and marketing the product resulting from the invention) or by exploitation through third parties, by assigning his right or by granting licenses to others. The latter choice, licensing, means the manufacturing and marketing of the product resulting from the invention through an enterprise other than the intellectual property right owner against royalties (license fees). Licensing agreements are one means through which a transfer of technology can be carried out. This part will address, more specifically, the role of licensing in relation to some aspects of technology transfer (in particular to developing countries), anticompetitive practices and patent pools.

(i) Transfer of Technology

100. Technology transfer may be achieved through several means, such as publications, cooperative research, development and marketing agreements between governments and research institutions, joint venture arrangements or foreign direct investments. The mere existence of dozens of millions of publicly available patent documents is in itself a giant

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[35] Among others, Arora, et. al., 2005; Maskus and Penubarti, 1995; Xu and Chiang, 2005.

[36] Among others: L. Kim, Technology Transfer and Intellectual Property Rights: Lessons from the Korean Experience, UNCTAD-ITCSD Issue Paper, 2002,

source of technological knowledge that can be used to identify business partners and licensors, as is described in Chapter III above.

101. In many cases of transfer of technology, patent licensing agreements play an important role, as they allow access to the technology in question. In addition, licensing agreements frequently also contain clauses on technical assistance and know-how needed to work the invention and, in the case of some products, to obtain regulatory approval. It goes without saying that, for a patent licensing agreement to work properly, patent protection in the relevant jurisdiction must exist. With the increase of globalization and transnational trade flows, the link between patents and technology transfer has been increasingly recognized at the national and international levels, as can be seen, for example, from Articles 7 and 8 of the TRIPS Agreement or Article 16 of the Convention on Biological Diversity. This relationship is generally understood to have both positive aspects, namely where useful technology is indeed transferred to the recipient, and a negative component, namely where patent rights or an abusive use of such rights, may equally hinder a transfer of technology.

102. Beyond this international dimension to transfer of technology as described above, there is a further aspect that needs to be looked into, namely the transfer from results of research institutions to real, tangible products for the market. One example is the Bayh-Dole Act in the United States of America, through which research institutions and universities can obtain patent protection for their inventions and thus enter into licensing agreements with industry. This allows some of them to generate considerable income and to finance further research. In addition, the practical result of such agreements may result in the creation of spin-off companies enriching the economic landscape of a given country. In view of these examples, a number of developing countries have also established patent and technology transfer systems in the public sector.

103. One argument that is put forward in favor of technology licensing in developing countries claims that such policies would create incentives for building technical know-how and expertise in those countries, which could encourage the creation of local industries. On the other hand, some question whether licensing is sufficient to achieve this purpose, considering that the licensing agreements do not necessarily disclose all the know-how necessary to exploit the technology, and suggest that more should be invested in tuition and education, as well as in improved public-private partnerships. In addition, it is sometimes also argued that in certain specific areas, for example, the health sector in developing countries, a licensing system based on the existing patent system will not produce the desired results, as this may rather attract funding into research that may result in profitable patents, but will not foster research into diseases targeting particularly developing countries, because developing markets cannot afford the costs of the resulting products. If institutions in developing countries aim their research toward obtaining patents to generate licensing income, they too are likely to pursue research on topics for which there is a market to generate industry licensing interest. Some data suggest that increased technology licensing has not significantly altered research priorities in the United States of America.[37] At the same time, as developing countries are in the process of building and expanding their research ability, one of the major objectives to consider in those countries is to encourage incentives increasing that capacity. In this respect, a sensible use of the patent system, and of its use for both international transfer of technology and public-private partnerships at the different stages

[37] Gregory K. Sobolski et al., Technology Licensing: Lessons From the US Experience, *JAMA*.2005; 294:3137-3140.

of research and development should be considered carefully, taking into account the flexibilities that the system offers in order to avoid abuses.

104. An issue which is different from the question of whether and which national licensing policies should be adopted by the various countries relates to making technologies from industrialized countries available to developing countries at affordable conditions, in order to increase flows of technology to developing countries. While many governments, sometimes for constitutional reasons, may not be in a position to dictate the conditions at which their companies have to give away their technologies, they may nevertheless provide various incentives, for example, of a fiscal nature, for such a transfer. In addition, they may consider establishing technology transfer programs that cover state-owned technologies. It should again be recalled, however, that such efforts may only be useful if they are accompanied by measures that foster economic growth in developing countries and by actions that ensure that such technologies can be absorbed in a given country.

105. In the past decades, the discussions on transfer of technology have gone through different phases:[38] while in the 1970s, countries focused on the differences among countries in respect of technology development, the weakness of companies in developing countries compared to those in industrialized countries and the effects of the patent system, in the 1990s, the accent was placed more on capacity-building and a better understanding and assimilation of technology. Today, while at least some of the concerns just mentioned are still valid, the focus is more on how to bridge the still existing technological divide, on how to have all countries participate in norm-setting, and how to best make use of existing flexibilities. The relationship between patents and transfer of technology is clearly a multifaceted one. In the further analysis that may be made on the subject, aspects such as the impact of patents on transfer of technology in respect of the decision to transfer, the method chosen to transfer technology, the effects on local innovation, and the broader issue of how the legal framework is adapted to contribute to technology transfer may be considered.

(ii) Anticompetitive Patent Licensing Practices

106. Licensing is important for economic development and consumer welfare, as it helps disseminate innovation. But equally important is competition as one of the main driving forces of innovation, and it is thus important to find the right balance between protecting competition and protecting intellectual property rights.

107. Under general legal principles applicable to contracts, parties are free to determine the contents of contracts and may derogate by mutual consent from the provisions relating to license contracts only where they are not barred by law. However, licensing agreements can also be used for anti-competitive purposes. For instance, when two competitors use a license agreement to divide markets between them, or when an important licensor excludes competing technologies from the market. Therefore, provisions in licensing agreements having monopoly effect or conflicting with the prohibition of antitrust or anti-competitive practices are usually considered null and void. The most important forms of abuse include, for example, tie-in clauses, export bans, tied royalties, grant-backs, conditions preventing challenges to validity and coercive package licensing. Tie-in clauses provide that the licensee

[38] Among others, Pedro Roffe, Technology transfer on the international agenda, in International Public Goods and Transfer of Technology, edited by Maskus and Reichman, 2005.

may purchase materials only from certain sources; grant-back clauses secure exclusive rights to improvements in favor of the licensor.

108. The above restrictions of the freedom of contract are reflected at the international level, as is shown by the following non-exhaustive list of examples:

- WTO Members are free, according to the TRIPS Agreement, to specify in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. A WTO Member may adopt, consistently with the other provisions of the Agreement, appropriate measures to prevent or control such practices in the light of the relevant laws and regulations of that Member.

- Article 81(1) of the EU Treaty prohibits agreements which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the common market. Under Article 81(3) an anti-competitive agreement may be exempted from the prohibition of Article 81(1) if the positive effects brought about by the agreement outweigh its negative effects, through so-called "block exemption" Regulations and Guidelines. The block exemption Regulation creates a safe harbor for most licensing agreements.

- In the United States the Department of Justice adopted certain antitrust guidelines that are similar to the European guidelines, which make it clear that antitrust concerns may arise in a licensing agreement if the restraints harm competition among entities that would have been actual (or likely) potential competitors. Further, a restraint in a licensing agreement will be subject to antitrust scrutiny "if it facilitates market division or price-fixing". The Guidelines also provide for a safety zone, with comparable objectives as the European block exemption.

- In Japan, the Unfair Trade Guidelines list several types of clauses as being highly likely to be deemed to be unfair trade practices, such as restricting the price of goods, imposing obligations after the termination of the agreement or expiration of the patent, imposing limitations on research and development programs of licensee.

(iii) Patent Pools

109. One issue that is at the heart of the potential conflict between patent law and competition law concerns the situation where many patent rights cover one technology, so that the sum of the licensing fees becomes prohibitive, not mentioning the difficulty to negotiate separate agreements with all rightholders. One way to deal with the situation where different patentees own a number of patents relevant to a technology is called a patent pool, which is an agreement enabling participating patentees to use the pooled patents, provide a standard license for the pooled patents to licensees who are not members of the pool, and to allocate each member of the pool a portion of the licensing fees in accordance with the agreement. Such patent pools are most frequent in the process of standardization, which, in certain areas such as digital technology and telecommunication, frequently involves many patents. One of the most successful patent pools is a pool established for the MPEG-2 standard: MPEG-2 is a widely used digital technology for video compression. A patent pool was established in order to ensure a fair, reasonable and non-discriminatory way to access the patented technology incorporated in the standard. In accordance with the pooling agreements, patentees license their MPEG-2 related patents to an administrative body, MPEG LA. It

offers a license that allows access to the pooled patented technologies on the same terms at fixed rates under a single license. In addition, it constantly reviews new patented technologies which merit inclusion in the pool. The pool covers over 120 “Essential Patents” and many more “Related Patents”.

110. Although many jurisdictions recognize that patent pools can have pro-competitive effects, there are also concerns that they might have negative effects. For example, patent pooling agreements could include concerted pricing practices or contain grant back provisions, to the effect that licensees would have to grant licenses to the pool on patents derived from the pools patents.

(b) Standards

(i) The Need for Standards

111. Interoperability is the key to the interplay of different technological components, in particular in, but not limited to, the field of information and communication technologies (ICT). More and more products need to be compatible and to interoperate, and this is often achieved by so-called technical standards, which are technical specifications allowing the replacement of one part of a given product with another part, or the assembly of such parts. Standards reduce transaction costs by providing uniform technical platforms and economies of scale for all the companies involved in a particular technical field. Standards create predictability, interoperability and competition between implementations, without imposing homogeneity. In sum, standards are considered vital to wide adoption of new technologies in the market place, in particular in the field of electronics and telecommunication.

112. A vast majority of products currently on the market were developed in compliance with one or more standards. Beyond ensuring interoperability, standards can also contain information about the quality, safety, reliability or a product’s effects on the environment.

113. Generally speaking, there are two categories of technical standards: *de facto* standards and *de jure* (or “formal”) standards. A *de facto* standard exists when a particular technology is widely implemented and deployed in the market. *De jure* standards are set up by standard setting organizations, which are often under some governmental influence. The standard setting organizations may be international (for example, the International Organization for Standardization (ISO)), regional (for example, the European Telecommunications Standards Institute (ETSI) and the African Organization for Standardization (ARSO)), or national (for example, the American National Standards Institute (ANSI)). These organizations are independent and coordinate and facilitate a voluntary standard-setting process through the involvement of technology suppliers. In certain cases, companies form a consortium to establish technical standards in a particular field, mainly in the telecommunication and computer technologies. The Internet Engineering Task Force (EITF) and the World Wide Web Consortium (W3C) are major international standard setting organization for the Internet and the world-wide-web.

114. Implementation of standards is, in general, voluntary and market-driven, safe exceptional cases such as public safety and health.

(ii) The Relationship between Patents and Standards

115. Patents and standards serve common objectives, insofar as they both encourage investment in innovation as well as the diffusion of technology. Filing a patent application allows technology producers to disclose their achievements openly and early. Patent protection works as an incentive for companies to contribute their technologies to standardization and allows licensing to implementers. In the framework of a standardization procedure, technical specifications, frequently incorporating patented technology, can be disclosed early for the benefit of industry and of the public. In the absence of such a possibility, technology producers may well opt for keeping their developments secret or for disclosing just the minimum required by the standardization procedure.

116. At the same time, inherent tensions exist between patents and standards, which become apparent when the implementation of a standard calls for the use of technology covered by one or more patents. Indeed, on the one hand, the objective of a standard setting organization (SSO), which in many cases consists of companies interested in the development of the technology in question, is to establish standardized technology that can be used as widely as possible in the market. On the other hand, patent owners in the relevant area may have an interest in the adoption, in the standard, of their own patented technology in order to benefit, at a later stage, from royalties.

117. In order to balance these competing interests, many SSOs have established patent policies that encourage the parties involved in the standard-setting process to disclose, to other members of the SSO, the existence of any relevant patents (and, sometimes, also patent applications) on technologies essential for the implementation of the technical standard under consideration, so that this fact can be taken into account during the standard setting process. In addition, SSOs typically require the patentee to agree to license the patented technology on reasonable and non-discriminatory (RAND) terms. If the patentee does not agree with such condition, the standard under consideration may not be adopted, and the SSO may decide to further review the standard. Some SSOs, for example W3C, have adopted a royalty free (RF) licensing policy, according to which patent holders are required to enter into reciprocal RF licenses. In other words, the patent holder makes his technology available royalty free provided that the licensee makes his patented technology, which is necessary to implement the standard, on the same RF condition. Even when they are royalty free, SSOs' IPR policies typically provide for other reasonable and non discriminatory conditions, such as field of use, reciprocity or restrictions on sublicensing.

(iii) Main Issues under Discussion

118. In recent years, the relationship between patent rights and standards has been increasingly debated. This is due, *inter alia*, to factors such as the greater attention given by companies to patents as important intangible assets, the rising number of standards that involve patented technologies (this being the case at least in certain specific technologies, such as ICTs) and issues relating to the perceived consequences of patents on the development and implementation of standards for consumers, competitors and society in general.

119. From a policy standpoint, the most essential objective appears to be, while keeping in mind the encouragement of innovation, to strike a balance between the interest of patent holders in exploiting their patents, the producers who want to license and produce the goods covered by the standard at a reasonable price, and the public which seeks the widest possible

choice among interoperable products. Some of the main concerns that have been put forward as possibly threatening this balance are: firstly, the possibility that a patent owner may conceal (or at least not adequately disclose) existing or pending essential patent rights during the process of adopting a standard, and disclose the rights only after such adoption (also called patent ambush), thus potentially allowing the patent holder to block the implementation of the standard.[39] Secondly, some competition issues are at the heart of the debate, such as the situation where the patent holder requires a level of royalties that makes it very difficult to produce the standard or leads to a significant impact on the price of the standardized technology;[40] perhaps to a lesser extent, there is the issue that possible price agreements during the standardization process have the potential for excluding third parties from that process. The patent policies adopted by many SSOs aim precisely at minimizing the risk of such conflicts and at assuring the smooth and wide dissemination of standardized technologies.

120. With the growing importance of standards, several avenues are being pursued to prevent conflicts from arising: one is to improve the self-regulatory mechanisms of SSOs, i.e., their patent policies, including considering patent searches, further encouraging early disclosure of essential patents and patent applications, and finding solutions to the issue of cumulative royalties by introducing criteria and mechanisms such as RAND or FRAND (fair, reasonable and non-discriminatory) criteria in respect of licenses granted by patent holders. A second avenue which is being looked into involves the application of legal mechanisms either internal or external to the patent system. The latter relates, in particular, to competition law that allows addressing certain aspects of the problem, such as abuse of a dominant position in fixing license fees or the violation of a SSO patent policy. However, where a company does not participate in a standard-setting process, or where no dominant position is abused, competition law may not offer a satisfactory solution. The former legislative approach addresses the issues from within the patent system, and may cover options such as limited exceptions, compulsory licensing or limitations on the enforcement of the patent rights. The advantage of those solutions is that they are universal, and also apply to non-members of a standard-setting process. Opponents to a legislative approach argue, however, that interfering too much in the standard-setting process via legislative measures would stifle this mainly industry-driven process and prevent the adoption of the optimal technologies in a standard.

(iv) Open Standards

121. Among technology standards, there is particular interest for “open standards”. While there is no universally accepted definition of that term, all open standards have the following common characteristics: (i) the specification is publicly available without cost or for a reasonable fee to any interested party; (ii) any IP rights necessary to implement the standard are available to all implementers on RAND terms, either with or without payment of a reasonable royalty or fee; and (iii) the specification should be in sufficient detail to enable a complete understanding of its scope and purpose and to enable competing implementations by

[39] For example, a San Diego federal court ruled in August 2007 that Qualcomm had engaged in standards abuse and aggravated litigation misconduct for deliberately concealing two patents as a committee developed the H.264 video standard. Qualcomm declared it would appeal the decision.

[40] In January 2008, the U.S. Federal Trade Commission has settled a complaint against Negotiated Data Solutions, a company that owns patents to a widely used Ethernet standard, saying the patent owner was attempting to collect huge license fees despite a prior commitment to the contrary (see http://www.ftc.gov/os/caselist/0510094/index.shtm).

multiple vendors. Some define open standards as publicly available technical specifications that have been established in a voluntary, consensus-driven, transparent and open process, others appear to add to this definition the requirement that an open standard has to be available royalty-free. The defenders of the first definition favor patent policies on a RAND basis, which they believe to maximize flexibility through a commitment to license combined with the right of patent holders to receive reasonable and adequate compensation for their sharing of their technology, and trust in the co-existence of this model and a royalty-free model. They also question how, in a royalty-free environment, investments in research and development could be maintained in the long run and how a broad participation in standard-setting processes could be maintained. On the other hand, the advocates of the latter approach are convinced that society as a whole would benefit from the open and royalty-free access to standards, as it is the case, for example, in the Internet context, which had been established precisely in order to allow the free publication and retrieval of information from the web. According to them, this model would best ensure interoperability, greater innovation and consumer welfare. In addition, they argue that, even where a royalty-free policy is adopted, the benefit of standardization may outweigh the loss of royalty income in certain technologies, simply through greater quantities of a certain product being sold.

122. In this context, the notion of “open source” is often mentioned, but it should not be confused with open standards. While open standards are technical specifications developed in transparent and open processes and are available for implementation on reasonable and non discriminatory terms, but not necessarily royalty free, “open source” rather refers to a software distribution model based on an IPR, mainly copyright. Generally speaking, open-source software refers to software for which the source code (underlying programming code) is made freely available for use, reading the code, changing it or developing further versions of the software, including adding amendments to it (see sub-Chapter (c)(i) below for further details regarding open source). While open source software has been used to implement some ICT standards, other standards are implemented through proprietary software or, as is increasingly the case, through the use of mixed platforms that combine both open source and proprietary software. When governments and other users are in the process of selecting a specific technology to meet their needs for interoperability and/or free use of that technology, in addition to the open or proprietary nature of any software involved, factors such as overall costs, the maturity of the technology, and the support offered, should be taken into account.

(c) Collaborative Research Projects

123. In a more and more complex world, research has not only become more international, but it has become dependent on a broad range of different - and often newly emerging - technologies, on increased cooperation between various research teams and on sufficient funding to face the exponential rise of costs over the past years. Business strategies today therefore need to be supporting global competitiveness, innovation and rapid market responsiveness. These factors have contributed, since the early 1980s, to the development of various initiatives in different areas of technology (e.g. computer sciences; mobile communication technologies; biotechnologies or, perhaps more importantly, public health) to address research in a more collective way at different levels, with the objective of establishing excellence in research projects and networks able to attract researchers and investments from many countries and industries, raise sufficient funding for such R&D and to turn the fruits of that research into concrete and useful products for society.

124. In this context, the argument is made by the advocates of the patent system that it offers an adequate incentive structure to foster innovation, as it uses the private sector with its financial and expert resources to achieve public policy objectives, has built an enormous source of technical knowledge that is freely available for further research and can be used for various other purposes. Its is further argued that the patent system, where it is considered not to be appropriate for certain countries or situations, contains a number of flexibilities that can be used, in particular, research exemptions and compulsory licenses. Others have voiced disagreement with this approach, as the patent system may stand in the way of the above-mentioned collaborative approaches to research and development by, in particular, blocking access to or use of necessary information. They argue, in particular, that the patent system prevents access to certain inventions needed for further research, increases cost and complexity by encouraging a system creating multiple licenses and does direct research towards products that are only expected to generate high benefits, thereby neglecting, for example, diseases that affect specifically poor countries. Therefore, according to these voices, collaborative models rather than exclusive rights have to be promoted. Two examples of such collaborative business models are briefly introduced here, namely the Open Source model and the so-called Research and Development (R&D) Treaty.

(i) Open Source

125. The open source model has been well known for many years in the area of software, where it has been established as a distribution model that is based on intellectual property rights (in the case of software, often copyright). 'Open source' software is often used as a general expression for many forms of non-proprietary software, which differ principally in respect of the licensing terms under which changed versions of the source code may be further distributed. The basic idea of open source is to make available the source code of the computer program and to thus permit a more collaborative way of follow-on innovation, subject to certain conditions, which are often more open than those governing traditional licenses, as they would give access to the programming code of the software and prevent the possibility of obtaining an exclusive right on follow-on innovation (see for example GPL[41]). Indeed, under open source, adding, for example, a new functionality to a specific software may be done without the permission of the creator of the original software, but no patent could for example be claimed on the result, even if it did, in principle, meet patentability requirements. The open source approach is not necessarily against intellectual property, as it is based on intellectual property rights, and is sometimes also used by businesses as a complementary strategy complementing intellectual property policies making use of patents and copyright, for example by IBM or SUN who use and promote open source as part of their business strategy.

126. Although some of the open source features developed in the area of software cannot be simply transposed to other areas, the main principle that certain parts of the commons should not be the subject of a proprietary right has been found interesting enough to be tested and applied in other areas. Examples include the Hapmap Project that compares the genetic sequences of individuals to identify halotypes. The information is made available to researchers freely, but subject to a data access policy, which forbids the users from reducing the access to data and shares the data with only those who had made the same agreement. Another example is the SNP consortium, which aims to create a public resource the access to which would not block access to data by other researchers and companies. One further

[41] http://www.gnu.org/copyleft/gpl.html.

example is the BIOS (Biological Innovation for Open Society) project by CAMBIA,[42] under which biotechnological inventions should be available to researchers with least restrictions. Under the BIOS project, BiOS Licenses have been developed as a model largely inspired by the GPL philosophy. It permits the use of all intellectual property for development and commercialization, but the licensee has an obligation to also grant licenses on further improvements.

(ii) The Proposal for a Medical Research and Development (R&D) Treaty

127. In the context of public health and the influence on it of intellectual property rights, it has been suggested to develop a so called medical R&D Treaty. The argument is that current pharmaceutical research and development results in too many resources being invested in the diseases affecting rich countries, thus neglecting poor countries' diseases, and that only a fundamental restructuring of the current research and development model can guarantee that the latter diseases are adequately addressed. The proposed draft R&D treaty would provide new obligations and economic incentives to invest in priority research projects, and addresses several other important topics such as open access publishing. It includes agreements that member countries reduce intellectual property protection in certain areas, such as to permit research exceptions for patents, and exceptions to patentability relating to certain open source medical databases. The core country obligation is to support medical R&D, which could be achieved, in particular, through public sector funding, tax credits, or purchases of patented medicines (measured by the R&D stimulated by such purchases), as well as through newer methods, such as medical innovation prize funds, competitive intermediaries, or various open source collaborative research projects. Countries may be obliged to provide a percentage of their GDP, under a progressive rate, for medical R&D, with minimum investments for priority research projects, such as investment in neglected diseases or global infectious diseases. The proposal would also create a system of credits to reward and stimulate investments in research projects considered socially important. Member countries meeting the obligation under the R&D Treaty would be exempted from obligations under other trade agreements on patents or drug prices. Critical voices of the initiative claim that it might weaken the incentives of pharmaceutical companies to continue investing in R&D and that all attempts to base research on a public approach rather than on private initiative have failed in the past.

(iii) Public-Private Collaboration

128. Among the various partnerships and networks that we have witnessed in the past years, a considerable part consists of inter-firm relationships, but collaborative innovation networks embrace more and more interaction among players from the private sector and government-funded agencies (so-called public-private partnerships). To a certain extent, almost all these collaboration models rely on patent strategies and contain provisions on the management and use of patent rights. In the present context, we will focus on the role of patent rights in the framework of collaborative research projects, as these rights are sometimes considered to be helpful to research networks in some aspects, but sometimes to be in the way of that same research cooperation, triggering fears that public policy interests may not be adequately protected.

[42] http://www.bios.net/daisy/bios/home.html.

129. One of the main questions is to identify the types of patent rights' management that would best serve advancing the creation and development of useful products for society with the participation of private companies, which is the fundamental objective of the patent system. This process covers, expressed very simply, three distinct aspects, namely the research phase which will form the basis of the creation of the new products, the transformation of those results into concrete new products and, finally, the distribution aspect of those products, including infrastructure, distribution channels and access in general. The following remarks will be limited to the first two phases mentioned and, in particular, to the second one, namely the transformation of academic results into tangible products for the market.

130. For a long time, universities and public research institutions were not able to get the results of their research converted into viable projects, mainly because of the absence of sufficient cooperation with the private sector. Frequently, patent rights belonged to the state, so that the research institutions could not assign or license their inventions. However, in order for the private sector to invest heavily into public research activities that are often aimed at basic research and thus may involve relatively long time frames, private companies frequently request some guarantees, one of which is ownership of patents. In this logic, the patent system may be considered to be one element of the bridge between basic research of the public sector and the marketing of products by the private sector. The patent system, in the framework of public private partnership agreements, is also used to control and regulate certain activities, such as for example, how the invention should be marketed and under which conditions. At an early stage of the research, the patent system will be helpful in identifying whether any basic technologies required for the research are protected or not and whether any partners and/or licenses are available. Equally, the access to the technology by the partners and by third parties may be regulated through some licensing system. Let us finally recall in this context that, should the conditions for access to certain products be considered insufficient, governments may decide to consider instruments to protect the public interest, such as compulsory licensing.

131. One of the first countries to recognize the role of the patent system for this type of partnerships and to act accordingly was the United States of America: the so called Bayh-Dole Act of 1980 allowed and encouraged research institutions in the USA to patent technology developed with federal funding, and to license those technologies in return for royalties. The Bayh-Dole Act triggered a substantial increase in patenting activity from US universities, in particular, and has been at the heart of the establishment of technology transfer offices in many US research institutions. This has resulted in a substantial growth of licensing revenues in those universities and research institutions, which has reached several billion $ US in licensing fees per year. It is, however, also important to note that the vast majority of institutions earn relatively little income with licensing fees, while a relatively small number of those institutions share the bigger part of the total income. But even for the most successful institutions, the return on sponsored research rarely exceeds 10%. According to some research, the positive economic effects of investing in and funding research institutions are not so much realized by patenting and licensing technology from research institutions, but rather tend to be indirect through spin-off companies.

132. As mentioned earlier, a number of developing countries have moved toward establishing patent and technology transfer systems in the public sector. While it is not sure that these will fulfill the expectation of being able to fund subsequent research to a great extent, it is hoped that such policies would create incentives for building local technical know-how and scientific expertise that could encourage domestic production in various

industries. Experience shows, however, that the successful development of new products often requires a certain form of cooperation between the public and the private sectors. In order to achieve such results, it may be argued that funding for research projects run by public-private partnerships in developing countries should be increased, in particular to augment such cooperation with companies from industrialized countries. Where this is the case, careful attention should be given to patent clauses, which may constitute a helpful instrument in managing research aspects, ownership, access and marketing of inventions.

V. CURRENT MULTILATERAL FRAMEWORK

(a) Existing International Instruments

133. By the second half of the 19th century, many countries had recognized the value of the patent system as a tool for technological and economic development. Consequently, they established a system for the protection of inventions at the national level. Since no international convention in the field of industrial property existed at that time, it was rather difficult to obtain patents in foreign countries. For instance, a stringent working requirement and differential treatments between foreign applicants and national applicants were often applied. Moreover, patent applications had to be filed roughly at the same time in all countries in order to avoid publication in one country destroying the novelty of the invention in the other countries. Such inadequate protection for foreign inventors made them refuse to participate in an international exhibition on inventions hosted by the Government of Austria-Hungary in 1873 in Vienna. This led the government to host the Congress of Vienna for Patent Reform in 1873 and eventually, the Paris Convention for the Protection of Industrial Property was adopted in 1883.

134. Since then, a number of international treaties have been concluded in the field of patents. Five treaties, namely, the Paris Convention for the Protection of Industrial Property (Paris Convention), Patent Cooperation Treaty (PCT), the Strasbourg Agreement Concerning the International Patent Classification (Strasbourg Agreement), the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (Budapest Treaty) and the Patent Law Treaty (PLT), are administered by WIPO, and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), which was contained in an Annex to the Agreement Establishing the World Trade Organization (WTO), is administered by the WTO. A brief summary of each treaty is presented in Annex I.

135. It should be noted that, in addition to the above international treaties, a number of regional agreements have contributed to the development of the international patent system through the harmonization and simplification of regional patent laws. Examples of such regional agreements are: (i) the European Patent Convention (34 member States); (ii) the Eurasian Patent Convention (9 member States); (iii) the Harare Protocol (African Regional Intellectual Property Organization (ARIPO)) (16 member States); (iv) the Bangui Agreement (African Intellectual Property Organization (OAPI)) (16 member States); (v) the Patent Regulation of the Cooperation Council for the Arab States of the Gulf (Gulf Cooperation Council (GCC)) (6 member States); (vi) Decision 486, a common intellectual property regime of the Andean Community; and (vii) legislations by the European Community.

(b) Framework Principles

(i) Paris Convention

136. The Paris Convention lays down a number of principles for the protection of industrial property abroad. Firstly, each member State of the Paris Union shall apply the principle of national treatment which obliges each member State to extend to the nationals of any other member States (including those persons and enterprises domiciled or having a commercial or industrial establishment in any other member States) the same treatment in respect of industrial property as it applies to its own nationals. The national treatment rule guarantees that foreigners will not be discriminated against in any way.

137. Another basic right known as the right of priority was adopted in view of the costs and additional work involved in preparing and filing patent applications in foreign countries. Any person who filed, in a Contracting State, an application for an industrial property title (patent, utility model, trademark or industrial design) shall enjoy a right of priority for the subsequent filing in any other member State within a defined priority period (twelve months for patents and utility models and six months for trademarks and industrial designs), provided that he meets the formalities prescribed in the Convention. Consequently, any subsequent application in another country before the expiration of the priority period shall not be invalidated by reason of any acts accomplished in the interval. For example, a subsequent application would not be refused because of any relevant prior art made available between the priority date and the actual filing date of the subsequent application.

138. In addition, patents granted in different Contracting States for the same invention are independent of each other. This means that the grant of a patent in one country for a given invention does not oblige any other member country to grant a patent for the same invention. Furthermore, a patent cannot be refused, invalidated or otherwise terminated in any Contracting State on the ground that a patent for invention for the same invention has been refused, invalidated, or terminated in any other Contracting State.

139. The Paris Convention, in Article 19, acknowledges the right of Contracting Parties to conclude special agreements among themselves for the protection of industrial property in so far as they do not contravene with the provisions of the Convention. A number of treaties, including the PCT, are such special agreements under the Paris Convention.

(ii) TRIPS Agreement

140. The TRIPS Agreement contains the national treatment principle and the most-favored-nation principle. The latter principle provides that any advantage, favor, privilege or immunity granted by a Member to the nationals of any other country (whether a Member or not) shall be accorded immediately and unconditionally to the nationals of all other Members, with certain specified exemptions. As is the case for national treatment, procedures provided in multilateral agreements concluded under the auspices of WIPO relating to the acquisition or maintenance of intellectual property rights are exempted from this principle.

141. Article 7 of the TRIPS Agreement in conjunction with the preamble of the Agreement sets out the objectives of the Agreement: the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of

technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations. Article 8 provides "principles" which recognize the rights of Members to adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement. It also recognizes that appropriate measures, provided that they are consistent with the Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

142. Compared with the treaties adopted under the auspices of WIPO, one of the main particularities of the TRIPS Agreement is the dispute settlement system established under the WTO Agreement. Articles XXII and XXIII of GATT 1994 (except subparagraph 1(b) and 1(c) of Article XXIII), as elaborated and applied by the WTO Understanding on Rules and Procedures Governing the Settlement of Disputes, apply to consultations and the settlement of disputes under the TRIPS Agreement. This means that benefits enjoyed in another trade area may be withdrawn in retaliation for the violation of the TRIPS Agreement (so-called cross-retaliation).

(c) Substantive Norms and Flexibilities

(i) Paris Convention

143. The Paris Convention provides certain common rules that are either required or permitted to be implemented under the national legislation. In the field of patents, they include the right of the inventor to be mentioned in the patents (Article 4*ter*), questions as to importation of articles covered by patents, failure to work the patented invention and compulsory licenses (Article 5A), grace period for the payment of maintenance fee (Article 5*bis*), limitation of patent rights where the patented invention is on a means of transportation entering temporarily in the territory (Article 5*ter*), process patent protection where a product manufactured by such process was imported (Article 5*quater*) and temporary protection in respect of goods exhibited at international exhibitions (Article 11). Many of those provisions leave a number of issues open to national legislators. For instance, Article 11 requires member States to provide temporary protection in respect of goods exhibited at international exhibitions, leaving member States to choose the means for implementing such protection by the domestic legislation.

144. The Convention also leaves the member States free to establish a number of fundamental issues concerning substantive patent law, such as the criteria for patentability, term of protection, rights conferred by a patent and enforcement of rights.

(ii) TRIPS Agreement

145. In addition to the general obligation to comply with the substantive provisions of the Paris Convention (1967), the TRIPS Agreement established standards concerning the availability, scope and use of patent rights. They include: (i) basic standards for patentability and a limited list of exceptions to patentable subject matter[43] (Article 27); (ii) in terms of the

[43] Inventions may be excluded from patentability if their commercial exploitation is prohibited for reasons of public order or morality; otherwise, the permitted exclusions are for diagnostic,

[Footnote continued on next page]

availability of patents and the enjoyment of rights, no discrimination as to the field of technology, the place of invention and whether products are imported or locally produced (Article 27.1); (iii) rights conferred by a patent (Article 28) and exceptions to the rights (Article 30); (iv) conditions concerning the disclosure of the invention in a patent application (Article 29); (v) compulsory licenses (Article 31); (vi) availability of judicial review process for any decision to revoke or forfeit a patent (Article 32); (vii) the term of protection (Article 33) and (viii) the burden of proof in deciding whether a product was obtained by a patented process (Article 34).

146. The TRIPS Agreement is a minimum standards agreement, which allows Members to provide more extensive protection of intellectual property if they so wish. Members are left free to determine the appropriate method of implementing the provisions of the Agreement within their own legal system and practice. The Agreement leaves flexibilities for the Members to design their patent system since certain issues are not addressed under the Agreement (for example, ownership of patents), not defined in the Agreement (for example, the definition of "invention"), or prescribed as alternative choices for the Members (for example, whether the best mode requirement be required or not).

(d) Formalities

(i) Patent Cooperation Treaty (PCT)

147. Under the PCT system, an applicant may file a single "international patent application" that has the same effect as a national application in each Contracting Party to the PCT. It also provides a streamlined procedure in those countries by establishing a single international procedure for certain operations to process patent applications (international phase). Consequently, the applicant can file an application and process his application under a single procedure with a single set of formality requirements during the international phase in accordance with the PCT and its Regulations. In accordance with PCT Article 27(1), as far as form or contents of the international application is concerned, the PCT provides standardized formality requirements that the applicants should fulfill. Details concerning the PCT are contained in sub-Chapter (f)(i) below.

148. The standardized formality requirements under the PCT, however, are not applicable to national applications filed under the national patent system of the member States. Further, with respect to any formality requirements which are not regulated by the PCT, a Contracting Party to the PCT may prescribe any requirements under the national law for the purpose of processing international patent applications after the international phase (national phase). This is where the PLT comes into play.

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therapeutic and surgical methods, and for plants and (other than microorganisms) animals and essentially biological processes for the production of plants or animals (other than microbiological processes). Plant varieties, however, must be protectable either by patents or by a *sui generis* system (such as the breeder's rights provided in a UPOV Convention). Further, detailed conditions are laid down for compulsory licensing or governmental use of patents without the authorization of the patent owner. Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health in August 2003, allows WTO Members to issue a compulsory license in view of exporting patented pharmaceutical products to countries with no or insufficient manufacturing capacity under certain conditions. New Article 31bis TRIPS states that a member may grant a compulsory license for the purpose of production of a pharmaceutical product and its export to an eligible importing Member.

(ii) Patent Law Treaty (PLT)

149. The aim of the Patent Law Treaty (PLT) is to harmonize and streamline formal procedures in respect of national and regional patent applications and patents. With the significant exception of the filing date requirements, the PLT provides maximum sets of requirements, which the Office of a Contracting Party may apply. This means that a Contracting Party is free to provide for requirements that are more generous from the viewpoint of applicants and owners, but are mandatory as to the maximum that an Office can require from applicants or owners.

150. The Treaty contains, in particular, provisions on the following issues:

- Standardized filing date requirements;

- A maximum set of formal requirements for national and regional applications, which are, as much as practical, in line with the requirements relating to form or contents of PCT international applications;

- Standardized Model International forms which shall be accepted by the Contracting Parties;

- Simplified procedures before the office such as the restriction on requiring evidence on a systematic basis and the exceptions from mandatory representation;

- Procedures for the avoidance of unintentional loss of substantive rights as a result of the failure to comply with certain formality requirements within a time limit.

(e) Administrative Cooperation

(i) International Patent Classification (IPC)

151. The Strasbourg Agreement (of 1971) concerning the International Patent Classification provides for a common classification for patents for invention, including published patent applications, utility models and utility certificates. The International Patent Classification (IPC) is a hierarchical classification system in which the whole range of technology is divided into a number of sections, classes, subclasses and groups, in total approximately 70,000 subdivisions.

152. Classification is indispensable for the retrieval of patent documents in the search for "prior art." Such retrieval is needed by patent-issuing authorities, potential inventors, research and development units, and others concerned with the application or development of technology, for establishing the novelty of an invention or for determining the state of the art in a particular area of technology.

153. Although only some 60 States are party to the Agreement, the IPC is used by the patent offices of more than 100 States, four regional offices and the International Bureau of WIPO under the Patent Cooperation Treaty (PCT).

154. In order to keep the IPC up to date, it is continuously revised and a new edition is regularly published. The current (eighth) edition entered into force on January 1, 2006. The

revision is carried out by a Committee of Experts set up under the Agreement. All States party to the Agreement are members of the Committee of Experts.

(ii) The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure

155. Disclosure of the invention is a requirement for the grant of patents. Normally, an invention is disclosed by means of a written description. Where an invention involves a microorganism or the use of a microorganism, disclosure is not always possible in writing but can sometimes only be effected by the deposit, with a specialized institution, of a sample of the microorganism.

156. In order to eliminate the need to deposit in each country in which patent protection is sought, the Budapest Treaty provides that the deposit of a microorganism with any "international depositary authority" suffices for the purposes of patent procedure before the national patent offices of all of the contracting States and before any regional patent office (if such a regional office declares that it recognizes the effects of the Treaty). The European Patent Office (EPO), the Eurasian Patent Organization (EAPO) and the African Regional Intellectual Property Organization (ARIPO) have made such declarations. The "international depositary authority" is a scientific institution - typically a "culture collection" - which is capable of storing microorganisms. Presently, there are 37 such authorities.

157. The Treaty is primarily advantageous to the depositor who is an applicant for patents in several countries. Instead of depositing the microorganism in each and every country in which he files a patent application referring to that microorganism, he can deposit it only once, with one depositary, with the consequence of saving costs incurred by multiple deposits. Further, the security of the depositor is increased by the fact that, for an institution to become an international depositary authority, solemn assurances as to the seriousness and continued existence of that institution must be given by a State or by an intergovernmental industrial property organization.

(f) International Filing and Processing System

(i) The Patent Cooperation Treaty (PCT)

158. Lastly, no description of the current multinational framework can be complete without the mentioning of the Patent Cooperation Treaty (PCT).

159. The PCT is a multilateral treaty among countries which are members of the Paris Convention, administered by the World Intellectual Property Organization (WIPO). The PCT makes it possible to seek patent protection for an invention simultaneously in each country party to the treaty (as of December 2007, 138 countries[44]) by filing a single "international" patent application instead of filing several separate national or regional patent applications. And the effect of an international patent application in each PCT Contracting State is the same as if a national patent application had been filed with the national patent office of that State.

[44] The list of those States can be found on the WIPO web site at www.wipo.int/treaties/en/documents/word/m-pct.doc.

160. The "international phase" consists of the international search (which outputs an international search report and a preliminary patentability opinion by the searching Office),[45] the international publication of the application,[46] and the optional international preliminary examination, during which the applicant can seek to obtain a positive patentability report through amendment of the application and by dialogue with the examiner. After the end of the international phase, the applicant must "enter the national phase," by furnishing to each Office in which he desires to actively seek patent protection a translation of the application into its official language and paying the requisite official fees. Ideally, the decisions of these national and regional patent offices should be facilitated by the contents of the search report, written opinion and, where available, by the international preliminary report on patentability.

161. The PCT procedure has significant advantages, including 18 months more time (than under the traditional patent system) for applicants to come up with the significant amounts of money required to internationalize a patent application, value-added information contained in the various search reports and patentability opinions on which to base the decisions about proceeding with the pursuit of patents, harmonization as to formality requirements which must be accepted in the national phase, international publication thus putting the world on notice of the application, and publication as well of the international search report, thus putting third parties in a better position to formulate a well-founded opinion about the potential patentability of the invention. Ultimately, the PCT brings the world within reach, postpones the major costs associated with international patent protection, provides a strong basis for patenting decisions, and is used today by the world's major corporations, research institutions and universities when they seek international patent protection.

162. Most recently the PCT Regulations have been amended to provide for:

- new solutions where elements or parts of the international application are missing;

- restoration of the right of priority;

- lowering the standard for rectification of obvious mistakes;

- modification of the physical requirements to facilitate scanning and OCR;

- the addition of patent documents of the Republic of Korea to the PCT minimum documentation;

- the addition to the minimum requirements for the appointment of new International Searching Authorities of quality management systems;

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[45] To date, 15 patent offices have been appointed as PCT International Searching and Preliminary Examining Authorities: Austrian Patent Office, Australian Patent office, Brazilian National Institute of Industrial Property, Canadian Intellectual Property Office, State Intellectual Property Office of the People's Republic of China, European Patent Office, Spanish Patent Office, National Board of Patent and Registration of Finland, Indian Patent Office, Japan Patent Office, Korean Patent Office, Federal Service for Intellectual Property, Patents and Trademarks (Russian Federation), Swedish Patent and Registration Office, United States Patent and Trademark Office, Nordic Patent Institute.

[46] 10 publication languages as of 1 January 2009.

- two new publication languages;[47] and

- the option of obtaining supplementary international searches.[48]

163. Further, at the PCT Assembly in September 2008, modifications to the fee reduction already in place for applicants from certain developing and least developed countries will be proposed in order to widen its coverage.

164. By any measure, the PCT has been a real achievement—the number of Contracting States, the number of applications filed, the companies which consistently file PCT applications, the practical harmonization that has taken place around its requirements, innovations in the PCT including electronic filing, electronic publication and dissemination of documents, etc. It has effectively become the cornerstone of the international patent system as it exists today. However, the PCT faces a number of particular challenges at this point in its history, including:

- limitations inherent in the current legal structure, which make it difficult to innovate and respond to evolving best practices, and to simplify the texts;

- the growth in the number of Contracting States and in the system's use;

- the performance of Offices and International Authorities, especially the timeliness of their work[49] and its quality;

- balancing the needs, desires and expectations of the Contracting States and the PCT users;

- the appearance of a number of "alternatives" to the PCT;

- ensuring that PCT contributes positively to solving the problems faced by the international patent system today.

165. A number of the problems which the PCT was originated to address still exist in the international patent system: high patent application backlogs, long pendency times, duplication of work by multiple offices on the same application, etc.[50] It is safe to say that

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[47] Portuguese and Korean as of 2009.

[48] Applicants may request, during the international phase of the PCT application, additional international searches to be made by additional International Search Authority (Authorities) so that international search covers the fullest prior art as possible. It is an optional system, both for applicants and for international authorities.

[49] In relation to the time limits fixed in the Treaty and Regulations.

[50] The first official statement made by a BIRPI body was made on September 29,1966, by the Executive Committee of the Paris Union. It reads as follows: "The Executive Committee of the International (Paris) Union for the Protection of Industrial Property," "Having noted: that all countries issuing patents, and particularly the countries having a preliminary novelty examination system, have to deal with very substantial and constantly growing volumes of applications of increasing complexity, that in any one country a considerable number of applications duplicate or substantially duplicate applications concerning the same inventions in other countries thereby increasing further the same volume of applications to be processed, and that a resolution of the difficulties attendant upon duplications in filings and examination would result in more

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these existing problems would be significantly worse today had the PCT not been created. The creators of the PCT knew that they would not be able to completely solve those problems, and the PCT was, after all, a compromise. Former WIPO Director General Arpad Bogsch stated:

> "In the second half of the 1960s (when the plans for a PCT were under discussion) and in the 1970s (when the PCT was adopted and signed), this compromise was the maximum of simplification that could be agreed upon. It still seems to be the maximum 25 years later. But I do not believe that it will remain the maximum also in the 21st century. On the contrary, I believe that further streamlining the procedures and a higher degree of relying on the results of the international search and examination can and will be realized. They should remain on the agenda of WIPO and should be vigorously pursued by the governments and the patent offices as well as by the International Bureau of WIPO."[51]

166. It seems clear that further opportunities to improve the international patent system will be able to be built on the foundation of the Patent Cooperation Treaty.

(g) Recent Discussions on Substantive Patent Law Harmonization; Developing Countries

167. As a number of questions relating to the harmonization of national and regional patent laws had not been dealt with either in the TRIPS Agreement, in the PLT or in any other patent-related treaty of global reach, following the conclusion of the PLT, the SCP took the decision, in November 2000, to undertake discussions in relation to the harmonization of certain substantive patent law requirements, with a view to finding solutions, in particular, to the problem of the significant cost of obtaining international patent protection, to facilitating cooperation among Patent Offices in respect of search and examination results in order to reduce the workload they face and to address the issue of quality of patents. The set of general items to be covered by a draft Substantive Patent Law Treaty (SPLT) should include, according to the SCP at that time, issues of direct relevance for the grant of patents, including, in particular, provisions relating to the definitions of prior art, novelty, inventive step (non-obviousness) and industrial applicability (utility), the sufficiency of disclosure of the invention in the application, and the structure and interpretation of the claims.

168. Since May 2001, the SCP has discussed several versions of the draft SPLT. While these discussions have produced agreement in principle on a number of points (such as the right to a patent, prior art, sufficiency of disclosure or the requirements of novelty and inventive step), other subjects have given rise to more significant difficulties. These difficulties were partially

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economical, quicker, and more effective protection for inventions throughout the world thus benefiting inventors, the general public and Governments," "*Recommends*: that the Director of BIRPI undertake urgently a study on solutions tending to reduce the duplication of effort both for applicants and national patent offices in consultation with outside experts to be invited by him and giving due regard to the efforts of other international organizations and groups of States to solve similar problems, with a view to making specific recommendations for further action, including the conclusion of special agreements within the framework of the Paris Union." See The First Twenty-Five Years of the PCT (1970 – 1995), pg. 12.

[51] The First Twenty-Five Years of the PCT (1970 – 1995), pg. 11.

due to differences in opinion among industrialized countries (technical character of an invention, principle of first-to-file or grace period), but also to concerns expressed by developing countries. Indeed, the latter have expressed fears, for example, regarding the possibility of introducing into the SPLT provisions going beyond the TRIPS Agreement, in particular regarding patentable subject matter, and losing certain existing flexibilities.

169. With a view to overcoming those differences, different user groups and certain countries undertook, outside the context of WIPO, discussions on the possibility of limiting the draft SPLT to a reduced number of provisions, including those relating to prior art, but excluding provisions of a more controversial or political nature. Such discussions took place between October 2003 and February 2004 as part of the trilateral cooperation between Japan, the United States of America and the European Patent Office, at meetings of the International Association for the Protection of Intellectual Property (AIPPI) and of the International Federation of Intellectual Property Attorneys (FICPI), and during a meeting of 24 non-governmental organizations.

170. Further to those developments, the United States of America, Japan and the European Patent Office submitted a joint proposal designed to limit the draft SPLT to the provisions relating to the definition of prior art, the grace period, novelty and inventive step at the tenth session of the SCP, which took place from May 10 to 14, 2004. The choice of these provisions was based, *inter alia,* on the following reasoning: (i) the prior art-related provisions of the SPLT would provide the best opportunity for near-term agreement and results, since more controversial issues would be left to national regulation; (ii) agreement on these issues would result in consistent examination standards throughout the world, improve patent quality, and reduce the duplication of work performed by patent offices; and (iii) an internationally recognized definition of prior art would improve patent quality and address concerns regarding protection of traditional knowledge, as discussed by the WIPO Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore (IGC).

171. This proposal obtained the support of a number of delegations, in particular those from industrialized countries. Other delegations, however, opposed it and emphasized the need to examine all the provisions of the current draft as a whole, taking into account their interdependent nature, and recalled the importance they attached to other matters that would be left outside the scope of discussions. During the following sessions of both the SCP and the General Assembly, positions remained divided, and Member States were unable to reach a consensus on a work program for the SCP. Among the arguments raised, the following may be mentioned:

> Delegations from the industrialized nations stated that it was in the common interest of all WIPO Member States and their nationals to improve patent quality, to simplify the procedures, to reduce the costs for users, and to reduce duplication of work by patent offices. In order to reach those objectives, it was necessary to establish more consistent and common examination standards among WIPO Members, so that offices could increase, if they so wished, mutual cooperation in terms of the use of search results. The delegations were convinced that the results of that work would be of benefit to the patent protection systems in both developed and developing countries. Some of those delegations stated that limiting the scope of the SPLT to discussions regarding the definition of prior art, grace period, novelty and inventive step provide the best opportunity for achieving near-term agreement of core prior art related principles of patent law and thereby provide the best opportunity for meaningful results. Agreement

on those issues would promote higher patent quality, facilitate work sharing and, more importantly, would allow innovators, in particular, individuals and small- and medium-sized enterprises, to benefit from their own innovation in a way that was not possible due to existing differences in laws throughout the world. As examples that may be of particular relevance to developing countries, the following were mentioned: introducing a worldwide prior art notion would prevent inventions based on public, but non-written traditional knowledge to obtain a patent everywhere in the world; imposing a strict inventive step requirement may prevent the patenting of many trivial inventions and a grace period could be helpful for those who are not fully aware of the complexities of international patent protection. At the same time, cooperating more closely on this type of technical issues would improve the international patent system without removing the liberty of countries to make full use of the flexibilities contained in the system today, for example, in the TRIPS Agreement.

172. Other delegations, in particular, those of developing countries, stated that negotiations on the draft SPLT should be addressed adopting an inclusive approach to examine the concerns of all member States. They were of the view that concerns of developing countries, such as the cross-cutting nature and the significant implications of this process on public policy objectives for developing countries, together with the importance of subjects such as public interest, flexibility on existing intellectual property laws, transfer of technology, curbing of anti-competitive practices and disclosure of the origin of genetic resources in patent applications for developing countries, needed to be duly considered. The proposal to narrowly focus the discussions on the SPLT on only four provisions, while leaving aside or deferring to other fora the issues and proposals of interest to developing countries, was not consistent with the “development dimension”. Some delegations were of the view that a fragmented approach to negotiations would in fact not allow all Member States to make their proposals in the negotiations on issues that they considered relevant. In order to strike a balance between the rigidities that would be created in the international intellectual property system by demands on upward harmonization of national patent laws, on the one hand, and the safeguarding of existing flexibilities and national policy space, on the other, it was considered that negotiations on the SPLT should take on board issues of concern to all Members as a single undertaking.

VI. PATENT SYSTEMS AND EXISTING FORMS OF COOPERATION

173. As indicated in Chapter V, the current international framework is characterized by a number of international norms which have brought national legal frameworks closer together. However, in order to accommodate different national interests and needs, there are differences in the architecture of the patent systems at the national level. While more commonalities among the national legal systems are found in respect of certain elements of the patent system, other aspects reflect substantially different approaches.

174. In addition to those international norms, other forms of bilateral and multilateral cooperation exist in respect of various aspects of the patent system. This Chapter focuses on some key elements of the patent system and describes how those elements are currently applied at the national level with a short explanation on existing cooperation mechanisms. With respect to sub-Chapter (e) to (k), information concerning current practices under various national/regional laws is provided in Annex II.

(a) The Application

175. Since the patent right is a territorial right, in principle, an application has to be filed in each country in which patent protection is sought. For applicants who wish to obtain patent protection in a number of countries, it is cumbersome and costly to prepare various applications each of which must meet different national requirements. This difficulty was partly relieved by the establishment of regional patent offices, which provide the possibility to file regional applications in order to obtain patent protection in all or part of the member States of such regional organizations. As indicated in Chapter V, the PCT further provides one set of requirements regarding the form and contents of international applications which have the effect of a regular national application in each designated State as of the international filing date.

176. In certain cases, for example, where an applicant seeks patent protection only in two or three countries, he may choose to file national applications in each country separately, claiming priority under the Paris Convention rather than using the PCT. The national/regional formality requirements relating to national and regional applications are partially harmonized by the PLT. The said requirements, however, are maximum requirements. Therefore, each PLT Contracting Party may provide different national/regional requirements under the applicable law within the maximum set of requirements permitted by the PLT. Although it is limited to the request part of the application, the PLT provides a Model International Request Form, which shall be accepted by all Contracting Parties. The Trilateral Offices adopted, in November 2007, a Common Application Format which will allow applicants to prepare a single application that should be accepted by each participating Office without the need for further amendments to be made to comply with formal requirements. The Common Application Format is based on the existing PCT format taking into consideration the promotion of electronic filing and processing.

177. In addition to the need to accommodate the application format to various national/regional requirements, in general, a patent application, or a translation of such application, has to be submitted in a language prescribed by the applicable law. For those applicants who wish to obtain patents in countries having different official languages, it is costly to prepare the necessary translations of the application in those different languages. As one example to reduce the cost for translation, the Member States of the European Patent Organisation concluded the London Agreement in 2000. The Parties to the Agreement undertake to waive, entirely or largely, the requirement for translations of European patents to be filed in their national language.[52]

178. In general, a patent application consists of the following parts: a request, a description, claims, drawings and an abstract. Although drafting requirements and practices differ from country to country, there are typically three basic requirements to be complied with. Firstly, the description shall disclose the invention in a clear and complete manner so that the invention could be carried out by a person skilled in the art. Sub-Chapter (i) below will specifically deal with this aspect. Secondly, the application shall relate to one invention only or to a group of inventions linked in a certain way, the so-called “unity of invention”. The unity of invention requirement not only increases legibility of the application, but also has a bearing on the financial income of the patent Office by preventing the applicant to include an

[52] Details concerning the London Agreement are found at: http://www.epo.org/patents/law/legislative-initiatives/london-agreement.html.

unlimited number of inventions in the same application. Although the PCT provides a harmonized rule on the determination of unity of invention, bearing in mind that not all national patent Offices conduct substantive search and examination, to what extent the grouping of inventions is permitted in one application differs from one country to another.[53]

179. Thirdly, for the application to proceed, it must contain claims which should be clear and concise. Since the claims define the scope of protection, the drafting and interpretation of the claims are crucial not only for the applicant but also for third parties who, as a general rule, would be obliged to obtain consent by the patentee to use the invention once it is patented. The national/regional practices regarding the drafting and interpretation of the claims, however, significantly differ from one jurisdiction to another. The format of claims (for example, multiple dependent claims) and any limitation to a number of claims accepted under the national/regional practices are different from one country to another.[54] Many national and regional laws provide different provisions that regulate the relationship of the claims to the disclosure.[55] Further, certain types of claims in particular, for example, product-by-process claims and means-plus-function claims are interpreted differently among the courts in different countries. One of the most difficult areas of patent claim interpretation is the determination of an infringement of a patent where one of the elements of the patented claim is substituted by an equivalent element. The doctrine of equivalents is applied significantly differently among the courts in various jurisdictions.

180. In sum, with respect to the formality requirements relating to patent applications, the PCT and the PLT have addressed a number of issues and have brought national/regional laws closer together. However, they fall short of establishing one application form or format accepted under the national systems of member States. The substantive requirements relating to patent applications are less harmonized. In particular, the national/regional practices regarding drafting and interpretation of the claims significantly differ from one jurisdiction to another. In certain cases, claims with exactly the same text could be interpreted differently, and thus the scope of protection would not be the same in different jurisdictions.

(b) Search and Examination

181. National/regional patent laws provide substantive patentability requirements that need to be fulfilled in order to enjoy patent rights. In some countries, the prior art search and substantive examination are conducted by the national/regional patent office in order to check the compliance with the conditions of patentability prescribed by the applicable law. Once all the requirements under the applicable law are met, the patent will be granted. The search and examination thus ensure that granted patents meet *a priori* the requirements prescribed under the applicable law. As a consequence, patent owners will enjoy more legal certainty when enforcing their patent rights. Such a higher quality of granted patents is also advantageous for third parties, since the cost of challenging issued patents in court is often expensive. On the other hand, a poor search and examination might be more misleading than no search and examination at all, since it may raise an incorrect expectation of validity. The quality of the

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[53] "Summary of Responses and Points for Discussion" (WIPO document SCP/WGM/2/1) http://www.wipo.int/scp/en/working_group/session_2/documents/doc/scp_wgm2_1.doc.

[54] "Summary of Responses and Points for Discussion" (WIPO document SCP/WGM/2/1) http://www.wipo.int/scp/en/working_group/session_2/documents/doc/scp_wgm2_1.doc.

[55] "Requirements Concerning the Relationship of the Claims to the Disclosure" (WIPO document SCP/7/6) http://www.wipo.int/edocs/mdocs/scp/en/scp_7/scp_7_6.doc.

search and examination, therefore, is important for the legal certainty of the patent system as well as for the confidence in the patent system by society at large. On the other hand, it is expensive to maintain full substantive examination. It requires a significant number of highly qualified examiners who are well acquainted with the patent law as well as the latest technological advances in their specialized field of competence. Further, in order to search prior art, the maintenance of an up-to-date prior art documentation is essential, which also requires important financial and human resources.

182. Conducting search and substantive examination for all applications may thus not be the best approach for all the patent offices in the world. The policy choice of the legal and administrative framework depends on various factors such as a rational use of resources and market demand. Complex tasks and costs associated with the administration of search and examination are well recognized, and finding the best way to allocate limited resources is a well-known challenge. The choice may also be dictated by both the administrative costs for the authorities concerned and the social costs for the inventors who wish to obtain and enforce their patents. Further, costs for third parties should also be considered so that society at large would benefit from the patent system. No single system can be applied to all countries. The different existing systems reflect these differences on the one hand, and the policy choice of governments wishing to maximize the benefits from the patent system, on the other hand. The organizational structure and administrative system relating to search and examination vary significantly from one country to another.

183. One option that some countries have chosen is to have the patent Offices check the formalities of the patent applications and, once the formality requirements are met, to grant the patent without substantive examination. When a patent is enforced at a later stage, the validity of the patent may be challenged by the alleged infringer in court. From the point of view of the patent Office, this leads to considerable cost saving in terms of staff expenditure, and the country may be able to allocate its resources to other areas of priority. However, since no search and substantive examination are carried out before the grant of the patent, there is no guarantee that the patents are valid. The costs for examining the validity of those patents which purport to protect an invention of significance to a competitor are transferred to the post-grant phase, in particular, to courts as well as to patent owners and third parties, who have to prove the validity (or invalidity) of the patent in court.

184. Another option for countries is to have the patent Office conduct a prior art search and to establish a search report by a search examiner of the national patent Office, once a patent application is filed and the formalities of the application are checked. The patent will be granted without examination as to the patentability of the invention, and the search report will be published together with the granted patent. Since there is no substantive examination, the procedure is less complex than if a full examination was conducted. The published search reports will, nevertheless, allow third parties to better assess the validity of the granted patents. The patent Office has to allocate resources for employing search examiners, who need technical expertise, and for maintaining prior art documentation (databases). Such a system may also permit an easy and effective outsourcing of the work to another office if it is desired not to maintain a local body of search examiners; arrangements of this nature are made by a number of countries, often by the establishment of “international-type” search reports by an International Authority under the PCT. For most international applications under the PCT, an international search report will be available already.

185. Yet another possibility for countries with limited resources is to re-register patents granted in another country, instead of providing formality checks and substantive

examinations. In general, an application for re-registration has to be filed with the Office within a certain time limit after the grant of the foreign patent. Thus, the validity of patents is guaranteed to a certain extent, since the patents have been subjected to substantive examination in another country. This system may only work satisfactorily if the legal and linguistic backgrounds of the country that grants the patent and of the country that re-registers the patent are very similar, if not identical. The country that re-registers foreign patents would have to accept the decisions made by the other Office as regards the grant of the patent, although it may be possible to revoke the re-registered patents on the basis of requirements under the national law. It may also be useful to establish a mechanism facilitating the obtention of patents abroad for national applicants, for example, by forwarding their patent applications to the foreign patent Offices concerned.

186. Yet another possibility is to entrust all the work relating to patent administration to another country. In particular, if the other country offers effective administration and high quality services, the country can benefit from such services. For example, by means of a bilateral agreement, Liechtenstein and Switzerland form a common territory for the purposes of patent protection, with the exception of certain enforcement aspects. Swiss patent law applies in the territory of Liechtenstein, and Swiss patents automatically extend to Liechtenstein. Further, Switzerland has concluded treaties with third States also on behalf of Liechtenstein. This type of arrangement may require not only similar legal and linguistic backgrounds between the two countries concerned, but also close political, economic and diplomatic ties. Since patent rights are granted and the patent registry is maintained by another country, the country applying the foreign law and administration would have very little control over the administration and patent policy in that country.

187. In view of the limited resources of patent offices, which are, in general, public administration bodies, in some countries, additional resources are sought for in the private sector or through consultation of the general public to assist search and examination procedures before the offices. For example, private entities are commissioned to conduct at least part of the search and/or examination work under the supervision of a patent office. In this case, the patent office should have the competence to evaluate the commissioned work. Another example is the involvement of third parties in the search and examination procedure. Already in a number of countries, based on the published applications, third parties may submit any prior art information to the office, which will be taken into account during the examination procedure. One office has launched a pilot program to determine the extent to which the organized on-line submission of prior art by the public will provide useful information for examiners.[56] It consists of a collaborative, online process in which members of the public pool together their knowledge and locate potential prior art.

188. The major concern of countries regarding the search and examination procedure is how to maximize the quality of granted patents with the limited resources of their patent office. The question has been primarily posed by countries whose patent offices have limited resources to conduct a full scale of search and substantive examination. However, in recent

[56] Under the Peer Reviewed Prior Art Pilot being conducted by the United States Patent and Trademark Office, patent applications are (with the consent of their owners) put forward to a website run by the independent Community Patent Review Project and assessed by a public group which identifies what it considers to be the most relevant prior art, to be sent back to the Office for consideration at the end of the review period.

years, the countries with full search and examination systems have been increasingly posing the same question because of their increasing backlogs (see sub-Chapter (d) below).

189. One answer to such concern is international cooperation. In certain regions, in order to make the procedures more efficient and economical, countries have established regional patent organizations that grant regional patents. The objectives of intergovernmental regional cooperation are generally to reduce the administrative burden of the States involved, to promote cost-effective IP systems for users and to foster trade and investment within the region concerned.

190. Another way to cooperate internationally is to utilize, in various ways, search and examination reports prepared by other offices.

191. Some offices, for example those of Australia, Malaysia and Singapore, require a search and examination to be carried out before grant, but allow the systematic replacement of a part or all of the national search and examination process by evidence that equivalent work has already been done before another (recognized) office. This might be in the form of an applicant supplying a search report, a search and examination report, or the specification of a patent actually granted on an equivalent application. This system permits the office to focus most of its resources on search and examination of local applications which have no equivalent in other States, while ensuring that all applications are searched and examined. Regulations generally determine the extent to which a local examination needs to take place should different types of documents be supplied, which ensures that important local requirements are checked if necessary.

192. Other offices always conduct their own complete search and examination, but require the applicant to submit information concerning searches, grants or refusals of equivalent applications in other States in order to provide additional information, which can then be used by the examiner to assist or improve the search and examination process.

193. The effective use of search and examination reports established by other offices depends on the knowledge of their existence, effective mechanisms for their access and an appropriate timing of work by different offices. Traditionally, this has required direct intervention by the applicant: informing offices of co-pending applications, sending copies of search results and, where necessary, requesting either accelerated or delayed processing in different offices to allow work to be completed in one place in time for use in another office. Furthermore, except in cases where an office is specially contracted to conduct out-sourced search and examination on specific applications for another office, the arrangements are generally unilateral ones: the office conducting the earlier search simply carries out its work in accordance with its regular national procedures, and that work is then passed on to other offices by the applicant. Recognizing that there may be efficiencies in making such arrangements more widely used and effective, a number of offices have initiated pilot projects, often in the form of bilateral arrangements, which aim to provide mutual benefits for the offices concerned. The Patent Prosecution Highway, Triway and SHARE projects, involving the Trilateral Offices and a range of other partner offices, are noteworthy examples. While the specific details of these arrangements vary, in general they include at least some of the following features:

- the office where the application is first filed accelerates the processing in order to ensure that the results of search or examination are available rapidly for use by other participating offices;

- offices where the subsequent applications are filed delay processing pending the search or examination report becoming available from the office where the application was filed first;

- offices may make arrangements for direct access to search and examination reports by the other office(s), to provide a more efficient process for the second office and reduce the burden of applicants; the first office may also be able to access the results of the later search and examination reports by other offices;

- an accelerated examination procedure may be available if the application is reported as being in order for grant by the other participating office(s).

194. There are also cases where no corresponding applications can be found in other countries. Some patent offices with limited resources, therefore, entrust the prior art search and examination to other patent offices, in general against payment.

195. For international applications, an international search report and an international preliminary report on patentability are, in principle, established before the application enters the national phase. This provides a high quality search and an opinion on novelty, inventive step and industrial applicability which, while not stating whether the invention is patentable according to any individual national law, will usually give a good impression of whether the most important aspects of most laws are likely to have been complied with. The international route also assists in identifying equivalent applications in the national phase so that further search and examination reports can be viewed when they are published by individual offices. In addition to the fact that family matching of applications is more reliable for PCT applications than for families constructed using Paris Convention priority details, 30 States (with more to come soon) provide details of their national phase entries through the PATENTSCOPE® Search Service, in some cases providing links directly to national websites with details of the national phase application.

196. Patent offices of developing countries may also use the service of WIPO under the ICSEI (International Cooperation for the Search and Examination of Inventions) program.[57] The program is intended to assist the offices of developing countries in examining pending applications which have been filed by non-residents of their respective countries.

197. In sum, based on a cost and benefit analysis, member States are creative in designing the search and examination mechanism that fits their national/regional patent system best. The shared challenge of patent offices, be it from a developing country or from a developed country, or an office with 20 staff or 2000 staff, is how to maximize the quality of granted patents with often limited resources. Although various forms of international cooperation have been developed already, more effective mechanisms to tackle this challenge are being sought by a number of Offices.

(c) Opposition

198. Although not ideal, in reality, it may happen that a substantive examiner overlooks a piece of prior art and advertently reaches a positive decision regarding the patentability of the

[57] http://www.wipo.int/patentscope/en/data/developing_countries.html#P109_10719.

claimed invention. In order to prevent the grant of a deficient patent during the procedure before the office, some patent Offices provide an opposition procedure for a limited period during which third parties may oppose the grant of the patent, for example, on the basis that the claimed invention is not new or does not involve an inventive-step. Through the participation of third parties who may be well informed about the technology concerned, the opposition procedure complements the examination procedure and increases the credibility of granted patents. In general, an opportunity to review a decision by the patent Office to grant a patent is provided either by a competent court or by an administrative/quasi-judicial body the decision of which can be reviewed by a judicial body. The opposition system provides an additional, administrative layer of review, which is simpler than a court procedure or a quasi-judicial procedure. Compared with the revocation procedure by a court, the grounds for requesting the opposition procedure may be limited to certain patentability requirements. In general, an opposition may be filed by any person, while a patent revocation procedure may be initiated by a party who fulfills certain conditions, for example, being an interested party or being adversely affected by the decision appealed.

199. With respect to the timing, some countries provide pre-grant opposition proceedings, some provide post-grant opposition proceedings and some provide both pre- and post-grant opposition proceedings. In the case of pre-grant opposition proceedings, generally, after a positive decision of the examiner to grant the patent, the application at the pre-grant stage is made available to the public and any opposition to the grant of the patent may be filed during the prescribed period. If no opposition was filed during that period, a patent will be granted. On the other hand, in case of post-grant proceedings, after the publication of a granted patent, third parties are given the possibility to oppose the grant before the patent Office within a certain time period. Therefore, a post-grant opposition system does not extend the period between the filing of the application and the grant of a patent, keeping in mind, however, that the number of applications subject to opposition is rather limited. In Europe, for example, the opposition proceedings usually take two to three years and the ratio of opposition to granted patents is about 5%.[58] In India, the opposition rate is around 4%.[59]

200. In addition to the differences between post-grant and pre-grant oppositions, the national/regional laws vary significantly in terms of both procedural and substantive requirements. Those differences include: the time limit to submit a request for opposition, the extent of participation by the opponent during the proceedings, whether it is an *inter partes* or *ex parte* procedure and whether a self-opposition by the applicant/patentee is permitted or not.

(d) Demand Management

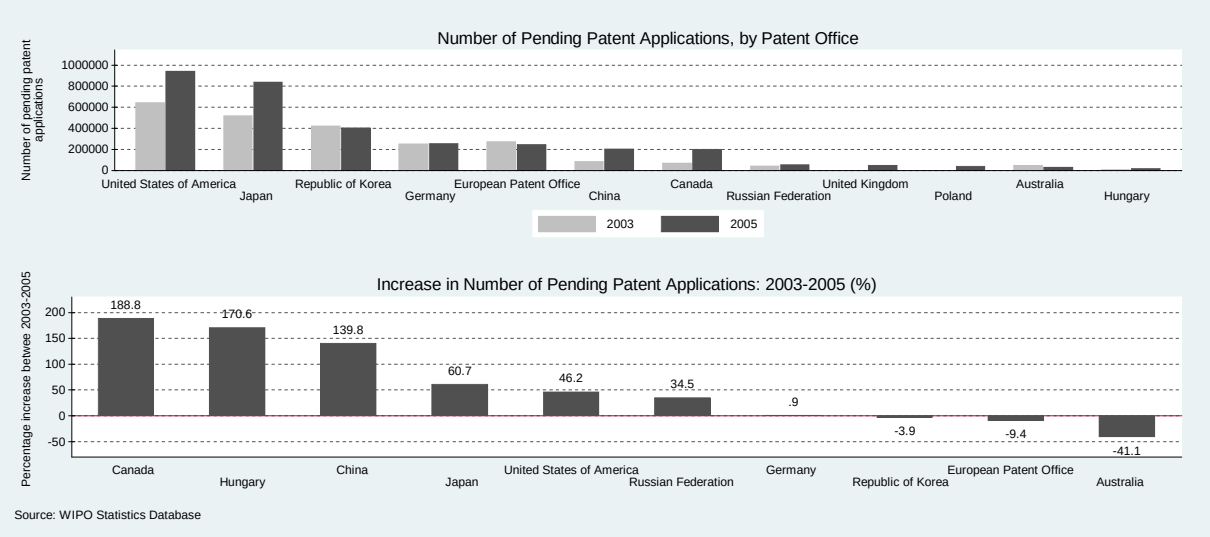
201. The increase in demand for patent rights places additional pressures on patent offices to examine and grant, or refuse, patent applications. Eventually, this results in increased backlogs in patent offices, and increasing pendency periods. Figure 11 shows, for those patent offices for which statistics are available, the number of patent applications pending examination in 2005 and the increase, or decrease, since 2003. Note that the definition of "pending application" may vary from one office to another due to different procedures,

[58] Adam Jolly and Jeremy Philpott "The Handbook of European Intellectual Property Management"; European Patent Office, Annual Report 2006.

[59] Intellectual Property India, Annual Report 2005-2006.

therefore the absolute numbers of pending applications in different offices may not be directly comparable.

Figure 11: Pending Patent Applications by Patent Office



202. The United States of America and Japan have the largest numbers of pending patent applications and the numbers have increased by 46.2% and 60.7%, respectively, between 2003 and 2005. It should be noted that, in the case of Japan, recent changes to the time limit for a request for examination have led to an exceptional increase in the examination workload which should decrease significantly in the next few years. Large increases are also seen in Canada, Hungary and China.

203. In some offices, such as Germany, the Republic of Korea and the European Patent Office, the numbers of pending applications have been relatively stable in recent years whereas a small number of offices have reduced the numbers of pending applications.

204. Consequently, countries have been taking various national measures to cope with the increasing demand with limited resources. Those measures include, for example:

- simplification and streamlining of the procedures before the office;

- hiring, training and retention of human resources;

- effective utilization of information technology for the purposes of office procedures as well as communication with applicants and representatives; and

- out-sourcing certain administrative tasks to a private sector.

205. Further, some offices have established practices to discourage applicants to file a large number of claims or mega applications through legal requirements as well as through the fee structure.

206. National measures, however, have a limited effect on resolving the issue of growing demand. The increase in the number of filings by non-residents in patent offices worldwide is one of the forces behind the increases in workload and numbers of pending applications.

There is evidence to suggest that, in many cases, applications for the same invention are being examined multiple times by different patent offices. Consequently, countries are increasingly seeking for international cooperation. One of the ways to effectively cooperate is to identify duplication undertaken by more than one office with regard to applications containing the same invention, and to streamline such duplication at the international level.

207. As regards the national and regional patent procedures, the major part of duplication in terms of workload of the offices is attributed to the search and examination processes, since they require considerable resources: competent substantive examiners who cover all fields of technology and are familiar with both technology and the patent law, shall read patent applications, conduct a search on patent and non-patent literature, and analyze the patentability of claimed inventions. According to Trilateral statistics, among the first applications filed in the Trilateral offices, around 240,000 applications are filed in more than one Trilateral offices, and thus search and examination work has been duplicated.[60]

208. Therefore, using search and examination results of other offices with respect to family applications is considered one of the promising means to cope with the increasing number of patent applications. As described under sub-Chapter (b), the form of such utilization varies from a unilateral decision to use search and examination results of other offices to more sophisticated and systematic way of usage. If the common usage of search and examination reports is one way to address demand management, questions arise as to what can be done, at the international level, to effectively support the international utilization of those reports and how to increase confidence towards the work done by other offices, in view of the fact that differences are observed under the national laws and practices regarding some key issues on patentability, such as novelty and inventive step.

209. With respect to the PCT procedure, as described under sub-Chapter (b), avoiding duplication of the procedures under the international phase and the procedures under the national phase would facilitate streamlining the whole PCT procedure. Further, duplication of work by the different offices involved, such as the receiving office, the International Searching Authority, the International Preliminary Examination Authority, the International Bureau and the designated/elected office, should be avoided for efficient operation of the system.

(e) Prior Art

210. "Prior art" determines the scope of novelty and inventive step, two major patentability requirements that prevent patents from being granted in respect of inventions which already exist or which are obvious compared to existing inventions. "Prior art" is, in general, all knowledge that has been made available to the public prior to the filing or priority date of a patent application under examination, whether it existed by way of written or oral disclosure or by way of public use.[61] Today, information published on the Internet is increasingly taken

[60] Trilateral Statistical Report 2006, Fig. 3.13 [http://www.trilateral.net/tsr/tsr_2006/3_worldwide_pat_act_2006.pdf].

[61] In some countries, even if it has not been made available to the public, an invention which was on sale in the country before the relevant date forms part of the prior art.

into consideration.[62] The questions as to what should constitute "prior art" at a given time, and the scope and timing of the "availability to the public",[63] have been the subject of debate for a long time in the context of the draft Treaty Supplementing the Paris Convention as Far as Patents Are Concerned (draft 1991 Patent Harmonization Treaty) and the draft SPLT. Although national/regional laws provide different definitions, as described in Annex II, many similarities exist among them.

211. One such difference is based on the distinction between printed publications and other disclosures such as oral disclosures and prior use. In some countries, information which was publicly disclosed orally or through use in a foreign country does not constitute part of the prior art. Accordingly, under the patent law of those countries, a patent may be granted on an invention which is identical to, or obvious from, undocumented knowledge already available in the public domain, for example, in the form of traditional knowledge, in another country. Without a universal recognition of the prior art effect, there is the risk that patent rights are granted on subject matter that is already in the public domain in another country. Further, in view of the increasing operational cooperation among patent offices, a universal understanding of the definition of prior art is the basis for a common understanding with respect to novelty and inventive step.

212. Another major difference among national/regional laws is the prior art effect of an application filed earlier, but published after the filing (priority) date of the application under examination. However, harmonization of the legal requirements on this particular point may have less impact on the operational cooperation among patent offices, since the earlier applications filed in a national office are different from one country to the other.

213. Since most countries apply a broad definition of prior art, i.e., any information made available to the public in any form without any geographical limitation form part of the prior art, it is essential to ensure an efficient and effective access to prior art information, in order to ensure a credible determination of novelty and inventive step.

(f) Novelty

214. It is generally understood that the patent system is a social contract between the inventor and the public: on the one hand, it grants exclusive rights to a patentee to prevent others from commercially using the patented invention without his consent, and on the other hand, it obliges him to disclose his invention in a manner that the invention can be carried out by a person skilled in the art. Since one of the features of the patent system is to make new information available to the public in exchange of the exclusive rights, an invention which has already been put in the public domain (and thus the public does not gain any new information through its disclosure) should be, by definition, excluded from patent protection.

215. Consequently, novelty of the invention is a fundamental and undisputed condition of patentability in any patent system. In Article 27.1, the TRIPS Agreement provides that, in order to be patentable, an invention shall be new. Since only the absence of novelty, but not

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[62] "Results of the Questionnaires Concerning Disclosure of Information on the Internet and Other Issues Relating to the Internet" (WIPO document SCP/5/4); "Disclosure of Technical Information on the Internet and its Impact on Patentability" (WIPO document SCP/4/5).

[63] "Information Provided by Members of the Standing Committee on the Law of Patents (SCP) Concerning the Definition of Prior Art - Brief Summary" (WIPO document SCP/6/INF/2).

its existence can be proved, in general, an invention is new if it does not form part of the prior art, or was not known, used or described before the filing or priority date.

216. Further, in order to examine whether a claimed invention is novel or not, it is necessary to determine the scope of the claimed invention. How claims are interpreted and how the scope of the claims is defined are thus decisive factors for examining the novelty.

(g) Inventive Step

217. As stated above, an exclusive patent right is justified only where it meets the objective of the patent system, i.e., to provide incentives to create new and useful inventions, which would benefit society at large. Obviously, an invention that already exists does not contribute to technological development and to social benefit. In addition, granting an exclusive right to an invention which can be obviously or easily conceived by others does not promote innovation and technological and economic development. Rather, it prevents others from using and making inventions that are nothing more than obvious modifications to the existing state of the art. Therefore, in order to justify the grant of an exclusive patent right, the invention shall, among other criteria, exhibit a sufficient "inventive step" (be non-obvious). In Article 27.1, the TRIPS Agreement provides that, in order to be patentable, an invention shall involve an inventive step.

218. In many laws, the inventive step requirement means that a claimed invention shall not be obvious to a person skilled in the art at the time of the filing date (or, where applicable, priority date), or at the time the invention was made, in view of the prior art. In some countries, instead of the expression "obvious" (or "non-obvious"), expressions such as "inventions which could have been easily made" or "[an invention] having prominent substantive features and representing a notable progress" appear in national laws (see Annex II). Whatever term is used, the definition of "prior art" or "state of the art", directly affects the determination of the inventive step. Where the scope of the prior art is limited, it is more likely that a certain claimed invention would be considered as involving an inventive step. Further, as for the novelty requirement, the interpretation and determination of the scope of the claimed invention is essential for the determination of the inventive step.

219. National and regional authorities have developed various methodologies that can be applied when assessing inventive step, such as the "problem and solution"-approach used in the EPO, the "Graham test" in the United States of America and the "reasoning test" in Japan. Further, the interpretation of the term "inventive step"("non-obviousness") by national courts has developed into a body of case law in many countries. Since a vast majority of inventions are based on existing inventions, how to assess inventive step in an invention based on a combination of existing features has been extensively developed in a number of jurisdictions. Based on such case law, a number of patent offices publish examination guidelines, which are addressed primarily to the office's examiners for consistent application of the law, but also to applicants and patent practitioners for a better understanding of office practices.[64] Such examination guidelines typically contain the methodology, various factors to be taken into consideration (for example, problems to be solved by the invention, advantageous effects of the invention and secondary considerations such as commercial success and long-felt needs) and practical examples in various technical fields.

[64] http://www.wipo.int/patent-law/en/guidelines.html.

220. The concrete application of the inventive step requirement is quite complex and it cannot be simply limited to a debate on a “high” level of inventive step versus a “low” level of inventive step.

(h) Grace Period

221. As indicated in sub-Chapter (e) above, in principle, any information made available to the public becomes part of the prior art. In other words, once an invention is made available to the public, it is not (or at least should not be) possible to obtain a patent on the same invention or on an invention which is obvious from the invention made available to the public. However, the strict observation of such rule may not always be appropriate in view of striking a balance between the interest of the inventor and those of third parties. For example, it may not be justified that each and every public disclosure, even if it was beyond the control of the inventor, should lead to the loss of the opportunity to obtain a patent. In other cases, the inventor may not be able to wait for disclosing his invention to a potential future partner or investor until the filing of the patent application. Under other circumstances, public research organizations, universities and certain firms may wish to disclose the results of the research to the public as early as possible, which may in fact facilitate access to research results by third parties. Therefore, preventing all public disclosures of an invention before the filing date may delay the dissemination of the knowledge to the public and be unreasonably restrictive to the inventor. On the other hand, any exception to the definition of prior art should take into account the legitimate interests of the inventor as well as of third parties.

222. Under the patent law of the United States of America, which applies the first-to-invent principle, the public disclosure of an invention before the filing date as such does not affect the patentabilty of the invention. If there was no time limit to file a patent application, an inventor would have no incentive to file a patent application in the first place, but rather, he might file a patent application and seek patent protection only where a competitor brings the same invention to the market. Such a strategy would increase legal uncertainty for third parties. Therefore, according to Section 102(b) of U.S.C. 35, an invention which was patented, described in a printed publication in any country or in public use or on sale in the United States of America more than one year prior to the filing date forms part of the prior art. In other words, where an invention was disclosed in a certain manner, the inventor has one year to file a patent application. Such a mechanism provides the possibility for an inventor to publicly disclose his invention under certain conditions prior to the filing of a patent application.

223. Lack or inadequacy of protection of industrial property at international exhibitions was one of the reasons which promoted the conclusion of the Paris Convention in 1883. The Paris Convention provides, in Article 11, an obligation for member States to establish and maintain legislation in order to protect patentable inventions in respect of goods exhibited at official or officially recognized international exhibitions held in the territory of any member States. The Convention, however, leaves it to the domestic legislation of a member State to choose the means for offering such protection, including the duration of the temporary protection. Consequently, as it can be observed in Annex II, the types of disclosures that are covered by the grace period, its length and conditions are not harmonized, although we can observe certain patterns in many countries.

224. One of the peculiarities of the grace period in the international patent system is that, unless a uniform grace period at the international level is established, an applicant cannot fully enjoy the benefits of the grace period at the national level, since the disclosure made

under certain conditions in one place might affect patentability in other countries. For example, if the duration of the grace period differs among national/regional laws, the applicant has no other choice than preparing and filing patent applications on the basis of the shortest grace period, and would need to be familiar with different rules under different national/regional laws. Even worse, if one of the countries in which the applicant seeks patent protection has no grace period, the applicant can practically not enjoy the benefits of the grace period in all those countries. The grace period also serves as a safety net for an applicant who is not aware of the definition of prior art under the patent law and inadvertently disclosed his invention to the public before filing a patent application.

(i) Sufficiency of Disclosure

225. As described in Chapter II, one of the pillars that justifies the patent system is the public disclosure function of the system. Consequently, one of the important requirements under the patent law is that the invention shall be sufficiently disclosed in the patent application so that, once it is published, the innovative knowledge contained in the patent application can be disseminated to the public.

226. According to Article 29.1 of the TRIPS Agreement, Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. Consequently, this is the minimum standard for WTO members, and as it can be found in Annex II, the provisions of national/regional laws are largely harmonized in this area. The interpretation of the provisions and of national/regional practices, however, may be more nuanced. The questions arising in respect of the interpretation of the disclosure requirement include, for example, the following: what is the definition of a “person skilled in the art”? What is the extent of disclosure that can be considered “sufficient and complete”? At which point in time shall the disclosure of the invention be considered sufficient?

227. Article 29.1 of the TRIPS Agreement further states that members may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date, or where priority is claimed, at the priority date of the application. Consequently, some countries require the best mode to be indicated in the application, while other countries allow any mode for carrying out the invention (see Annex II).

228. Further, in many countries, where the application refers to biologically reproducible material which cannot be sufficiently disclosed in the written application, the sufficient disclosure requirement is considered to be complied with by the deposit of such material, to the extent that the disclosure requirement cannot otherwise be complied with. The Budapest Treaty provides a mechanism that the deposit of a microorganism with any “international depositary authority” suffices for the purposes of patent procedure before the national patent offices of the Contracting States (and regional patent offices which recognize such effect) in order to eliminate the need to deposit the microorganism in each country in which patent protection is sought. The Budapest Treaty, however, does not regulate the formal and substantive requirements concerning national/regional deposits with respect to national/regional applications under the laws of its Contracting States. For example, the timing for the deposit to be made is not internationally harmonized. In certain countries, the deposit has to be made at the latest on the filing date of the application, while at least in one country, it may be made during the pendency of the application under certain conditions.

(j) Subject Matter Coverage and Exclusions

229. What is considered subject matter entitled to patent protection? This is one of the fundamental questions that characterize the patent system. There is a general understanding that the patent system protects "inventions", but not literary or artistic works, signs or aesthetic appearances. Article 27.1 of the TRIPS Agreement states that, in principle, "any inventions, whether products or processes, in all fields of technology" shall enjoy patent protection. The scope of the term "invention", as well as how it is defined in the national legislation, are not uniform, although certain common underlying features can be found (see Annex II). The differences in the national laws reflect the political choice of the country concerned in view of the aim of the patent system to promote innovation and technological and economic development.

230. One of the differences is that in the majority of the countries, the concept of invention includes some form of technical character or technical idea. Therefore, business methods as such and financial methods as such are not patentable subject matter in most countries. In other countries, technicality is not a requirement for patentable subject matter. Further, in some countries, the term "invention" is defined in the law, while in others, the scope of the term "invention" needs to be extracted from a non-exhaustive list of subject matter.

231. As an exception to the above general scope of the invention, Article 27.2 and 3 of the TRIPS Agreement provide that certain inventions may be excluded from patentability by WTO Members. Those inventions are:

- inventions the prevention within their territory of the commercial exploitation of which is necessary to protect order public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law (TRIPS Agreement, Article 27.2);

- diagnostic, therapeutic and surgical methods for the treatment of human or animals (TRIPS Agreement, Article 27.3(a));

- plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof (TRIPS Agreement, Article 27.3(b)).

232. Consequently, a number of countries provide some or all of those exceptions in the national legislation (see Annex II).

233. In connection with subject matter coverage and exceptions, Article 4*quater* of the Paris Convention provides that the Contracting States shall not refuse the grant of a patent or invalidate a patent on the ground that the sale of the patented product or of a product obtained by means of a patented process is subject to restrictions or limitations resulting from the domestic law, for example, relating to the security or quality of the product.

234. As provided in Article 27.3(b) of the TRIPS Agreement, this provision has been under review at the Council for TRIPS since December 1998. The Doha Ministerial Declaration[65] touched upon the review of Article 27.3(b) together with the review of the implementation of the TRIPS Agreement under Article 71.1 and negotiations on outstanding implementing issues. The Doha Ministerial Declaration mandated the Council for TRIPS to examine, *inter alia*, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by members pursuant to Article 71.1. In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension.

(k) Exceptions and Limitations to the Rights

235. In view of the policy objective of the patent system, the scope of the exclusive patent right is carefully designed under national patent laws, which aims to strike a balance between the legitimate interests of the right holders and the legitimate interests of third parties. Article 30 of the TRIPS Agreement allows members to provide exceptions to the exclusive rights conferred, provided that such exceptions do not conflict with the normal exploitation of the patent and do not prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties.

236. The Paris Convention, in Article 5, also contains provisions concerning compulsory licenses. Further, Article 5*ter* provides certain limitations on the exclusive rights in cases where strict enforcement of such rights may be prejudicial to public interest in maintaining freedom of transport. In principle, if ships, aircraft or land vehicles temporarily enter the territory of foreign countries, it is not necessary to obtain licenses on patents in force in these countries in order to avoid infringing such patents.

237. Taking into consideration the above international rules, a number of countries provide in their national legislations certain exceptions and limitations to the exclusive rights (see Annex II). For example, the rights conferred by a patent do not extend to the following acts under some national laws:

- acts done for private and non-commercial use;

- uses for articles on aircraft, land vehicles or vessels of other countries which temporarily or accidentally enter the airspace, territory or waters of the respective country;

- acts done only for experimental purposes or research purposes;

- acts performed by any person who, in good faith, before the filing date (priority date) of the application on which the patent is granted, was using the invention or was making effective and serious preparation for such use in the respective country (prior user's exception);

- acts solely for uses reasonably related to the development and submission of information required for obtaining a regulatory approval;

[65] http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm.

- preparation of drugs in accordance with a medical prescription.

238. Further, in Article 31, the TRIPS Agreement provides that a Member may allow, under the stipulated conditions, other use than that allowed under Article 30 without authorization of the right holder. In connection with Article 31, the Doha Ministerial Declaration on the TRIPS Agreement and Public Health[66] specifically states that each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted, and to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency. Furthermore, in order to solve the problem of Members with insufficient or no manufacturing capacities in the pharmaceutical sector facing difficulties in making effective use of compulsory licensing under the TRIPS Agreement, following the instruction under paragraph 6 of the Doha Ministerial Declaration on the TRIPS Agreement and Public Health, WTO Members decided on a "waiver" that removed limitations on exports under compulsory license to countries that cannot manufacture the pharmaceuticals themselves in 2003[67] and made that decision permanent by amending the TRIPS Agreement.[68]

239. As regards the exhaustion of the patent right, Article 6 of the TRIPS Agreement states that, for purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 of the TRIPS Agreement, nothing in the TRIPS Agreement shall be used to address the issue of exhaustion of intellectual property rights. The Doha Ministerial Declaration on the TRIPS Agreement and Public Health clarified that the effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions under the Agreement.

240. The above exceptions limit the enforcement of rights conferred by a patent. In the laws of some countries, there exist exceptions that extend the enforcement of rights, i.e., acts which may be deemed as patent infringement under certain circumstances. An example of such exceptions is an indirect infringement or a contributory infringement. In principle, making, using and selling only one or some elements of the claimed invention does not constitute infringement. However, a strict application of such principle may not always protect the right holder from a third party who unfairly took advantage of the patented invention. For example, a third party may supply parts which relate to material elements of the patented invention for a final assembly by individuals, or a third party supplies a machine which is exclusively used to make a patented invention. Taking into account the legitimate interests of the right holder and the legitimate interests of third parties, certain actions are considered as indirect infringement, under some national laws. The conditions of indirect infringement, however, are significantly different from one country to another.

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66 http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.
67 http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.
68 http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm.

(l) Quality

(i) Objectives of Quality Management

241. Errors in patent grant and administration procedures can cause difficulties for rights-holders, competitors, users of patent information and the patent Offices themselves. Correcting an error can be difficult and expensive. Failure to recognize that an error exists can also have costly effects. For example, the grant of a patent which does not meet the necessary requirements may cause competitors to believe that they cannot enter the relevant market unless they negotiate a license with the patentee, or they might have to undergo expensive litigation in order to have the patent revoked to avoid an infringement action. Failure to update the register to show that a patent has been renewed may mean that the patent has expired and competitors may begin to make investments, only to discover later that the patent was still in force.

242. Consequently, many offices have introduced quality management systems to ensure that their procedures are appropriate for delivering high quality results. Some have had their quality management systems certified in accordance with a recognized standard, most commonly ISO 9001:2000. Such standards cover the processes and systems of an organization rather than the quality of the service actually delivered, but are indicative that systems are in place which encourage high quality results and measure outputs to check the quality of the work and to address any problems, thus encouraging continued improvements in systems.

243. Actual implementations of quality management systems vary enormously from office to office, depending on office size and the types of work involved (examination systems differ greatly in needs from registration systems). The details need to be tailored to meet the particular needs of the Office and its partners (such as Offices in other States) and users (including patent applicants and those affected by national rights or using the published information). However, certain general principles run through any system operating at various levels. At a fundamental level, the Office should be clear on its functions and provide the necessary resources (staff, premises, equipment and training) to deliver these functions effectively. Procedures should be properly documented and feedback mechanisms provided (both internal and through customer communication) to identify problems and opportunities so that procedures could be improved to avoid recurrence of problems. Staff responsibilities should be clear and, to the extent possible, objectives should be measurable.

(ii) Importance of Quality Management at the International Level

244. Quality management is important to individual Offices for ensuring that their own domestic responsibilities are discharged properly. However, it also has an international aspect in that a large proportion of patent applications are pursued in more than one jurisdiction, whether through the Paris Convention or PCT route. In such cases, the same application (subject to translation and changes designed to meet particular local requirements) is processed separately and often simultaneously by several different Offices, each conducting effectively the same checks in parallel. In the case of large Offices, the result is an enormous amount of duplicated work. Clearly, each Office has a responsibility to ensure that the local standards are met, but the effort involved in doing this can be significantly reduced if an Office clearly understands what work is being done by other Offices, taking into account any significant differences between their patent systems, so that further work only needs to be done to the extent that it is objectively necessary.

245. Even in the case where two Offices have very different procedures, knowledge of the other Office's quality management systems may be important. For example, in the case of an office where applications are registered without first conducting search and examination, it may be of relevance for applicants and third parties to know the outcome of search and examination in other offices. In this case, knowledge of the existence of effective quality management systems in such other offices may significantly increase the confidence in the reader's view of the reports and granted patents, allowing a better assessment of the extent to which the local patent meets domestic patentability requirements.

(iii) Existing Mechanisms to Ensure Quality

246. Existing quality management systems take a wide variety of forms. Most major offices have had some form of quality review for many years. In the last decade, many have seen the need to review and extend these systems to ensure that they are truly comprehensive, rather than providing isolated quality review systems for individual functions (especially search and examination) which have often developed independently and in an *ad-hoc* manner. The main influences on these systems have been the popular quality management approaches, such as ISO 9001:2001 and the EFQM Excellence Model, as well as the PCT Common Quality Framework for International Search and Preliminary Examination, set out in Chapter 21 of the PCT International Search and Preliminary Guidelines. These Guidelines require International Authorities under the PCT to establish quality management systems with certain features important to ensuring effective search and examination according to the requirements of the PCT. The systems established in accordance with the Guidelines are reported by International Authorities and discussed by the Meeting of International Authorities. Other mechanisms for common discussion and development of quality systems also exist where Offices work together on a formal basis, most notably the European Quality System which forms an integral part of the European Patent Network established within the European Patent Organisation.

247. It should also be recalled that many patent laws have quality-related aspects built into them. As described in sub-Chapters (b) and (c), these include requirements for search and examination, the opportunity for third parties to make comments or even become directly involved in the review of rights through opposition or validity proceedings, and requirements for patent applicants to submit information relating to searches and examinations carried out on corresponding applications in other States. Offices are exploring means to extend such reviews to be faster, cheaper and more effective.

(m) Challenges in the Fields of Emerging Technologies

248. Technologies develop and new technologies emerge constantly. The term "Internet year" typically describes the incredible speed of new technological development and possibilities that could be offered to the public. Since their creation, the patent system has faced, and developed together with, new developments in technologies such as mechanics, chemistry and electronics. More recently, it has been facing challenges from biotechnology, digital technology and nanotechnology. The aim of the patent system, i.e., to foster innovation, put the patent law in a position that it is constantly reviewed in the face of new technological developments.

249. There are a number of systemic challenges when the patent law faces new emerging technology. The first area of concern relates to the question as to whether a new innovation is

covered by patentable subject matter under the patent law (also see sub-Chapter (j) above). Biological materials, transgenic living entities and software implemented business methods are some examples that have spurred debates. Secondly, when a new technology emerges, there are few relevant items of prior art which provide the basis for determining novelty and inventive step. Also, when the technology is very new, for example, the current stage of nanotechnology, it is said that there is no set of established nomenclature within the field. With few references to conduct patentability examination on the one hand and various undefined terms used by experts on the other hand, it is often criticized that patents are issued on overly broad claims at the time the new technology emerges. In the same manner, determining the compliance with the disclosure requirement and industrial applicability (utility) requirement can also be difficult. Past experiences suggest that, with the development of technology from a cutting-edge stage to a more mature stage, questions relating to the applications of patent law on that technology would gradually be clarified and legal certainty and predictability would increase due to convergence of practices and case law.

250. Since the exclusive right conferred by a patent is justified by public disclosure of the full scope of the patented invention, defining the breadth of the claims which are supported by the disclosure of the invention is a cornerstone of the patent system. However, with very little information available in the field, the right amount of disclosure is not always obvious. The above difficulties are aggravated when technology develops in a cross-cutting area, such as bioinformatics and nanotechnology. The comprehensive analysis of the technology and the determination of patentability are more complicated in such cross-disciplinary field of technology.

251. Beyond those concerns addressing the compatibility of new inventions with the current patent law, a more fundamental question has also been posed. That is, whether the current patent law is an appropriate mechanism to foster innovation in a specific new technological area. For example, licensing and other issues related to the exploitation of patents are areas of discussion particularly in the areas of biotechnology and information and communication technology. In the biotechnological field, down-stream innovations may be covered by a broad patent granted at an early stage of innovation. It was pointed out that an extensive patenting of upstream research may hinder the development of downstream research. The number and breadth of patents granted to early fundamental research have raised concerns about patent thickets and royalty stacking. Particularly in the area of biotechnology, reach-through claims in patents, especially for research tools, were flagged as potential impediments to further research and development.[69] Ethical issues (see Chapter IX) surrounding the enforcement of biotechnological inventions are controversial as well. Further, recent developments in the field of information and communication technology have brought the possibility of consolidating various features and functions into one product. This possibility could be further extended by nanotechnology. As described in Chapter VIII(c), situations which are so-called “patent thickets” have been addressed by recent studies.

252. In the area of software-implemented inventions, due to the special characteristics of software innovation, some people consider that patent protection of software would inhibit competition in this field. It is said that software innovation typically involves cumulative,

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[69] Various arguments concerning gene patents are summarized in “Gene Patents: A brief Overview of Intellectual Property Issues” CRS Reports for Congress, October 3, 2006; W Cohen and J. Walsh “Real Impediment to Academic Biomedical Research”, May 15, 2007, [http://www.nber.org/books_in_progress/innovation8/cohen-walsh6-19-07.pdf].

sequential development and re-use of others' work. In the field of information and communication technology, it inherently requires that the users are "connected". In other words, the value of a good or service depends on the number of users of that good or service (network effect). In order to communicate and share information and files, interoperability needs to be preserved among programs, systems and network components. Under those circumstances, a lock-in effect may occur. Consequently, some argue that the mechanism of the patent system that grants an exclusive right does not promote the development of the software industry, but promotes other models such as an open source.

253. The open source provides successful alternative models to manage the ownership of the copyright on software. One of the concerns relating to open source software is that software developed under an open source license may infringe a patent covering the open source software. In order to cope with the reality that a number of computer-implemented inventions have been granted in many jurisdictions, the GNU General Public License version 3 (GPL v3) explicitly provides that users are protected from patent infringement suit by the program's contributors and redistributors.

VII. SUPPORT STRUCTURES FOR THE PATENT SYSTEM

254. The patent system does not exist in a vacuum. In order to truly empower the patent system as a tool for technological development and economic growth, it has to be viewed in a broader context, together with national economic and development policies and strategies. A number of countries have thus formulated national intellectual property policies which are integrated in their scientific, cultural, trade, economic and educational policies.[70] The intellectual property policies support coherent and effective implementation of intellectual property strategies nation-wide with a view to optimizing the benefits derived from intellectual property rights.

255. While the patent law provides the legal framework for the patent system, a number of other features support the patent system so that it works in the way it is intended to work. To name but a few, human resource development, education, effective and efficient IP office administration, awareness of the potential impact of the patent system by researchers in the private and public sectors, universities, civil societies and the public, and effective and efficient enforcement of rights by judiciaries and customs. Where a dispute relating to the enforcement of rights or the validity of patents cannot be resolved between the parties, the possibility of settling the dispute through arbitration or mediation exists if both parties agree. However, in some cases, a court ruling is sought to resolve the dispute. Therefore, accessibility of court procedures, legal certainty and timely judgments are relevant to the effectiveness of the patent system (see Chapter VIII(a)). Further, in order to leverage the value of the IP assets, the market structure should be supportive to knowledge dissemination and technology transfer.

(a) Patent Attorneys

256. Among the various direct and indirect support mechanisms in respect of the patent system, patent attorneys and patent agents play a significant role in developing a functioning patent system. They are generally recorded in a registry of industrial property offices after

[70] http://www.wipo.int/ip-development/en/strategies/national_ip_strategies.html.

passing qualifying examinations. However, it is not possible to generally define the title "patent attorney" or "patent agent", since the qualification and the bestowed power under the applicable law are different from one country to the other. In some countries, patent attorneys may be legally qualified in general law and additionally pass an examination. Consequently, they are entitled to represent a party before the courts. In other countries, patent attorneys may not be required to have legal qualification (although they may need to have at least intellectual property law expertise and legal training).[71]

257. The role of patent attorneys is, in general, giving advice and assisting inventors and applicants in order to obtain and maintain patents: for example, drafting and preparation of patent applications, representing the applicant before the patent office, responding to office actions and assisting the patentee to maintain and enforce his right. The patent attorneys may also represent a third party during the opposition and invalidation proceedings. Therefore, not only the knowledge of technology, but also the knowledge of at least substantive and procedural patent law as well as some familiarity with case law are required to become a patent attorney. The patent attorney should be able to provide a full range of possible protection or enforcement option available to the client and assist the client if a patent was erroneously granted or an abuse of right was found.

258. The patent attorneys, therefore, play an important role in the "checks and balances" mechanism of the patent system. Whether a local inventor can obtain patent protection with a maximum scope of claims, whether he can defend his rights or whether he can successfully challenge another's patent may, to a significant extent, depend on the skills of his local patent attorney. A recent report shows that low public awareness of IP creates less IP business opportunities, which leads to a vicious circle of lower availability of professional IP services and lesser familiarity with IP.[72]

(b) Professional Privilege

259. In general, when a client seeks an opinion from a qualified lawyer, communications between the lawyer and his client are accorded the "privilege" of not being required to be disclosed in a court of law. The purpose of establishing such a privilege is to encourage those who seek advice and those who provide advice to be fully transparent and honest in the process. Those who seek advice should provide the advisor with all the information that could be relevant to obtain the best advice, including aspects which may run counter to his position. On the other hand, the advisor should be able to be completely frank. Therefore, in order to ensure a high quality of legal advice, the exchange of instructions and advice should not be restricted due to the fear of disclosure of their communications.

260. In the course of a legal action for patent infringement, it is usual for one side or the other to oblige another party to disclose any documents relating to the communication between the patent attorney and the party in the hope that damaging statements may be found on the record which would destroy an alleged infringer's defense or show that there had been

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[71] In view of the diversity of the definition, the term "patent attorney" is used in this paper to describe a person who is a professional representative, in a general sense, for the purposes of patent prosecution.

[72] Prof. T. Ogada "Challenges Faced by Developing Countries in Teaching and Conducting Research on Intellectual Property" [http://www.wipo.int/academy/en/meetings/iped_sym_05/papers/pdf/ogada_paper.pdf].

abuse of rights by the patentee. Communications between patent attorneys and clients often contain technical matters which are closely inter-related with legal questions under consideration by a court. However, when a client seeks the opinion of a patent attorney, not all countries provide privilege to the advice the patent attorney gave to his client or keep the communication between the patent attorney and the client confidential from the court. The national rules in this respect vary significantly from one country to another. Some countries recognize that legal professional privilege extends to patent attorneys. On the contrary, some countries do not recognize a privilege between patent attorneys and their clients. In some countries, the protection of patent attorneys' communications takes another form or receives additional protection, for example, it may be a crime or violation of professional rules for a patent attorney to disclose clients' confidences.[73] Even if the patent attorney's privilege is recognized, the scope of communications covered by the privilege and the extent of privilege that overseas patent attorneys enjoy are different from one country to another. In some countries, the patent attorney's privilege is recognized for the qualified patent attorneys in that country, but not for patent attorneys qualified overseas.

261. Since more and more applicants seek patent protection abroad, the lack of uniform standards on privilege and on the recognition of a privilege in different countries causes serious concerns among practitioners. For example, if the privilege is not recognized in one of the several countries in which a patent owner wishes to enforce his patent, there is a risk that he receives an order by a court which does not recognize the legal privilege to disclose the contents of the confidential communications of the advice obtained in the country in which the privilege is available. Consequently, the effect of the privilege in the advice will be lost. In another case, if only patent attorneys who are qualified in the country can enjoy a professional privilege before the court of that country, a client is not protected from a court's order that requires the disclosure of communication between the client and an overseas patent attorney with respect to the patent under question and corresponding family applications and patents.

262. In view of the lack of standardized rules available at the international level, the International Association for the Protection of Intellectual Property (AIPPI) adopted a resolution on the Attorney-Client Privilege and the Patent and/or Trademark Attorneys Profession in 2003, in which it supports the provision of attorney-client privilege for patent and trademark attorneys throughout all of the national jurisdictions.[74]

(c) Creating a Marketplace

263. Against the backdrop of intensifying global competition, the R&D cycle of products is becoming shorter and shorter. Further, technology has become more complex and sophisticated. To meet such challenges, in addition to the traditional vertical integration of the value chain, open innovation models have been widely introduced in the business sector.[75] Instead of conducting and performing all the activities from R&D to the market entry within the same company, procurement of knowledge is sought from external sources through, for example, contractual research, R&D cooperation, licensing and outsourcing. Collaboration

[73] Report of AIPPI Special Committee Q163, March 2002.

[74] Resolution, Question 163 — Attorney-Client Privilege and the Patent and/or Trademark Attorneys Profession, AIPPI; in cooperation with the AIPPI, WIPO will organize a Conference on Client Privilege in Intellectual Property Professional Advice on May 22 and 23, 2008 in Geneva.

[75] The Economist, October 11, 2007.

with public research institutes and universities, licensing out, creation of joint ventures and spin offs are well-known models. A number of companies invite, on their web sites, new ideas from consumers and others, and offer potential partnerships in order to expand the source of innovation (user-driven innovation model).

264. What is common in all business models regarding open innovation is that there is a transfer of knowledge from one party to another, and the patent system plays a fundamental role to support the mechanism of transferring knowledge between a party who wants to leverage the technology and a party who wants to procure external technology.

265. In order to realize such transactions of technology, in the first place, potential buyers and potential sellers of technology, should be identified. The United States Patent and Trademark Office, for example, publishes information concerning patents available for license and sale in its Official Gazette.[76] A number of national and regional authorities are active in promoting licensing through assisting market assessment and finding business partners. They also provide a user friendly platform on the Internet where potential buyers and sellers can meet.[77] Generally speaking, such platforms provide a description of technology offered/searched or a list of licensable patents and contact information. A number of commercial patent transaction businesses also exist, for example, IP auction businesses.[78]

266. Another common mechanism to encourage technology transfer is to provide financial incentives. A number of countries provide a discount on patent maintenance fees if a patent owner offers a non-exclusive license to any third party. In addition, tax reductions on royalty income generated by patent licenses are accepted in some countries.

267. With the broader recognition that patents are useful instruments to trade technologies, as the term “IP asset” suggests, patents are increasingly recognized to be intangible assets in the financial market. Patents can be exploited as a means to attract external sources of financing. For a small start-up company, patents play an important role to raise funds from venture capital. Some companies offer securitization of patents which uses royalty fees generated from securitized patents as capital for investors. In addition, some banks accept patents as collateral for bank loans. One of the keys to the broader application of transaction of patents is patent valuation. Credible and reliable patent valuation mechanisms, in particular, monetary valuation, are needed in order to further facilitate the transaction of patents.

268. The supportive mechanisms for funding and transferring technology exist not only in developed countries but also in developing countries. For example, the Gujarat Grassroots Innovation Augmentation Network (GIAN) and the National Innovation Foundation (NIF) supported by the Department of Science and Technology in India provide venture capital funding and assist commercialization of high potential grassroots innovation.[79] It is said that,

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[76] http://www.uspto.gov/web/patents/patog/week50/OG/TOC.htm#ref11.

[77] For example, a patent licensing database by Japan’s National Center for Industrial Property Information and Training (NCIPI) [http://www.inpit.go.jp/english/index.html], Innovation Relay Centres (IRCs) by the European Commission [http://irc.cordis.lu], the National Technology Transfer Center (NTTC) in the United States of America [http://www.nttc.edu/default.asp] and IP Market Place for Patents by the Danish Patent and Trademark Office [http://www.dkpto.org/].

[78] It was reported that a patent for a continuous play broadcast system was sold for US$1.75 million at one of those auctions. [Managing Intellectual Property Weekly News, October 26, 2007].

[79] http://www.gian.org.

for those grassroot innovators whose only resource is knowledge, protection of intellectual property rights is necessary to leverage the knowledge.[80] In Malaysia, the Malaysian Technology Development Cooperation was initially set up by the Government of Malaysia in 1992 to promote and commercialize local research and to invest in new ventures that can bring in new technologies from abroad. Since then, it has evolved to an integrated venture capital solutions provider.

VIII. PERCEIVED THREATS TO THE EFFECTIVENESS OF PATENTS AS INCENTIVES TO INNOVATION

269. In general, the patent system is considered to establish a trade-off between the exclusive rights granted to patentees and the public disclosure of patented inventions, aiming at promoting innovative activities by society at large. To this end, policy makers search for an effective and efficient system for obtaining, maintaining, and enforcing rights with an adequate mechanism to disseminate innovative knowledge and technology. In previous chapters, the importance of quality, timing and costs for the effective and efficient patent system that develops hand in hand with the globalization and technological development has been highlighted. In particular, overall costs of obtaining, maintaining and enforcing patents at the international level are primary obstacles for enhancing the access to the international patent system. Since R&D and marketing activities are increasingly carried out across the border, under the principle of territoriality, lack of harmonized rules regarding substantive patent law, court procedures and cross-border jurisdiction, among others, increase costs and the risk of legal uncertainty.

270. The patent system presumes the existence of competitors who are capable of learning and analyzing the published patents and developing further inventions which could be alternatives to the patented invention or a new invention with a new or superior function. Through the promotion of such further innovation by competitors, the public would benefit from increased choice or quality of products available in the market. In the recent past, concerns have been raised as to whether patents are impinging on the possibility of further innovation by third parties by granting exclusive rights on subject matter the availability of which is, by definition, limited. In the case of DNA patents, it is limited by nature, and in the case of patents on standard technologies, alternatives are not possible due to *de jure* or *de facto* rules. The potential conflict between the need to ensure interoperability and the exclusive patent rights in the area of network and communication technology was already mentioned. Is the trade-off between exclusivity and disclosure an effective incentive to boost future innovation while maximizing social welfare?

271. Since a patent right is a negative exclusive right, i.e., it is not a right to use the patented invention, but is a right to prevent others from using such invention without the patentee's consent, it allows the patent to be exploited in various ways. Patented technology can be exclusively used by the patentee. Patents can be used to block competitors from entering the market, or it may be obtained with a view to securing future freedom to operate. The motive to patent may be for a cross-licensing deal, or a patent may be licensed-out for royalty income. Patents may be used for financing purposes or for generating income, such as through a patent auction. In some cases, patents may be obtained in order to provide incentives to employee researchers. Depending on the business environment, those various

[80] http://www.nif.org.in/intellectual_management.

ways of exploitation may be strategically combined for the purpose of maximizing a return on investment.

272. Most recently, patents are used as financial devices for capitalization, and the production of goods can be separated from the exploitation of the rights. One of the most criticized examples are patent trolls. On a positive note, patents can be used to attract venture capital, bank loans or securities markets for, in particular, but not limited to, start-ups. The development of computer and information technology allows us to collect and analyze patent information and other technical data, create and evaluate patent portfolios, and set up patent strategies in more thorough and systematic ways.

273. In this Chapter, three issues, namely, litigation, costs and patent thickets are considered as to their effects on the functioning of the patent system.

(a) Litigation

274. Where a dispute arises in respect of the enforceability of rights, litigation is the last resort to resolve the case. Since a patent is worth nothing if it is not enforceable, accessibility to court procedures, legal certainty and timely judgments play an important role for the correct well-functioning of the patent system. There are a number of questions, however, concerning the functioning of the current litigation system.

275. In general, legal actions in the patent field involve high costs. It is said that the average cost of patent litigation is US$2 million in the United States of America,[81] €150,000 to €1,500,000 in the United Kingdom and €50,000 in Germany.[82] As shown in Chapter II(b), patenting activities are increasingly going beyond national borders. Because the rights attached to patents can be enforced only in the territory of grant, parties face litigation not only in their home country but also abroad with respect to the same invention. The cost of litigation could then become prohibitively expensive for a party without financial resources, such as a private party or a small and medium-sized enterprise. Cross-border litigation raises costs partly because of the fact that patent laws as well as court procedures are different from one country to the other. In the case of patent infringement, courts in different countries estimate damages in different ways. The absence of harmonized rules creates legal uncertainty at the international level, and encourages so-called “forum-shopping” by those who know how to benefit from the differences among national systems or among different courts.

276. The costs and legal uncertainty may further increase due to the time it takes a court to deliver the judgment. The longer it takes, the more not only the parties involved in the case, but also third parties as well as consumers are affected by the legal uncertainty.

277. Since disputes relating to patents may often involve highly technical elements, judges need both legal and technical understanding and competencies. In certain countries, technical experts are assigned to assist judges, or a special patent court, or an intellectual property court, has been established in order to meet the needs of quality and timeliness of the judgments.

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[81] AIPLA 2003 Report of Economic Survey.

[82] Assessment of the Impact of the European Patent Litigation Agreement (EPLA) on Litigation of European Patents, European Patent Office, February 2006.

278. With respect to the remedies available in the case of patent infringement, in general, a patent owner may seek an injunctive order against the infringement, demand damages or seek measures for recovery of damages to the reputation due to such infringement. With the development of patent-based business models and the ever-increasing complexity of technology, some raise concerns over the current practices regarding injunctive relief and the calculation of damages. For example, a number of business models today rely on the patented technology itself and the exploitation of patent rights without any production of patented products. Some of them may be research-based start-ups whose income is based on research results protected by patents. In other cases, they may be patent trolls whose only purpose is claiming damages or high settlement fees through aggressive lawsuits. Should injunctive relief be accorded to all patent infringement cases, and if not, what are the criteria for its application? Similarly, where a product involves thousands of patents, what would be a fair practice to calculate the damages caused by the infringement of one particular patent?

279. Since more parties face litigation not only in their home country but also abroad, questions regarding jurisdiction for infringement actions, such as cross-border injunction, and applicable law have been addressed at the international level in recent years, but the issues have been largely unresolved.[83] Further, since R&D cooperation and business alliances may be formed across borders, disputes regarding the rights of co-owners with respect to the exploitation of patents may be subject to questions of international private law as to which national law would be applicable in a specific case. National laws significantly differ in this regard, although in general, the freedom of the co-owners to regulate their relationship is acknowledged.[84]

280. As alternative mechanisms to settle disputes, mediation, arbitration or other alternative dispute resolutions (ADR) are available. ADR is appropriate for most intellectual property dispute, especially between parties from different jurisdictions. If well managed, it can save money and time, and parties may retain better control over the dispute resolution process.[85]

(b) Patent Thickets

281. In general the term “patent thicket” describes a situation where a product involves a web of patents that are owned by a number of different patentees so that a company which wants to commercialize the product is required to “clear” all the patents involved. This phenomenon is well-known in complex technologies, such as information and communication technologies, and in technical fields where a number of companies compete at the same level so that a fragmentation of patent ownership occurs. A changing research environment, increasing complexity and sophistication of technology and certain patenting strategies may have an influence on patent thickets.

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[83] WIPO Forum on Private International Law and Intellectual Property, Geneva, January 30 and 31, 2001 (see, in particular, WIPO documentWIPO/PIL/01/3); Convention on Choice of Court Agreement, June 30, 2005.

[84] AIPPI Question 194: The Impact of Co-ownership of Intellectual Property Rights on Their Exploitation; Resolution adopted on October 9, 2007.

[85] Further information about WIPO Arbitration and Mediation Center is available at: http://www.wipo.int/amc/en/.

282. Although there is no generally agreed objective definition of the term "patent thicket", it suggests negative effects due to a "thicket" of patents, in particular, in the sense that third parties may be blocked from using a patented technology. The potential problems addressed are centered on the excessive transaction cost. Some suggest that cross-licensing may solve the vertical R&D and hold-up problems. By entering a cross licensing agreement, companies may secure freedom to operate. On the other hand, there is a risk that the problem is exacerbated because each competing company tries to build a bigger patent portfolio than competitors in order to create a better bargaining power to negotiate cross licenses. Another solution consists of patent pools to reduce a transaction cost, although some raise concerns about their compatibility with competition law (see Chapter IV(a)).

283. It can be expected that combination and assimilation of technologies will further develop in the future. The boundaries of so-called "fields of technology" are more and more blurred. The same is true for various industries. It is said that, in the future, communication, computing and consumer electronics (3C) will be integrated in a single home network. According to an OECD report, as innovation becomes more science-based, and multi-disciplinary research draws together researchers and innovators from different fields with different practices for protecting IP, limitations on research access could become more widespread.[86]

284. The results of the empirical studies in this area vary. One study found that, among academic researchers in the biomedical field, only 3% abandoned a project during the last three years because of too many patents covering their research field. It found that access to tangible research input was more problematic, as 20% of academic-to-academic requests were refused.[87] However, another survey found that 40% – including 76% of those in the biosciences industry – responded that their research was affected by difficulties in accessing patented technologies: 58% reported delays, 50% reported changes in their research plans, and 28% abandoned their research. The most common reason for changing or abandoning the research was overly-complex licensing negotiations (58%), followed by high individual royalties (49%).[88]

285. In sum, threats to an effective and efficient patent system are perceived in respect of the following key concepts:

- Accessibility: The access to the international patent system covers not only patent granting procedures but also patent enforcement and invalidation procedures. Overall costs of obtaining and enforcing patents are primary obstacles for enhancing the access to the international patent system and to the benefits derived therefrom. Further, lack of support structures in the social, legal and economic market frameworks is another obstacle. The concept of accessibility also includes accessibility to technologies within the framework of the international patent system at fair cost. Further, certain emerging technologies and some particular business models have raised concerns as to the costs for third parties.

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[86] Valuation and Exploitation of Intellectual Property (OECD document DSTI/DOC(2006)5).

[87] *Reaping the Benefits of Genomic and Proteomic Research*, National Academy of Sciences [http://www.nationalacademies.org/gateway/pga/3330.html].

[88] Intellectual Property in the AAAS Scientific Community: A Descriptive Analysis of the Results of a Pilot Survey on the Effects of Patenting on Science, American Association for the Advancement of Science [http://sippi.aaas.org/survey/].

- Timeliness: The unprecedented increase in demand for patent rights and the subsequent increase of the workload for patent offices has resulted in longer prosecution periods. Although a number of international efforts have been undertaken to address this problem, the need to develop improved platforms to facilitate further cooperation has been advocated.

- Quality: A high legitimacy of the output of patent offices (for example, decisions to grant a patent or refuse a patent application) is desirable, since the costs arising from the mistakes made by patent offices will generally be borne by the users of the patent system, including the general public. An international mechanism to ensure the quality of patents would facilitate further cooperation among the offices. National patentability requirements are also under scrutiny, since national search and examination results increasingly have an international dimension.

- Flexibility: The flexibility of the international patent system has undergone a twofold test. The first test related to the harmonization of patent laws, with a view to enhance accessibility, legal certainty and quality of the system and promote international cooperation. The second one tested the diversity of participants in the international patent system as well as the geographic distribution of patents. Further, depending on the fields of technology and business models, innovation and exploitation mechanisms vary significantly. An international framework that is flexible enough to support and meet various needs is requested.

IX. THE INNOVATION INCENTIVE IN THE CONTEXT OF PUBLIC POLICY OBJECTIVES

286. The patent system, as a conscious regulatory intervention to advance certain public policy goals, has long attracted skepticism as to its validity and public benefit. This is in part because of a fundamental paradox, an aspect of the patent system which is to some counter-intuitive – the patent system seeks to promote the production of public goods, yet it does this by creating exclusions from the public domain – even if these are carefully confined exclusive rights over certain well-defined forms of new technology. Ideally, as a policy tool, the patent system is intended to create those exclusive rights that are necessary to harness private interest sufficiently to create public goods – in this case, public goods being new technologies, effectively and practically made available to the public, without undue impositions on the public.[89] The first codification of the core doctrines of patent law in the common law legal tradition, the English Statute of Monopolies of 1624, was passed to promote competition and to abolish monopolies that hindered legitimate trade. It took aim at monopolies that had been granted "upon misinformations and untrue pretences of public good." The patent of invention was recognized as an exception under this law, confirming that some exclusive rights are necessary to promote innovation within a legal mechanism aimed at promoting competition.

[89] Judge Rader from the United States Court of Appeals for the Federal Circuit stated that the patent system can be viewed as a "generation gift" that offers free use of technology once a patent has been expired. [http://ipcenter.bna.com/pic2/ip.nsf/id/BNAP-6WAK96?OpenDocument].

287. This contrast between the public interest and the public domain leads to a second paradox or policy tension. Those very fields where the public interest and access to new technologies is most important – in general, the life sciences, and especially those technologies that provide for basic human needs (health, food, a safe environment) – can be the very same areas of technology where harnessing sufficient resources and focusing them on areas of greatest need can be most problematic, where market-oriented incentives are felt to be inadequate, and where public funded technological inputs can be most significant. It is therefore no coincidence that much of the current debate over the legitimacy and effectiveness of the patent system as a public policy tool focus on these specific areas of technology. This is most strikingly the case for biomedical technologies, and pharmaceuticals and vaccines in particular: thus there are proposals for alternative incentive structures focused on public health, such as prize funds[90] and an R&D treaty;[91] proposals for alternative innovation mechanisms for public health innovation, such as adaptations of 'open source' structures;[92] the debate over how public-funded IP should be effectively and appropriately managed typically concentrates on medical technologies,[93] because of the strong public interest. These proposals and models variously involve new ways of exercising patent rights, or avoiding use of patents altogether.

288. The analysis of the innovation effect of the patent system in the context of public policy objectives should be undertaken at macro and micro levels:

- At the *macro* level, how does the patent system function on the whole, in garnering new resources and focusing them on innovation that is in the public interest, in promoting effective disclosure and dissemination of technological knowledge together with metadata about technology actors and trends;

- At the *micro* level, how do individual actors – patent holders and patent licensees – actually behave, and how can and should they behave, in making choices over how to deploy patent rights, given the diverse array of options, ranging over exclusive exploitation, exclusive and non-exclusive licensing, open source or cross licensing structures that may create a defined technology commons,[94] waiving rights for

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[90] E.g. Love and Hubbard. The Big Idea: Prizes to Stimulate R&D for New Medicines. KEI Research Paper 2007:1.

[91] E.g. Public Health, Innovation and Intellectual Property Rights, Report of the Commission on Intellectual Property Rights, Innovation and Public Health, World Health Organization, 2006 (at 90-91): Recognizing the need for an international mechanism to increase global coordination and funding of medical R&D, the sponsors of the medical R&D treaty proposal should undertake further work to develop these ideas so that governments and policy-makers may make an informed decision.

[92] An early proposal included : Maurer et al. Finding cures for tropical diseases: is open source an answer? PLoS Medicine, 2004, 1:183–186.

[93] Rai, Arti K. and Eisenberg, Rebecca S., "Bayh-Dole Reform and the Progress of Biomedicine" . Law and Contemporary Problems, Vol. 66, No. 1 Available at SSRN: http://ssrn.com/abstract=348343 or DOI: 10.2139/ssrn.348343.

[94] E.g. BiOS (Biological Open Source) Licenses ('a legally enforceable framework to enable the sharing of the capability to use patented and non-patented technology, which may include materials and methods, within a dynamically expanding group of those who all agree to the same principles of responsible sharing, a "protected commons"'), at http://www.bios.net/daisy/bios/licenses/398.html.

certain users or humanitarian licensing,[95] humanitarian and tiered pricing, and other public-welfare-oriented licensing strategies.

289. The net impact of the system depends on the broader policy and legal settings that shape the system at the macro level, but also, critically, on the cumulative impact of millions of decisions and actions taken at the micro level.

290. The macro analysis – analysis of the system as a system – can focus on how it functions in its own terms, such as the likelihood that the system, in practice, corresponds to the objectives established for it in principle – in other words, the degree to which patents, as actually granted, conform with the public interest as defined in the patentability criteria, and in turn whether the system is accordingly functioning to promote the development of beneficial new technologies or is rewarding opportunistic use of gaps in the documented prior art or trivial adaptations of established technologies. The incentive to innovate, however, is also measured in terms beyond the patent system, in the broader realm of public policy and public international law. Hence there is debate about the macro analysis of how the incentive effect of the patent system interacts with other regulatory mechanisms and how it affects other policy interests – for example, whether granting of some biotechnology related patents contradicts the principles of the Convention on Biological Diversity, and whether permitting patents on pharmaceuticals unacceptably impedes access to affordable healthcare, thus frustrating public health programs.

(a) Health

291. It is, understandably enough, the field of public health in which the incentive effect and the public welfare impact of the patent system are most critically under scrutiny – this being where public welfare is most at stake. This debate has not been confined to conventional IP policy forums. A major task of the World Trade Organization in the first half of this decade has been the establishment, under the TRIPS Agreement, of a mechanism calculated to recalibrate the balance between incentive and access within the patent system, with a focus on the public health needs of developing countries with limited industrial capacity. It is a measure of the significance of this issue that the sole amendment agreed to in the entire complex package of WTO agreements - since the WTO was established in 1995 - concerns patents and public health. The World Health Organization has undertaken important initiatives to promote policy analysis and debate in this area as well, through the Commission on Intellectual Property, Innovation and Public Health (CIPIH) and the work of the Intergovernmental Working Group (IGWG).

292. Debate and analysis of the health policy implications of the patent system has addressed both the macro and micro levels as identified above. The initial focus has been on the macro level – concerning such questions as the overall legal framework for the international patent system, the extent of the policy space defined by the legal framework, and the flexibilities available within that space. But there has been an increasing focus also on the micro level, or the manner in which individual choices are made (i) concerning the granting of patents (strengthening the capacity of patent examiners to make optimal assessments on patentability), (ii) concerning the licensing and other exercise of patent rights (such as humanitarian use and open source licensing options), (iii) concerning the exercise of

[95] Brewster et al, "Facilitating Humanitarian Access to Pharmaceutical and Agricultural Innovation" in *MIHR-PIPRA IP Handbook of Best Practices*, 2007.

exceptions to patent rights (such as government use and compulsory licensing authorizations) and (iv) concerning the enforcement of patent rights (such as the grant of injunctions and the quantum of damages to be awarded). Taken together, these macro and micro factors have potentially enormous influence on the overall impact of the patent system in promoting public health. A key challenge for the international public health and IP policy communities is how systematically to work through this complex range of issues, to assess the impact and implications of the many choices available within the overall framework of the system.

293. In the meantime, there is a widespread view that the empirical basis for debate and analysis on the relationship between patents and public health needs strengthening through the greater availability of clear, accessible and geographically representative information about patenting activity in the domain of human health. WIPO is currently developing, in dialogue and partnership with the WHO, a range of pilot landscapes on patents in key public health areas, with a view to developing more comprehensive information resources for public health policymakers in line with the priorities and needs that they set.

(b) Biological Diversity and Traditional Knowledge

294. The international patent system had until recently operated with the conventional assumption that traditional knowledge (TK) and biological diversity were a background input to inventive activity and not of direct operational concern to the practical functioning of the patent system. This past assumption has been vigorously challenged, at both the micro and macro levels of analysis, on the basis of concerns that:

- legal definitions and their practical implementation have systematically excluded certain TK and genetic resources from the purview of patent search and examination for patentability;

- where patent applications and granted patents make direct use of TK and genetic resources to attain the claimed invention, in some cases patent claims are made out directly to cover pre-existing TK and genetic resources in circumstances that raise questions about; and

- where genetic resources and TK are used in claimed inventions, there may not be adequate arrangements to ensure that the resources and knowledge were used with the prior informed consent of the custodians concerned, and that benefits of such use are shared equitably in line with the principles and objectives of the Convention on Biological Diversity (CBD).

295. The CBD's objectives concern the conservation of biological diversity, sustainable use of its components, and equitable sharing of benefits arising from its use. It recognizes the role of TK relating to biodiversity. The challenge for the IP system, and for the patent system in particular, is to recognize genuine innovation, while operating consistently with the principles of prior informed consent and equitable benefit sharing. Two essential scenarios are put forward in the discussion:

- the direct patenting of source material: a patent (or application) directly claims as an invention genetic resources (or associated traditional knowledge) obtained from a separate source;

- patenting inventions derived from source material: a patent (or application) claims an invention that is somehow derived from or somehow makes use of genetic resources or TK.

296. Background questions that are under active debate concern how to guarantee that genetic resources or TK have been legitimately accessed, how to ensure patents as granted are consistent with equitable benefit-sharing, and how the patent system can overall promote and advance equitable benefit-sharing.

297. The responses to these questions again operate at the macro and micro levels. At the macro level, international proposals have been developed in several fora – the CBD, the WTO and in several WIPO fora – that would link the grant or exercise of patent rights more directly and explicitly to the circumstances of access and the nature of use of genetic resources (and associated TK). Such "disclosure requirements" would create or confirm a legal linkage between genetic resources or TK used and the claimed invention. Their effective legal scope may in some cases go beyond disclosure *per se* (that is, beyond a simple requirement to provide information about genetic resources or TK), and may have an effect on substantive legal questions such as the patentability of invention as such; the applicant's entitlement to apply for or to be granted a patent; and the enforcement of patents that are considered to be obtained inequitably. Other systematic responses to these concerns have included practical steps within the PCT system and the International Patent Classification for the more systematic and appropriate consideration of relevant TK and genetic resources in the course of patent search and examination, the development of guidelines and other resources for patent authorities to deal with TK and genetic resources in a more informed and effective manner, and the strengthening of the legal and practical framework for the recognition of relevant TK (including recognition of orally disclosed TK).

298. Supplementing these core macro level questions, there is considerable activity to ensure more positive linkages between the patent system and TK and genetic resources at the practical, micro level – focusing on patent search and examination, so that in practice there is reduced likelihood of illegitimate patents being granted that claim genetic resources/TK directly or non-inventive derivatives of genetic resources/TK, but also to facilitate the equitable sharing of benefits from legitimate patenting of derivative inventions, through the development of practical capacity and awareness on the part of custodians of TK and genetic resources, and work on guidelines to support choices in the way mutually agreed terms for access to genetic resources are structured so as to safeguard equitable sharing of resulting benefits.

(c) Ethics

299. In addition to the general legal and policy framework, life sciences research and development are subject to particular scrutiny from an ethical perspective. Life sciences research touches on fundamental human needs such as human health, food and a safe environment, and on fundamental values such as human dignity and integrity: it is therefore subject to strong public interest and ethical considerations. It is a sector which has a strong component of public and publicly-funded or philanthropically funded research, and many important inputs to applied research and development can be traced to public sources. The products of life sciences research are typically subject to intensive and lengthy regulatory processes, which (i) create the need to establish appropriate mechanisms and incentives to generate necessary data on the impact of new technologies (such as clinical trials for the safety and efficacy of new pharmaceuticals), and in turn lead to (ii) concerns about access to

and use of such data. There can be significant ethical questions regarding genetic inputs to research, whether these are human genetic resources or genetic resources obtained through bioprospecting or research collaboration.

300. These ethical concerns flow also into the use of patents for life sciences research. These concerns arise at four distinct levels:

- The ethical aspects of a technology as such: certain practices may be considered unethical and contrary to morality and consequently simply prohibited. However, such prohibition alone does not automatically prevent the grant of patents related to this knowledge. In addition, not all countries may have the same restrictions. As a result, many patent laws exclude explicitly the grant of patents where the exploitation of inventions is considered to be contrary to *ordre public* or morality.

- The ethical aspects of national authorities granting exclusive IP rights over a technology: for instance, patenting genes has been controversial, from the point of view of whether it is, for instance, ethically sound for society to grant exclusive property rights over nucleotide sequences that are derived from the human genome, and what constraints should apply.

- The ethical aspects of an individual seeking exclusive IP rights over a technology: for instance, the argument has been made that there should be legal or ethical constraints on seeking patents for an invention based on genetic resources or traditional knowledge obtained without prior informed consent and without equitable benefit sharing, and legal measures have been introduced in national laws and proposed for international law to enforce this. Similarly, there is a debate over the patenting of inventions derived from research on human subjects, without their explicit consent not to medical treatment as such but to the commercial use and patenting of such derivatives.

- The ethical aspects of the forms of exercising exclusive rights over a technology by an IP right holder: for instance, there has been a debate over the ethical basis of exclusive or restrictive licensing of diagnostic tools that are in themselves the legitimate subject matter of valid patents.

301. Such ethical questions, by their very nature, are dependent on the cultural and social values of different communities and societies, leaving questions over the appropriate role of an international patent system which spans numerous different communities and considerable diversity in ethical views and moral systems. A clear distinction may be made, on the one hand, between the recognition, within the international system, of the role and significance of ethical and moral considerations – a macro level question, that may be dealt with on an international plane; and on the other hand specific findings and assessments about the ethical implications of a particular patent or patented technology – a micro level question, which is likely to be dealt with in diverse ways in different societies.

302. At the international level, four general trends can be discerned, however:

- Transparency: The Universal Declaration on Bioethics and Human Rights calls for the greatest possible flow and the rapid sharing of knowledge concerning medical, scientific and technological developments. The patent system has a fundamental role to play in promoting this flow of timely information, disclosing new

technologies at an early stage in their development as well as the identity of inventors, commercial enterprises, as well as governmental and educational institutes that are involved in the creation and development of those technologies. The transparency of the patent system may therefore help to support ethical scrutiny of biotechnology and can help to inform the bioethics debate, provided more accessible information resources are available for policymakers.

- Consent: Bioethics cases have concerned the use of human tissue as inputs for research, leading to patented inventions, raising questions about prior informed consent of the human subjects concerned, and whether consent extends to the patenting of outputs from research. A similar debate applies to other genetic resources, such as genetic resources obtained through bioprospecting, which are subsequently used in research to create new technologies for which patent protection may be sought. For instance, the CBD, at the level of international law, provides that the use of genetic resources is subject to the principle of prior informed consent. Consent is a key issue in bioethics, and it can be helpful to explore the relationship and the boundaries between legal and ethical aspects of consent to use genetic inputs to research.

- Equitable sharing of benefits: A further crosscutting theme is how the benefits of research should be shared, and what it means for the sharing to be equitable. This potentially has both legal and ethical aspects. For example, the CBD establishes as an international legal principle that the benefits of research on genetic resources should be equitably shared. Similarly, articulating a principle at the level of bioethics, the UDBHR calls for 'equitable access to medical, scientific and technological developments as well as the greatest possible flow and the rapid sharing of knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries.' As one means of generating benefits from biotechnological research, the IP system and in particular the patent system could have a potential ancillary role in helping to identify and equitably apportion such benefits.

- Accommodating different value systems: ethics may be guided by the community's sense of morality and the values of the community, raising questions about how these different value systems should be recognized in the interpretation and application of exceptions in patent law for technology that is contrary to morality. Generally, the scope for ethical assessments is marked out at the international level, but the application and assessment of ethical questions remains within the province of national law. Thus at the level of international law, States may choose to exclude from patent protection inventions where the prevention of the commercial exploitation of those inventions within their territory is necessary to protect *ordre public* or morality.[96] But it is at the national level that a country may choose to pass a law giving effect to such a 'morality' exclusion, and when such a law is implemented, a decision maker would be required to assess whether the commercial exploitation of a certain technology would be contrary to *ordre public* or morality from the standpoint of the prevailing ethical values of that country.

[96] Article 27.2, WTO TRIPS Agreement.

X. DEVELOPMENT RELATED CONCERNS

303. While attempts have been made to address the development dimension in relation to each of the issues discussed in the previous parts of the present document, this chapter sets out a summary of some of the most frequently raised aspects relating to development.

304. Undoubtedly, development is one of the most urgent challenges that the international community is facing today. Its importance is acknowledged not only for the benefit of developing countries but also for the benefit of developed nations. In the context of the United Nations, the United Nations Millennium Declaration was adopted in 2000 in order to respond to the world's major development challenges. The Declaration recognizes that the central challenge is to ensure that globalization becomes a positive force for all. In addition to an intensified globalization, the world is in a transition to a knowledge-based economy where knowledge will become a strong competitive advantage in the globalized market.

305. Against this backdrop, the implementation costs and benefits of the international patent system for developing countries have been vastly debated in the past years. In WIPO, a proposal for a development agenda for WIPO was first launched by Argentina and Brazil and supported by an additional 12 developing countries at the 2004 WIPO General Assembly. The proposal resulted in the adoption of a Development Agenda consisting of 46 recommendations to enhance the development dimension of the Organization's activities, including the establishment of a Committee on Development and Intellectual Property (CDIP), which will monitor, assess, discuss and report on the implementation of all recommendations adopted, in coordination with relevant WIPO bodies, and will discuss IP and development-related issues as agreed by the Committee and decided by the General Assembly. In the context of the deliberations on the international patent system, among the six clusters of activities adopted, the proposals in Cluster B (norm-setting, flexibility, public policy and public domain), Cluster C (technology transfer, information and communication technologies (ICT) and access to knowledge) and Cluster D (assessment, evaluation and impact studies), may be considered to be of particular relevance.[97]

306. The patent system was created as a mechanism to promote technological development, diffusion and transfer of technology and private investment flows. The international patent system is aiming at achieving, or at least facilitating, those goals at the international level. However, a fundamental concern has been raised in respect of the international patent system, namely that the current system runs counter to, rather than to be complementary to, the individual national efforts of development. As the UNCTAD's Innovation Capability Index suggests, there are large gaps among countries in terms of technological activity and human capital. This gap does not just exist between developed and developing countries, but also among the developing countries and countries in transition economies.[98] At one end of the spectrum, there are countries with high technological activities and highly skilled human capital. Other countries are characterized by moderate technological activities, but by a high

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[97] General Report Adopted by the Assemblies (WIPO document A/43/16) [http://www.wipo.int/edocs/mdocs/govbody/en/a_43/a_43_16-main1.doc].

[98] UNCTAD, World Investment Report 2005 – Transnational Corporations and the Internationalization of R&D. The Report also found that major businesses are shifting more of their R&D to selected developing countries as a reaction to increased competition. The types of such R&D have been shifting towards technology developments for regional or global markets and applied research.

level of skilled human capital capable of absorbing imported technology, thus involving a risk of imitation and free-riding. At the other end of the spectrum, there are countries which have little technological activity and are poorly connected with the global network of learning and knowledge creation.

307. In view of this innovation capacity gap, the question has been raised as to whether, and to what extent, the international patent system is supportive of the national efforts of development irrespective of the level of the country's economic development. First, there are concerns about the costs incurred vis-à-vis the benefits flowing from the international patent system. Some say that access to the international patent system by innovators in developing countries is prevented due to its high costs.[99] As described in Chapter VIII, the cost of obtaining, maintaining and enforcing patents at the international level is one of the issues at the heart of the challenges to the efficiency of the international patent system. Despite the globalized economy, the territoriality of the patent system requires competitors and third parties to challenge the validity of patents and to pursue litigations in foreign countries.

308. Further, one of the functions of the patent system is the diffusion of technology through the publication of patent applications and patents. As indicated in Chapter III, patent information is not only a source of technological knowledge, but also a source of information useful for business and national policy decision-making. However, the cost to make such information easily available to the public as well as the lack of infrastructure and support mechanisms at the national level make it difficult for some countries to fully benefit from patent information. From the viewpoint of national governments, establishing and maintaining a national patent administration is costly. In particular, substantive search and examination of patent applications require both financial and human resources, which may not always be easily available in all countries. As indicated in Chapter VI, designing a national patent system that maximizes the quality and validity of granted patents in an environment of limited resources is a real challenge.

309. Secondly, there are concerns that the international patent system does not sufficiently allow countries to tailor their national patent system in a way such as to respond to national development and other policy objectives.

310. Not only in developing countries, but also in developed countries, the international procurement of technology has been recognized as an essential means to stimulate innovative activities and to be competitive in globalized markets. Given the large innovation capability gap, countries with a lower level of technological development rely extensively on technology transfer from countries with more technological capacities. In the context of the WIPO Development Agenda, some countries have raised concerns that technology transfer does not yield the expected results and that unwillingness to transfer technology might cause a competitive threat. It is said that sustainable economic development requires active, continuous technological efforts by enterprises, along with government policies that help firms attract, absorb and adapt technologies.[100] In addition to technological skills, expertise to negotiate fair technology transfer agreements would be one of the elements for successful

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[99] Precisely speaking, such concerns are also valid for innovators from developed countries who do not have enough financial means. However, in those countries, supportive market mechanisms, such as joint ventures, may be available.

[100] UNCTAD, World Investment Report 2005 – Transnational Corporations and the Internationalization of R&D.

technology transfer. As indicated in Chapter IV, the contributions of the international patent system to transfer of technology are multifaceted, and the concerns surrounding the international patent system and technology transfer are equally multifaceted.

311. Another concern often raised by developing countries is the perceived negative impact of the international patent system on fundamental public policy objectives such as public health, nutrition, education and the conservation of biological diversity. If any international instrument was to be established, it is argued that it should acknowledge and seek to preserve public interest flexibilities and the policy space of member States. In particular, the importance of safeguarding the exceptions and limitations existing in the domestic laws of member States is highlighted. As indicated in Chapter IX, in the context of public policy objectives and the innovation incentive which the patent system is intended to achieve, the issues surrounding public health and access to drugs have been intensively debated in the last years, as some argue that patents restrict access to such goods (as well as to knowledge) and their exploitation by those who might need it most. Another area of concern is how the international patent system could constitute a supportive mechanism to pursue the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of benefits arising out of the utilization of genetic resources, as stated in the Convention on Biodiversity.

312. Thirdly, concerns have been raised as to how to implement, in the national laws, the public policy flexibilities that best fit the needs of each country. The current international frameworks allow member States to exercise their power to provide a number of mechanisms to prevent abusive uses of patent rights (for example, measures against anticompetitive patent licensing practices and issuance of compulsory licenses) and that take into account the public interest.

313. Many of the above concerns have been widely expressed in the SCP when a proposal designed to limit the draft SPLT to the definition of prior art, the grace period, novelty and inventive step was made. For a detailed report of those discussions, see Chapter V(g). Those who supported the proposal stated that it was in the common interest of all member States to improve patent quality, simplify the procedures and to reduce the costs and duplication of work by patent offices. In order to reach those objectives, it was argued that an agreement on more consistent and common standards on core prior art-related principles of patent law would facilitate mutual cooperation among WIPO member States and provide the best opportunity for meaningful results for both developed and developing countries in the near future.

314. Those who opposed the proposal, however, were of the view that the concerns of developing countries, such as the cross-cutting nature and the significant implication of this process on public policy objectives for developing countries, together with the importance of subjects such as public interest, flexibility on existing intellectual property laws, transfer of technology, curbing of anti-competitive practices and disclosure of the origin of genetic resources in patent applications, needed to be duly considered. In order to strike a balance between the creation of the international intellectual property system with demands on upward harmonization of national patent laws, on the one hand, and the safeguarding of existing flexibilities and national policy space, on the other, it was considered that negotiations on the SPLT should take on board issues of concern to all Members as a single undertaking.

315. In sum, the concerns of developing countries appear to be twofold. The first question is whether the current, or any future, international patent system could be compatible with national policy objectives. As demonstrated by the process that led to the adoption of a protocol amending the TRIPS Agreement, multilateral fora to improve the international patent system exist, and can function effectively, where a specific element of the international patent system is recognized to impinge on sectors of vital importance to the public interest. The second question is how to implement, and take advantage of, the international patent system at the national level taking into consideration the existing public interest flexibilities embedded in the international instruments. Given the different levels of development, there might be no answer that fits all. Development is a long-term goal, and the determination of how the international patent system could contribute to development may require long-term strategies.

316. The SCP is invited to consider the information contained in the present document in defining the future work of the SCP.

[Annexes follow]