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THE IMPACT OF THE INTERNATIONAL PATENT SYSTEM ON DEVELOPING COUNTRIES: A STUDY BY NG SIEW KUAN, ELIZABETH

Document submitted by the Secretariat

The study reproduced in this document is one of four studies on the impact of the international patent system on developing countries commissioned by the Director General and made available as documents A/39/13 Add.1 to Add.4. For further background information, see document A/39/13.

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The views expressed in the study are those of the author and not necessarily those of the Member States or the Secretariat of WIPO.

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A study by Ng Siew Kuan, Elizabeth,
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July 2003

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PREFACE

This study was commissioned by the World Intellectual Property Organization (WIPO) to assess the main implications of the international patent system on developing countries and analyze the reform opportunities. It does not offer a comprehensive engagement of the issues that confront the international patent system. Neither does it plead for, nor oppose, the specific causes and interests of any nation or group of nations. Instead, it adopts a broad global perspective on the issues canvassed. Where pertinent, references to statements that substantiate or augment alternative global viewpoints are included.

As part of the research undertaking, I have during the two months of the project sought to consult broadly with key organizations from the Asia-Pacific region including Bangladesh, Bhutan, Brunei Darussalam, Cambodia, China, DPR of Korea, Fiji, India, Indonesia, Iran, Laos, Malaysia, Maldives, Mongolia, Myanmar, Nepal, Pakistan, Papua New Guinea, Philippines, Republic Of Korea, Samoa, Singapore, Sri Lanka, Thailand, Tonga and Vietnam. Unfortunately, many expressed interests but were unable to participate due to the short notice. Written submissions and views received from organizations and eminent individuals are available separately as “Compiled Comments” related to this study on WIPO’s Web site at http://www.wipo.int/patent/agenda.

Due to time constraints and limitation of resources, I regret that many equally significant issues had to be omitted from this study or were given less attention than merited. Thus, it is hoped that further consideration and collaboration with the public and private bodies of developing and developed nations will continue to take place on these and other major issues that have raised in this study and other eminent works.

I wish to thank Dr Kamil Idris, Director-General of the WIPO for the honor of being appointed a consultant to undertake this study. I would also like to thank Germán Cavazos-Treviño of the WIPO for his kind support and assistance. A special note of thanks also goes to the Honourable Mr. Yong Pung How, Chief Justice of Singapore, Mr. Chan Sek Keong, Attorney-General of Singapore, Prof. Edison Liu, Director Genome Institute of Singapore, Prof. John Wong, Vice President (Research/Life Sciences) of National University of Singapore (NUS), and Prof. Seeram Ramakrishna, Director of NUS Enterprise, for their kind comments, contributions and assistance. Finally, my gratitude and thanks to Associate Professor Stephen Phua, Faculty of Law, NUS, for his invaluable contributions and editorial assistance.

The views expressed in this report are solely mine and I remain responsible for all errors and omissions therein.

NG Siew Kuan, Elizabeth
July 2003

EXECUTIVE SUMMARY

This work attempts to develop on the works of scholars on the relationship and impact between intellectual property rights (IPRs) and national performance. The consensus of some analysts appears to confirm that good reasons substantiate the insight that economic benefits of adopting robust IPRs may not accrue uniformly or equitably to every nation or groups of nations. Some have cited statistical bases to infer positive and perhaps non-linear correlations between IPRs, industrial performance and technological effort. Different rates of, or gains from, participation may well be explicable on other grounds. While it may be speculative to pinpoint precise motivations behind each country's adoption of specific IPR policies and standards, national support for different IPR standards may be intuitively connected with economic self-interest. While the utility in such analyses is undeniable, research outcomes based on such broad geographical divides as between developed and developing nations, however defined, carry risks of presenting mere manifestations of the real casual links as the causes they belie.

However, there are genuine challenges and imbalances that threaten to undermine the attainable objectives of the global IPR regime if measures within our grasp are not implemented to redress the tensions. No system of laws is immutable. This report falls short of making a case for radical reform to a system that is fundamentally robust and functional. Nevertheless, it is important to seize the opportunities presented by such threats to engage in incremental selective reform. The innovation age is likely to accentuate the polarity and disparity between nations in IPR creation, exploitation and utilization. Some differences may never be equalized but if wider and more meaningful participation of all nations is desired, global and open dialogues must prevail to forge common values and principles to underpin an international patent system that is enamoured of all.

Guided by common principles of sound governance, it is submitted that there is room for further exploitation of the inherent flexibility that has been incorporated into the international patent system. A robust IPR system is not negotiable. Standards that are products of mutual agreement ought to be strictly and consistently enforced. Yet this in no way precludes a more structured differentiation of IPR standards that can accommodate greater flexibility in implementation. The lack of homogeneity in industry as well as national economic and technological performance may compel more rigorous differentiation over time, space and subject-matter to accommodate any overriding immediate public interests. The goal to realize a harmonized and integrated international patent system is commendable and intact but due care must be taken to avoid any haste that may produce severe adverse outcomes.

As comprehensive studies on the technical rules of IPRs have been accomplished elsewhere, general observations on some procedural and substantive laws that are amenable to reform are offered for further consideration. Processes and procedural rules that clearly contribute to costly and wasteful duplication ought to be eradicated. Where feasible, member nations may be encouraged to pursue deeper and wider elective recognition of search, examination reports and other documents. While this study does not reveal a case for radical reform of substantive rules, several areas that could benefit from some incremental reform are highlighted. Biotechnology, public health and traditional knowledge are areas that are likely to prove challenging and would profit from further detailed studies.

One of the key objectives of reform must be to avert any risks of potential alienation of any member nation or alignment of national blocs along lines of mutual interests. As with

any reform, some may be controversial; others provide challenges in the long term. To reform is proactive. Few initiatives possess universal appeal but we cannot afford to be indifferent to differences. Hopefully, common principles of governance would serve to chart the course where difficulties prove intractable. Change is a process and in itself is unlikely to constitute an immediate panacea for the confluence of political, economic and social pressures constantly being exerted on the international patent system. Courses may change but the final destination may prove to be worth the delicate journey.

CHAPTER 1:

A SURVEY OF THE INTERNATIONAL PATENT SYSTEM:[1] ROLES AND CHALLENGES

1.1 THE IMPORTANCE OF INTELLECTUAL PROPERTY

The advent of new technologies has led to a dramatic shift in business strategies and global economic development. Countries are racing to keep up with the technological revolution, to attract foreign investments and to develop frameworks that encourage research and development into areas that would generate innovation and intellectual property rights. In this innovation age, the effective exploitation of knowledge and information will be a major force to propel national economic growth. Intellectual property, particularly patents, is a tool for "technological advancement, economic growth and wealth creation for all nations."[2] It has been termed the "new gold of our time"[3] that is waiting to be mined and exploited. The increasing reliance on the patent system can, for example, be seen in the rapid development and implementation of patent strategies and the growth of international licensing in recent years.

Regardless of the levels of their economic development, many nations have come to realize the enormous benefits of having high value-added industries ranging from biotechnology and healthcare, food and agriculture, to information technology and bioinformatics. The chart below amply illustrates the dramatic increase in the participation of developing nations in this new source of wealth creation.

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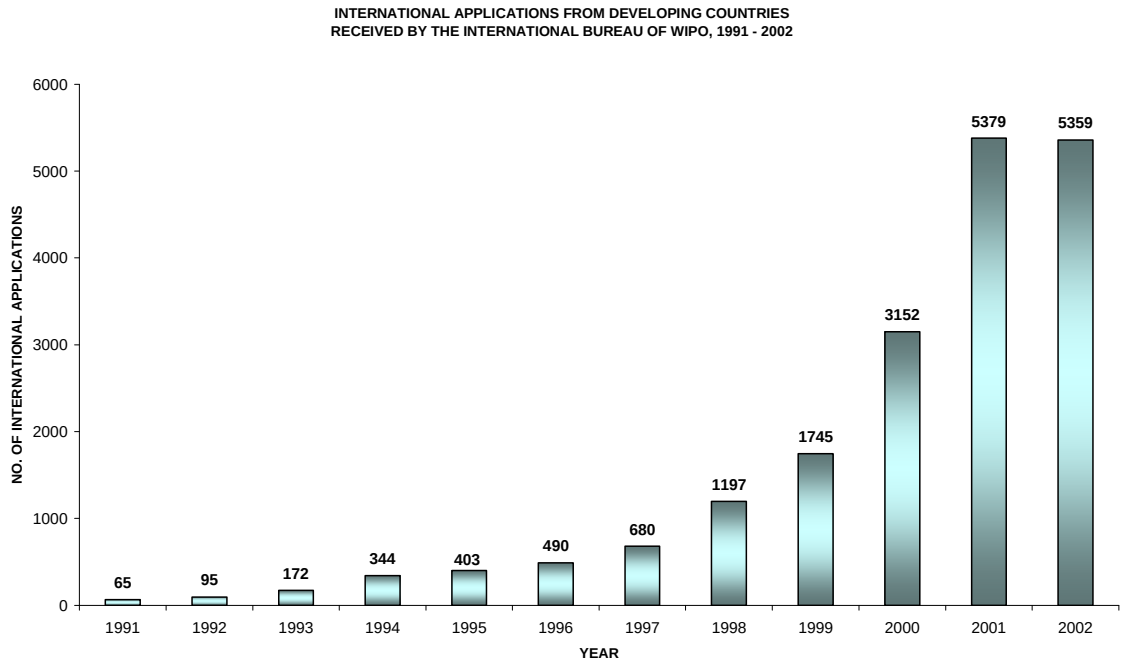
1 The WIPO has used the term "international patent system" in a very broad sense to mean "not only the legal system at all levels, including national and regional as well as the PCT, together with any future initiatives that may emerge, but also the supporting infrastructure for the administration, maintenance, exploitation and enforcement of applications and patents under the various legal regimes. This involves national and regional patent offices, the International Bureau of WIPO, partner organizations in public and private sectors, such as ministries of justice, trade, science and technology, other relevant government agencies, enforcement agencies, private industry, universities and research institutions, and associations of industry users, inventors and patent professionals. See Memorandum of the Director General of the WIPO on the Agenda for Development of the International Patent System (A/36/14) ["WIPO Patent Agenda (A/36/14)"] at p 2.

2 *Ibid.*

3 Opening address by Senior Minister of State for Law and Home Affairs, Associate Professor Ho Peng Kee at the Europe Asia Patent Information Conference (EAPIC) September 2002 in Singapore.



However, as the WIPO has highlighted, the international patent system must operate to the "maximum benefit of the countries that participate in it, taking account of their widely varying stages of technological and economic development."[4] Indeed, the heterogeneity of nations has been noted in many scholarly works, including those of the Commission on Intellectual Property Rights (CIPR)[5] and the World Bank.[6]

Like other intellectual property rights, a patent[7] derives its scope of protection from the unique domestic laws in force in each country.[8] It is widely accepted that material inconsistencies in the national patent laws and regulations among countries may pose impediments to the desired appropriation of benefits from patent rights. As noted by the WIPO:

> "A more unified framework for obtaining patents worldwide would encourage more users to develop and commercialize their inventions on a truly international basis, with less fear that their work would not be evenly and effectively protected, thus fostering innovation and economic growth more effectively and at lower cost."

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4 See WIPO Patent Agenda (A/36/14), *supra* note 1, at p 2.

5 See Report of the UK Commission on Intellectual Property Rights, Integrating Intellectual Property Rights and Development Policy (2002) (CIPR report). Note also: The UK Government response to the CIPR report from the Department for International Development and Department of Trade and Industry at http://www.dfid.gov.uk.

6 See World Bank, 'Intellectual property: balancing incentives with competitive access' (2001) Global Economic Prospects 129-150 at http://www.worldbank.org/prospects/gep2002/chapt5.pdf.

7 A national patent awards an inventor the right to prevent others, inter alia, from making, selling, or using the protected product or process without authorization for a fixed period of time within a country. In return, society at large obliges the disclosure of the claimed invention in sufficient detail to disclose how the invention works, thereby increasing the stock of public knowledge. See World Bank (2001) 'Intellectual property: balancing incentives with competitive access," *supra* note 6.

8 See WIPO Patent Agenda (A/36/14), see *supra* note 1, at p 2.

As a result, many countries appreciate the need for, and have forged a number of, regional[9] and international patent systems[10] to secure more effective technology transfer in an age of increasing free trade and commerce. The tabling of intellectual property rights issues at international trade negotiations, such as the Uruguay Round of negotiations of the General Agreement on Tariffs and Trade (GATT) [now the World Trade Organization (WTO)] that culminated, *inter alia*, in the Agreement on Trade Related Aspects of Intellectual Property Rights ("TRIPS Agreement") serves to underscore a major transformation in the role played by intellectual property in free trade. Arising from the TRIPS Agreement, a global framework for the mandatory implementation of minimum standards of intellectual property protection was created for all members of the WTO.[11]

1.2 THE TRADITIONAL ROLE OF THE PATENT SYSTEM

> "A robust and dynamic industrial property system, and particularly the patent system, supports and encourages technological innovation, brings more and better products onto the market for the benefit of people, and promotes investment and technology transfer."[12]

The traditional role of the patent system that aims to seek an ideal balance between the desire to encourage innovations with appropriate incentives and the need to preserve reasonable access to, and use of, the knowledge and information thereof remains intact today. Legal protection for the products of successful investments prevents illegal copying, and enables the patent owner to benefit from an "exclusive market position" with a temporary ability to set prices above the marginal costs of production.[13] On the other hand, there is also great societal benefit in the dissemination of, and access to, knowledge and information that may be derived from patents. The patent system seeks to achieve an appropriate balance between these two objectives by, *inter alia*, setting limits on the types of patentable subject-matter, the scope and duration of protection and exceptions thereto. Upon the expiry of the duration of "protected exclusivity," the knowledge and information can be used by the public unfettered by patent rights.

However, what constitutes an "appropriate trade-off" between incentive and dissemination has been very much a matter of debate. The development of new technologies entails considerable investment in research and development that is fraught with significant risks and uncertainties. In addition, the emergence of a highly competitive market has

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9 Examples include the European Patent Convention (EPC), the Agreement establishing the African Intellectual Property Organization (OAPI), the Eurasian Patent Convention, the Protocol on Patents and Industrial Designs within the Framework of the African Regional Industrial Property Organization (ARIPO) (the "Harare Protocol"). Note also the European Community Patent System which will provide for the grant of a unitary patent that has legal effect in all European Community member countries.

10 Apart from the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement), other examples include the Paris Convention (adopted in 1883), Patent Co-operation Treaty (PCT), Patent Law Treaty (PLT).

11 See the TRIPS Agreement.

12 See WIPO Patent Agenda (A/36/14), see *supra* note 1, at p 1.

13 See World Bank (2001) 'Intellectual property: balancing incentives with competitive access,' *supra* note 6.

generated some degree of divergence in views over the factors, and their respective weights, that ought to be taken into account in determining how the balance should be struck.[14]

Traditionally, the patent system developed as a public policy tool using the "creation and exercise of private [exclusive] rights as a means of promoting the public good."[15] Its critics have argued that this symbolizes "the shift of control and ownership over technology from the public to the private, serving to commodify vital technological information that they argue should remain in the public domain."[16] Thus, any enhancement of patent rights may be perceived to be prioritizing private rights over public welfare. This may well account for some of the resistance to extend patent protection to new technological advances, such as those in the field of biotechnology.[17]

1.3 ADAPTING TO MEET THE CHALLENGES OF THE INNOVATION AGE

> "The future evolution of the international patent system should provide an appropriate balance between the rights of inventors [and their investors] and the general public, while at the same time taking into account the implications for the developing world."[18]

The rapid pace of scientific and technological advances over the last few decades has triggered an unprecedented technological revolution that poses immense challenges to the international patent system. One of these is the increased pressure faced by many nations to conform to new international standards to facilitate the growth of, or participate in, a highly integrated and competitive global market. The revolution spawned, in particular by the biotechnology and info-communication industries, has created wealth for many, just as it has sparked outrage from others. These challenges have been succinctly noted by the WIPO:

> "The international patent system … enjoys levels of use far beyond what would have been imagined only a decade ago... Yet, this great success has not given rise to universal satisfaction, either within the immediate circle of administrators and users of the patent system or among the intended beneficiaries of the system more widely in society. The system today faces twin challenges: an internal challenge, concerning the actual operation of the system [e.g. workload crisis faced by many patent offices, duplication of work, need for expert patent examiners etc.]; and an external challenge, concerning the policy role, and the economic and social impact of the patent system ... [A]t the broader level of public debate, general perceptions of the international patent system are marked by apprehension and unease. After a long period of relative obscurity … it has more recently emerged into the public spotlight. Yet this increased prominence has not resulted from the contribution of the patent system to the creation and spread of new technology. Rather, it comes from concerns about perceived

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14 See World Bank (2001) 'Intellectual property: balancing incentives with competitive access', *ibid*.

15 See Memorandum of the Director General of the WIPO on the WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6).

16 See WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6) at Annex I p 3.

17 Take, for example, the African Group's demand that patents on all life forms and living processes should be prohibited. See Khor, "TRIPS debate on biological materials: Africa reiterates proposal to ban life patents" (June 11, 2003) at http://www.twnside.org.sg.

18 See WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6), *supra* note 15.

negative effects of the system: first, the controversy over the possibility that patents may be hampering governments' attempts to deal with urgent policy issues; and second, concerns about the granting of patent protection for some forms of new technology, especially, biotechnology."[19]

1.3.1 New Technologies: Biotechnology

The patent system has had to adapt to the needs of rapid advances in new technologies, particularly in the field of biotechnology. In the process, it has been confronted, and will continue to do so, with many difficult and often controversial issues in the field of biotechnology and bioethics. The biotechnological race has brought about an acute sense of urgency for many countries to seek and create the ideal environment that would attract talents and investments to their shores. This has generated a multi-national and multi-disciplinary inquiry into the legal, economic, technological, environmental and social aspects of intellectual property creation, exploitation and management. This intricate web of legal, scientific, ethical, environmental and business policy considerations in the field of biotechnology is a fertile ground for global initiatives and collaboration.[20] The furore over stem cell research and the recent global dilemma relating to human reproductive and therapeutic cloning serve to highlight some of the difficulties involved. Other controversial and difficult challenges that have arisen in recent years include those relating to genetically modified (GM) food and life forms, tissue engineering, medical and gene therapy, patentability of genes and biological molecules (such as, DNA, RNA, EST, SNP, protein etc.), xenotransplantation, embryo testing and selection, animal cloning and the recent creation of the hybrid human "she-males."

In addition, the amalgamation of biology and information technology has spawned bioinformatics inventions that are estimated to generate more than a billion dollars in revenue annually worldwide due to the potential from healthcare advancements.[21] This has also raised interesting questions relating to the protection of bioinformatics under the intellectual property regime. Issues relating to the protection of biological sequences, biological databases and bioinformatics software and hardware, such as, "thermocyclers" and gene chips, will straddle many branches of the intellectual property regime including patents, copyright, trade secrets and database protection.

1.3.2 New Technologies: Information Technology

Apart from the biotechnology revolution, the advent of internet technology has led to a "seismic shift" in the way information is being dealt with in the 21st Century. This has increased global competition and posed many challenges that profoundly affect the social, economic, as well as, the legal systems of the world. Instantaneous access and the ease of

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19 See WIPO Patent Agenda: Options for development of the international patent system (A/37/6) at Annex I p 2.

20 It is worth noting that some countries, such as, the USA, India, Japan, Korea and Singapore have recently completed their consultation paper on stem cell research.

21 See M. Scott McBride, "Bioinformatics and Intellectual Property Protection" (2002) 17 Berkeley Techonology Law Journal 1331, citing John Thackray, BIOINFORMATICS Grows LEGS, ELEC. BUS., July 2001 (stating from a report by Strategic Direction International (SDI) that "Bioinformatics generated worldwide revenue [in 2000] of more than $700 million … and total bioinformatics volume could exceed $2 billion [in 2001]").

reproduction make geographical boundaries inadequate benchmarks of protection. The existing flux over the extent and mode of protection of computer software in general and those available over the intangible media such as the internet has posed great challenges to the patent system.[22] This is further reflected in the tremendous increase in patent applications that have been filed in the information, communication and technology (ICT) sectors. Take, for instance, the European ICT sector where patent applications have more than doubled over the last decade. (See 2 charts below: A recent report by Eurostat, the statistical office of the European communities, has shown an increase in EPO patent applications for the ICT sector as follows).

[22] See, generally, David Bainbridge, "Software Patents" (2002) 7 IP & IT Law 5; "Japan gives software patents green light" (2002) Managing IP (April); Stephen Whybrow, "Directive diverges from practice" (2002) Managing IP (May); David Booton & Peter Mole, "The Action Freezes? The Draft Directive on the Patentability of Computer-implemented Inventions" [2002] IPQ 289.

Increase in ICT patent applications to the EPO

Figure 1: Evolution of the ICT sector's share in total patent applications to the EPO from EU-15, Japan and the USA (1)

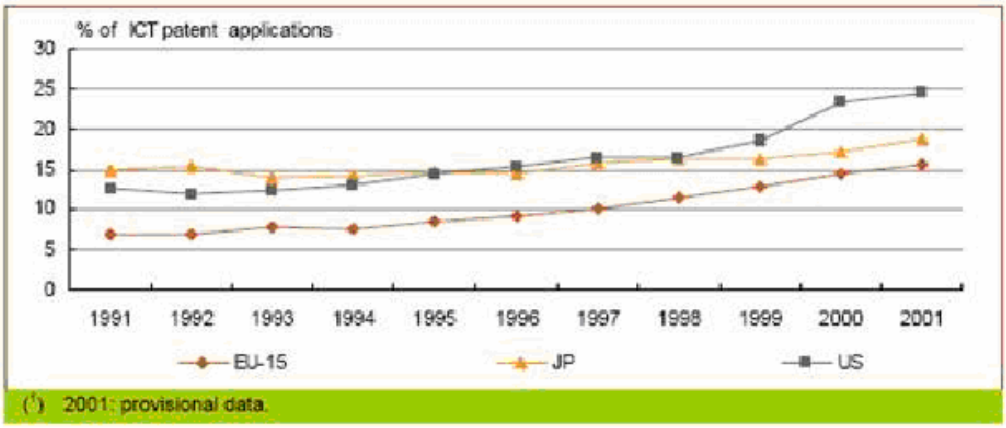
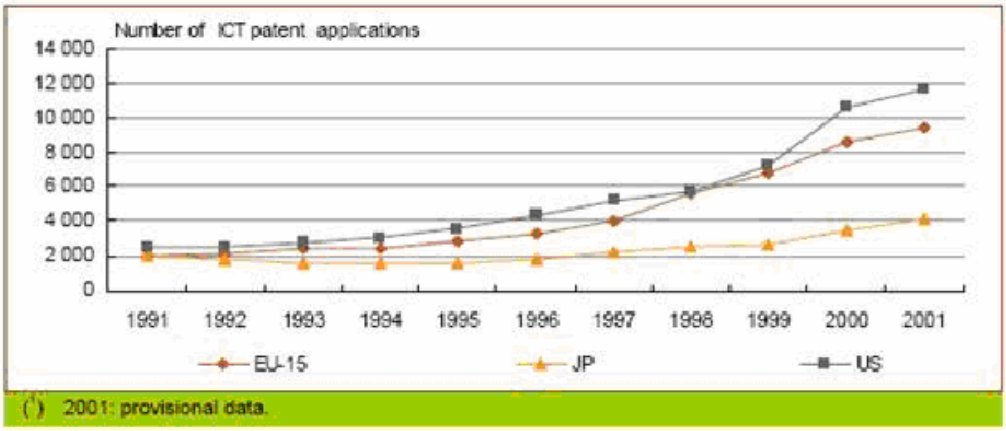


Figure 2: Evolution of ICT sector patent applications to the EPO from EU-15, Japan and the USA — Total number (1)



- In 2001, the share of the Information and Communication Technology (ICT) sector in the total number of patent applications to the European Patent Office (EPO) from EU-15 was 2.3 times larger than that of 1991. This ratio was 1.3 and 2.0 times larger for Japan and the US respectively.
- ICT patent applications to the EPO accounted for 15.5 % of the total for the EU in 2001, 18.7 % for JP and 24.6 % for the United States.
- 6 countries accounted for 90.7 % of the EU's ICT patent applications to the EPO: Germany (29.9 %), UK (18.6 %), France (15.3 %), the Netherlands (10.4 %), Sweden (8.9 %) and Finland (7.5 %).

(Source: Guido Strack, 'Increase in patent applications to the EPO in the ICT sector between 1991 and 2001)

The convergence of legal and technological domains in the field of international internet transactions (namely, e-commerce) and the law of patents have also generated much controversy, for example, in relation to business method patents. The intersection between global e-commerce and patent law has generated both multi-jurisdictional "forces of conflict and forces of convergence among national patent laws."[23] This in turn is exacerbated by the divergence of patent laws in force in different countries over issues such as the patentability of business methods.

1.3.3 Other Challenges

The recent controversy arising from the HIV/AIDS pandemic also serves to highlight another unprecedented challenge faced by the international patent system in the field of public health. The resulting WTO's Doha Ministerial Declaration on the TRIPS Agreement and Public Health[24] was said to be at "core a response to the concern of many governments that they should have adequate policy flexibility at a national level to address public health problems."[25]

The increased integration between intellectual property and trade, coupled with an acceleration in international trade and commerce, call for a cooperative international approach to the evolution of an effective international patent system that holds to its core principles that have the public interest at their center.[26] Unless they are satisfactorily articulated and addressed, tensions and imbalances are likely to be exacerbated.

Chapter 2 seeks to identify and evaluate some of the correlative and possibly causative factors that may account for real or perceived inequities being experienced by participants in the current international patent system.

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23 A distinguishing characteristic of this intersection was noted by the WIPO as "the interdisciplinary nature of electronic commerce, and the corresponding impact that this element brings to the forces of convergence." See the World Intellectual Property Organization, "Primer on Electronic Commerce and Intellectual Property Issues" at http://ecommerce.wipo.int/primer/section1.html cited in Larry A. DiMatteo, "The New 'Problem' of Business Method Patents: The Convergence of National Patent Laws and International Internet Transactions" (2002) 28 Rutgers Computer and Technology Law Journal 1. See also Eugene R. Quinn Jr, "The Proliferation of Electronic Commerce Patents: Don't Blame the PTO" (2002) 28 Rutgers Computer & Technology Law Journal 121.

24 It recognized the importance of intellectual property, particularly, patent protection for the development of new medicines.

25 See WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6).

26 See WIPO Patent Agenda: Options for development of the international patent system (A/37/6) at Annex I p 2.

CHAPTER 2:

TENSIONS AND IMBALANCES

2.1 INTRODUCTION

Intellectual property rights, particularly patents, are tools that can enhance or hinder national economic and technological development. A less than appropriate utilization of them can potentially cripple a country's development. However, if aptly employed, they are capable of securing superior rates of scientific and technological innovations to support investments that lead to increased global trade, thereby promoting economic, social and technological development.

However, many developing countries face real policy and structural dilemmas, *inter alia*, about the extent and timing of their participation in the international patent system. It has been succinctly pointed out that:

> "As their national economic circumstances improve, such countries need to pass through the stage of integration into the international patent system to the point where they are full participants, whose nationals gain tangible benefits not only from the importation of patented products and technology but also from ownership of patent rights."[27]

Many other views have been raised and it will suffice to highlight some of the key points and observations here. It is worth noting that these differing, and often conflicting, interests have been alluded to in debates along the lines of 'Whether IPRs are "good or bad" for developing countries.'

IPRs: GOOD OR BAD?
(Some viewpoints)

On the side of the net exporters of IPRs (usually associated with the developed world), arguments highlighted have included the following:

- *It is argued that IPRs are "good for business, benefit the public at large, act as catalysts for technical progress" and so "if IPRs are good, more IPRs must be better." Per Hugh Laddie J's Foreword to the CIPR report.*

- *In strengthening their IPRs regimes … developing countries may be able to attract greater inflows of technology through international trade in goods & services, foreign direct investment (FDI), and contractual licensing of technologies. (See World Bank (2001) 'Intellectual property: balancing incentives with competitive access', in Global Economic Prospects, 129-150, Washington, DC.)*

On the side of the net importers of IPRs (commonly associated with the developing or least developed world), arguments highlighted have included the following:

[27] See WIPO Patent Agenda (A/36/14), see *supra* note 1, at p 3.

– *"IPRs are likely to cripple the development of local industry and technology, will harm the local population and benefit none but the developed world" and so "if IPRs are bad, the fewer the better." Per Hugh Laddie J's Foreword to the CIPR report.*

– *IPRs could lead to higher prices for imported products and new technologies under IPR protection and loss of economic activity due to the closure of imitative activities; the possible abuse of protection by patent holders, especially large foreign companies. (See Maskus, K. (2000) Intellectual Property Rights in the Global Economy, Washington DC: Institute for International Economics. Note, however, that the author argues that the costs are more than offset by the longer-term benefits of IPRs, even in developing countries).*

A recent World Bank publication has noted that:

> "There are reasons to believe that the enforcement of IPRs has a positive net impact on growth prospects. On the domestic level, growth is spurred by higher rates of innovation – although this tends to be fairly insignificant until countries move into the middle-income bracket … In particular, poorer countries … may find it advantageous to stage implementation of some aspects of IPRs."[28]

ENFORCEMENT OF RIGHTS INCREASES WITH INCOME

Several stylized facts emerge from the literature about the level of development and IPRs.

1. Countries with a high ratio of R & D in gross domestic product (GDP) or a high proportion of scientists and engineers in the labor force have markedly stronger patent rights than others. Clearly such countries desire to protect returns on inventive activity.

2. Interests in encouraging low-cost imitation dominate policy until countries move into a middle-income range with domestic inventive and absorptive capabilities. Only at high income levels do patent rights become strongly protective.

– *Least developed countries devote virtually no resources to innovation and have little IP to protect.*

– *As incomes and technical capabilities grow to intermediate levels, some adaptive innovation emerges but competition flows primarily from imitation. Thus, the majority of economic interests prefer weak protection.*

– *As economies mature to higher levels of technological capacity and demands shift toward higher-quality products, domestic firms come to favor protective IPRs.*

[28] See World Bank, 'Intellectual property: balancing incentives with competitive access,' *supra* note 6.

– *The strength of IPRs shift upward at the highest income levels (Evenson and Westphal 1997). Not only do legislated IPRs become stronger, but enforcement and compliance also rise with income levels.*

3. Countries that are more open to trade tend to have stronger patent rights.

– *This result suggests that trade interacts positively with the demand for IP protection.*

– *The size of an economy, as measured by absolute GDP, has no detectable correlation with patent rights.*

Source: World Bank (2001) "Intellectual property: balancing incentives with competitive access" (2001) Global Economic Prospects, 129-150. See also Evenson and Westphal (1997) "Technological Change and Technology Strategy" in Behrman and Srinivasan (Eds.), Handbook of Development Economics (Vol. 3A).

2.2 CORRELATION OR CAUSATION: AN OBSERVATION

It is not within the scope of this study and resources available to engage in a comprehensive evaluation of the perceptions and real causes surrounding the apprehensions and reservations about the current international patent system. Countries in developed and developing worlds appear to be divided over the directions and developments that the international patent system ought to take. It would be difficult to confidently isolate the major causes of these tensions as the chains and agents of causation are often complex and inter-connected.

Notwithstanding this, it may be worthwhile to highlight some of the more common grounds that allegedly contribute to the imbalances that exist in the international patent system. It should be noted that many of these grounds, as with the others, deserve more attention and deliberation than this study can afford.

2.2.1 The TRIPS Agreement

In this innovation age, a drive towards a more uniform or "one-size fits all" patent regime may serve to exacerbate the existing gap between the developed nations (generally regarded as net exporters and owners of IPRs) and developing nations (generally regarded as net importers and users of IPRs). Indeed, it has been argued that the implementation of the TRIPS mandatory minimum standards of IP protection on all WTO members has reinforced, rather than shrink, this gap.[29]

Whilst the effects of the TRIPS Agreement on industry and technology will vary according to the countries' levels of economic and technological development,[30] it has been noted that

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29 See Laddie J's Foreword to CIPR report, *supra* note 5.

30 See, for example, Sanjaya Lall & Manuel Albaladejo, "Working Paper Number 85: Indicators of the Relative Importance of IPRs in Developing Countries," QEH Working Paper Series – QEHWPS85 (April 2002) ("Lall & Albaladejo") ; Braga, C.A.P., Fink, C. and Sepulveda, C.P. (1999) 'Intellectual property rights and economic development', World Bank, background paper

[Footnote continued on next page]

"TRIPS has decidedly shifted the global rules of the game in favor of [industrialized countries]" since the overwhelming majority of intellectual property is created there.[31]

The World Bank has observed that many of the developing countries agreed to the TRIPS Agreement in order to gain concessions from rich ones in other areas of economic activity (or for greater aid)[32] and expressed the view that "developing countries went along with [it] for a variety of reasons, ranging from the hope of additional access to the agricultural and apparel markets in rich nations, to an expectation that stronger IPRs would encourage additional technology transfer and innovation."[33] However, the "promise of long-term benefits seems uncertain and costly to achieve in many nations, especially the poorest countries."[34] Apart from the structural costs of implementation, some less developed countries face immediate obstacles such as the "administrative costs and problems with higher prices for medicines and key technological inputs."[35] In addition, these countries generally lack the requisite technological capability to benefit from domestic innovation and hence, expect less intellectual property to be generated. It is thus not surprising to find that some developing countries encourage low-cost imitation in the hope of securing rapid capacity building.

ECONOMIC CASE FOR TIGHTENING IPRs?

Given the clear net short-term costs to less industrialized countries from IPRs – higher prices for technology and protected products – a valid economic case for them to accept TRIPS (interpreted here as the tightening of IPRs) entails that they reap larger net long-term benefits (technology and FDI inflows and stimulus to local innovation). Moreover, the present value of these benefits … must more than offset the present value of these costs…. [T]his requires that the benefits be very large and accrue in the medium term: any that accrue after, say, a decade would be practically worthless in terms of present value.

Source: Sanjaya Lall & Manuel Albaladejo, "Working Paper Number 85: Indicators of the Relative Importance of IPRs in Developing Countries," QEH Working Paper Series – QEHWPS85 (April 2002).

It, therefore, remains an open question as to whether the developing countries that agreed to the TRIPS Agreement in order to gain concessions from the developed world in

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for the World Development Report 1999, Technet Working Paper available at http://www.cid.harvard.education/cidtrade/issues/ipr.html; Maskus, K. (2000) Intellectual Property Rights in the Global Economy, Washington DC: Institute for International Economics at http://www.iie.com/publications/publication.cfm?pub_id=99.

31 See World Bank (2001), 'Intellectual property: balancing incentives with competitive access,' *supra* note 6.

32 See Lall & Albaladejo, *supra* note 30, at p 85. See also World Bank (2001) 'Intellectual property: balancing incentives with competitive access,' *supra* note 6.

33 See World Bank (2001) 'Intellectual property: balancing incentives with competitive access,' *ibid*.

34 See World Bank (2001) 'Intellectual property: balancing incentives with competitive access,' *ibid*.

35 *Ibid*.

other areas of economic activity (or for greater aid) actually did so.[36] There is indeed a case for further review of the scope and operation of the TRIPS Agreement. If there is any real or potential detriment arising from material imbalances in the trading of concessions between the developed and developing countries over the TRIPS Agreement and its actual, rather than intended, operation then the solutions available to redress them are certainly within our grasp.

2.2.2 Structural Inadequacies in Developing Countries

While the issues highlighted with respect to the TRIPS Agreement are unlikely to disappear in the near future, it may be rather simplistic or premature at this stage to attempt any conclusions about the role played by the TRIPS Agreement, or any other similar multilateral agreement, in some of the developing countries' failure to reap the benefits expected from a fuller participation in the international patent system. Notwithstanding this, there is little doubt that some developing countries have valid concerns that need to be addressed. However, the solution does not lie in recriminations of international obligations that have been duly adopted in the exercise of national sovereignty. Where there is incontrovertible evidence of deficiencies, pragmatism demands a dedicated search for consensual compromises that might mitigate the effects of unforeseen and unintended repercussions experienced by different countries.

As with all other international agreements, benefits from participation are difficult to quantify, let alone equalize. The links between intellectual property rights, innovation, foreign direct investments (FDI) and long-term economic growth are poorly understood, and remain controversial.[37] It appears to be non-linear and certainly seems to be dependent on other factors, such as, the level of economic development,[38] maturity of the legal system, political will to adopt appropriate initiatives, quality of the labor force, effective transfers of technology and the effective functioning of state machinery. In the short term, it may be illusory to contemplate that mere enhancements to existing intellectual property regimes would constitute an immediate panacea for the observable structural inadequacies in some of the developing countries.

2.2.3 Issues of Public Interest: Health and Food

Since one of the key objectives of the patent system is to reward innovation by allowing innovators to charge "higher prices" for protected products, it has been argued that a fully functional patent system would result in an inverse relationship between the cost of such products and affordability of access.[39] Some have gone further to suggest that the global intellectual property system is facing a crisis of public legitimacy as citizen groups around the

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36 See World Bank (2001), 'Intellectual property: balancing incentives with competitive access,' *supra* note 6 and Lall & Albaladejo, *supra* note 30.

37 See World Bank (2001) "Global Economic Prospects and the Developing Countries 2002: Making Trade Work for the World's Poor" at p 135.

38 See, for example, Carsten Fink, "Intellectual Property Rights and US and German International Transactions in Manufacturing Industries." Manuscript, World Bank, 1997, Washington, D.C.

39 See Lall and Albaladejo, Indicators of the relative importance of IPRs in developing countries, paper prepared for the UNCTAD/ICTSD Capacity Building Project on Intellectual Property Rights and Sustainable Development, April 2002, at pages 2- 3.

world are raising questions, for example, on how patents may be blocking the access of ordinary people to medicines.[40]

While a stronger patent regime may provide the incentive (noted by the World Bank to be "marginal")[41] for pharmaceutical firms to discover new treatments for some "third world" diseases, there is an urgent need to consider corresponding enhancements in access to medicine. The situation in some least-developed countries that are facing a critical need for urgent access to some pharmaceutical products to treat HIV/AIDS, malaria, tuberculosis and other diseases merits serious attention. It is submitted that the patent regime can rise to the challenge of improving the accessibility of some medicines to the poor and possibly differential pricing for costly treatments that often accompany new medical breakthroughs.[42]

The call for such moves has also been echoed recently by Jean-Pierre Garnier, GlaxoSmithKline's chief executive officer,[43] in his impassioned call on drug innovators to use their discoveries to help those who need it most.[44] He urged pharmaceutical and biotechnology companies to provide cheap medicines to sufferers in the developing world.

2.2.4 A Case of Perception Rather than Reality?

The perception of a tilt in global IP rules in favor of the developed world and the uncertainty surrounding the nature of the long term benefits to the less developed world have made the underlying unhappiness of some less developed countries more acute in recent years. This is particularly so when compared to their immediate costs[45] and benefits in settling for a weaker IP regime. The push by developing countries for greater protection in traditional knowledge and genetic/bio-resources, the recent controversy arising from the HIV/AIDS pandemic, the call for better access to some pharmaceutical drugs and treatments are manifestations of increased tensions between the developed and the developing worlds.[46]

The intensity of these tensions has in no small part been exacerbated by the arguments of various interest and lobby groups. On the one hand, some deduce that "there is no reason why a system that works for developed countries could not do the same in developing

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40 See, for example, Martin Khor, Patents System Facing Legitimacy Crisis, Earth Trends, Monday 26 March 2001 at http://www.twnside.org.sg/title/et0110.htm.

41 See World Bank (2001) 'Intellectual property: balancing incentives with competitive access,' *supra* note 6.

42 See also, World Bank (2001) 'Intellectual property: balancing incentives with competitive access,' *supra* note 6.

43 The head of the world's second largest drugs company.

44 See article by Legal Media group, "Glaxo chief challenges industry on cheap drugs" (22 June 2003) at http://www.legalmediagroup.com/default.asp?Page=1&SID=12738&CH=5&CN=&CountryName=&Type=News.

45 It is argued that the costs (higher prices of imported products and new technologies under IPR protection; loss of economic activity due to the closure of imitative activities; the possible abuse of protection by patent holders, especially large foreign companies) are more than offset by the long-term benefits of IPRs, even in developing countries. See Maskus, K. Intellectual Property Rights in the Global Economy (2001), Institute for International Economics, Washington DC. Available at http://www.iie.com/publications/publication.cfm?pub_id=99

46 See also Intellectual Property Office of Singapore (IPOS) submission. (See Compiled Comments).

countries."[47] On the other hand, others proceed on historical perspectives that in the early industrialization of today's developed world, weak patent protection was leveraged off to enable them to build up their scientific and technological capabilities through copying and reverse engineering, and the call for a stronger patent regime grew over time as these countries progressed up the technological ladder to become leaders in their fields.[48] This call has been reiterated recently by the CIPR:

> "[D]eveloping countries should not be deprived of the flexibility to design their IP systems that developed countries enjoyed in earlier stages of their own development, and higher IP standards should not be pressed on them without a serious and objective assessment of their development impact … We need to make sure that the IP system facilitates, rather than hinders, the application of the rapid advances in science and technology for the benefit of developing countries."[49]

Some will find these arguments neither persuasive nor entirely fallacious. Be that as it may, it is submitted that as each nation evolves through various stages of technological, economic and social development, it is likely to derive different types and degrees of benefits in any system of rules. It is highly unlikely that the international patent system will succeed in moving in tandem with the subjective needs of any nation whether it is at its early stages of technological industrialization or is a technological leader in the world. The merits of the international patent regime ought not to be too harshly judged on its ability to eliminate inevitable unevenness or transient inequities in the benefits expected by all participants from both the developed and developing worlds. Whatever the real cause or combination of causes may be, there are clearly differing rates of participation and gains experienced by developing countries in the international patent system. See the charts below:

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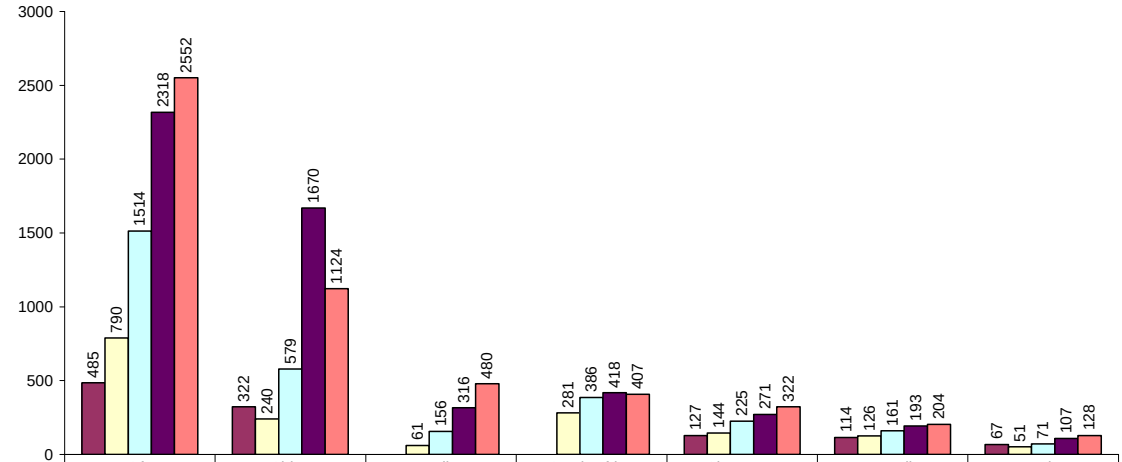
47 See CIPR report, *supra* note 5, at p 1.

48 See Lall & Albaladejo, *supra* note 30; see also Edmund W. Kitch, "The Patent System: A Design for All Seasons?" paper delivered at the WIPO Conference on the International Patent System, Geneva, March 25 to 27, 2002.

49 See CIPR report, *supra* note 5, at p 8.

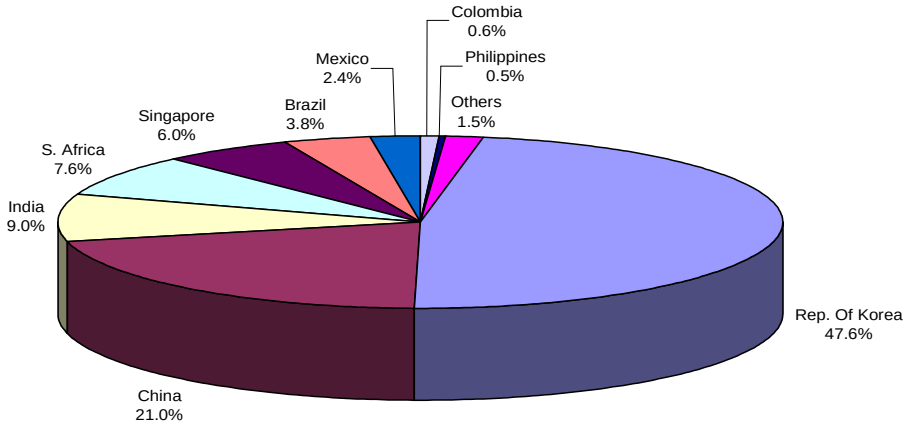
EVOLUTION OF PCT FILINGS IN SEVEN MAJOR DEVELOPING COUNTRIES (1998-2002)



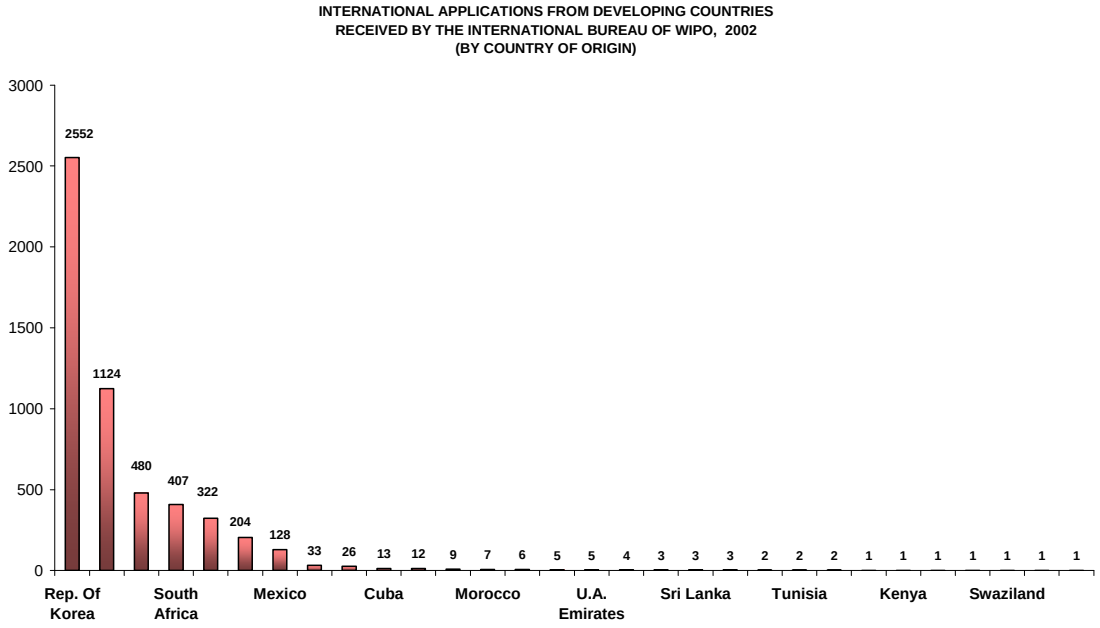
	Rep. Of Korea	China	India	South Africa	Singapore	Brazil	Mexico
1998	485	322			127	114	67
1999	790	240	61	281	144	126	51
2000	1514	579	156	386	225	161	71
2001	2318	1670	316	418	271	193	107
2002	2552	1124	480	407	322	204	128

(Source: WIPO)

INTERNATIONAL APPLICATIONS FROM DEVELOPING COUNTRIES RECEIVED BY THE INTERNATIONAL BUREAU OF WIPO, 2002 (BY COUNTRY OF ORIGIN - PERCENTAGE)



(Source: WIPO)



(Source: WIPO)

2.3 CONCLUSION

It has been suggested that it would be in the interests of the developed/industrialized countries to provide assistance to the less developed world[50] and to support a more flexible international patent regime. The importance of flexibility in creating an effective international patent system must be a critical component for "governments and policy-makers, for inventors and industry, for national and international markets, and for consumers and the general public."[51] This would better optimize the benefits that may accrue to all nations at different stages of development.

It is submitted that the key to avert undesirable escalations of tensions between nations is to further enhance the flexibility that could be built into the existing framework of the international patent system. It would be idle to pretend that any group of nations is homogeneous. The call for further differentiation of countries within the group of "developing countries"[52] certainly merits attention. In addition, the international patent system could strive to support differentiation of patent laws by degree, content and industry that is compatible with the economic, social, political and technological developments of a country.

The timely establishment by the Director General of the World Intellectual Property Organization (WIPO) of its Patent Agenda and the UK Government of its Commission on Intellectual Property Rights (CIPR) are desirable steps in our search for meaningful solutions. Indeed, the current study into the impact of the international patent system on developing

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50 See World Bank (2001),'Intellectual property: balancing incentives with competitive access', *supra* note 6.

51 See WIPO Patent Agenda (A/36/14), see *supra* note 1, at p 1.

52 See IPOS submission (Compiled Comments).

countries serves to re-affirm the urgency of the matter and hopefully would lead to more global dialogues on these and other related issues.

Any neglect in establishing timely and effective responses to these problems may serve as a catalyst for the erosion of its credibility and legitimacy. In its search for solutions, it is vital that the international patent system holds firmly to "its core principles: principles that have the public interest at their center."[53] It should encourage international cooperation that will enhance a flexible patent policy tool for public and private stakeholders in developed, developing and least developed countries alike so that patent rights are managed as "part of a nation's stock of intangible assets" to be exploited for the ultimate and widespread public benefit of all.

This study does not seek to re-state the many exemplary activities in the WIPO, such as those relating to the:

- Patent Law Treaty (PLT),
- Draft Substantive Patent Law Treaty (SPLT),
- Reform of the Patent Cooperation Treaty (PCT),
- Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, and
- Various information technology projects.

Instead, it will seek to propose some key guiding principles and highlight selected areas for consideration.

[53] See WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6) at Annex I p 3.

CHAPTER 3:

PRINCIPLES OF GOVERNANCE FOR THE EVOLUTION OF AN EFFECTIVE INTERNATIONAL PATENT SYSTEM

3.1 INTRODUCTION

It is a trite suggestion that any attempt to achieve full global patent harmonization is likely to be futile, at least in the near future. Neither can much value be gained from a profiling of countries, or groups of countries, for the main purpose of identifying or resolving the causes of imbalances that exist within, and between, some of the developed and developing worlds. Nevertheless, there are concerns highlighted in the WIPO Patent Agenda, CIPR report, and those expressed by national governments that are valid and deserve further attention.

An immediate evaluation of the causes of the imbalances and tensions within, and between, some of the developed and developing worlds, and the practical solutions for ameliorating them, will be a useful step towards a search for a more effective global patent regime that caters to the varying needs and interests of its participating countries. While the survey on the impact of the current international patent system on developing countries may appear to be conducted along geographical blocs that are evidently not homogenous, there is little doubt that it will reveal common issues such as causes and degrees of tensions/imbalances as well as the nature of the solutions required. This study will eschew "micro-evaluation" for some broad guiding principles that are regarded as pertinent for a comprehensive approach to these challenging issues and solutions. They are, namely, as follows:

3.2 SUGGESTED PRINCIPLES OF GOVERNANCE

(1) CONVERGENCE, NOT FULL HARMONIZATION, IS THE PROCESS

In an increasingly integrated world economy, it is imperative to secure a more uniform international patent regime across countries. Critical inconsistencies and incompatibilities in national patent laws and regulations between countries will pose severe impediments that may distort the efficient flows of technology and investment. It is worthwhile to note that the bilateral, regional and international agreements and treaties relating to patents, such as, the Paris Convention, Patent Cooperation Treaty (PCT) and the TRIPS Agreement seek to ameliorate some of these distortions.

The WIPO has noted that whilst one of the prevailing questions for the international patent system is that of patent law harmonization that may produce the "world patent,"[54] it is "not an end in itself, but a tool - a means to an end. It is not … important exactly what legal form or structure this harmonization takes. What matters is to give national and regional patent authorities access to a common operational platform that permits them to cooperate, exchange information, share resources and reduce duplication in their work."[55]

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[54] See WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6) at Annex I p 3.

[55] See WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6), *ibid*.

If and when harmonization is to be attempted in whatever form and degree, it is submitted that a distinction between the procedural and substantive patent law aspects of the international patent system ought to be maintained. At the procedural level, some degree of harmonization would further streamline the operational aspects of the international patent system. For example, the Patent Law Treaty (PLT) aims to harmonize patent formalities to enhance "legal certainty whilst continuing to streamline and simplify practices and procedures, reduce costs and [maintain] quality in the rights granted."[56]

To the extent that some standardization of aspects of substantive patent laws may be necessary to support procedural harmonization, they ought to be advanced.[57] Beyond that, it is submitted that any measure to achieve full scale harmonization of substantive patent rules worldwide may be questionable, at least in the near future. Indeed, the WIPO has also noted that "full and deep harmonization remains a long way off."[58]

Instead, the international patent system could consider first moving towards a convergence of outcomes, rather than full harmonization of substantive rules. It is submitted that convergence of the desired outcomes in substantive patent laws and policies ought to be one of the major tools with which an ideal international patent regime can be created. Each desired outcome may be defined by reference to a set of measurable standards that are capable of being calibrated to take into account factors including the specific needs of an industry/technology or the developmental needs of a country. By way of an illustration, the desired outcome of improving access to medicine in the field of public health relating to HIV/AIDS and other diseases may be achieved through different means, such as, compulsory licensing, parallel imports, differential pricing or any other mechanism that may be developed from time to time.

(2) FLEXIBILITY AND DIFFERENTIATION ARE THE KEYS

In achieving this goal, it is imperative for the international patent system to remain flexible and amorphous centered on the public interest[59] to accommodate the different stages of technological, economic, social and political development of nations at any given point in time. A "one-size fits all" patent regime would only serve to exacerbate the existing tensions between nations that perceive an inequitable distribution of benefits. Instead, it should adopt a more sophisticated framework in which there are degrees of differentiation in outcomes and standards by content and time, to cater to the specific needs of each technological industry and nation.

Indeed, the WIPO Patent Agenda, CIPR report and the current study on the impact of the international patent system on developing countries are clear affirmations that flexibility is

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56 See WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6), *ibid*.

57 See, for example, the draft Substantive Patent Law Treaty (SPLT) relating to the harmonization of substantive patent laws worldwide.

58 See WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6), *ibid*.

59 The WIPO Patent Agenda states the core principles of the patent system as "principles that have the public interest at their center." See WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6), *ibid* at Annex I p 3.

a critical component in creating an effective international patent system for "governments and policy-makers, for inventors and industry, for national and international markets, for consumers and the general public."[60]

(3) IDEAL BALANCE IN A ROBUST SYSTEM IS THE GOAL

A robust and dynamic international patent system that "operates to the maximum benefit of the countries that participate in it, taking account of their widely varying stages of technological and economic development"[61] to promote technology transfer and investment for the advancement of the public good is the goal. The pursuit of an ideal balance between the desire to encourage innovations with appropriate incentives and the need to preserve reasonable access to, and use of, knowledge and information arising therefrom may involve a conflict between allocative[62] and dynamic[63] efficiencies. However, policy makers are recognizing that dynamic efficiency remains the vital growth engine.[64] Yet, it is important to bear in mind that simply offering enhanced protection does not necessarily lead to more ideas and innovation. On the contrary, over-protecting IP can sometimes "stifle further ideas and innovation because future innovation depends on the ability to use past ideas that may be protected by intellectual property rights. [A] careful balance needs to be drawn between protecting ideas to encourage innovation and ensuring that those protected ideas do not stifle further innovation."[65] This will require the interests and needs of both developing and developed countries to be taken into account recognizing that patent is "one of the tools for technological advancement, economic growth and wealth creation for all countries."[66] In this regard, it may be useful to bear the following general principles in mind, namely, that:

(a) No Perfect International Patent System

There is no perfect international patent system that can satisfy all the needs and interests of inventors, investors, users and the general public within, and between, developed and developing countries. Furthermore, an international patent regime operates within the complex economic, political and social sub-systems of each country.

(b) Market Forces to Determine Pricing Policies

It is clearly beyond the scope of this study to evaluate the relationship between patents and the existence of predatory pricing, monopolistic business strategies or other exorbitant

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60 See WIPO Patent Agenda (A/36/14), see *supra* note 1, at p 1.

61 See WIPO Patent Agenda (A/36/14), see *supra* note 1, at p 2.

62 "Allocative efficiency," which is a short-term concept, requires that new information should be disseminated as widely and quickly as possible at cost and that IPRs (such as patents) should be limited in scope and length. See the submissions from the Ministry of Trade and Industry (MTI), Singapore (Compiled Comments).

63 "Dynamic efficiency" is concerned with optimal innovation over time, recognizes that innovation needs incentives therefore creators need to be rewarded by broadening the scope and length of IPRs (such as patents). See the submissions from the Ministry of Trade and Industry (MTI), Singapore (Compiled Comments).

64 See the submissions from the Ministry of Trade and Industry, Singapore. (Compiled Comments).

65 See the submissions from the Ministry of Trade and Industry, Singapore. (Compiled Comments).

66 See WIPO Patent Agenda (A/36/14), see *supra* note 1, at p 3.

pricing policies that may arguably compromise the objectives and goals of the patent system. However, it would be worthwhile to consider embarking on a detailed study of pricing policies and access in a separate study or forum. In the absence of a specific regulatory pricing framework for patents, it would be desirable to allow market forces to achieve the balance.

(c) Need to Preserve the Benefits of Competition

The evolution of an effective international patent system cannot be achieved to the exclusion of benefits that come with the preservation of some degree of competition in the global and borderless marketplace. While the adoption of selective sectoral regulation and open markets may to some extent ensure a competitive environment in the domestic economy,[67] nonetheless, there are risks in the concentration of market power in a few giant corporations of the world.[68] While competition laws may curb the legitimate rights of a patent owner,[69] the unmitigated exercise of full patent rights may degenerate to abusive practices that diminish innovation and knowledge diffusion.[70] It is important to reconcile these inevitable, though not necessarily conflicting, tensions. In the evolution of the international patent system, there may be a need to augment the causes of actions and remedies available under national patent laws that are consistent with the rationale of competition laws or the principles embodied therein.

(d) Rule of Law Is Fundamental

With increasing tensions arising from any real or perceived imbalance within, and between, some of the developing and developed world, there is an urgent need to take immediate measures to redress these tensions that may threaten to undermine the attainable objectives of a global patent regime. Negative perceptions of the international patent system are inimical to the rule of law that underpins it. It has been said that the powerful and vociferous lobbies "for" (on behalf of the developed world) and "against" (on behalf of the developing world) a strong international patent regime has ended in an undesirable aftermath of "persuasion is out, compulsion is in."[71] A failure to address these issues effectively may, to some extent, "legitimize" piracy and low cost imitation.

The "unprecedented public health challenge" arising from the "humanitarian calamity of HIV/AIDS"[72] is but one manifestation of the "rising apprehension and unease." This resulted in the WTO's Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration) that was "at core a response to the concern of many governments that they

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67 As in the case of Singapore which has no generic competition law, although she intends to enact a generic competition law by 2005. See the submissions from the Ministry of Trade and Industry, Singapore. (Compiled Comments).

68 See Martin Khor, "The WTO and the South: Implications and recent developments" at http://www.twnside.org.sg/title/pli-cn.htm.

69 See, for example, submissions from Ministry of Trade and Industry, Singapore, generally. (Compiled Comments).

70 Take, for example, "pricing restrictions" and "tie-in" or "tie-up" clauses in patent licensing agreements.

71 Laddie J. in the Foreword to the CIPR report.

72 WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6), *supra* note 15, at p 2.

should have adequate policy flexibility at a national level to address public health problems."[73]

The preservation of the rule of law is fundamental for an effective international patent system with enforceable standards. This will minimize the risk of breakdown, rejection, circumvention and compliance in form (but not in substance) of the laws of countries that participate in the international patent regime.

(e) Stringent and Cross-Border Enforcement of Patent Laws

It is trite to emphasize that strict enforcement of patent rights is as important as the rigor of the substantive rules themselves. The extent to which violations can be detected or are penalized consistently under national system plays a critical role in the integrity of the international patent regime. Where serious violations amount, *inter alia*, to offences under the national laws, it may be worthwhile to explore the benefits of enhancing the opportunities for mutual assistance and cooperation between national agencies.

(f) Effective Resolution of International Patent Disputes

An effective mechanism for the resolution of international patent disputes is critical to the evolution of a robust international patent system. Such a mechanism will not only complement the patent enforcement regime but will also provide the much needed certainty and impetus for the global exploitation of patents. An effective mechanism should aim to provide finality to the outcomes of dispute resolution within a reasonable time-frame to avoid any undue delay in exploitation and deployment of patents.

(4) REFORM IS A MUST

A more integrated global market coupled with the strengthening of IP protection have, to a large extent, contributed to the imbalances and tensions between some of the developed and developing countries. As scientific and technological developments gather pace, the pressure to reform some aspects of the international patent system will increase. The WIPO PatentAgenda, CIPR report and other national and international studies, including this one, portend meaningful international reforms that would further strengthen the goals of the patent system.

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[73] See WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6), *supra* note 15, at p 3.

CHAPTER 4:

OPPORTUNITIES FOR REFORM

4.1 INTRODUCTION

The confluence of forces exerted by politics, economics, technology and public interests has aggravated the tensions between some developed and developing countries. Indeed, the "need to find immediate solutions to some acute problems have given rise to renewed momentum for change … Change in the wide sense is vital, and it should be based on long-term needs and objectives, in addition to addressing present critical concerns."[74] Any reform "solely at a national level is impractical, and in some cases would even be counter-productive."[75] An effective reform strategy requires international consensus on priorities that require immediate action.

This study is not a technical review of the detailed provisions of national and international sources of law, as they have been comprehensively addressed in numerous scholastic works and outstanding national and international initiatives.[76] Instead, it provides observations on broader concerns that may be dealt with in 2 parts. Part 4.1 "Procedural and Infrastructural aspects of patent law" offers perspectives into some issues on processes in connection with the grant of patents as well as some implications arising from some provisions of the Patent Law Treaty (PLT) and ongoing reform of the Patent Cooperation Treaty (PCT). In Part 4.2, "Selected Substantive aspects of patent law reform," I highlight reform options in some major substantive areas of patent laws that relate to public health, protection of biotechnology-related inventions and traditional knowledge.

4.2 SOME PROCEDURAL AND INFRASTRUCTURAL ASPECTS OF PATENT LAW REFORM

4.2.1 Administrative Capacity and Human Resources

> "[I]internationalization of the patent system is not just an interesting and lofty idea: it is an inevitable fact of life."[77]

In this regard, considerable progress has been achieved through existing regional[78] and international patent systems, such as, the Paris Convention, PLT,[79] PCT,[80] Budapest Treaty[81]

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74 See Dr. Kamil Idris, Director General of the World Intellectual Property Organization (WIPO), Opening address to the WIPO Conference on the International Patent System, Geneva, March 25 to 27, 2002.

75 See WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6) at Annex I p 4.

76 Such as the WIPO Patent Agenda, CIPR and works by other national and international organizations. See also other works published by the WIPO under its many initiatives including those relating to the Patent Law Treaty (PLT), the draft Substantive Patent Law Treaty (SPLT), reform of the Patent Cooperation Treaty (PCT) and the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore.

77 See WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6) at Annex I p 4.

78 Regional patent systems include the Organisation Africaine de la Propriete Intellectuelle (OAPI), African Regional Industrial Property Organization (ARIPO), the European Patent

[Footnote continued on next page]

and the TRIPS Agreement. These have made major inroads into streamlining the procedural aspects of the international patent system. But "[r]apidly advancing technology and changes in the way that the system is used mean that processes which were appropriate in the past, both in the PCT and national systems, may need reevaluation."[82] The WIPO's Patent Agenda succinctly identified features of the patent system that "can or should be truly internationalized" and those which "could be enhanced or facilitated at the national level by options made available through international arrangements."[83]

However, much of the procedural and infrastructural concerns of reform appear to be confined to the amelioration of problems faced by patent offices and users of the international patent system. As a result of globalization of trade and commerce, "technology-based, internationally focused, export-oriented enterprises" file multiple patent applications in many different countries.[84] This has strained the ability of some patent offices to meet the growing user demands at the national, regional and international levels.[85] Some of the immediate concerns are elaborate patent procedures, excessive workload and unnecessary duplication experienced by some patent offices.[86] In some cases, this is aggravated by a lack of expertise in search and examination of patentability of a broad range of new technological subject-matter.

The 2 charts below show an exponential increase of more than 8000% in international patent applications received by the WIPO from developing countries between 1991 and 2002. Of these, more than 80% of the patents filed in 2002 were from the Asia-Pacific region.

[Footnote continued from previous page]

Office (EPO), and the Eurasian Patent Office (EAPO). For more details, see WIPO Patent Agenda (A/36/14), *supra* note 1, at p 3.

79 The main aim of the PLT is the harmonization of procedures for application, acquisition and maintenance of patents. It expressly excludes substantive aspects of patent law. See WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6) at Annex I p 9. See also the South Centre, T.R.A.D.E. Working papers on "The WIPO Patent Agenda: The Risks for Developing Countries" (2002).

80 The PCT provides for procedural standards of patent law. Ongoing reform of the PCT aims to further simplify and streamline international patent procedures. See WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6) and Working Group on the Reform of the Patent Cooperation Treaty (PCT): Options for Future Development of International Search and Examination (PCT/R/WG/4/7) (May 2003).

81 The Budapest Treaty on the Deposit of Micro-organisms provides a system for the international recognition for deposits of micro-organisms for the purposes of patent disclosure.

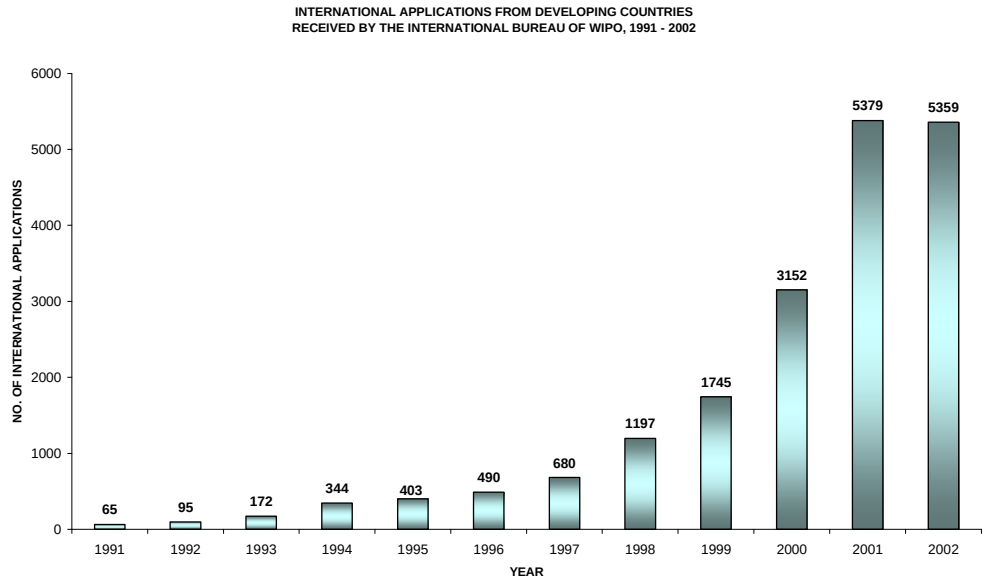
82 See Memorandum of the Director General of the WIPO on the WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6) at Annex I p 7.

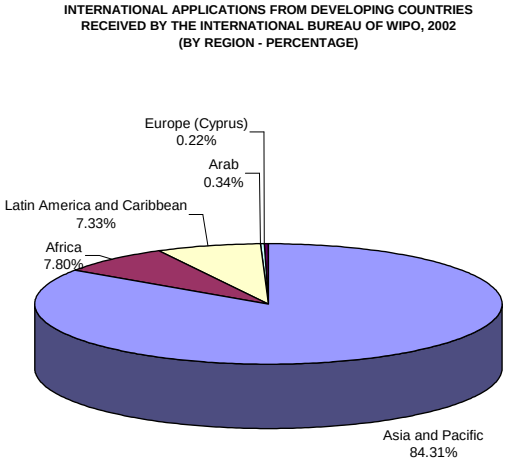
83 See the Memorandum of the Director General on the "WIPO Patent Agenda: Options for Development of the International Patent System" (A/37/6) at Annex I p 5.

84 See WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6), *supra* note 15, and WIPO Patent Agenda (A/36/14), see *supra* note 1.

85 See WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6), *supra* note 15.

86 See the 2 charts above.





(Source: WIPO)

4.2.2 Some Possible Solutions and Responses

The unprecedented escalation of workload in national patent offices is a result of both increased world trade as well as an effective international patent system. The extent to which an increased load impairs work performance could also be a function of structural efficiency and operational productivity. While the risk of severe paralysis to the system has not been presented, many scholars support the ongoing reform of areas that may afford some vital relief. In this regard, it is submitted that the costs of separate or simultaneous work by numerous patent offices to process and grant patents for the same invention are prohibitive. An evaluation of potential measures to eliminate costly and wasteful duplication may require a separate scrutiny of the search and examination processes for the grant of patents.

The CIPR has noted that such duplication could be “avoided by harmonizing differences in standards and criteria in search and examination procedures. For some, the

ultimate goal is an international patent, valid throughout the world and based on a single application process."[87] Although that goal of a "world patent" is commendable and intact, full global patent harmonization is unlikely to be achieved, at least in the near future. Currently, there is "not yet the degree of harmonization, confidence and experience necessary to establish a fully integrated international patent system."[88] Notwithstanding the difficulties and controversies, the scholarly works[89] in this area carry many recommendations that may be worthwhile to pursue. The opportunity for selective incremental reform ought not to be passed over.

For example, it has been recommended that under the PCT, "an international search opinion, equivalent to a written opinion in the international preliminary examination procedure (under Chapter II of the PCT) … [be] produced at the search stage for every application"[90] wherein the "international search and international preliminary examination procedures will be combined to a much greater extent than is the case at present."[91] There is also merit in exploring possible alignments to the recently adopted PLT that seeks to achieve further harmonization of patent formalities. The procedures for application, acquisition and maintenance of patents can be further streamlined.[92]

Currently, the extent to which a patent office makes use of materials derived from another patent office has been left to the discretion of individual states.[93] In this regard, the WIPO's proposal for patent offices to envisage certain forms of "recognition or exploitation of the work of other offices"[94] deserves serious consideration. Various alternatives put forth include an exchange or recognition of search reports by other patent offices and unilateral recognition of examination results of other offices. The possibility of setting up an international assurance system to benchmark the quality of search and examination results has also been mooted.[95] The value of a quality assurance mechanism cannot be overlooked as the

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87 See CIPR report, *supra* note 5, at p 113.

88 See WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6) at Annex I p 6.

89 See, for example, WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6), WIPO Patent Agenda (A/36/14), see *supra* note 1, the paper by the Working Group on the Reform of the Patent Cooperation Treaty (PCT): Options for Future Development of International Search and Examination (May 2003), South Centre report, *supra* note 79, and CIPR report, *supra* note 5.

90 See WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6) at Annex I p 8. See also the observation by the South Centre report, see *supra* note 79, at p 15, that reform "does not entail establishing a PCT Search Report which is regarded as conclusive. This is a positive element, since it will preserve the room for national patent offices to disagree with the conclusion reached in the report. It is also indicative … that … developed countries are not prepared to lose their autonomy in the examination of patent applications."

91 See South Centre report, *supra* note 79, at p 13.

92 See WIPO Patent Agenda (A/36/14), see *supra* note 1, at p 7. See also generally WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6).

93 See WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6) at Annex I p 6.

94 See WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6) at Annex I p 10.

95 See WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6). It is worth noting that some countries, for example, Singapore, have unilaterally implemented schemes that recognize the search and examination results obtained in other patent offices.

next big step towards the formation of a uniform mutual recognition system that facilitates an elective exchange of materials between all patent offices.[96] However, some developed countries, such as the USA, have called for more radical reforms including a "more fundamental overhaul of the PCT system in order to facilitate global patenting."[97]

4.2.3 What is the Fair Price for Further Harmonization?

The pain that accompanies every change may be successfully mitigated if we remain vigilant to the risks of neglecting the need to re-integrate disaffected nations that may have common interests or causes. Yet, the strive to reform the international patent system cannot and must not be hindered by private or parochial concerns. What these concerns might be may be difficult to articulate. The appropriate price and time to pay for extracting efficiency gains from further harmonization has to be determined by all participants of the international patent system.

It is vital to seize opportunities to create a broad and deeper participation between developed and developing countries in the process of reform. For instance, it is submitted that developed countries could assist developing countries in capacity building programs such as the training of patent examiners, management of patent registries and enhancement of search and examination processes. The assistance could extend to include financial grants and other aids to educate and provide technical support to the officers of patent offices and users.

In addition, there is a need to keep abreast of improvements in information technology to optimize the gains from reform efforts. National patent offices of some developed countries could consider integrating relevant databases to support unified search, retrieval and storage functions. Where appropriate, information that would aid the reduction of costs and redundancy may be migrated to the public domain. Technology can be harnessed to free the patent system from the multiplicity of potentially incompatible data and functions without compromising procedural standards[98] that may "open the door for manipulation and fraud."[99]

4.2.4 Some Reservations by Developing Countries

Some developing countries have expressed reservations that the operation of the system seems to "prioritize the interests of existing patent applicants, typically larger companies in the developed world, over the broader public interest."[100] As it is, there is a perception that

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96 See WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6) at Annex I p 6.

97 See South Centre report, *supra* note 79, at p x.

98 It has been argued that the relaxation of standards relating, for example, to the conditions for the admission of a patent application and the determination of filing date (that will impact on the assessment of novelty and inventive step of an invention) may permit the "deliberate submission of an application prior to the actual conception of an invention," as well as, allow the introduction of "new, different or additional subject matter and claims while benefiting from an earlier filing date." See South Centre report, *supra* note 79, at p 6.

99 Due to the lax requirements, uncertainty about the identity of the applicant may occur and lead to manipulation and fraud. See South Centre report, *supra* note 79, at p. 6.

100 See WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6) at Annex I p 4.

the system poses severe obstacles to a more meaningful and homogeneous participation of individual inventors and smaller enterprises from developing countries.[101]

For instance, the proposal to overhaul the PCT has sparked grave concerns in some quarters that it could "move away from its current, non-binding patentability opinions and adopt procedures where substantive rights could eventually be granted via the PCT."[102] It is argued that the corollary is that positive examination results from *certain* PCT authorities may bind PCT contracting states. More seriously, there is fear that should the PCT eventually create a "world patent" within all contracting states[103], "it would not only mean that most national patent offices would become superfluous but, more importantly for developing countries, the current flexibilities permitted by the TRIPS Agreement with regard to rules on patentability and exceptions thereto would be eliminated."[104]

Another example may suffice. The proposal for the establishment of international "mutual recognition" of search and examination results with quality assurance certification has raised fears that it may further alienate the participation of developing countries. In particular, some of these countries may not satisfy the required standards of process certification if these are adopted and implemented swiftly. Nor are they likely to have the confidence to aspire to be one of the select group of "PCT authorities" that may eventually issue reports that are binding on PCT members. Thus, in the short term, some countries are more likely to see a certain loss of current flexibility for no or little immediate national benefits.

It is easy to appreciate that the validity of some of these concerns may be questioned. However, the management of any change is as important as the change itself. Few reforms can be successfully advanced by simply ignoring the resistance and opposition. Education and dialogues must continue.

4.3 SELECTED SUBSTANTIVE ASPECTS OF PATENT LAW REFORM

The WIPO has stated that the overall objective of further harmonization of substantive patent laws is:

> "[T]o achieve enhanced legal certainty whilst continuing to streamline and simplify practices and procedures, reduce costs and maintaining quality in the rights granted."[105]

The main aim of this part is to offer observations on some areas of substantive patent law that may benefit from some review to strengthen and advance legal certainty in the patent system. With reform of substantive patent law, it is hoped that a patent application filed in one country would satisfy both the formalities and patentability criteria in more, and eventually, all countries. As with procedural reform, further standardization in key areas of substantive laws would greatly ameliorate the workload of patent offices through a reduction

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101 See WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6), *supra* note 15.

102 See South Centre report, *supra* note 79, at p 11.

103 See South Centre report, *supra* note 79, at p 11.

104 See South Centre report, *supra* note 79, at p x.

105 See WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6) at Annex I p 10.

or elimination of redundancies. Indeed, it has been argued that the harmonization of substantive patent law is a central piece in the new proposed architecture"[106] towards achieving a "world patent."

4.3.1 Need for Further Harmonization of Substantive Patent Law Worldwide?

In this respect, considerable progress in reform has been made through existing regional and international treaties. The Paris Convention[107] operating in conjunction with the TRIPS Agreement went some distance in standardizing some areas of substantive patent laws. However, the divergent, and often conflicting, interests of different users made it difficult to establish common grounds on the need and extent of desirable harmonization. For instance, in the area of patentability of subject-matter, many states feel a "particular policy need to retain the flexibility which is available under the present framework."[108] It has been argued by some developing countries that flexibility is consistent with the exercise of sovereignty over key domestic policy issues in areas such as public health, access to bio/genetic resources, patentability of some subject-matter in biotechnology[109] and protection of traditional knowledge.

The ongoing negotiations on the draft Substantive Patent Law Treaty (SPLT) appear to have generated some degree of controversy although several issues appear to have found agreement in principle.[110] As an extension of the mandated requirements in the TRIPS Agreement, the draft SPLT seeks to standardize substantive patent law standards relating to issues such as the requirements of patentability,[111] drafting and interpretation of patent claims, sufficiency of disclosure, revocation and invalidation of a patent. This study does not seek to evaluate the detailed provisions of the SPLT as these have already been comprehensively covered in many scholarly works.[112]

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106 See South Centre report, *supra* note 79, at p 11.

107 The Paris Convention establishes substantive standards in many areas of IP, including patents. It is often said to be the corner stone of the current international patent system. See South Centre report, *supra* note 79.

108 See WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6) at Annex I p 11.

109 Take, for example, the controversy over gene-related patents and cloning. In this regard, it may worth noting that the African Group has reiterated their demand that patents on all life forms and living processes be prohibited. See Khor, "TRIPS debate on biological materials: Africa reiterates proposal to ban life patents" (June 11, 2003) at http://www.twnside.org.sg.

110 Take, for instance, the draft provisions relating to what constitutes "prior art" and industrial application/utility. See WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6).

111 These are, namely, the requirements of novelty, inventive step/non-obviousness and industrial application/utility.

112 For example, See WIPO Patent Agenda (A/36/14), see *supra* note 1, and "WIPO Patent Agenda: Options for Development of the International Patent System" (A/37/6); "Working Group on the Reform of the Patent Cooperation Treaty (PCT): Options for Future Development of International Search and Examination (May 2003). See also South Centre report, *supra* note 79, and CIPR report, *supra* note 5.

SPLT may create a new set of rules on the conditions of patentability – "the political substance of a potential world patent system"[113] – that has implications for both developed and developing nations. Take, for example, issues relating to patentability of subject-matter relating to biotechnology[114], the requirement of "technical character" of inventions, concept of "prior art," interpretation of patent claims and the doctrine of "equivalence." It is thus not surprising that it elicited strong reactions such as:

> "The SPLT is potentially … the most troublesome building-block of the proposed international patent system from the perspective of developing and least developed countries. If adopted, it would establish new binding international standards in critical areas of patent law, so far left to the discretion of national legislation. Strong pressures to adopt such standards both bilaterally and multilaterally … can be anticipated."[115]

Notwithstanding these observations, there is merit in some of the recommendations to standardize provisions especially if they are advanced in conjunction with procedural harmonization such as those outlined above. For example, there is clearly benefit to see some degree of standardization in the exact scope of the concept of "prior art,"[116] "non prejudicial disclosures/grace periods."[117] There are valid concerns, for example, that "in the absence of any international harmonization on ["non prejudicial disclosures/grace periods"], an inventor risks losing patent rights in a jurisdiction [that does not recognize such disclosures] because of disclosure in one that does."[118] Another example relates to the recent proliferation of patents for "trivial inventions" that has sparked calls to raise the standards of inventiveness. The CIPR has urged developing countries to explore "whether a different higher standard is more desirable," pointing out the impact it might have on the "ability of domestic enterprises to protect their own innovations."[119] Where appropriate, it has been suggested that certain class of innovation (i.e. "sub-patentable or incremental innovation") could be protected under the utility model or petty patent systems, or by "improvement patents or certificates of addition." A delicate balance has to be struck to ensure that the standard of inventiveness is not pegged too high that it impedes rather than encourages innovation.

Whilst full harmonization of substantive patent rules may not be attained in the near future,[120] it may be worthwhile to address fears that some developed countries are seeking to impose their "own standards of patentability on the rest of the world"[121] through "webs of

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113 See GRAIN, "WIPO moves toward "world" patent system" (July 2002). Available at http://www.grain.org/docs/wipo-patent-2002-en.doc. Cited in South Centre report, *supra* note 79, at p 20.

114 Such as, genes, proteins and research tools [e.g. expressed sequence tags (ESTs) and single nucleotide polymorphisms (SNPs)]. For a more detailed discussion on biotechnological inventions, see below.

115 See South Centre report, *supra* note 79.

116 Take, for example, the recommendation of the CIPR on whether it should include "disclosure through use anywhere in the world."

117 Namely, disclosures of an invention preceding the filing of the patent application for that invention that do not destroy the novelty of that invention.

118 See CIPR report, *supra* note 5, at p 116.

119 See CIPR report, *supra* note 5, at p 116.

120 See Chapter 3: Principles of Governance for the Evolution of an Effective International Patent System.

121 See South Centre report, *supra* note 79, at p 15.

coercion," whereas, developing countries have had to work through "webs of dialogue."[122] In removing "a significant number of flexibilities"[123] from the TRIPS Agreement, some critics have gone further to predict that the SPLT "could make the World Trade Organization's Trade-Related Intellectual Property Rights (TRIPS) Agreement obsolete."[124]

This merely serves to highlight the rising policy tensions that exist between some developed and developing countries.[125] If such tensions are allowed to fester, it will derail even the finest blueprint for reform. Active engagement of any developing country would greatly entrench the interests of a broader group of stakeholders in the evolution of the patent system. Besides the contents of the draft SPLT, many other controversial issues arising from the application of substantive patent rules would have to be confronted. Several of these, namely issues relating to the protection of inventions in biotechnology, public health and traditional knowledge, are canvassed below.

4.3.2 Challenges Posed by the Application of Patent Law

4.3.2.1 Biotechnology Revolution

Introduction

> "The patent system has never been immune from skepticism as to its validity and public benefit, yet the very success and growth in use of the patent system in recent decades has accentuated policy tensions that are increasingly the subject of international policy debate ... The controversy over the possibility that patents may be hampering governments' attempts to deal with urgent policy issues … and … concerns about the granting of patent protection to some forms of new technology, especially biotechnology."[126]

The biotechnology revolution has generated controversy, as well as promise, that the world has not been confronted with for a long time. The "remarkable development and application of new genetic technologies" have generated "profound changes in the way in which research is commercialized in the life sciences.[127] The phenomenal developments, just to name a few, in genetics,[128] transgenic life forms,[129] medical and gene therapies, xenotransplantation, tissue and organ engineering, embryo selection, proteomics and functional genomics, highlight an urgent need to evaluate the balance between stimulating 'innovation for the public good" and rewarding inventors for useful inventions in

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122 See Braithwaite and Drahos, Global Business Regulation (2000) at p 26, cited also in South Centre report, *supra* note 79, at p 17.

123 See CIPR report, *supra* note 5, at p 132.

124 See South Centre report, *supra* note 79, at p 20.

125 See Chapter 2: Tensions and Imbalances.

126 See WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6) at Annex I pp 2 & 28. See also See WIPO Patent Agenda (A/36/14), see *supra* note 1, generally.

127 See Nuffield Council on Bioethics, The ethics of patenting DNA (July 2002) at p xi.

128 Including human stem cells research [particularly embryonic stem cells (ES cells)] and cloning processes (e.g. reproductive and therapeutic cloning). See, for example, the "Edinburgh patent" highlighted below.

129 Take, for example, Dolly, Polly, ANDi, oncomouse and the recent creation of the hybrid human "she-males." See also the "Edinburgh patent" discussed below.

biotechnology. There are "thousands of patents which assert rights over DNA sequences [that] have been granted to researchers across the public and private sector."[130] (See table below). Patents in gene-related inventions may be construed as a form of "assertion of ownership over components of life"[131] and there are calls to confine protection to "those patents that assert rights over DNA sequences that reflect a significant contribution by the researcher."[132]

Many of the controversy, such as the patenting of life forms and human stem cells[133] and tissues, traverse ethical,[134] social, moral, religious, environmental and regulatory issues[135] that are beyond the immediate concerns of the patent system. This may not be the appropriate forum to discuss these and many other difficult issues. However, observations on two of these issues, namely, the patentability standards for biotechnological inventions, including a discussion on patenting of "research tools," and the appropriate scope for gene-related patents will be offered.

Trends in the patent applications of biological sequences

Over the past 20 years, the increase in the number of sequences being claimed in patent applications has been phenomenal. Sequences first began appearing in patent applications in 1980, just 16 sequences all year. By 1990 that figure had risen to over 6,000 sequences. Throughout the 1990s the growth of patent applications of sequences expanded exponentially, and this looks set to continue. In 2000 over 355,000 sequences were published in patent applications, a 5000% increase over 1990. (Source: Giles Stokes, "Lies, damned lies, and statistics: Patent applications of genetic sequences - on the up and up" (April 2000) at http://www.derwent.com/ipmatters/statistics/genetics.html)

130 *Ibid.*

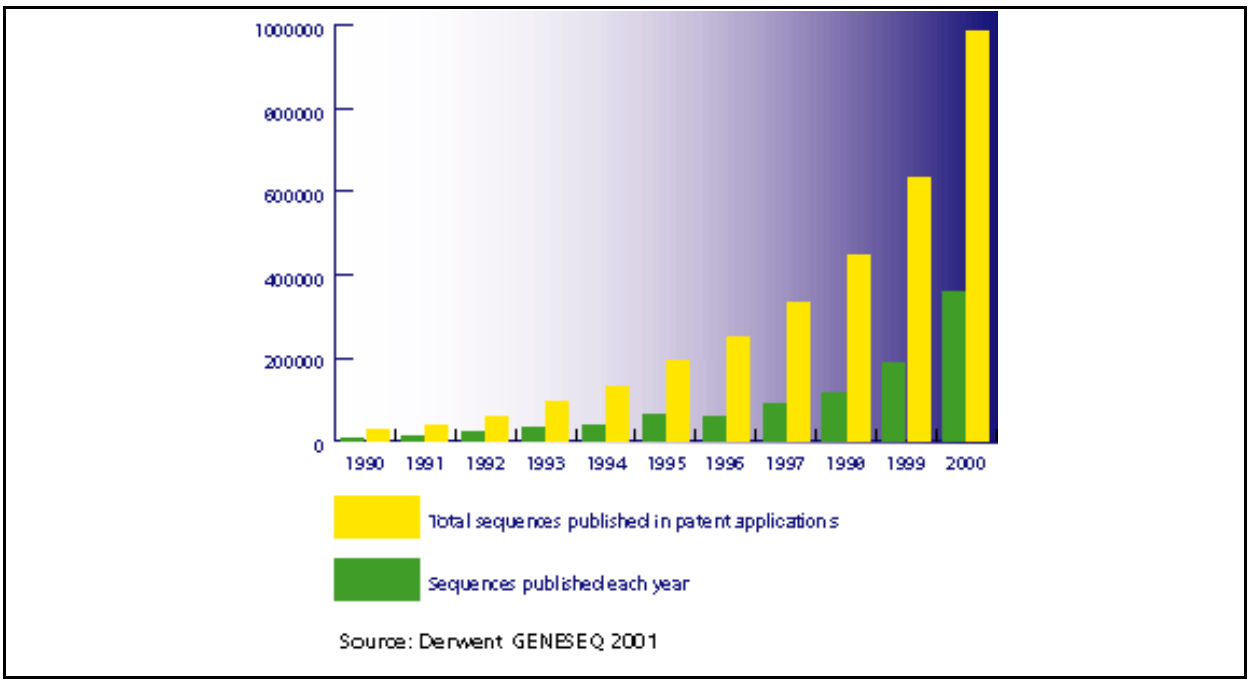
131 See WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6) at Annex I p 31.

132 See Nuffield Council on Bioethics, The ethics of patenting DNA (July 2002) at p *xii*.

133 Including derived cell lines. See for example the Edinburgh patent (EP 0695351).

134 See, for example, Nuffield Council on Bioethics, The Ethics of patenting DNA: a discussion paper (July 2002); Nuffield Council on Bioethics, Animal-to-Human transplants: The Ethics of Xenotransplantation (March 1996).

135 Such as the current debate over whether patenting of some biotechnology-related inventions will contradict the principles of the Convention on Biological Diversity (CBD). See WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6) at Annex I p 28.



Difficulties in Determining Patentability Standards

It would come as no surprise that there is a lack of global consensus on patentability standards for biotechnology-related inventions. It has been observed that:

> "In general, the law has, in our view, tended to be generous in granting patents in relation to DNA sequences. Not only are many of the patents broad in scope, but they have been granted when the criteria for inventiveness and utility were weakly applied."[136]

While there appears to be common ground that a human being *per se* cannot constitute a patentable invention, controversy rages on, *inter alia*, as to gene-related patents, such as sequences or partial sequences of genes or therapeutic proteins, that are said to be "mere discoveries" rather than "inventions."[137] The issue of "whether an isolated and purified form of a natural product is patentable"[138] would also extend to human tissues and cells[139] that are isolated from the human body (or otherwise produced by means of a technical process) that are identical to that of a natural element. In this regard, it should be noted that the exclusion from patentability of inventions the exploitation of which would be contrary to "public order

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136 See Nuffield Council on Bioethics, The ethics of patenting DNA (July 2002) at p 47. See also Trilateral Project B3b, "Comparative Study on Biotechnology patent practices: Patentability of DNA fragments" at http://www.jpo.go.jp. And Trilateral Project B3b, "Nucleic acid molecule-related inventions whose functions are inferred based on homology search" at http://www.jpo.go.jp.

137 See the EU Directive on the Legal Protection of Biotechnological Inventions (98/44/EC) relating to the protection of biotechnology-related inventions, Article 5.1 and the recital thereto. See also EPC Article 53 and EPC rule 23.

138 See South Centre report, *supra* note 79, at p 18.

139 Including human stem cells and cloning processes (e.g. reproductive and therapeutic cloning).

or morality" are found in the patent laws of many jurisdictions. Similar issues arise in the patenting of chimeras, as well as animals, as highlighted by the Harvard oncomouse saga.[140]

Three Main Pillars of Patentability

These issues touch on the three fundamental pillars of patentability – novelty, inventiveness and industrial applicability/utility. In their application to biotechnology-related inventions, it is unclear, for example, whether "novelty" means "new" in the sense that it is not "pre-existing" or is it sufficient if it is new in a prior art sense?[141] Can biological material that has been isolated from its natural environment be the subject of an invention? There is no global consensus on this, although some jurisdictions have sought to provide guidance on this issue.[142]

Difficulties have also arisen in relation to the requirement of inventiveness. Although there is no uniform global standard of inventiveness, the prevalent test seems to be linked to "a person skilled in the art."[143] Discourse is prevalent even on "basic" issues, such as, who is the notional "skilled person in the art," what is the level of expertise possessed by this person in relation to biotechnological inventions and whether the performance of experimental work by a skilled person employing routine means to achieve the solution satisfies the requirement of inventiveness. As an illustration of the potential divergence, the EPO has indicated that *in silico* identification of genes[144] would not be regarded as inventive.[145] The EPO has stated that the "structural non-obviousness is not a reason to accept an inventive step; sequences as well as all other chemical compounds should solve a technical problem in a non-obvious manner to be recognized as inventive."[146]

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140 In the USA, the oncomouse was patented in 1988. It is also patented in Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden and the United Kingdom. A similar patent has been issued in Japan. See also EPO Harvard oncomouse case [1992] OJ EPO 588. Cf. Commissioner of Patents v. President and Fellow of Harvard College (December 2002) (Supreme Court of Canada).

141 See also South Centre report, *supra* note 79, at p 18.

142 For example, in the USA an isolated and purified form of a natural product is patentable, see South Centre report, *supra* note 79, at p 18. See also the EU Directive on the Legal Protection of Biotechnological Inventions (98/44/EC) relating to the protection of biotechnology-related inventions that provides, inter alia, that "Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature." Similarly, an "element isolated from the human body … including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element. (See Articles 3.2 and 5.2 thereof). Contrast this with the Brazilian Patent Law that excludes from patentability "biological materials found in nature" even if isolated, including "genome or germplasm" of any living being; see South Centre report, *supra* note 79, at p 18.

143 Namely, that in order to be inventive, the invention must not be "obvious to a person skilled in the art."

144 I.e. whether to allow "rights asserted over DNA sequences that have been identified and characterized only by in silico analysis of the DNA sequence and comparisons with other identified sequences," see the Nuffield Council on Bioethics, The ethics of patenting DNA (July 2002) at p 50.

145 With whom the Nuffield Council of Bioethics concurs.

146 See the Report of Trilateral Project B3b of the European, Japanese and US Patent Office (November 2001) Annex 2 at p 43 at http://www.european-patent-office.org/tws/report/report_start_page.htm.

Last, there is an urgent need to determine whether the requirement of industrial application is satisfied where only a speculative utility is disclosed. Although there are many well-known applications of DNA sequences, such as, in diagnostic testing, gene therapy and the production of therapeutic proteins,[147] some observations relating to the recent controversy generated by the patenting of research tools will be made.

Patenting Research Tools

The dilemma in patenting research tools, such as expressed sequence tags (ESTs) and single nucleotide polymorphisms (SNPs), has been highlighted in many eminent reports.[148] Such DNA research tools are "to be used principally as a means of developing a commercial product, such as a medicine or vaccine, rather than constituting a product in itself."[149] In some cases, such technologies may be "outputs of one research process but are possible inputs into one or several downstream processes."[150] However, they often reveal "no immediate therapeutic or diagnostic value" beyond research "to identify potential targets for the purpose of designing new medicine."[151]

Research tools are vital to propel research and development. Granting patents over these DNA "research tools" may hinder their use to aid research in the discoveries of new medicine, therapies and treatment. Indeed, it has been argued that "the progress of science may be slowed down, particularly in developing countries and in public research institutions."[152] Access to such tools may not be adequately met by licensing or other schemes as these are often complex and involve "unpredictable cost."[153] Despite the "potential to yield commercial products in the future when their function is better understood,"[154] the Nuffield Council on Bioethics has recommended that, in general, "routine discoveries with weakly demonstrated or speculative uses" should seldom deserve "the status of patentable inventions" and that grants over DNA sequences as research tools should be discouraged.[155]

The observations on the impact of granting patents over research tools certainly merit further consideration. It may be argued that the monopoly inherent in patenting research tools

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147 Comprehensively dealt with elsewhere. For example, Nuffield Council on Bioethics, The ethics of patenting DNA (July 2002).

148 "Research tool" has been defined as the "full range of resources, methods and techniques that are used in research." See CIPR report, *supra* note 5, at p 174. The Nuffield Council on Bioethics uses the term "research tool," defined in the Report of the National Institute of Health (NIH), Working Group on Research Tools (1998), as: "We use the term "research tool" in its broadest sense to embrace the full range of resources that scientists use in the laboratory, while recognizing that from other perspectives the same resources may be viewed as "end products."

149 See Nuffield Council on Bioethics, The ethics of patenting DNA (July 2002) at p 56.

150 See CIPR report, *supra* note 5, at p 112.

151 See Nuffield Council on Bioethics, The ethics of patenting DNA (July 2002) at p 56.

152 See South Centre report, *supra* note 79, at p 20.

153 See South Centre report, *supra* note 79, at p 20. See, for example, patents relating to Malaria – MSP-1 protein (merozoite surface protein 1) that is discussed in the South Centre Report, *ibid*, at p 20 and the Nuffield Council on Bioethics report on The ethics of patenting DNA (July 2002) at p 43.

154 See Nuffield Council on Bioethics, The ethics of patenting DNA (July 2002) at p 56.

155 See Nuffield Council on Bioethics, The ethics of patenting DNA (July 2002) at pp 57, 59.

may have a deleterious effect on society overall such that it may justify an enquiry into whether the deleterious effects of not making some departure from the protection currently offered by the patent system outweighs the beneficial effects. In this context, steps taken by the USPTO[156] and EPO[157] to make the utility requirement "more stringent"[158] are instructive. For example, a demonstration of a substantial, credible and specific use when rights are asserted over DNA sequences in patent applications is now required in some jurisdiction.[159]

RESEARCH TOOL PATENT: CASE STUDY OF THE CCR5 RECEPTOR – HIV/AIDS

In February 2000, Human Genome Sciences Inc (HGS), a US company, was granted a US patent which asserted rights over the gene that codes for the CCR5 receptor. (See US patent 6,025,154). The CCR5 receptor is the route by which the HIV/AIDS virus enters a cell. When HGS originally isolated the gene for this receptor and filed for the patent in June 1995, its estimate of how it would meet the criterion of utility was that the CCR5 protein product would be a cell-surface receptor. Their patent claims did cover a viral receptor, but at the time, they were unaware of the receptor's role in HIV/AIDS. Instead, the researchers expected to exploit the patent primarily for the development of anti-inflammatory therapies. Subsequently, the role of the CCR5 receptor in HIV/AIDS was revealed by other researchers, six months after HGS filed its patent application. Another researcher, Dr M Parmentier, had isolated the gene some years earlier but only filed a patent application in March 1996 when its biological function had been confirmed. His team and a number of other research groups simultaneously published the finding that CCR5 was indeed a critical site for entry of the HIV virus into the cell. Parmentier's patent has not yet been granted. HGS has already agreed to several licenses for the use of the CCR5 receptor gene in research into new drugs. In one recent example, Praecis Pharmaceuticals was licensed to develop therapies for AIDS, employing the receptor. Future therapeutic interventions will depend on licensing of the HGS patent. At present, it appears that HGS does not plan to prevent academics from undertaking unlicensed research involving CCR5.

The Nuffield Council on Bioethics has stated that the outcome of this case clearly illustrates that the level of protection granted is not reflected in the extent of the contribution made by the applicant whereby a broad US patent was granted to the company even though it was unaware of the actual role of the receptor in HIV/AIDS. (Source: Nuffield Council on Bioethics, The Ethics of Patenting DNA (July 2002) at pp. 41, 57). Note also: Euroscreen's patent (US patent No. 6,448,375) of September 2002, relating to CCR5 receptor in HIV infection. This patent is said to directly challenge the HGS patent (No. 6,025,154) for the CCR5 receptor that was issued in February 2000. (Source: PR Newswire, "Euroscreen

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156 I.e. United States Patent and Trade Mark Office (USPTO). See USPTO Utility Examination Guidelines (Fed Reg 66: 1093) and Written Description Guidelines (Fed Reg 66: 1103).

157 I.e. European Patent Office (EPO). See, for example, ICOS Corporation patent: EPO Opposition Decision revoking European patent No. 0 630 405 on the grounds, inter alia, that a DNA sequence encoding a protein without a credible function is not a patentable invention: see Official Journal EPO 05/2002 (June 20, 2001) at http://www.european-patent-office.org. See also EU Directive on the legal protection of biotechnological inventions.

158 See the Report of the UK Commission on Intellectual Property Rights "Integrating Intellectual Property Rights and Development Policy" (2002) at p 116.

159 See, for example, the USPTO Utility Examination Guidelines. Note the Nuffield Council's approval of these Guidelines in the report of the Nuffield Council on Bioethics, The ethics of patenting DNA (July 2002) at p 59.

Awarded US Patent Covering Key HIV Target" (September 12, 2002) available at http://www.cafezine.com.)

Scope of Patents over DNA Sequences

Finally, a quick word should be said on the scope of patents over biotechnology-related invention, particularly DNA sequences It is a feature of DNA that "one gene will often generate more than one product, for example, different proteins." It has been observed that many of the patents that have been granted in relation to DNA sequences appear to be broad. Some may allow inventors to secure broad protection on all uses of the DNA including the proteins that the DNA produces.[160] It has been said that the granting of "too many broad patents at too early a point in the development of an emerging area of science may restrict others from having access to the genetic information covered by the patents."[161]

The scope of patents,[162] particularly product patents,[163] is another area that could profit from some global consensus. The USA and German approaches appear to provide absolute protection for all possible uses without restricting it to the particular use set out in the patent claim. This would result in the rights encompassing even "uses which have not yet been anticipated or discovered."[164] The Nuffield Council on Bioethics has proposed curtailing the breadth of some product patents over DNA sequences by "limiting the scope of product patents that assert rights over naturally-occurring DNA sequences to uses referred to in the patent claims, where the grounds for inventiveness concern the use of the sequence only, and not the derivation or elucidation of the sequence itself."[165]

In the light of the proliferation of patents, particularly over DNA sequences, a re-evaluation of the appropriate scope of some of these patents would indeed be timely. An effective review would extend to an evaluation on the construction and interpretation of patent claims. This is so particularly in view of the differing approaches that currently exists, for example, on "equivalence"[166] doctrines.

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160 See Nuffield Council on Bioethics, The ethics of patenting DNA (July 2002) at p 47. See also the CCR5 case study above.

161 See Nuffield Council on Bioethics, The ethics of patenting DNA (July 2002) at p 65.

162 See, for example, the "Edinburgh" Patent (EP 0695351) entitled "Isolation, selection propagation of animal transgenic stem cells" which as granted by the EPO had claims arguably encompassing the cloning of human beings but has since been amended to exclude this possibility. The patent owner stated that it had never intended to the scope of the patent to extend to the creation of transgenic human beings. See http://www.european-patent-office.org.

163 Including product-by-process patents.

164 See Nuffield Council on Bioethics, The ethics of patenting DNA (July 2002) at p 65.

165 See the Nuffield Council on Bioethics, The ethics of patenting DNA (July 2002) at p 66. For example, if the scope of such patents is not construed too broadly, there will be more incentive for others to "invent" around it.

166 The "doctrine of equivalence" is well-developed in the US. In Europe the approach is to seek a balance between "fair protection to the patentee" and "reasonable degree of certainty to third parties" (see Protocol on the Interpretation of Article 69 of the EPC), supplemented by possibilities of equivalence.

Conclusion

Indeed, it has been noted that:

> "[T] he massive private sector investment in biotechnological research is exactly the sort of research and innovation that [the patent system] was intended to promote. Healthcare is the major beneficiary of biotechnology. At the same time, vast amounts of money must be found to finance biomedical research. The [patent system] embodies the public policy that those who directly benefit from an invention should be asked, through the patent system, to pay for it, at least in part."[167]

In determining the appropriate price, the competing policy tensions within and beyond the patent system must be effectively managed to ensure optimal relevance for those that participate in the system. The many challenges highlighted above are relevant to countries in both the developing and developed worlds.

Finally, it may be interesting to note the suggestion for the establishment of "IP-free" zones to demarcate that some "kinds of precious information resources must be off limits for private ownership. As we grapple with the emerging realities of a knowledge-based economy, it will prove to be of … enormous value."[168] It has been noted that a carefully crafted IP-free zone, for example, "over the raw sequence data of the human genome can prevent a lot of bitter litigation and acrimony - not to mention helping to speed the next generation of drugs and treatments to the market."[169] If adopted, this may provide the balance that will allow "biotechnology and pharmaceutical firms to develop new drugs and treatments while still insisting that the infostructure in this area - the raw sequence data of all human genes - remains resolutely in the public domain."[170] As has been noted by the Supreme Court of Canada, "the mobility of capital and technology makes it desirable that comparable jurisdictions with comparable intellectual property legislation arrive at similar legal results."[171]

4.3.2.2 Public Interests: Public Health

Introduction

In recent years, major concerns have been expressed by some developing countries that the implementation of effective intellectual property regimes may "affect their efforts to improve public health … particularly if the effect of introducing patent protection [is] to increase the price and decrease the choice of sources of pharmaceuticals."[172] The controversy generated by the "unprecedented public health challenge of the humanitarian calamity of

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167 See Commissioner of Patents v. President and Fellow of Harvard College (December 2002) (Supreme Court of Canada).

168 See Shulman, 'It's Time For "IP-Free" Zones" (August 2000). Available at: http://www.derwent.com/ipmatters/features/shulman.html.

169 *Ibid.*

170 *Ibid.*

171 See *Commissioner of Patents* v. *President and Fellow of Harvard College* (December 2002) (Supreme Court of Canada).

172 See CIPR report, *supra* note 5, at p 29.

HIV/AIDS"[173] serves to highlight tensions that patents on some pharmaceuticals "may be hampering governments' attempts to deal with urgent policy issues" by "unacceptably imped[ing] access to affordable healthcare, thus frustrating public health programs."[174] This outcry is but another manifestation of broader underlying tensions and imbalances that exist between the developed and developing worlds.

There is, therefore, an urgent need to reconcile and effectively manage the competing policy interests to facilitate better access to drugs in certain circumstances. Indeed, this is also echoed in the WTO Doha Declaration on the TRIPS Agreement and the Public Health as follows:

"We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."[175]

Some Observations on Selected Avenues of Reform

The ultimate goal in this discussion is to ensure that medicines can fulfill their central role in improving the access to medicine for some and health for all. Similarly, the recommendations proceed solely on the basis of improving access and affordability of medicines for those in need. In conjunction with the other published studies on the laws and other related issues,[176] some observations on selected proposed options will be discussed.

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173 See WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6) at Annex I p 2.

174 See WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6) at Annex I p 28. See, for example, the recent outcry by a consortium of non governmental organizations in Kenya over the high cost of Aids drugs. This has called for a consideration of the following: "How does a mercilessly globalizing world balance the 3Ps - Pharmaceuticals, Patents and Profits - with the right of patients to access essential drugs? See Odour Ong'wen, Crocodile Tears: How 'Trips' Serves West's Monopoly, The East African, March 12 2001.

175 See paragraph 4 of the DOHA Declaration on the TRIPS Agreement and Public Health WT/MIN(01)/DEC/W/2) at http://www.worldtradelaw.net/doha/tripshealth.pdf. Note also Articles 8 and 73 of the TRIPS Agreement relating to the protection of public health and essential security interests. Indeed, it has been argued that the flexibility and safeguards allowed under the TRIPS Agreement, particularly that relating to the protection of public health, should be preserved. See South Centre report, *supra* note 79, at p 27. See also the Royal Society, Keeping Science Open: the effects of intellectual property policy on the conduct of science (April 2003) at p 15 where the Royal Society endorsed the importance of ensuring an adequate supply of medicines to developing countries at low prices.

176 See, for example, CIPR report, *supra* note 5; see WIPO Patent Agenda (A/36/14), *supra* note 1; WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6); South Centre report, *supra* note 79; Scherer & Watal, Post-Trips Options for Access to Patented Medicines in Developing Countries, WHO Commission on Macroeconomics and Health (2001) at http://www.cmhealth.org/docs/wg4_paper1.pdf ("Scherer & Watal"); Maskus, Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries (April 2001); the report of the International Intellectual Property Institute (IIPI), Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa (2000) available at http://www.iipi.org.

Numerous options proposed include the call to incorporate a general exception into the draft SPLT that deals with the protection of public health and environment.[177] Other policy avenues include compulsory licensing, parallel imports, price control and differential pricing, charity (drug donation), provision of aid and appealing for greater corporate responsibility to society.

Off-Patent Drugs

It has been noted that the vast majority of pharmaceutical products are off-patents and are therefore available for use in the public domain. A recent survey suggests that only about 20% of antiretroviral drugs for treating HIV/AIDS remain patented.[178] The table below[179] reveals further interesting information:

DISEASE	PATENTS ON RELEVANT DRUGS
TB and malaria	Some 95 % of the pharmaceutical products on the World Health Organization's Essential Drugs List are now "off patent," i.e., no longer protected by patents.[180] This list includes 9 anti-tuberculosis drugs and 8 drugs against malaria.[181]
HIV/AIDS	Most anti-retroviral drugs not protected by patents in majority of developing countries.[182] Some 95 % of the pharmaceutical products on the World Health Organization's Essential Drug List - which includes many drugs used to treat various aspects and side effects of HIV/AIDS - are now "off patent" that is, no longer protected by patents.[183] This list includes 12 antiretrovirals.[184]

As such, it has been argued that the creation of "vigorously competitive supply" of these generics might have increased the affordable access to medicine. Developing countries were urged to ensure that "trade in generic drugs is not restricted and that vigorously competitive

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177 See South Centre report, *supra* note 79, at p 20. See also Scherer & Watal, *supra* note 176, at p 4 on how many of today's developed countries also excluded pharmaceutical products from patent protection until quite recently.

178 See Kirk, "Competing demands on public policy," paper presented at the WIPO Conference on the International Patent System, Geneva, March 25 to 27, 2002 quoting a recent study on 53 African countries published in the Journal of the American Medical Association that only 3 of 15 antiretroviral drugs for treating HIV/AIDS remain patented.

179 Source: IPOS submission (Compiled Comments).

180 See http://www.wipo.org/about-ip/en/studies/publications/health_care.htm: WIPO Emerging issues in IP: Patents & access to drugs and health care - "Striking a Balance: Patents and Access to Drugs and Health Care."

181 See http://www.who.int/medicines/organization/par/edl/eml.shtml: WHO Essential Medicines Model List (Revised April 2002) Core List.

182 See "Patent Protection and Access to HIV/AIDS Pharmaceutical in Sub-Saharan Africa," Report Prepared for The World Intellectual Property Organization (WIPO), International Intellectual Property Institute, 1996, 2000 at p 36.

183 See http://www.wipo.org/about-ip/en/studies/publications/health_care.htm: WIPO Emerging issues in IP: Patents & access to drugs and health care - "Striking a Balance: Patents and Access to Drugs and Health Care."

184 See http://www.who.int/medicines/organization/par/edl/eml.shtml: WHO Essential Medicines Model List (Rev. Apr 2002) Core List.

world markets emerge."[185] However, it has been noted that many developing countries "have hurt themselves by not taking full advantage of the opportunities for encouraging generic substitution."[186]

Notwithstanding this, issues concerning the affordability of patented drugs will continue to hog the agenda.[187] Indeed, the African, Caribbean and Pacific Group of States (ACP) have noted that in view of the outbreak of new diseases, such as SARS, a solution that is straightforward, easy to implement and effectively workable, needs to be found now as a matter of urgency.[188] A further evaluation of some possible solutions is therefore timely.

Patented Drugs

The call by some developing countries for better access to affordable medicine is an important and pertinent issue in relation to some patented drugs. However, it should be borne in mind that it is difficult to establish meaningful criteria to determine absolute or objective affordability. It is often relative and varies directly with the degree of poverty. The final price of a patented drug payable by the consumer is a function of many variables that incorporate the selling price of the manufacturer, availability of substitutes or alternative treatment, distribution costs and profit markups, economies of scale, regulatory and structural impediments, subsidies, taxes and other custom tariffs.

While the price demanded by the owner of the patent is undoubtedly a major component, it may well be misleading to conclude that some drugs are exorbitant by virtue only of the fact that they are patented. Moreover, the argument that "nations cannot simply free-ride on the research and development efforts of multinational pharmaceutical enterprises"[189] may be difficult to ignore. It is submitted that four of the options highlighted below may yield some relief to the tensions between these competing interests.

(a) Competition from Generics

It has been noted that "pharmaceutical product prices fall sharply when generic entry occurs following the expiration of the patents."[190] As such, developing countries that are not, or not yet, subject to the obligation of full implementation of the TRIPS Agreement may exploit the opportunity to take full advantage of generics. Resources permitting, some

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185 See Scherer & Watal, *supra* note 176, at p 60. See also a recent survey by Frost & Sullivan Asia Pacific noting that the East Asian market is driven by generic pharmaceutical companies whose current strength lie in their dominance of local markets. A recent survey on the generic pharmaceutical markets in Malaysia, Philippines, Singapore and Taiwan shows the following: The total generic pharmaceutical market in the 4 countries was estimated at more than $500 million in 2001 and is expected to reach over $1 billion by 2007: see Frost & Sullivan Asia Pacific, "The Asian Generic Pharmaceutical Market" (October 3, 2002) at http://pharmalicensing.com. See also Frost & Sullivan Asia Pacific, "The Generic Invasion – An Inside Scoop to the Pot of Gold" (March 27, 2003) at http://pharmalicensing.com.

186 See Scherer & Watal, *supra* note 176.

187 See Adelman (see Compiled Comments).

188 See Communication from the African, Caribbean and Pacific Group of States (ACP) on Paragraph 6 of the DOHA Declaration on the TRIPS Agreement and Public Health (May 28, 2003) at http://www.wto.org.

189 See Scherer & Watal, *supra* note 176.

190 See Scherer & Watal, *supra* note 176.

developing countries could beef up their generic drug manufacturing capability[191] to manufacture and export lower-cost generic versions of patented drugs to countries that permit or encourage the import and use of generic substitutes. By its nature, this may not be a long-term solution for some but it remains extremely attractive.

In addition, the invention and development of competing drugs and treatment for the same disease condition may be another option to constrain the "monopoly power of patented drugs."[192] It is, therefore, mainly in the new "break-through drugs that face little therapeutic competition in treating critical and widespread disease conditions"[193] that more serious pricing and access concerns arise.

COMPETITION FROM OTHER MEDICINES

A survey found that of the 148 new drugs introduced into the United States market between 1978 and 1987, only 13 (or about 8%) had no close substitute in their therapeutic class.

(Source: Lu and Comanor, "Strategic pricing of new pharmaceuticals" (1998) Review of Economic and Statistics 80:108-118 quoted in Scherer and Watal, Post-Trips Options for Access to Patented Medicines in Developing Countries, WHO Commission on Macroeconomics and Health (2001) at http://www.cmhealth.org/docs/wg4_paper1.pdf.)

(b) Parallel Imports

It should be noted 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 of Articles 3 and 4."[194] The freedom to apply the doctrine of exhaustion of rights to limit the rights conferred by patents, has led to a wide variety of national policies on parallel import or "parallel trade." A country may implement a "national

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191 It may be worth noting that the East Asian market is driven by generic pharmaceutical companies whose current strength lies in their dominance of local markets. A recent survey by Frost & Sullivan Asia Pacific into the generic pharmaceutical markets in Malaysia, Philippines, Singapore and Taiwan showed the following: The total generic pharmaceutical market in the 4 countries was estimated at more than $500 million in 2001 and is expected to reach over $1 billion by 2007. See Frost & Sullivan Asia Pacific, "The Asian Generic Pharmaceutical Market" (October 3, 2002) at http://pharmalicensing.com. See also Frost & Sullivan Asia Pacific, "The Generic Invasion – An Inside Scoop to the Pot of Gold" (March 27, 2003) at http://pharmalicensing.com.

192 See Scherer & Watal, *supra* note 176.

193 See Scherer & Watal, *supra* note 176.

194 ee para 5(d) of the DOHA Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/W/2) at http://www.worldtradelaw.net/doha/tripshealth.pdf. See also Article 6 of the TRIPS Agreement that provides for exhaustion of rights as follows: "For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights." For a discussion on compulsory licensing and parallel importation, particularly the softening of the US and EU thereto, see the report of the International Intellectual Property Institute (IIPI), Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa (2000) at pp 14 -19, available at http://www.iipi.org.

exhaustion" regime and prevent parallel imports, while a country that adopts "international exhaustion" legalizes parallel imports.[195]

It has been noted that parallel imports in patented pharmaceutical products arise "for a variety of factors associated with price differences across markets: price discrimination by manufacturers, vertical price setting within distribution systems and differential systems of price controls."[196] Parallel imports therefore affect the maintenance of differential pricing and regulation thereto. It has been referred to as a "form of arbitrage, tending to reduce differences in prices across diverse markets."[197]

This is another area that developing countries may seek to explore in their search for access to affordable drugs. However, in order to encourage pharmaceutical companies to supply medicines at preferential prices, it is important to address their concerns that these may emerge in other markets through parallel exports. It has been noted that parallel export of "drugs sold at low prices in less-developed nations could undermine the willingness of the pharmaceutical manufacturers to sell at those low prices or even to supply low-income markets at all."[198] Thus, it may be necessary for developing countries to implement satisfactory measures to prevent subsequent parallel exports of drugs imported at reduced prices. In this context, it has been emphasized that:

"[T]here is an important rationale for restricting parallel exports of medicines from low-income countries to high-income countries, though the former group could remain open to [parallel import]. This idea could be supplemented by regimes of regional exhaustion among poor countries in order to increase market size within which prices are integrated."[199]

The recent adoption of EU Regulation of 26 May 2003 that aims to prevent pharmaceutical products sold to developing countries at reduced prices to be brought back into the European market underscores the need to insulate and track parallel imported drugs within regional blocs of developing countries and strictly enforce against their re-export from their borders.[200]

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195 The "exhaustion" doctrines is also 'sometimes known as the "first sale" doctrine, the exhaustion principle allows a member state to limit application of a patent right once a product protected by the patent has been sold.": see the report of the International Intellectual Property Institute (IIPI), Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa (2000) at p 30, available at http://www.iipi.org. For a detailed discussion on parallel imports in pharmaceuticals, see Maskus, Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries (April 2001).

196 See Maskus, Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries (April 2001), report presented to the WIPO under terms of Special Service Agreement at p 41. For the potential benefits and costs of permitting parallel imports, see Maskus, *ibid*.

197 See Scherer & Watal, *supra* note 176.

198 See Scherer & Watal, *supra* note 176.

199 See Maskus, Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries (April 2001), report presented to the WIPO under terms of Special Service Agreement at p 3. This was echoed by Scherer & Watal, *supra* note 176.

200 This provides an extra mechanism for protection, which applies irrespective of whether these medicines are IP-protected, in order to encourage companies to supply medicines at reduced prices." See Communications by the EC on the Implementation of the Implementation of the DOHA Declaration on the TRIPS Agreement and Public Health (June 24, 2003) (IP/C/W/402).

[Footnote continued on next page]

(c) Compulsory Licensing

The use of compulsory licensing to enhance access to affordable patented drugs is controversial.[201] It has been said that they "introduce the dynamic effects of competition that can pressure prices lower over time."[202] Indeed, the CIPR has opined that they "do not regard compulsory licensing as a panacea, but rather as an essential insurance policy to prevent abuses of the IP system."[203] This has been echoed by the call for governments, as:

> "[C]ustodian of the public interest, [to] closely monitor the activities of patent owners and be prepared to intervene actively with counter-measures where necessary. Compulsory licensing and … competition laws are the obvious tools … Governments [should] further facilitate compulsory licensing and application of competition law in situation where single or multiple patents, do on balance, unreasonably affect use and development of inventions."[204]

The TRIPS Agreement has narrowed the circumstances under which compulsory licensing may be deployed to remedy anti-competitive and other practices.[205] One of the restrictions is that the use must be "predominantly for the supply of the domestic market" of the authorizing state. While this condition may be waived, where the compulsory license is granted to remedy anti-competitive practices, [206] its effect in curtailing the export of drugs manufactured under such licenses will greatly impact on some developing countries that rely on such imports. These are countries that are unable to make effective use of the compulsory licensing option available to them due to the lack of infrastructure and technological capability to "reverse engineer" and manufacture the drugs themselves.

This concern has been clearly noted in the Doha Declaration as follows:

[Footnote continued from previous page]

This is also echoed by the Royal Society that "Access to such medicines is critical if society is to fight the major pandemics affecting the third world. Poverty is the critical issue but IPRs must not be used to prevent availability of medicines at low prices. A corollary is that developed and developing countries should cooperate in ensuring legal and practical measures to prevent resale in developed countries of low-priced medicine destined for developing countries." See the Royal Society, Keeping Science Open: the effects of intellectual property policy on the conduct of science (April 2003) at p 15.

201 Take, for example, the fundamental problems that South Africa, Brazil and Thailand now face over the patent system - namely the problem of the multilateral trading system securing monopoly rights over, among other things, life saving knowledge and technology, see Bank, "Differential Pricing and Politics of Health Development" (April 25, 2001) at http://www.twnside.org.sg/title/politics.htm. See also the report of the International Intellectual Property Institute (IIPI), Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa (2000) available at http://www.iipi.org.

202 See Statement of Information made by the Consumer Project of Technology ("CPTech") at the Competition Commission of South Africa.

203 See CIPR report, *supra* note 5.

204 See the Royal Society, Keeping Science Open: the effects of intellectual property policy on the conduct of science (April 2003) at p 10.

205 See Article 31 of the TRIPS Agreement and note also Article 40 relating to Control of Anti-Competitive Practices in Contractual Licences.

206 See Article 31 (f) of the TRIPS Agreement.

> "We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement…."[207]

It has been suggested that developing countries should press aggressively for expansive interpretations of the TRIPS provision,[208] as clarified by the Doha Declaration.[209] Since the TRIPS Agreement clearly envisaged that some export under "compulsory licence in the exporting nation will be allowed," [210] it has been argued that such export possibilities should extend to any other country that has issued compulsory licenses or those with insufficient or no manufacturing capacities in the pharmaceutical sector.[211]

Apart from the TRIPS restriction, other limitations include the lack of compulsory licensees in the manufacture of essential drugs with small or unprofitable markets. In such cases, it has been highlighted that government subsidy or manufacture in government-owned facilities may be needed.[212] Stronger domestic initiatives, financial and fiscal incentives may be needed to encourage more effective participation by the pharmaceutical industry in ameliorating this problem.

While the threat of compulsory licensing may be a weapon that can "enhance [a nation's] bargaining power"[213], it is certainly far from a "magic wand" for obtaining affordable access to patented medicines in developing countries.[214] In fact it is noted that "in practice, however, compulsory licensing is rarely imposed" and that under the TRIPS agreement "the circumstances under which compulsory licensing may be considered have narrowed." [215] The Nuffield Council further acknowledges that:[216]

> "Opposition to compulsory licensing is particularly strong in the pharmaceutical industry at a time when the costs of research and development are rising and the rate of production of new medicines is falling. Moreover, there is a view more generally that once compulsory licensing is deployed in one sector, the principle will be more readily applied elsewhere. We recognise the dilemma: in the case of medicines generally,

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207 See paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/W/2) at http://www.worldtradelaw.net/doha/tripshealth.pdf.

208 See Scherer & Watal, *supra* note 176.

209 Paragraph 5(b) of the Doha Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/W/2) makes specific reference to each member's "right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted." See http://www.worldtradelaw.net/doha/tripshealth.pdf

210 Scherer & Watal, *supra* note 176.

211 See Statement of Information made by the Consumer Project of Technology ("CPTech") at the Competition Commission of South Africa.

212 Scherer & Watal, *supra* note 176.

213 Scherer & Watal, *supra* note 176.

214 Scherer & Watal, *supra* note 176. Note also the view expressed by the IIPI that "it is not at all clear whether the attempts to abrogate patent protection through compulsory licensing and parallel importation will ultimately result in better access to medicines and healthcare.": see the report of the International Intellectual Property Institute (IIPI), Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa (2000) at p 20, available at http://www.iipi.org.

215 See Nuffield Council on Bioethics, The ethics of patenting DNA (July 2002) at pp 54-55

216 *Ibid* at p 55.

there are those that are too expensive to be made available for all of the patients who need them; but the widespread imposition of compulsory licensing could seriously erode the capacity for research and development of the pharmaceutical industry. A careful balance would, therefore, need to be struck so that compulsory licensing is only invoked in those cases in which the existence of a monopoly is creating an unacceptable and unfair situation. The guiding principle here would be that the protection which was granted by the patent system should be commensurate with the contribution made by the inventor. In fact, extensive application of compulsory licensing … may not be required, as experience has shown that the mere threat of compulsory licensing has been sufficient to encourage industry to devise other solutions."[217]

The Nuffield Council concludes it observations by rejecting a "wholesale and indiscriminate use of compulsory licensing."[218] Instead, it supports the further exploration of an OECD suggestion to create a 'clearing house' to reduce transactions and obstacles to commercial laboratories seeking licenses for 'genetic inventions'.[219] Other options, such as, charity has been said to be the "only alternative to death or debility."[220] In this regard, it may be useful for some nations or patent owners to consider granting "voluntary or consensual" licenses in appropriate circumstances in the spirit of good corporate social responsibility (CSR).[221]

(d) Consensual Licensing: Good Corporate Citizenship

The pharmaceutical and biotechnology industries are major multi-billion dollar conglomerates of international players whose products profoundly affect public health and safety in both the developed and developing world. The licensing of the production and exploitation of drugs by the pharmaceutical industry solely for the promotion and safeguard of public health in appropriate circumstances other than under compulsion of law and pure pursuit of profits may ameliorate the lack of access to affordable medicine in some developing countries. This adoption of some degree of self-regulation will not only constitute another milestone by the stakeholders of patents that will ease some of the tensions that inevitably arise between themand the society at large, but will also greatly enhance their public standing.

Today, multinational corporations disregard their social roles in the community at their own peril. It is no longer possible to operate a business globally while remaining totally aloof

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217 Other solutions may include the use of differential pricing of anti-retroviral medicines for the treatment of HIV/AIDS in several developing countries.

218 Further arguments against the use of compulsory licensing include the potential costs and complexity accompanied by a detrimental decrease in the incentive to invalidate or revoke patents as it would be easier to obtain a licence than to dispute the patent.

219 See Organisation for Economic Co-operation and Development short summary report of the workshop on Genetic inventions, Intellectual property rights and licensing practices, Berlin, Germany, 24-25 January 2002 at p 56 at http://www.oecd.org/pdf/M00031000/M00031448.pdf.

220 Scherer & Watal, *supra* note 176.

221 CSR has been defined by the World Business Council for Sustainable Development ("WBCSD") as "the continuing commitment by business to behave ethically and contribute to economic development while improving the quality of life of the workforce and their families, as well as the local community and society at large." See "Corporate Social Responsibility: Making Good Business Sense, January 2000" at http://www.wbcsd.ch/templates/TemplateWBCSD1.

to social issues around it. CSR has gained increasing prominence and importance as can be seen in its exponential growth in the last decade with more companies than ever engaged in serious efforts to define and integrate CSR into all aspects of their businesses.[222] The idea that business has obligations to society that go beyond, and yet are not inconsistent with, profit and shareholder value is gaining increasing appeal among global corporations. Measured by profit alone, some of the developing countries form such small markets that they have only a small effect on the profit margin of the pharmaceutical industry and so have little or no impact on the industries' R & D, manufacturing and marketing policies.

The adoption of good corporate social responsibility may be an ideal response to the growing calls by leading institutional investors for pharmaceutical companies to take a more proactive stance towards the public health crisis, "whether from a reputation, market development or corporate citizenship perspective."[223] Indeed, a group of Europe's largest institutional investors,[224] has put forward a "Statement of good practice" calling on 20 companies – including AstraZeneca plc, GlaxoSmithKline plc and Novartis AG to:

(a) establish pricing for their drugs based on capacity to pay in different markets,

(b) prevent low cost drugs from being diverted back to the developed world, and

(c) stop enforcing patents in the poorest countries.[225]

While acknowledging the significant contributions of the pharmaceutical industry's programs towards the improvement of public health in many countries, particularly developing countries, the IFPMA[226] has called for the pharmaceutical industry's public profile in CSR to be raised.[227]
Moving forward, the industry would have to develop a framework to strike a delicate balance between the preservation of the stakeholders' immediate economic interest through strict enforcement of patent rights and the provision of access to affordable life-saving drugs for the poor. That balance may be expressed in the form of consensual licensing, the actual form of which is a matter that requires further consideration.

4.3.2.3 More Effective Solutions to the Protection of Traditional Knowledge

It is trite that we live in a world that is rich in biological diversity and bio/genetic resources. There has been increasing discomfort over the use of the patent system to grant protection over traditional knowledge.[228] While one may be excused for thinking that the

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222 See http://www.globalethicsmonitor.com.

223 See Financial Times, 24 March 2003.

224 Representing £600bn ($940 billion U.S.) in assets. They include Henderson Global Investors, ISIS Asset Management, Morley Fund Management and Schroder Investment Management.

225 See Financial Times, 24 March 2003.

226 International Federation of Pharmaceutical Manufacturers Associations

227 See IFPMA's Issue Paper on "Drug Donations," http://www.ifpma.org. The International Federation of Pharmaceutical Manufacturers Associations ("IFPMA") has noted that from 1998 to 2001, pharmaceutical companies and their NGO partners in the USA provided more than US$1.9 billion in financial assistance and donated medicines, see IFPMA's statement on corporate social responsibility, http://www.ifpma.org.

228 See "Traditional Knowledge and Intellectual Property: Issues and options surrounding the protection of traditional knowledge" at http://www.quno.org.

observation that has been made that these biological and genetic resources "would soon be processed into unimaginable value-added products and chemicals elsewhere that no material transfer agreements can cover nor be enforceable"[229] has been put too strongly, there is a growing consensus of an urgent need "to ensure that traditional knowledge is accorded sufficient respect and worth."[230] It is outside the scope of this study to delve into an evaluation of this very important area that clearly merits the serious consideration of a separate forum. However, some observations on the many proposals that have been ventured will be offered.

There have been calls from many developing countries for the establishment of "an obligation on the patent applicant to disclose the origin of any biological materials claimed."[231] Such an obligation, it is said, will "help to limit or remedy the misappropriation of genetic resources and traditional knowledge, since it would permit patent offices to obtain more complete information on the 'prior art.'"[232] A possible way to implement this recommendation is through the PCT. Any material relating to traditional knowledge could be considered for incorporation into the PCT minimum documentation.[233] This would require some comprehensive documentation of all known materials relating to traditional knowledge in the prior art database.

However, such a move would most certainly prove to be incomplete without simultaneously addressing the issue of what constitutes a disclosure that may destroy the novelty of a claimed invention. There is no global consistency as to the form that such disclosures must take and the circumstances under which they are made. Some countries[234] "do not recognise an unwritten disclosure to be novelty-destroying if it occurs outside their jurisdiction. This has provided opportunities for firms to obtain … patents, which can disadvantage the original holders and users of such knowledge."[235] For these countries, the Royal Society has called for "a change … to recognize as 'prior art' knowledge outside [their jurisdictions], even if not in written form."[236] The need for congruity cannot be over emphasized since traditional knowledge may by nature comprise unwritten knowledge that "communities have always generated, refined and passed on"[237] from generation to generation.

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229 See Lerson Tanasugarn, "IP and Biotechnology in Southeast Asia," paper presented at the "Biolaw 2002" International Conference (September 4, 2002), Bangkok, Thailand.

230 This was affirmed at the 27th General Assembly of ICSU (the International Council for Science) at Rio de Janeiro, 20 - 28 September 2002, see the Royal Society, Keeping Science Open: the effects of intellectual property policy on the conduct of science (April 2003) at p 15.

231 See South Centre report, *supra* note 79, at p 22.

232 See South Centre report, *supra* note 79, at p 22. See also Correa, "Intellectual Property Rights and Foreign Direct Investment," (1995) 10 International Journal of Technology Management No. 2/3.

233 See WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6) at Annex I p 29.

234 Such as the USA.

235 See the Royal Society, Keeping Science Open: the effects of intellectual property policy on the conduct of science (April 2003) at p 15.

236 *Ibid*.

237 See CIPR report, *supra* note 5, at p 73.

Another area of concern is the need to evaluate possible unintended results from the interaction of the patent system with other branches of IP law[238] and regulatory instruments. For example, there may be a need to clarify and resolve "possible inconsistencies amongst international conventions" such as those pertaining to patents and the Convention on Biological Diversity (CBD).[239] It has also been suggested that developing countries could do more to capitalize on the "access and profit sharing" mechanism in the CBD. In addition, there have been calls from some quarters[240], for a thorough review of the existing rules on "informed consent and sharing of benefit." The provision of "guidelines for 'informed consent' and 'profit sharing' that can be translated into the different practical situations involved in the exploitation of traditional knowledge for the benefit of the holders of traditional knowledge and of all humankind"[241] would be welcomed.

Last but not least, the issue relating to the protection of plant varieties, particularly local or indigenous plant varieties deserves mention. The flexibility afforded by the TRIPS Agreement for its protection under UPOV-style[242] legislation, patent or *sui generis* system has already been thoroughly discussed elsewhere.[243] As such, the observations offered are confined to the reliance on genetically modified (GM) food to alleviate "hunger and food security." As the recent controversy over GM food illustrates, there may be merit in the call to set up an international advisory committee to assess the interests of private companies and developing countries in the generation and use of transgenic plants to benefit the poor. There are also related issues such as the need to preserve the "farmers' rights," where appropriate, "to save seeds for future use (re-use seed) if they wish to do so."[244] In addition, new technologies will continue to generate new life forms, such as, "terminator seeds"[245] that are likely to demand new solutions.

As with all other beneficial reforms, it has been said that the resolution of these and other problems "would help to remove some of the major irritations to developing countries of the patenting of inventions based on traditional knowledge."[246] Since all countries are to a certain extent rich in some form of biological diversity and bio/genetic resources, it would be a mistake to consider the problems raised as being in the sole confines of the developing countries. A framework for the protection of traditional knowledge without the hindrance of its unique ambiguities would endure to the benefit of all nations.

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238 E.g. trade secrets protection.

239 See the Royal society, Keeping Science Open: the effects of intellectual property policy on the conduct of science (April 2003) at p 14 citing its report on "Transgenic plants and World Agriculture (2000).

240 Such as the CIPR and the Royal Society.

241 See the Royal Society, Keeping Science Open: the effects of intellectual property policy on the conduct of science (April 2003) at p 15.

242 International Union for the Protection of New Varieties of Plants (UPOV).

243 See CIPR report, *supra* note 5, particularly chapter 3.

244 See Royal society at p 14 citing its report on "Transgenic plants and World Agriculture (2000).

245 "Terminator seeds – plants genetically engineered to render sterile seeds (that is, the second generation seeds will not germinate). Terminator technology is being developed as a biological mechanism to extinguish the right of farmers to save and re-plant seeds from their harvest, thus creating greater dependence on the commercial seed market." See ETC Group, "Terminator technology – Five years later" (2003) ETC Communiqué, Issue 79 (May/June) at http://www.etcgroup.org.

246 See the Royal Society, Keeping Science Open: the effects of intellectual property policy on the conduct of science (April 2003) at p 15.

4.4 CONCLUSION

This study has proceeded on the basis of an urgent need, and the resolve, to deal with some of the tensions and imbalances that have been articulated. There are many other challenging issues and solutions beyond those highlighted in this study. Further dialogues and more focused research would be fruitful in assisting all participants to identify and prioritize for immediate attention the key areas of common concern. The need for reform to real problems is no doubt compelling. Yet, it is equally important not to see "the trees for the woods." However, it may be prudent to take stock of the matter and examine the developments carefully to determine if the patent system, with or without reforms, is evolving closer to the intended outcome.

However, it may be delusive to imagine that the existence of problems is a function of a lack of solutions. Even if resources were unlimited and all possible solutions have been canvassed and diligently applied, new problems will inevitably emerge. As with any system, the fault-lines that exist will threaten to derail the blue-print for a more effective international patent system into sectoral, political, economic and technological boundaries. Some of these may become evident upon an analysis of the developments relating to the subject matter, the quality of patent protection and the link to trade between nations.

The patent system has been under some strain to extend protection beyond subject-matter that was clearly not contemplated. It suffices to name but a few. The protection of biotechnology-related inventions (such as, gene-related patents[247] and genetically modified animals, human embryos and "Frankenfood") has generated an intricate web of legal, moral, ethical, environmental and public interest considerations. Developments in bioinformatics have exposed the potential overlap in the protection afforded by different branches of IP law for the same subject-matter. There are also multi-jurisdictional conflicts over issues such as the patentability of business methods. Similarly, increasing bio-piracy has resulted in calls for a more comprehensive response to the protection of traditional knowledge and bio/genetic resources at the international level either under the patent regime or under a *sui generis* system.

Apart from the pressures that traversed on the subject matter of patent protection, the segmentation in the quality of patent protection has been a cause for concern not only in the developing world but also in the developed world. It has been observed that the consistency in the rules governing the grant of patents and the uniformity of protection is being eroded. On the one hand, some countries appreciate the value of a trade-off between less stringent standards for patent grants and shorter/weaker protection in relation to minor adaptations to existing technologies.[248] This may be contrasted with the unique demands by the pharmaceutical industry for a review to increase the term of patent protection as pharmaceutical products may experience long delays in obtaining the requisite "FDA"[249] approval. Yet, an extension cannot be sanctioned without regard to the other cogent initiatives aimed at enhancing the access of the poor to medicine. In this regard, there are also

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247 E.g. ESTs, SNPs, proteins, etc.

248 See, for example, petty patents or utility models.

249 The term "FDA" is used broadly here to denote the relevant authorities whose approval must be obtained for the manufacture and/or marketing of pharmaceutical products. Take, for example, the Food and Drug Administration in the USA.

calls for an urgent review of the entire matrix of developments to ensure coherence with existing schemes such as parallel imports, generics, compulsory licensing, differential pricing, drug donation, governmental aid and corporate social responsibility. As it is, there is a general perception in the US that many more patents of "low quality" and broad scopes have been issued in recent years that will have a profound effect particularly in the pharmaceutical industry where the public will be deprived of valuable drugs and therapies.[250]

Last but not least, the link between intellectual property protection and trade between nations is increasingly being entrenched by bilateral and multilateral agreements. Since these agreements are products of negotiations, the international patent system is likely to witness further divergence in the rules that regulate patent protection. As free trade may not be conducted among equals, any lack of equilibrium may precipitate hasty and exclusive developments in patent protection in some countries. This is particularly so in recent years as some nations seek to pursue economic synergies through Free Trade Agreements (FTAs).[251] While it is acknowledged that FTAs may provide an impetus for accelerating some aspects of patent reform, the risks of imbalances are not insignificant.

A robust international patent system is one that achieves its goals and yet possesses the versatility to endure the diverse needs and to sustain the meaningful participation of all its members. The evolution of such an effective international patent system is not an event but a process that aims to secure and not demand the unwavering support and perseverance from "governments and policy-makers … inventors and industry … national and international markets, and … consumers and the general public."[252]

While the destination is becoming clearer and the course may change, the quote below exemplifies the challenging journey ahead:

> "The patent system, as a policy mechanism specifically intended to use the grant of private rights in order to promote the broader public interest, must entail a dynamic synthesis of public and private interests. While this is often construed as a direct conflict between private interests and the public domain, the patent system represents a choice by legislatures to channel private rights and private interests towards the service of public goals … [I]t follows that the patent system cannot at once stimulate private investment in technology development, and yet undercut the rationale for that investment. Nonetheless, the need to establish the right balance of public and private interests is at the core of many patent policy issues, and especially in mapping out the interface between the patent system and other areas of public policy ... [As] these areas involve a careful balance of a range of policy factors and involve diverse national interests, it is inherently less likely that a convergence of exact policy mechanisms would meet the needs and interests of all WIPO Member States."[253]

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250 See CIPR report, *supra* note 5, at p 2.

251 See, for example, the US-Singapore Free Trade Agreement (USSFTA) that imposes obligations over and above those mandated by the TRIPS Agreement, such as, the agreement on both sides to limit the use of compulsory licenses to safeguard against anti-competitive practices, public-non commercial use, national emergencies and other circumstances of extreme urgency. See the submission by MTI, Singapore (see Compiled Comments).

252 See WIPO Patent Agenda (A/36/14), see *supra* note 1, at p 1.

253 See WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6) at Annex I p 31-32

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