Commission on Intellectual Property Rights

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"HOW INTELLECTUAL PROPERTY RIGHTS COULD WORK BETTER FOR DEVELOPING COUNTRIES AND POOR PEOPLE"

DAY 2

BACKGROUND DOCUMENTS

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SESSION 5: TECHNOLOGY, DEVELOPMENT AND INTELLECTUAL PROPERTY RIGHTS

Paper 1a. Executive Summary – Intellectual Property and Economic Development: Lessons from American and European History

Paper 1b. Executive Summary – Intellectual Property Rights, Technology and Economic Development: Experiences of Asian Countries

Workshop 1. Minutes – Technology, Development and Intellectual Property Rights – 25th January 2002

Commission on Intellectual Property Rights

Study Paper 1a

Intellectual Property and Economic Development: Lessons from American and European History

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EXECUTIVE SUMMARY

The relationship between intellectual property rights and economic development has attracted a great deal of attention from economists, but their conclusions have been ambivalent and offer little definitive guidance for policy makers. My paper explores the economic history of patents and copyrights in the United States, Europe and Japan, and highlights the lessons that are relevant to the experience of developing countries today. The study offers policy options regarding key issues in national intellectual property regimes and legislation, the broader policy framework, and the international arena.

National Intellectual Property Regimes and Legislation

1. *The economic history of Europe and America underlines the importance of democratization, in order to assure access to property rights to all members of society.*

Both patents and copyrights were introduced in Europe in the form of privileges that limited access to special classes of society. Even when these systems were reformed, the design and administration served to perpetuate the advantages of privileged individuals and favoured high valued capital intensive methods of production.

The United States stands out as having established one of the most successful intellectual property systems in the world. Secure patents were universally acknowledged as an important factor in early economic growth. At least one part of its industrial and economic success owes to a democratization of access to intellectual property. To give just one example: fees were deliberately set at an affordable level and encouraged broad-based participation in the inventive activity. When Britain followed the U.S. example and reformed its system to facilitate patenting by the working class, the benefits were immediately evident.

2. *It is important to encourage domestic innovation through effective mechanisms to disseminate information.*

In England, the vast majority of patents were obtained by urban inventors, in part because the complexity of the system gave an advantage to those who were actually resident in London. In contrast, the United States implemented policies such as transparent and predictable rules, and the prompt publishing of information regarding patent grants and expired patents. Patent volumes were made freely available to public institutions such as libraries, the patent office established branches throughout the country, and the records were meticulously kept. As a result, when markets expanded in America, the major response came from relatively ordinary individuals living in rural areas, who contributed a plethora of important and incremental inventions that enhanced productivity growth in both capital-intensive and labour-intensive industries.

3. *Patents and copyrights warrant very different treatment. The analysis of the appropriate policies towards copyright is complicated because, in*

addition to economic questions, copyrights have implications for basic rights.

The first Article of the U.S. Constitution included a clause to Apromote the progress of science and useful arts by securing for limited times to authors and inventors the rights to their respective writings and discoveries.@ But, despite their common basis in the Constitution, the United States has always followed very different policies towards patents and copyrights. The scope of copyrights was more abbreviated in the United States relative to the European countries and the American term of copyright was one of the shortest in the world next to Greece. Copyrights were always more circumscribed because of concern about the protection of the public interest.

Although American copyright laws were adopted directly from the British Statute of Anne, there were significant differences that were related to the undeveloped state of American literature. Today the United States is notorious for denouncing acts of copyright piracy in countries like Taiwan and China. This is somewhat ironic, since the US itself was notorious as a copyright pirate for a hundred years. In the paper I discussed the costs and benefits, and conclude that the US likely benefited from its piracy. In short, the continual expansion of copyright grants today at the prompting of producers threatens longstanding efforts to balance private and social interests in a direction that promises to reduce social welfare and learning in developing countries.

4. *IPR management should incorporate limits on proprietors= rights of exclusion.*

The United States has strenuously opposed policies such as compulsory licences that limit *patents***,** although *copyright* policies allow for compulsory licences in certain industries. At the same time, these policy instruments have been widely used by the majority of other developed countries since the earliest years of the Venetian patent grants. Germany stipulated both working requirements and compulsory licences; and so did Britain in the early twentieth century. Moreover, even the U.S. enforces quite stringent antitrust remedies that have overturned corporate rights not only to patents, but also to trade secrets and know-how, in order to ensure the assimilation of the technology. The moral here is obvious.

5. *Within the categories of patents and copyrights, different levels of protection may be appropriate for different sectors, as part of a more general industrial policy.*

The majority of developed countries have exempted particular industries from patent protection in accordance with their needs at the particular time. For instance, the French in 1791 did not allow patents to issue for medicines. Britain countered German competition in chemicals by not offering product patents in this area. Thus, history reveals a policy of discretionary grants in order to promote industrial development in specific areas. Moreover, the European and Japanese experience suggests that developing countries should distinguish between different types of patent grants. Domestic innovation and diffusion in these countries are likely to benefit from patents of

introduction or utility models, which are directed towards the protection of incremental inventions with shorter duration than the current full patent term of twenty years.

6. *Policy makers need to pay more attention to other means of appropriation and rewards such as data encryption, unfair competition laws, and private contracts. .*

The discussion of appropriability tends to be some what myopic in its focus on *state provided* patents and copyrights. American copyright piracy during the 19th century did not lead to ruinous competition. Publishers were able to appropriate returns through a number of strategies, including first mover advantages, reputation, and price and quality discrimination. The dominant firms cooperated in establishing *private rights* of exclusion in foreign-authored books, which were tradeable. Such practices suggest that publishers were able to simulate the legal grant through private means, although at higher cost since such rights were not enforceable at law. Courts were also able to offer more individualized protection through alternative doctrines in contract laws, misappropriation, and unfair competition. *These alternatives may increase the costs to proprietors, but may also result in a net increase in social welfare*

Broader Policy Framework

- *The impact of intellectual property rights will depend on their institutional context. This implies that changes in IPR rules must occur in tandem with developments in the legal system, the market system, and cultural norms. IPRs also have to be assessed within a broader policy context that includes trade policies and antitrust*

In the United States, the laws were enforced by courts that explicitly attempted to implement decisions that promoted economic growth and social welfare. Their instrumental policies were consistent with an economy that included a free market as a central feature. Trade in IP contracts flourished owing to the security of property and contracts. In contrast, in France and England, the legal system led to insecurity which was reflected in much lower numbers of patents and assignments. Developing countries that adopt strong IPRs will find that the benefits are likely to be minimal unless these contextual institutions are also reformed. The high resource costs required for such strong systems may be minimized through institutional innovations such as a registration system with provisions for opposition.

- *The movement to harmonize intellectual property rights has led to a race to the top. For many of today's developing countries, harmonization has meant the exogenous introduction of rules and standards that may be ill-suited to their particular circumstances.*

Discussions to harmonize patents have reflected American efforts. The first international patent convention was held in Austria in 1873, at the suggestion of U.S. policy makers, who wanted to be certain that their inventors would be adequately protected at the International Exposition in Vienna that year. Subsequent revisions of international patent legislation have been towards the American model, such as the introduction of examinations, lower fees, and

the weakening of provisions for compulsory licences and working requirements.

In contrast, France took the lead in the harmonization of copyright laws. France was 'the foremost of all nations in the protection it accords to literary property.' During the Ancien Regime, the rhetoric of authors' rights had been promoted by French owners of book privileges as a way of deflecting criticism of monopoly grants and of protecting their profits. Publishers in Britain and America had tried the same strategies but were defeated by the courts in the landmark cases Donaldson v. Beckett and Wheaton v. Peters.

The Berne Convention has drawn from French laws, most notably in the declaration of moral rights. Today Berne recognizes the right of disclosure, the right of retraction, the right of attribution, and the right of integrity. These rights all infringe on the public domain relative to economic rights. In short, the self-interested rhetoric of the owners of monopoly privileges in 17th century France now shapes international copyright laws in the twenty first century. History has its ironies.

In yet another irony, the United States for over one hundred years resisted foreign pressures to alter its international copyright laws in order to protect its infant publishing industry and in so doing provides a model for developing countries in the 21st century. It should be clear that, if outcomes are held to be efficient when they are aligned with the preferences and interests of the constituent members of the global economy, developing countries today should resist harmonization as not only inefficient, but harmful to their interests.

CONCLUSIONS

The world today is obviously different from previous centuries, but this does not imply that the questions and answers are entirely novel. Patent and copyright systems have continually evolved in the past several hundred years. Some of these changes implemented technical improvements such as a move towards patent examination systems. Others such as the extension of copyrights to foreign nationals, the general strengthening of copyright protection, product exemptions, and the use of compulsory licences, involved adaptations that seem related to the stage of economic development.

When other countries wished to establish their own patent and copyright systems, they looked towards the historical experience of the early industrializers. However, they also indulged in a 'wise eclectism' and adopted measures that were more appropriate for their own particular circumstances and stage of industrial and economic development. Today, those same countries are attempting to impose strong patent and copyright policies in a manner that is designed more to protect their domestic industry than to promote strategies that will further social welfare in developing countries. Although such tendencies should be resisted, at the same time,

policy recommendations for developing countries should focus on alternatives that are feasible as well as desirable.

The reality of the matter is that, given the existing international political economy, countries that engage in outright piracy are likely to be subject to punitive sanctions. Political economic problems require political economic solutions. The policies of Britain towards its colonies are instructive. During the nineteenth century British administered a two-tiered international intellectual property system that attempted to address the needs of its colonies. The 1847 Foreign Reprints Act allowed colonies to import the works of British authors without copyright protection, and also allowed legal price discrimination with significantly lower prices for overseas editions. The current tendency towards uniformly strong IP regimes will only be restrained if some of the developed countries similarly use their influence to provide countervailing power to the 'one size fits all' pressure group.

Commission on Intellectual Property Rights

Study Paper 1b

Intellectual Property Rights, Technology and Economic Development: Experiences of Asian Countries

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Executive Summary

There has been a lot of controversy on the role of intellectual property protection (IPP) regime especially the patent system in fostering innovation, technology and industrial development of a country. IPP is expected to encourage innovation by rewarding the inventor. Strong IPP regime may also inhibit diffusion of knowledge and even technology development in the countries that are technology followers. Countries have fine-tuned their IPP regimes as per their developmental requirements. Against this backdrop, the on-going attempt to harmonize and strengthen the IPP regimes worldwide, as a part of the TRIPs Agreement, is widely seen to be adversely affecting the technological activity in developing countries by choking the knowledge spillovers besides implications for the access and affordability to lifesaving drugs by the poor. This paper critically reviews the literature on the role of IPP regime with a particular reference to the Asian countries to draw policy options for consideration by the Commission.

Patterns and Trends in Global Innovative Activity

The global technology generation or innovative activity is highly concentrated in a handful of technologically advanced developed countries with just top ten countries accounting for as much as 84 per cent of global R&D activity, 94 per cent of US, and 91 per cent of global cross-border technological payments. Prominent among the emerging countries that are beginning to obtain US patents in increasing numbers are Taiwan and South Korea. Therefore these countries together with Japan make important cases for analyzing the role played by IPRs in their technology development.

IPR Regime and Economic Development: The Evidence

IPR regime is likely to affect growth indirectly by encouraging the innovative activity that in turn is the source of total factor productivity improvements. The IPR regime could also affect the inflows of FDI, technology transfers and trade that might impinge on growth. The relationship between IPR and development could be subject to the causality problem as developed countries are likely to have stronger IPRs regime than the poorer ones. Studies have found the relationship between IPR protection and level of development to be non-linear suggesting that patent protection tends to decline in strength as economies move beyond the poorest stage into a middle-income stage in which they have greater abilities to imitate new technologies. Quantitative studies have also shown that universally imposed minimum standards for patent protection are not likely to contribute to increased growth in countries below a certain threshold in terms of level of development.

IPRs as Determinants of Innovative Activity

The existing empirical literature suggests that the effectiveness of patent protection varies from industry to industry and inventive activity is sensitive to protection only in a few industries such as chemical and pharmaceutical industries. A study of the impact of strengthening of pharmaceutical patent protection in Italy since 1978 showed little or no impact on R&D expenditures or on new inventions. Furthermore, R&D activity is found to be significantly

determined by absorption of spillovers of others' R&D activity particularly in the case of chemicals and electrical and electronics. The importance of foreign R&D spillovers as a determinant of R&D activity could be even more critical in developing countries where much of the R&D activity is of an adaptive nature. A number of studies have empirically demonstrated the ability of rather weaker IPRs in stimulating domestic innovative activity in developing countries. Therefore, the evidence on the role of IPRs as a determinant of innovative activity is quite weak. In fact stronger IPRs may actually affect the innovative activity adversely by chocking the absorption of knowledge spillovers that are important determinants of innovative activity.

IPRs, FDI Inflows, Technology Licensing and Trade

Stronger protection increases the revenue productivity of a firm's intellectual property and should help exporters by making counterfeiting more difficult as has been corroborated empirically by studies. However, the effect of IPR strength on FDI and licensing is not that straight forward. By reducing the transaction cost of transfer of knowledge by MNEs to foreign countries, stronger protection may encourage arm's length licensing of the knowledge and reduce the need for undertaking FDI. On the other hand, it has been argued that poor IPR regime tends to adversely affect the investment climate and hence the probability of MNE investments. Empirical studies have generally shown that the strength of IPP promotes arm's length licensing but they have generally no significant effect on internalized technology transfers viz. FDI. Even the location of R&D investments abroad by MNEs was found to be not significantly affected by strength of IPP. Thus the contention that stronger norms of IPR protection will facilitate greater inflows of FDI in the country is rather weak in either theoretical or empirical terms.

IPRs and Economic and Technological Development in East Asia

The rapid growth at the rate of 5.5 per cent in per capita GDP sustained over the 1960-90 and even more impressive growth rate exports in the East Asian economies, viz. Japan; South Korea, Taiwan, Hong Kong and Singapore (first tier Asian nies), Malaysia, Thailand, and Indonesia (second tier nies) and China, generally termed as the 'East Asian Miracle', has attracted a large volume of literature. While some analysts have attempted to dismiss the East Asian achievement as a result of factor accumulation along the production function, voluminous empirical evidence is now available to corroborate that a substantial proportion of East Asian growth was contributed by growth of total factor productivity (TFP) that has averaged between 2 to 4 per cent per year over 1960-89 thus contributing over a third of the growth of output in these countries. Furthermore, evidence is now available to confirm that the assimilation of foreign technology was a 'critical component of the Asian Miracle'. There seems to be a general consensus that the East Asian success owes a lot, in general, to their ability to imitate, absorb, assimilate, replicate or 'duplicative imitation' of foreign inventions. The existing evidence on the role of IPRs regime in promoting growth is largely anecdotal. Although the literature is not explicit in acknowledging its role, the soft IPP regime adopted by these countries in the period of duplicative imitation or reverse engineering has played and important

role in facilitating the firm level technological learning as becomes clear from the case studies of Japan, Korea and Taiwan.

Japan

Japan is known to have greatly benefited from intellectual property generated in other developed countries in the early stages its development. in Japan the patent protection has been designed with an ultimate objective of contributing to the industrial development and not as an end by itself and contains several features that have helped the absorption of spillovers of foreign inventive activity by domestic enterprises. For instance, food, beverage, pharmaceutical products and chemical compounds were excluded from the scope of patent protection until 1975 to facilitate the process innovations. Japanese IPR system provides for utility models to encourage minor adaptations or improvements over the imported machinery or equipment by domestic inventors, and protection of industrial designs that only needed to demonstrate novelty and not inventiveness. The utility models and industrial designs have allowed Japanese firms to receive protection on technologies that were 'only slightly modified from the original invention'. JPS also employs the first-to-file principle rather than the first-to-invent principle incorporated in the US law, pre-grant disclosure, compulsory license, and (until 1988) narrow claims. All these features have been designed to favour adaptations by domestic enterprises. Almost all of the utility models and industrial design have been granted to nationals. Quantitative studies have confirmed that the weaker patent system employed by Japan has facilitated absorption, transfer and diffusion of technology and contributed to the TFP growth during the period 1960-93. The scope of patent system was expanded to cover chemical and pharmaceutical products only in 1975 to provide protection to technological capability that had developed adequately by then.

South Korea

South Korea adopted the patent legislation only in 1961. However, the scope of patenting did not cover patenting of products and processes to manufacture food products, chemical substances and pharmaceuticals. The US pressure pushed Korea to strengthen its IPR regime in 1986, and extend product patent protection to new chemical and pharmaceutical products, adopt a comprehensive copyright law, and extend the patent term from 12 to 15 years. Korea has also followed an IPR regime that facilitated adaptations and imitative duplication of foreign technologies by domestic enterprises through utility models and industrial designs. That the soft IPR regime adopted initially was a part of conscious policy of the government to facilitate imitation by domestic enterprises has been documented well in the literature on Korean technological capability.

Taiwan

Taiwan has also employed a weak IPR policy to facilitate local absorption of foreign knowledge through reverse engineering on the lines of Japan and South Korea. In fact Taiwan's government seemed to openly encourage counterfeiting as strategy to develop local industries until 1980s. Taiwan allowed patents on food, beverages, micro-organisms, and new uses for

products, only in 1994 under heavy US pressure. Like Japan and Korea, Taiwan also provides for utility models and design patents.

To sum up, the East Asian countries have absorbed substantial amount of technological learning under weak IPR protection regime during the early phases. Their patent regimes facilitated the absorption of innovation and knowledge generated abroad by their indigenous firms. They have also encouraged minor adaptations and incremental innovations on the foreign inventions by domestic enterprises and developed a patent culture through utility models and design patents. The other case that is viz. that of India, although following a weak patent regime since 1970, is different in one crucial respect from the East Asian countries in that it did not provide an encouragement to adaptive and minor inventive activity of domestic enterprises with utility models and design patents. In the chemicals and pharmaceuticals it did not prove a constraint as the process patents in the absence of product patents essentially served the purpose of encouraging process adaptive activity of domestic firms. As a result, the domestic chemicals and pharmaceutical industries have developed in their capabilities considerably over the past three decades. However, in the engineering industries and others, there was not a mechanism for encouraging minor adaptations of domestic firms. This difference could perhaps explain not so encouraging performance of Indian enterprises in other industries. Furthermore, IPR regime is only one of the determinants of the technological capability building. The domestic technological effort in absorbing the foreign technologies and innovations in East Asian countries has been vastly more substantive and has been sustained over a much longer period compared to India that attempted to build capabilities with softer patent regime only since the mid-1970s.

IPP Regime Change and Development of Local Capability: The Indian Case

India had inherited The Patents and Designs Act 1911 from the colonial times that provided for protection of all inventions and a patent term of 16 years. However, a few domestic chemical and pharmaceutical enterprises that tried to develop their own technology in the 1960s were prevented to work their technologies by foreign patent owners using broad and vague provisions of the Patent Act. Under pressure from domestic industry, government adopted a new Patents Act in 1970 that reduced the scope of patentability in food, chemicals and pharmaceuticals to only processes and not products. The term of process patents was reduced to 7 years in food, drugs and chemicals and to 14 years for other products. The compulsory licenses could be issued after three years. It is by now widely recognized that the 1970 Act has facilitated the development of local technological capability in chemicals and pharmaceutical industry by enabling the process development activity of domestic firms as confirmed by a number of quantitative studies. The gradual build up of technological capability of Indian enterprises is visible from a rising trend of residents in patent ownership in India, and in terms of the ability of India to raise her share in the US patents. India ranked seventh amongst all developing countries in terms of US patents obtained (ahead of Brazil, China

and Mexico) and fourth in the chemicals sector and in biotechnology (in 1998).

In particular, the rapid evolution of Indian pharmaceutical industry since the mid-1970s highlights the fact that weak IPRs regime could be instrumental in building local capabilities even in a poor country such as India. In 1970 much of the country's pharmaceutical consumption was met by imports and the bulk of domestic production of formulations was dominated by MNE subsidiaries. By 1991, domestic firms accounted for 70 per cent of the bulk drugs production and 80 per cent of formulations produced in the country. With their cost effective process innovations, Indian companies have emerged as competitive suppliers in the world of a large number of generic drugs. A steady growth of India's exports of drugs and pharmaceuticals has transformed the industry from being one being highly import dependent to one that generates increasing export surplus for the country. The share of pharmaceuticals in national exports has increased from 0.55 per cent in 1970-71 to over 4 per cent by the 1999/00. India's share in world exports of pharmaceuticals has risen by 2.5 times over the 1970 to 1998 period making her the second largest exporter of pharmaceuticals after China among developing countries. Inter-firm comparisons show that domestic enterprises are more dynamic in terms of growth of investment and output, export-orientation, R&D activity, technology purchases and labour productivity compared to MNE subsidiaries. The development of process innovation capability of Indian enterprises has enabled them to introduce newer medicines within a short time lag of their introduction in the world market. The drug prices in India at a fraction of those prevailing in the developed countries are among the cheapest in the world making them affordable to poor masses. The technological capabilities of Indian companies and institutions have attracted leading MNEs to start R&D joint ventures, commission contract research and set up R&D centres.

Thus the Indian pharmaceutical industry has evolved from one dependent upon imports and some formulation activity in the late sixties to one that is able to introduce some of the most sophisticated products indigenously produced within a relatively short lag and at a fraction of the cost, and export a growing proportion of its produce. It is a remarkable achievement especially because it has been accomplished within two decades of the change of patent regime. The case study of India, besides those of the East Asian countries, further highlights the critical importance of fine-tuning and calibrating the IPR regime to the level of development of the country.

Implications of the TRIPs Regime for Developing Countries

The full implementation of the TRIPs Agreement is likely to have an important bearing on the patterns of development in developing countries. The process of acquisition of local technological capability by developing countries is likely to suffer a set back. The strengthening of IPRs regime may further limit the access of technology by developing country enterprises. A number of local enterprises in developing countries will come under pressure to close down or form alliances with larger firms, resulting in a concentration of the industry and

dependence on imports may go up. Drug prices are likely to go up upon introduction of product patents with substantial welfare losses to developing countries. TRIPs will lead to a substantial increase in flow of royalties and license fees from developing countries to developed countries. It is by no means clear that strengthening of IPRs will increase inventive activity even in the developed world especially for solving the problems and diseases faced by developing countries. A strengthened IPP regime may actually slow down the pace of technological development by stifling the flow of R&D spillovers that are important inputs in research.

Issues for National and International Action to Moderate the Adverse Effect

Among the policy responses that developing country governments can take at the national level include exploiting the policy spaces available in the TRIPs Agreement fully. These include: incorporating the provisions of compulsory licensing in the IPR legislation, incorporating the research exception, early working exception or 'Bolar' provision, allowing parallel imports or grey-market imports, incorporating breeders exceptions and farmers exceptions in *sui generis* plant variety protection. In addition effective competition policy could help in dealing with possible abuse of monopoly power by patent owners. Price controls could also be useful for keeping prices of essential drugs under check. The experience of several East Asian countries suggests that petty patents and industrial design patents could be effective means of encouraging domestic enterprises to undertake minor adaptive innovations and foster a innovation based rivalry among them. Finally, developing countries should resist the attempts of developed countries to evolve TRIPs plus patent regime and ever-greening of patents.

Among the areas for international action include: building a consensus on the moratorium on further strengthening of IPR regime, granting flexibility to low income developing countries below a certain level of per capita income in implementing the provisions of TRIPs, incorporating specific provisions for transfer of technology, and adopting differential pricing strategies for developed and developing countries. Finally, one of the ways of compensating the low income countries for the adverse effects of strengthened IPR regime is to provide increased technical assistance and international R&D funding to local enterprises to help them build local capabilities. One possibility in this respect could be that developed countries donate (a substantial proportion of) technology license fees collected from low income countries to a fund created in the respective countries to assist inventive activities of domestic enterprises. Furthermore, the additional funding for research on tropical diseases recommended by CMH, for instance, could be made available exclusively to eligible and competent institutions and companies of low income countries to help moderate some of the adverse effects on the inventive activity in these countries.

Commission on Intellectual Property Rights

Workshop 1: Technology, Development and Intellectual Property Rights

25th January 2002

Participants: Graham Dutfield (ICTSD), Zorina Khan (Bowdoin College), Nagesh Kumar (RIS), Stuart Macdonald (Sheffield University), Keith Maskus (World Bank), Ruth Mayne (Oxfam), Jerome Reichman (Duke University), Pedro Roffe (UNCTAD), David Wield (Open University)

Commissioners: Carlos Correa (Chair), John Barton, Ramesh Mashelkar, Sandy Thomas

Secretariat: Charles Clift, Tom Pengelly, Rob Fitter

Summary: The workshop focussed on the links between IP protection, economic development, and the development and acquisition of technology. Specifically, the following six sets of questions were addressed:

1. What role has intellectual property and its protection played in development at different stages of industrialisation? What lessons from the past that are relevant to today's developing countries?
2. How has the drive for greater international harmonisation of IPR standards affected development particularly in poorer countries?
3. What role does local innovation play in development and does IPR protection encourage local innovation? What economic and social costs has IPR protection produced that may be of particular concern to poor countries because of their stage of development?
4. Is there any evidence that IPR protection is the most efficient way of encouraging the creation of new knowledge **and** innovation? Are there alternative mechanisms that might be preferable as alternatives and complements?
5. Are there models of IPR protection specifically suitable to developing countries (e.g. utility models or petty patents; non exclusive rights for "minor" innovations). To what extent do other features of the legal and regulatory systems in place in countries at a given stage of development make specific kinds of IP protection more or less appropriate?
6. Does IPR protection facilitate foreign and/or domestic investment and innovation and technology transfer? If so, how important is IPR protection relevant to other factors influencing investment decisions and technology transfer in poor countries? In which sectors is investment most sensitive to the level of IPR protection? Will increased harmonisation and standardisation of IPR protection reduce any impact that that IP has on foreign investment?

Session 1: Intellectual Property and Economic Development: Lessons from American and European Economic History

Presentation by Zorina Khan

Dr Khan's presentation traced the history of patents and copyrights in Europe and the United States as a means to convey a number of important points relevant to the workshop. With respect to the United States, she explained that the patent and copyright systems were inspired by democratic principles and the idea that the rights provided existed to enhance the development of the country. But the application of such principles produced different results. The patent system was extremely progressive, providing secure protection and accessibility to all sectors of society. It was also relatively non-discriminatory towards foreigners (though not at all times). The copyright system, on the other hand, was initially much less friendly to the interests of individual authors and artists, *especially if they were foreign*. In fact, the U.S. was notorious during much of the 19th century for the scale of intellectual piracy. In sum, the historical record demonstrates 'that appropriate policies towards intellectual property are not independent of the level of development nor of the overall institutional environment.'

The main policy implications were as follows:

- The economic history of Europe and America underlines the importance of *ensuring wide access* to intellectual property protection. A democratic intellectual property system is necessary to ensure that returns to individual investments in creativity accrue to society as a whole;
- It is important to encourage domestic innovation also *through effective mechanisms to disseminate information.*
- Policy makers need to set limits on *proprietors' rights of exclusion*;
- In designing pro-development IPR systems, policy makers must understand that patents and copyrights warrant very different treatment.
- Different levels of protection may be appropriate for *different sectors*, as part of a more general industrial policy;
- Changes in IPR rules must occur in tandem with development of the institutional environment including the legal and market systems;
- IPRs must be assessed within a broader policy context that includes trade and antitrust policies;
- Policy makers need to pay more attention to other means of appropriation such as data encryption, unfair competition laws, and private contracts. These may increase costs for proprietors but they lead to greater benefits in terms of social welfare.

Discussion

The role of developing countries in the evolution of IP regulation has been very small. They have generally failed to devise original national IPR systems, and in consequence have tended to copy the IPR systems of developed countries. This lack of experience in creative IP policy making is

disadvantageous since 'off-the-peg systems' are unlikely to address their specific needs.

To make matters worse, the public domain is being attacked by what may be referred to as 'the new enclosure movement'. This threatens the free exchange of scientific information, the continuation of which is vitally important for developing countries. The European Community's *sui generis* protection of databases was singled out as being especially problematic as it effectively provides perpetual and very strong rights, in addition to which, the EC is trying to export this model worldwide.

One way to reverse the trend would be to rely less on strong exclusive property rights and more on liability rules which operate on the principle of 'use now pay later' rather than exclusivity.

It was questioned how useful a historical overview is that misses out the finer details such as trends, for example, in patent breadth and in interpretations of key concepts like non-obviousness. While the U.S. patent system undoubtedly contributed to economic growth, its effects varied widely between different industrial sectors especially from the mid 19th century onwards. And while it was argued that the historical experiences of present day developed countries suggest that the TRIPS Agreement is detrimental for developing countries, applying lessons from the past to the modern globalised world should be done with caution.

Session 2: Intellectual Property Rights, Technology and Development: Experiences of Asian Countries

Presentation by Dr Nagesh Kumar

Dr Kumar's paper covered six topics: (i) patterns and trends in global innovative activity; (ii) a selective review of the evidence linking IPRs with economic and technological development; (iii) IPRs and economic and technological development in East Asia; (iv) IPR change and technological capacity building within the Indian pharmaceuticals sector; (v) implications of TRIPS; and (vi) issues for national and international action.

Dr Kumar explained that in East Asia (Japan, South Korea and Taiwan), a combination of relatively weak IPR protection and the availability of second-tier IPRs like utility models and design patents encouraged technological learning. The weak IPRs helped by allowing for local absorption of foreign innovations. The second-tier systems encouraged minor adaptations and inventions by local firms. Later on, the IPR systems became stronger partly because local technological capacity was sufficiently advanced to generate a significant amount of innovation, and also as a result of international pressure.

The case of India has similarities to those of the East Asian countries studied, except that no second-tier protection was provided. This did not hurt the

chemical or pharmaceutical industries, but may have hindered the development of innovative engineering industries.

Based on his findings, Kumar suggested some national and international-level policy responses.

At the national level developing countries should:

- Build adequate provisions for compulsory licensing in their IPR legislation in order to safeguard them from possible abuses of monopoly power;
- Incorporate provisions allowing researchers to use a patented invention for research purposes;
- Incorporate a 'bolar provision' in their patent laws allowing generic producers to use a patented drug for the specific purpose of seeking marketing approval. Such a provision helps ensure that as soon as the patent expires, generic drugs enter the market and the price of the drug falls;
- Allow parallel imports in order to force prices of certain goods down;
- Implement a competition regime to prevent the abuse of IPRs to unfairly restrict competition;
- Incorporate breeders' exemptions and farmers' privilege in plant variety protection legislation;
- Introduce price controls for essential drugs;
- Introduce utility models and industrial designs.

International level proposals:

- A moratorium on the further strengthening of IPRs;
- Granting developing countries additional flexibility in implementing TRIPS;
- Incorporating specific provisions on technology transfer;
- Increasing technical assistance and R&D funding to local enterprises in low-income countries to help them build local capacities. One suggestion is that developed countries should donate a proportion of technology license fees collected from low-income countries to a fund to support inventive activities of domestic enterprises;
- Differential pricing of patented medicines to improve access for poorer countries.

Discussion

The discussant noted the continuing uncertainties regarding the links between IPRs and technology transactions. He also drew the group's attention to the Working Group on Technology that the WTO members agreed in Doha to establish. He pointed out that all the actions proposed in Dr Kumar's paper are TRIPS-compatible but questioned whether the idea of creating a fund out of a share of licensing fees was feasible. He clarified also that the issue for developing countries to consider today is not whether to have IPRs or not to have them – they now recognise their valuable role – but how to design a system that meets their specific needs.

It was cautioned that measuring innovation levels by numbers of patents can be misleading. A great deal of innovative activity may not be protected by patents. (This view was reiterated by other participants). It was also suggested that in the United States at least, it is not the big corporations with their enormous patent portfolios that drive the economy but the smaller firms that in many cases do not rely heavily on the patent system. Many of them profit by reverse engineering and inventing around other companies' patents. Developing countries need to learn how these firms do this legitimately.

Another point that came up was that there is no need for developing countries to be given more flexibility allowing them to implement TRIPS as they see fit. The flexibility is there as long as they are allowed to use it. This view was not shared by all of the Workshop participants who felt that TRIPS does limit developing countries' room for manoeuvre.

Session 3: Policy Implications for Developing Countries: TRIPS and IPR Institutions and Practices

Presentation by Jerome Reichman

Professor Reichman referred to an earlier article of his[1] which offered a five-prong strategy for developing countries:

- Exploiting the flexibility of TRIPS in pursuit of national development goals
- Using competition law to curb the abuse of market power
- Fashioning IPRs to stimulate local innovation
- Restricting the drive for stronger IP protection
- Strengthening national infrastructures for the acquisition and dissemination of scientific and technical knowledge

Exploiting the flexibility of TRIPS

He explained that the main issue for developing countries is not that of compliance with TRIPS but of promoting their national systems of innovation (NSIs), which differ from one country to another. Developing countries need to improve their organisational and administrative capacity to identify what exactly their NSI needs are. They need to set up inter-ministerial coordinating committees operating at both national and regional levels and to work with civil society organisations. He warned against the WIPO Standing Committee on the Law of Patents initiative of drafting a Substantive Patent Law Treaty, which he considered as providing no benefits for developing countries since it would further limit their options.

[1] 'From free riders to fair followers: global competition under the TRIPS Agreement'. *New York University Journal of International Law and Politics* vol. 29, pp. 11-93, 1996-97.

Using competition law

Professor Reichman suggested that competition law can be highly beneficial for developing countries. But if the WTO members commit to a competition agreement, they will need to improve their negotiating strategy or else they will end up with a harmful agreement. This means they must act in a coordinated fashion. Unfortunately developing country government ministries tend not to operate harmoniously and developed country negotiators are able to exploit this.

He also condemned the United States government's continuing pressure on developing countries to comply with TRIPS through its 'Special 301' trade law provision. This has a chilling effect on developing country use of the flexibilities of TRIPS. He argued that this behaviour is in breach of the required procedures as laid down by Article 23 of the Dispute Settlement Understanding[2] and that developing countries should take advantage of this fact, such as by suspending their own obligations as permitted by the Vienna Convention on the Law of Treaties.[3]

Fashioning IPRs to stimulate local innovation

Professor Reichman explored the possible uses of liability regimes for sub-patentable inventions along the lines of an article he published recently called

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[2] *See* Article 23 (Strengthening of the Multilateral System), which states that:
'1. When Members seek the redress of a violation of obligations or other nullification or impairment of benefits under the covered agreements or an impediment to the attainment of any objective of the covered agreements, they shall have recourse to, and abide by, the rules and procedures of this Understanding.
2. In such cases, Members shall:
(a) not make a determination to the effect that a violation has occurred, that benefits have been nullified or impaired or that the attainment of any objective of the covered agreements has been impeded, except through recourse to dispute settlement in accordance with the rules and procedures of this Understanding, and shall make any such determination consistent with the findings contained in the panel or Appellate Body report adopted by the DSB or an arbitration award rendered under this Understanding;
(b) follow the procedures set forth in Article 21 to determine the reasonable period of time for the Member concerned to implement the recommendations and rulings; and
(c) follow the procedures set forth in Article 22 to determine the level of suspension of concessions or other obligations and obtain DSB authorization in accordance with those procedures before suspending concessions or other obligations under the covered agreements in response to the failure of the Member concerned to implement the recommendations and rulings within that reasonable period of time.'

[3] *See* Article 60 (Termination or suspension of the operation of a treaty as a consequence of its breach), which states that:
'2. A material breach of a multilateral treaty by one of the parties entitles:
(a) the other parties by unanimous agreement to suspend the operation of the treaty in whole or in part or to terminate it either:
(i) in the relations between themselves and the defaulting State, or (ii) as between all the parties;
(b) a party specially affected by the breach to invoke it as a ground for suspending the operation of the treaty in whole or in part in the relations between itself and the defaulting State;
(c) any party other than the defaulting State to invoke the breach as a ground for suspending the operation of the treaty in whole or in part with respect to itself if the treaty is of such a character that a material breach of its provisions by one party radically changes the position of every party with respect to the further performance of its obligations under the treaty.'

'Of green tulips and legal kudzu: repackaging rights in subpatentable innovation'.[4]

In many developing countries small-scale innovations are the most common type. Since these are likely to be unpatentable because of their cumulative nature, policy makers seeking to protect them through a property regime would have to lower the eligibility requirement or alternatively protect them through utility model or industrial design systems. Reichman proposes that instead of a property rights system that might well intrude on the public domain, raise barriers to entry, and hinder follow-on innovation, it would be better to introduce a liability regime that would guarantee a return on subpatentable innovations that are easy to copy. It would do this by requiring follow-on innovators to compensate initial innovators who would have the right to receive such compensation but not to exclude innovation by others.

Reichman explained that there are at least two reasons why utility models and industrial have become less suitable for developing countries than they were before. First, these systems have gradually become more proprietarian over time. For example, the Italian utility model system was originally a weak one that simply gave first-movers a lead time advantage. Over time, the system provided stronger exclusive rights and now hinders follow-on innovation. Second, utility models have become subject to the TRIPS national treatment requirement following a recent WTO Appellate Body ruling. The proposed system would not be.

Restricting the drive for stronger IP protection

Professor Reichman's view is that the TRIPS Agreement is flexible enough to accommodate the specific needs of each developing country WTO member. But strengthening the rights would not be in their interests. Consequently they should counter pressure to agree to such strengthened IPR protection.

Strengthening national infrastructures

He explained that accessing scientific and technological information has never been easier than it is today. One of the biggest problems for developing countries is their lack of physical infrastructure for public sector research and technology transfer. Another 'dark cloud' on the horizon is the possible globalisation of the European Community's database protection model which is in the forefront of the 'new enclosure movement'.

Discussion

The discussant felt the liability model presented by Professor Reichman had some positive aspects, especially the fact that it would reduce transaction costs for follow-on innovation. With respect to international negotiations, he suggested that developing countries should take advantage of the dispute

[4] In: R. Dreyfuss and D. Zimmerman (eds.) *Expanding the boundaries of intellectual property: innovation policy for the knowledge society*. Oxford University Press, 2001.

settlement understanding to a much greater extent. With respect to negotiating capacity, he acknowledged the lack of expertise. During the discussion it was mentioned that the Quaker United Nations Office in Geneva, Oxfam and Medicines sans Frontieres were instrumental in producing the Doha Health Declaration. This highlights this lack of capacity problem.

It was also suggested, with some empirical evidence from Britain to support the view, that patents are generally not very important for small companies. The same may be true for companies in developing countries, most of which are also small, and therefore lack the resources to accumulate and assert large patent portfolios.

Session 4: Where should the Commission focus its recommendations?

During the 1970s, the question of licensing was a key area of interest for policy makers. Nowadays, more internalised forms of technology transfer are more common such as through foreign direct investment. The issue cuts across several agreements, not only TRIPS, but also the General Agreement on Trade in Services, the Agreement on Technical Barriers to Trade, and multilateral environmental agreements like the Framework Convention on Climate Change and the Convention on Biological Diversity. Successful technology acquisition and adoption requires appropriate skills and a conducive institutional environment.

The WTO Ministerial Conference has agreed to set up a Working Group to examine 'the relationship between trade and transfer of technology, and of any possible recommendations on steps that might be taken within the mandate of the WTO to increase flows of technology to developing countries'. For the Working Group to make a useful contribution, it might consider undertaking work in four areas: (1) analytical work; (2) the relationship between trade and transfer of technology; (3) technical cooperation; and (4) consensus building.

One of the main historical measures to ensure technology transfer was to require patent-holders to work their invention. The restriction of this option in TRIPS is a loss for developing countries. To make matters worse, many companies do not want to share their technologies with competitors. Developing country firms often cannot compete if they can only use older technologies.

However, it was cautioned that compulsory licensing is not necessarily a panacea since acquiring the technologies can still be time-consuming and entail high transaction costs.

Key issues and recommendations for the Commission's enquiry

The following issues and recommendations for the Commission, and for policy makers more generally, were made by the participants.

Key issues

- History provides important lessons for present-day policy makers.

- Capitalising on the benefits of IP protection in developing countries requires a range of complementary changes to the environment for investment and risk taking. This implies reforming IP systems as part of forward-looking and sensibly formulated economic policy. But this places increased burdens on policy makers, and highlights the need for considerable technical assistance.

- Policy makers should adopt as broad a paradigm as possible in attempting to explain technological change and development of national innovation capabilities in countries. And when analysing the role of IPRs, they need to distinguish between the different roles played by each type of IPR (patents, copyright etc.) rather than lump them all together as "single IPRs".

- Science and technology policy as well as IP policy have a key role to play in creating a conducive environment for innovation. But policy makers must be aware of the need also to consider what is feasible as well as what is desirable in the real world.

- Policy makers should not underestimate the task of improving the institutional infrastructure in developing countries so they can operate an effective IP regime. They need to pay particular attention to that fact that in spite of its importance, little has so far been done in this area.

- Policy makers should concentrate on technology and innovation capacity building in developing countries, bearing in mind how little invention and knowledge creation is actually patentable and how much takes place outside of the formal IP system and formal innovation system as operated by big companies. This is more important than just trying to figure out how developing countries can use the formal IP system better.

- Technology transfer is significantly affected by transfer of people between companies and countries. This is true because people can transfer technologies as effectively as can licensing agreements. In order to facilitate technology transfer of this kind, a commitment to

training people in the art and knowledge of the patented invention could be made a condition for the granting of patents.

- Developing countries need flexibility to fine-tune their IP laws. It is not IP laws per se that are the problem for development but the drive towards full harmonisation across countries with very different levels of development. There is a need to preserve the autonomy of countries to calibrate their IP regimes within the parameters of TRIPS.

Recommendations for the Commission

- The Commission should take into consideration the relationship between IPRs and the economic and technological development of both developed and developing countries in drawing up its final recommendations.

- The key message that one size does not fit all needs to be made loudly and clearly by the Commission. A possible solution could be to examine the concept of threshold levels of economic development as triggers for compliance with international IP standards. And insofar as harmonisation may be a reality for some time to come, policy makers need to find ways to compensate the net technology importers such as by returning a share of technology licensing fees paid to rich countries back to low-income countries.

- There is a need for better monitoring of the impacts of IPRs in different economic sectors in developing countries. The Commission should therefore recommend a standing international mechanism to review the impact on development of the increased protection (à la TRIPS) of IPRs worldwide in which all countries could participate formally (i.e. through one of the international organisations such as WTO, WIPO or elsewhere in the UN system).

- The Commission should bear in mind the benefits of markets and market-based solutions for economic and technological development in developing countries. At the same time, it should exercise caution in unreservedly recommending the use of state intervention into markets through instruments such as compulsory licenses.

- The Commission should indicate that public agencies have a key role to play in regulating technology transfer to developing countries, though not perhaps in the traditional sense of screening every licensing agreement.

- The Commission should call for studies on how innovation takes place in SMEs.

- Consideration should be given to investigation how to use competition law to create pro-competitive IP systems and encourage broad

decentralised innovation systems. There is a need to better understand competition law and its relation to IP law. The Commission might consider recommending some analytical work in this area.

- The Commission should draw attention to the potential benefits of greater ODA investments in R&D in developing countries. Carefully done, such investments could be very productive in stimulating innovations and increasing access to them.

- The Commission should make clear that TRIPS is not a perfect instrument. It could be improved through the review process that is currently biased in favour of ever higher levels of protection ('strengthening' the system tending to be viewed as being synonymous with 'improving' it). In that context, there is a need to express particular caution about 'TRIPS plus' elements creeping into IP regimes in developing countries. Perhaps a "stand-still" should be recommended for a period.

- The Commission should recognise that new IP laws are hard to undo once they have been implemented. This is a tricky issue because it is hard to predict the effects of new IP laws, especially in new technologies like biotechnology. Developed countries need to be more sympathetic about this and stop pushing for rapid and radical strengthening of IPRs in developing countries.

- The Commission and policy makers should consider ways to better operationalise TRIPS Art 7 and 8.

- The Commission should highlight the need for policy makers to understand that for most developing countries TRIPS envisages rapid changes in levels of IP protection over a very short time period. Stronger IP protection in the least-developed countries is unlikely to provide any positive contribution to development, at least in the short term. It is especially important to develop national IP systems in a pro-poor manner and not to believe that the US or European systems are necessarily the right models to be followed.

- The Commission should address the urgent need to find ways to extend to developing countries the kind of analytical and technical resources they will need to participate more effectively in the important IP-related rule making processes that will be happening in the near future (e.g. the new WTO negotiations and the various WIPO processes).

- It is important to know who advises developing countries on IP law reform. In this context the Commission should request answers to such questions as why the flexibilities in (for example) TRIPS are not being used as much as they might be. These questions should be carefully addressed to guide the future provision of technical assistance.

SESSION 6: MEDICINES AND VACCINES

Paper 2a. Executive Summary – WTO TRIPS Agreement and Its Implications for Access to Medicines in Developing Countries

Paper 2b. Executive Summary – Using Innovative Action to Meet Global Health Needs through Existing Intellectual Property Regimes

Workshop 2. Minutes – Pharmaceutical and Vaccines – 20th November 2001

Commission on Intellectual Property Rights

Study Paper 2a

WTO TRIPS Agreement and Its Implications for Access to Medicines in Developing Countries

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This report has been commissioned by the Commission as a background paper. The views expressed are those of the author and do not necessarily represent those of the Commission.

Executive Summary

This study accepts the consensus of experts that developing countries should make use of policy options such as compulsory licensing and parallel importation to increase the supply of low-price medicines and vaccines. The interests of the OECD and its consumers will not be undermined by such action since, *inter alia*, Pharma is not significantly dependent on profits from developing countries to pursue its research mission.

The Doha Declaration on the TRIPS Agreement and Public Health mandates that the agreement be interpreted in a manner that supports public health interests and promotes access to medicines for all. This study analyzes the TRIPS Agreement in light of that mandate.

As of January 1, 2005, developing countries (excluding least developed) will be required to implement and enforce pharmaceutical product patent protection and operationalize patents based on mailbox applications that were submitted during the TRIPS transition period. At that time, the world supply of low-price off patent medicines will decrease. Not only will supplies of low-price medicines within developing countries decrease, but supplies available for export by these countries will gradually diminish.

The Doha Declaration provides to least developed countries (LDCs) an extension until January 1, 2016, to implement or enforce pharmaceutical product patent protection. That extension will have a limited effect on supplies since LDCs will remain dependent on low price imports from developing countries that may no longer be available. LDCs might best take advantage of the transition period by increasing their intra-LDC capacities to make and trade medicines and vaccines, but there are practical obstacles to accomplishing this.

When the developing country transition period ends, the restriction imposed by Article 31(f) of the TRIPS Agreement on exports under compulsory license is likely to have a significant effect on the world supply of low price medicines and vaccines. If a predominant part of compulsory licensed production must supply the local market, the quantity of available exports will be limited. To remedy this problem, the TRIPS Agreement should be amended to delete Article 31(f).

If Article 31(f) is not deleted, Article 30 of the TRIPS Agreement regarding exceptions to patent rights must be interpreted so as to permit making and export of pharmaceutical products and other public health related inventions to meet public health needs. The adoption of a formal interpretation by the WTO Ministerial Conference or General Council would provide legal security for countries following this approach. This study provides a detailed analysis of Article 30 indicating that such exception from the rights of patent holders is permitted, and suggests criteria on which implementation of this exception may be evaluated.

Article 8:1 of the TRIPS Agreement authorizes the adoption of necessary public health measures provided they are “consistent” with the terms of the TRIPS Agreement. There is no justification for the TRIPS safeguard to be more restrictive than the safeguards applicable to goods and services. Article 8:1 should be amended to permit the adoption of necessary public health measures inconsistent with the TRIPS Agreement.

Developing countries may consider revisiting the position many of them advocated during the GATT Uruguay Round, and propose amendment of Article 27:3(a) of the TRIPS Agreement to allow exception from patenting of public health related inventions, including medicines and vaccines.

Developing countries should implement the TRIPS Agreement recognizing that its provisions do not demand excessive levels of protection promoted by only a few OECD countries.

Knowledgeable observers agree that meeting the public health needs of developing countries requires substantial subsidization from OECD countries and international organizations such as the IMF and World Bank. The Global Fund does not to date evidence that it will be adequately funded so as to address urgent developing country needs for public health supplies. Developing countries must be prepared for self-reliance, and this self-reliance requires increased capacity to produce low price medicines and vaccines, whether or not such products are under patent by Pharma enterprises. This intensifies the importance of interpreting and amending the TRIPS Agreement to reinforce developing country capacity to act in their own best interests.

Increasing attention must be devoted to research and development on medicines and vaccines of particular relevance to developing countries. Neither the market nor the TRIPS Agreement provides a solution for the lack of attention to this R & D. An option to be further explored is increasing the level of funding for publicly undertaken R & D.

Commission on Intellectual Property Rights

Study Paper 2b

Using Innovative Action to Meet Global Health Needs through Existing Intellectual Property Regimes

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and

Chris Collins
Independent Consultant

Executive Summary

A key challenge facing all stakeholders in the global health arena is how to simultaneously encourage more innovation and R&D into new, more effective products and ensure that those needing these products can afford and have access to them. Intellectual property rights (IPR) sits at the center of this debate.

This report investigates the literature and on-going political debates surrounding two issues: the link between IPR and R&D, especially in diseases prevalent predominately in the developing world (henceforth, neglected diseases); and the link between IPR and patient access to finished products.

The key findings are:

1. IPR is a necessary but insufficient incentive to encourage companies in the developed or the developing world to commit R&D resources towards neglected diseases;
2. IPR, to the extent that it affects the price on on-patented drugs, negatively affects poor patients' ability to afford and therefore access new drugs and vaccines.
3. Affordability does not ensure access as many other barriers exist. A comparison of the experience to date of HIV drug access in India, Brazil, and South Africa demonstrates the relative importance of IPR laws, government commitment to fighting the disease, and financial resources in ensuring access to HIV treatments.

Evidence suggests that win-win solutions can be developed to work within the current IPR system but all parties must still commit much more work and resources. New global norms of technology licensing agreements and pricing must be adopted. These include: differential pricing, controlling for the flow back of the cheaper priced products to the industrial countries in disease cases where there are global markets; and commitments by companies in technology licensing agreements that in exchange for IPR they will help ensure that any future products gaining market approval in neglected diseases, get to the patients who need them. In addition, governments in developed countries must make substantive financial commitments to help fund the development and purchase of new products.

The R&D Problem

Neglected diseases such as malaria, TB, and leishmaniasis are a low priority of both public and private investors in pharmaceutical R&D because of the perceived small paying market and thus low expected returns from any product developed. In an attempt to design effective solutions to this problem, attention has been given to what role IPR plays either as part of the problem or as part of the solution.

The pharmaceutical industry is generally seen as a textbook case of where patents are an essential mechanism of appropriating the economic returns on

innovation. Two features of pharmaceutical R&D explain why. First, the sunk costs of R&D are high, averaging $300-600 million per new product. Second, the marginal cost of production of pharmaceutical products is often low. The R&D process is lengthy and risky but most pharmaceutical products once launched are relatively cheap and easy to reproduce. This second feature is what permits generic firms to be able to produce products at prices well below the price of a branded product.

Over time, the form of innovation and the role of IPR in the pharmaceutical industry have evolved. In the present era, characterized by a mix of large, vertically integrated multinational corporations and small and medium sized technology and/or product focused biotechnology companies, product and process patent protection are one of a combination of regulations and competencies deemed necessary for competitive success through innovation.

IPR is paradoxically both essential and potentially burdensome for small biotech companies. To get started and for years to come, scientists turned entrepreneurs rely on external funding with no evidence of competence but their publication record and the patents from their research. At the same time, in order to develop their ideas into marketable products, they depend on gaining access, sometime only through costly and lengthy negotiations, to technologies and ideas developed and patented by others.

Evidence of the importance of patents for pharmaceutical innovation can be drawn from country cases such as Canada, where the strengthening of IPR (through the abolishment of compulsory licensing) in combination with tax incentives produced an up turn in R&D investments by local and foreign companies. Surveys of MNCs also suggest that patent policies rank high in the decision criteria for foreign direct investment by pharmaceutical companies. Finally a significant factor determining the successful development of the US biotech industry since 1981 and the absence of one in (west) Germany, despite their comparatively strong and competitive MNCs, was the reform in the US of shifting the rights of publicly funded research to the universities. In Germany, the rights remained with the scientist who, on her/his own, lacked the resources to patent and commercialize their research. As a result, German scientists, until recently, worked with established companies as consultants rather than attempting to set up their own companies.

With regard to the impact of introducing TRIPS compliant IPR laws for less developed country (LDC) infant pharmaceutical industries, it is still too early to judge. Predictions for a case such as India are that the introduction of product patent protection will put out of business hundreds of small local generics companies but may provide new opportunities for those willing and able to invest in R&D capabilities and larger generics companies who will be able to enter global markets as products go off patent. In the absence of significant injections of funds for basic research, training, and technology transfer it seems unlike that in and of itself IPR will create new innovative companies. That said, it will improve the prospects for cross-national joint ventures and

opportunities for scientists trained in the US and Europe to return home and make a significant contribution to the building of their own companies.

There is even less evidence that the introduction of TRIPS will encourage companies and scientists in endemic countries to invest in treatments for neglected diseases. In one focused study of "new research activity" globally post 1980 in tropical diseases found only slight changes developments in malaria. Patent and investment behaviour in all others was stagnant despite new entrants to the R&D pharmaceutical industry.

Explicit, targeted policies and initiatives are needed above and beyond IPR to channel some of the resources and capabilities of the pharmaceutical industry towards neglected diseases.

Policy Options

A number of new product development *public private partnerships* (PPPs) have been set up to develop drugs or vaccines to address specific diseases. All rely on contracts with industry and specify terms in those contracts to address the problem of future affordable access up front. In exchange for funds and other support, the PPPs tend to secure the IPR rights to develop and deliver any final product at affordable prices to the developing world markets[5]. In some cases, such as leishmaniasis, that may imply the entire market. In others, such as malaria, there is a paying travelers' market that the industry partner may have first rights to.

High attrition rates and the limited budgets mean that PPPs must be considered only part of the R&D solution for any one disease. Their efforts by no means fill any box in an "intervention-disease" matrix. Attempts to legislate *national policies* in the US and the UK to *incentivize* companies to invest in neglected diseases along lines similar to orphan drug policies have been less successful[6]. The idea, in theory, is to combine cost-saving policies, such as grants and tax credits, and revenue-enhancing policies, such as the creation of a purchase fund.

Another "pull" proposal is to offer companies a patent extension on a product of their choice in exchange for their successfully developing and marketing, at affordable prices, a product for a neglected disease. While attractive from a research orient company's standpoint, such a policy is unlikely to find favour with the patients using the other drug or the generics industry whose portfolio strategies depend on predicted dates of product patent expiry in large, profitable markets. An interesting and as yet unexplored question is how companies in the developing world such as India, China, or Brazil would

[5] In the case of the International Aids Vaccine Initiative, the company retains the patent rights to all markets under the conditions that it will guarantee access at affordable prices to developing country markets.

[6] The UK included tax credits for vaccine research in neglected diseases in the 2001 budget but the treasury has not yet approved the measure.

respond to the creation of a global fund or nationally based tax incentives to address disease of concern to their own populations.

The Impact of IPR on Product Access

Patents are one of several important factors that help determine access to new medicines in LDCs. The current literature and lessons from India, South Africa and Brazil demonstrate that the presence or absence of patent protection has affected drug prices and access, as well as development of domestic industry. But though patents are important, it is possible to overemphasize their effect on drug access and ignore other important factors such as the availability of international and domestic financial resources for health care, infrastructure needs, and political leadership.

The move towards stronger IP protections through the TRIPS agreement presents complex issues. There is evidence that strong patents can have a negative effect on affordable prices by delaying the entry of generic options. Industry continually raises concerns that the erosion of patent protections will undermine incentives for product development. Since Africa represents only 1.1% of the global pharmaceutical market (Attaran, 2001) it is difficult to see how lower prices in this market significantly impact MNC profits.[7] The real fear is that lower prices will undercut acceptance of higher prices elsewhere, and could lead to importation of comparatively cheap drugs to richer markets. Criticism by elected officials in the United States regarding differential prices for drugs commonly purchased by the elderly is a recent example of the political pressures working against differential pricing.

Policy Options

In looking for a coherent policy that addresses the needs of LDCs, examples from the three countries mentioned above can be useful. They each demonstrate the critical importance of a *combination of factors, including health funding, political commitment, and flexibility in implementation of IP law*. Of the three countries, Brazil has shown the most impressive successes at extending drug access to its population. In that country, development of domestic public manufacturing capacity and willingness to use options in trade law have allowed the government to be a powerful negotiator with patent-owning MNCs. IP policy should encourage flexible policies within the context of TRIPS, and affirm a variety options that strengthen the negotiating hand of LDCs with MNCs.

The Brazil model is less applicable to lower income countries without domestic industry. In these countries, significant injection of resources is absolutely necessary, combined with greatly reduced prices for pharmaceuticals. Political and economic incentives for *differential pricing* (particularly for essential medicines) can and must play an important role

[7] Given comparatively low per capita incomes in most African countries, there is little to suggest industry is hoping for significant market expansion in these countries at industrialized world prices.

here. For example, expanded efforts by industrialized and LDC governments will be needed to prevent re-importation of cheaper drugs to wealthier markets.

Generic competition, or its threat, has been a crucial element in achieving reduced drug prices in LDCs. It would be irresponsible to constrain the ability of LDCs to use compulsory licensing for in-country production or importation of generic products necessary to address health priorities. The question of compulsory licensing for product import was left unresolved at the WTO consultation in Doha in November 2001. LDCs without production capacity clearly need to be able to use compulsory licensing for drug importation if they are to meet the health care needs of their populations. It also makes little sense to expect each LDC in the world to have its own production facility for every essential on-patent drug, particularly given the economies of scale in pharmaceutical production.

That said, compulsory licenses should not, however, be seen as a "magic wand" for obtaining affordable access to patented medicines in developing countries. Scherer and Watal (2001) have highlight three limitations. First, compulsory licensees must have the capability to "reverse-engineer" or import the product without the co-operation of the patent owner[8]. Increasingly, larger domestic companies in developing countries are raising their R&D investments and are collaborating with multinational companies to achieve advanced capabilities and reach more markets. Sustainable cooperation will not allow for these companies to undercut their "partners" in other products areas with generic copies.

Second, exports of compulsorily licensed products from large markets destined for small, least-developed countries can only work where the disease patterns are common to both markets.

Third, compulsory licensees will be only attracted to large and profitable drug markets, and so essential medicines with small potential volumes or mostly poor patients will not attract many applicants, however important it is from the perspective of public health (31). Thus, existing and future drugs for most of the neglected diseases discussed earlier in the report are not likely to be the focus on private generics producers either.

The AIDS pandemic demonstrates the desperate need for policies that foster early and broad access to life saving drugs, as well as the promotion of research on future technologies needed in LDCs. This is the difficult and urgent challenge to policy makers.
As LDCs increasingly demand funding and policy options to increase health care access, and policy makers begin to appreciate the role of health status in creating a more stable world, this challenge of balanced and equitable IP policy becomes ever more important.

[8] Transfer of technology, often recommended as a solution, requires the active cooperation of the patent owner or, in the context of South-South cooperation, of his competitors.

Commission on Intellectual Property Rights

Workshop 2: Pharmaceutical and Vaccines Workshop

20th November 2001

Participants: Fred Abbott (Florida State University), Harvey Bale (IFPMA), Francisco Cannabrava (Brazil Mission to WTO), Hannah Kettler (Institute for Global Health), Chris Collins (Consultant), Julian Fleet (UNAIDS), William Haddad (Mir Pharmaceuticals), Ruth Mayne (Oxfam), Nelson Ndirangu (Kenya Mission to WTO), Jonathan Quick (WHO), David Rosenberg (GSK), F.M. Scherer (Harvard University), Ellen t'Hoen (MSF), Jayashree Watal (WTO)

Commissioners: Daniel Alexander (Chair), Carlos Correa, Ramesh Mashelkar, Gill Samuels, Sandy Thomas

Secretariat: Charles Clift, Tom Pengelly, Phil Thorpe, Rob Fitter

Summary: There were presentations by the authors of the study papers commissioned by the Commission, which were followed by a response by two discussants and then general discussion of the papers. The first paper (Kettler and Collins) reviewed the evidence available on the impacts of the role of IPR in relation to the problems and solutions for increasing research and development (R&D) for neglected diseases and made a series of recommendations on the use of PPPs for enhancing R&D. The second paper (Abbott) focused on relative benefits to countries in the implementation of TRIPS, and the need for developing countries to exploit to the full the flexibilities in TRIPS. The second session looked into the relevance of IP to access to medicines in developing countries. The third session considered he implications of IP protection for R&D for neglected diseases. The final session highlighted the most important areas for the Commission to focus on.

Session 1: Presentation and Discussion of Study Papers

Kettler and Collins Presentations

The role of IPR as a Problem/Solution for increasing R&D for Neglected Diseases

Key Points

- Private industry is essential for pharmaceutical innovation, and IP protection is a necessary condition to incentivise R&D by private and public actors. Any policy package must work from this starting point.

- IPR is only one part of the solution to the issue of lack of restricted access
- The new commercial model of PPPs uses IPR as a tool to increase R&D through creative licensing.
- This PPP model is an explicit statement to recognise IP as a tool to protect the various actors.
- Evidence was presented revealing that strong IP is related to higher prices, which restricts access
- Country evidence was presented to demonstrate that financial and political commitment is essential to address the AIDS pandemic where generally branded product prices have not matched income.

Recommendations

R&D Direction

- Different markets need different policies that address the need for IP protection as a necessary condition to incentivise R&D by public and private actors
- Limitations on resources and know-how in the public sector indicates the need to mobilise private sector capacity for relevant research.
- PPPs enable the drawing out of the major relative advantages of the private and public sectors.
- Use IPR as a tool to enhance the commercial model (which is a private-led process) to increase R&D into neglected diseases. Promote creative licensing approaches to deal-making in public-private partnerships.
- Review the management of PPPs and apply best-practices to new models to maximise effectiveness.

Pricing

- Establish political and financial commitment by governments to prevent prohibitively high pricing.
- Differential pricing strategies should be promoted.
- Establish political commitment to control re-exportation of drugs.
- The threat of compulsory licensing should be seen as a necessary weapon to help bring prices of medicines down.

Discussant

The paper was thought to be correct in asserting that patents play an important role in incentivising R&D but are not sufficient. Equally it was agreed that patents do present a barrier to medicines for poor people.

It was recognised that many assumptions made by the discussants were based on three models: the private, public and PPPs, and it is recommended that the efficiency of each model is ascertained in order to understand the strengths and weaknesses of each, identify where waste is occurring and

validate or nullify some of the arguments. What could be said about the relative efficiency of private versus public research? How were research priorities set? The IP system oriented priorities to the discovery of new drugs, rather than the survey of the existing portfolio for new uses.

It was recommended that the feasibility of using the roaming patent be investigated. Issues such as who sets the priorities for R&D, who pays for R&D and commercialises new discoveries need to be addressed. Spending by the public sector, including the NIH, on relevant research needed to be increased. The very small proportion of even publicly funded research in areas relevant to developing countries (e.g. through the NIH) was noted.

Issues of access also include rational selection of drugs, pricing, financing and reliable health systems. The Brazil AIDS programme was interesting but not, on the face of it, replicable.

It was recognised that the flow-back of price information to the North (which would effectively be paying for drugs provided to the South) was a major problem in establishing a tiered pricing system. More use of voluntary licensing needed to be considered. Packaging and branding of drugs could help prevent problems of physical flow-back to high price markets. The overall problem was how to establish differential pricing in a manner that was sustainable and predictable.

Discussion

The role that the IP system played in stimulating innovation in today's competitive landscape was debated. The case of countries that had industrialised without a patent system was considered (see, for instance, Eric Schiff "Industrialization without National Patents: The Netherlands 1869 - 1919, Switzerland, 1850 -1907" Princeton University Press, 1971).

Incentive regimes needed to be devised to serve the needs of low value markets. An international orphan drugs agreement might be considered offering tax and other incentives to stimulate R&D internationally.

Abbott Presentation

- Present TRIPS Agreement standards will principally benefit commercial pharmaceutical enterprises located in the OECD countries, and more specifically in the United States, Japan, Switzerland, Germany and the United Kingdom.
- Increased developing country R & D on medicines and vaccines brought about by adoption of strong patent protection is highly unlikely to yield the development of new pharmaceutical products the income from which would offset increased patent rents that will flow from the developing to the developed countries based on the introduction of such protection.

- Developing countries should take advantage of the policy options afforded by the TRIPS Agreement including the granting of compulsory licenses and authorization of parallel importation. Price controls may be effective in specific contexts. Restrictions on exports of tiered-priced drugs may be useful in specific contexts.
- Substantial subsidization of developing country purchases of medicines is necessary if highly active antiretroviral (ARV) treatment (HAART) is to be provided to address the HIV/AIDS pandemic.
- Funding for R & D on medicines and vaccines of particular relevance to developing countries is inadequate. Private enterprise will not undertake such research as a consequence of lack of perceived market incentives. Mechanisms to facilitate R & D on medicines and vaccines of particular relevance to developing countries should urgently be developed and put into operation.

The principal questions at this stage of inquiry are less directed to the objectives that need to be met, but rather to the best policy options for accomplishing these objectives. It was recommended that there should be:

- Increased reliance on production of medicines and vaccines by generic producers, facilitated by relaxation of TRIPS Agreement rules;
- An enhanced leadership role for the IMF and World Bank in arranging the financing necessary to respond to epidemic disease, in particular to facilitate production and acquisition of low cost medicines and vaccines, and;
- Increased reliance on public sector R & D for the pursuit of new medicines and vaccines of relevance to developing countries, supported by public financing.

Regarding production of existing medicines and the conduct of R & D, the author's recommendations differ to a modest extent from those of the majority of the WHO Macroeconomics Commission. In respect to financing, they differ from the current emphasis on establishing a Global Fund through new contributions by OECD governments, suggesting potential political advantages of increased reliance on existing multilateral financial institutions

Discussant

It was felt that settling the compulsory licensing for export issue, where Doha had postponed a decision, was an absolute priority for poor countries.

Figures were presented on the number of scientists in relation to the population in a variety of countries which served as an indicator of the extreme lack of scientific and technological capacity, particularly in most of Africa. The fact was that it was unrealistic to think of creating such a capacity, even in the medium term or to expect that such countries could contribute significantly to the development of new drugs relevant to developing countries.

In those circumstances, one needed to look at what the private sector could offer. The example of integrated circuits was given where the private sector, not government, had spearheaded innovation. Setting up large funds (such as the Global Health Fund) was one approach but there were political problems in the explicit use of taxpayers' money in this way. A system of tax credits, that could be calibrated to make relevant R&D expenditure by firms costless or even remunerative, might be a more feasible solution.

Discussion

What effect will the Doha declaration have? In the context of the issue of compulsory licensing for export, the case of India (as a potential exporter) was noted. Only the four latest ARV drugs would be likely to be patentable after 2005 and it would take several years for these to be examined and granted. That left eleven important ARV drugs which could be freely imported from India as generics. Thus TRIPS would bite only very gradually.

The WTO meeting at Doha was seen as a mechanism for clarification of the rights within TRIPS, but was not a relaxation of the agreement. Doha attempted to balance the interpretations of Article 7 & 8, which had been too narrowly read by some countries, and was thought to have been successful in this attempt.

Session 2: Relevance of IP to Access to Medicines

Following from the previous session, the debate was essentially divided into two broad categories – 1) How to get drugs to the poor at affordable prices, and 2) How to promote R&D in appropriate directions to address neglected diseases.

Issues of access encompass delivery systems, infrastructure, safety issues, and so on.

It was generally agreed that a package of policy mechanisms should balance access, pricing and R&D direction issues, but the emphasis varied among participants.

TRIPS

Changes in attitudes in exploiting the flexibilities in TRIPS were evident from the outcome of Doha. There was some confidence, post-Doha, that a feasible solution could be found on the question of compulsory licensing for export.

It was said that an opportunity had been missed in the Uruguay Round to leverage, say 10% of R&D, for developing countries in exchange for the developing countries accepting TRIPS. An analogy was drawn with the US/Canada deal where US firms agreed to move R&D facilities to Canada in exchange for Canada removing its liberal compulsory licensing regime. This

had apparently been successful, although it was argued that the additional investment was more on clinical trials than R&D.

IP Strategies and R&D Investment

It was agreed that IP is a necessary incentive to innovation for private, public and PPP sector activities. The private sector, it was argued, has the necessary know how and some resources not currently available to the public sector and is a necessary part of the solution. The private sector should be incentivised to work alongside the public sector in neglected disease areas through a range of IP and fiscal mechanisms that address the dual goals of making a profit whilst saving lives.

Issues were raised again as to whether there was waste in expenditure by the private sector and it was suggested that further research is carried out into the efficiency of R&D investment.

IP is viewed as necessary in PPPs, which have been, to some degree, pushed by private industry. Patents have ensured good prices and returns on investment, which have in turn enabled R&D into neglected areas because they do not have other issues regarding 'access' to prevent commercial interest. Debate ensued as to whether a package of fiscal incentives would be sufficient, or whether, without the promise of a market, there will be little incentive for private partners to join PPPs at all.

It was argued that the patent system should be less money-driven and should revert to its original purpose, which was to provide a time-limited monopoly to provide incentives for innovation.

The impact of Bayh-Dole in the US was discussed. It had had a rather profound impact on universities' approach to research. There were varied views as to whether this was a good thing (through increased innovation) or whether it introduced undesirable distortions into research priorities.

Developing Countries

<u>IP and Pricing</u>

It was argued by some that prices are higher in LDCs as a result of patent protection, although some prices have reduced dramatically recently as companies respond to political pressure. The contrary contention that patents were not widespread in low income countries, and therefore for the most part could not affect prices was noted. In any case, it was felt that the consumption of drugs by the poor was very sensitive to price, as most drug purchases were privately as opposed to state funded. It was agreed that the IP issue was only one among many factors affecting access to medicines, but there was obviously less agreement as to whether it was hardly relevant at all, or quite important.

Asymmetries in technical capacity

It was argued that different countries should tailor their IP system to fit their particular circumstances, in particular variations in their levels of scientific and technological development. IP protection for a country without significant manufacturing capacity or intellectual capital was largely irrelevant in stimulating R&D. But it had costs, both in terms of establishing IP capacity and enforcement, and in the costs inherent in conferring patent monopolies.

Generics and IP

It was argued that it was important, in the context of compulsory licensing, that there was competition. It was suggested that five suppliers of a particular drug might be appropriate to achieve competition, and drive down price. Given the size of the market in poor countries, this suggested the need to look at how compulsory licensing might be done on a regional, or even global, basis.

Countries such as India have created drugs in an IP vacuum, through reverse engineering and imitation, which requires sophisticated scientific ability and high manufacturing and safety standards. But it was also argued that generic manufacture was very simple, and the constraints should not be overstated.

Compulsory Licensing

It was argued by some that compulsory licensing should be encouraged to foster the generics industries to produce cheaper medicines. On the other hand, liberal use of compulsory licensing could act as a deterrent to foreign investors and that R&D and manufacturing investment in developing countries could be adversely affected.

Current Patent Practices

Evidence was presented that some current patent practices were not so much about innovation, as about maximising profits and commercial advantage by exploiting aspects of the system to prolong monopolies e.g. so-called “evergreening”. Of the thousands of patents issued per year to the pharmaceutical industry, around only 80 patents were issued for NCEs. The rest are incremental, and have little to do with innovation as such. It was also noted that the generics industry can introduce the “older, non-evergreened” product.

Session 3: The need for IP protection to encourage R&D for diseases affecting developing countries – The Evidence.

The R&D Problem – A Result of Inadequate IP Protection or Lack of Effective Demand?

Lack of effective demand for products of research was argued to be at the core of the 'R&D Problem'. The existence of IP protection was not sufficient to stimulate R&D for products whose sole markets were in poor countries. The necessary demand had to be provided through the greater involvement of public money, nationally and internationally. If the private sector was then to be involved, through PPPs or otherwise, then how IP rights were allocated, and the conditions for licensing technologies became important.

It was recommended that an inventory of incidence of disease in developing countries be undertaken to ascertain priorities in R&D for neglected diseases.

For products that had global markets, IP was important.

Developing Countries with Scientific Capability

Weak IP protection in developing countries with scientific capability is an issue for developed country industries, because of the competitive impact of generic industries in such countries. On the other hand some developing countries can also see advantages in appropriate IP protection, in particular to stimulate a transition to a research-based pharmaceutical industry. However, because Northern markets were also the most attractive to low cost research-based firms, it was not apparent that IP protection in such countries would increase R&D in neglected areas significantly, despite the potential for much lower cost R&D than in developed countries.

Capacity Issues

Given that in many developing countries patents were arguably a factor in limiting access to medicines, and had little or no impact on relevant R&D, it had to be asked, in view of the substantial costs of setting up and running an IP protection system, what the benefits were to developing countries in this category.

Recommendations for PPPs

It was suggested that research should be undertaken into the specific roles, incentives and motivations of actors in PPPs alongside a report on the rate of progress of each PPP model.

It was argued that a series of IP lawyers should be rallied to provide a blueprint of IP 'value' for various stakeholders in a range of models to establish codes of practice for PPPs.

Session 4: Conclusions and Recommendations

This session dealt with the issues participants felt the Commission should focus on its report. The following is a list of what each participant raised, and not necessarily points with which all agreed.

These included:

TRIPS

- The compulsory licensing issue for export arising out of Doha (Article 31 f, inter alia)
- Transfer of technology issues in TRIPS (Article 66.2, inter alia)
- Data Protection issue (Article 39.3)
- Should TRIPS be a ceiling as well as a floor?
- Transition periods for ldcs; indicators for transition.
- Should the review of TRIPS be used to effect fundamental reform – not just review implementation?
- The relationship between IP and competition policy (Article 8.2 and 40)
- Non violation and related procedures and how they affect developing countries
- Changes to the way the TRIPS Council works

IP System More Generally

- Imposition of TRIPS Plus through bilateral agreements
- Role of WIPO in encouraging (too) high IP standards e.g. Patent Law Treaty
- Evergreening of patents
- Research tool patenting
- Implementation of differential pricing; how to avoid read-across to developed country prices
- Desirability of Bolar exception in national legislation
- Creative use of IP in private-public partnerships
- How can IP be used to encourage research on neglected diseases? An international treaty? How can fair burden sharing to cover costs of research be set up?
- Will fiscal incentives be effective in promoting private sector R&D and technology transfer? Do they overcome the market constraint?
- How does compulsory licensing affect R&D incentives?
- Need for competition and the issue of compulsory licences – more generally how to develop competition policy in developing countries as a complement to IP protection
- High costs of establishing and running IP systems in developing countries

SESSION 7: RESEARCH TOOLS, GENE PATENTING AND PUBLIC – PRIVATE PARTNERSHIPS

Paper 10. Executive Summary – Human Genome Patents and Developing Countries

Workshop 10. Minutes – Research Tools, Public Private Partnerships and Gene Patenting – 22nd January 2002

Commission on Intellectual Property Rights

Study Paper 10

Human Genome Patents and Developing Countries

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This report has been commissioned by the Commission as a background paper. The views expressed are those of the author and do not necessarily represent those of the Commission.

Executive Summary

There is an international consensus among countries, reflected, among other things, in the UNESCO Declaration on the Human Genome and Human Rights, 1997, that human genome sequence information should be freely available. This would ensure that important research is carried on without restriction in developed countries as well as in those developing countries with the means to do so. However, developments in patent law have meant that human gene sequences are being patented, raising the spectre of restricted access to such information as well as high prices of any useful products developed. There is a need to clarify what information on the human genome is freely available, and to what extent national patent systems should be allowed to impinge on the international consensus.

It is recommended that the relevance of the UNESCO Declaration on the Human Genome and Human Rights be re-evaluated. The Declaration also states that the benefits derived from knowledge about the human genome should be shared by all countries. Merely making the genome sequence itself available freely on the internet for example, satisfies this principle only in letter and not in spirit. The situation should be clarified with respect to industry expectations of patent protection as well as developing country expectations about public health improvement. It is recommended that gene sequences should remain pre-competitive information so that greater quantum of research and analysis can be carried out in the post genome sequence phase.

I. The possibility and implications of patenting of human genetic material taken from developing countries:

The following question was used as a guide to this section:
How widespread is the patenting of human genetic material derived from developing countries, or relevant to them?

The patenting of genetic material is a matter of relevance for all countries, developing and developed, because of the public health implications of advances in biomedical technology as well as due to rights implications for the human participants in such research. For many reasons, developing countries present ample scope for genetic research, both population genetics as well as study of individual genetic make up. But proposals for such study have been greeted with caution and suspicion by most developing countries. These responses have come from both, 'vulnerable' groups within developing and developed countries as well as national governments of developing countries. This has largely taken the form of indigenous peoples declarations, and regulations that govern international collaborative agreements as well as protect the subjects of such research. This is a reaction to a common perception that such studies may lead to unethical collection of genetic material as well as result in profits and medical advances that the participants in developing countries will not have access to.

Oversight of the compliance of such regulations in developing countries is difficult without control over researchers who may be based in another country. To aid developing countries oversee enforcement of local laws; it is recommended that patent applicants be asked to mention the source of human genetic material. Also it would be useful to have such information indexed in patent databases so that at the very least, country of origin of the human genetic material can be flagged and used as a basis for policy formulation.

II. Patenting and informed consent of participants in genetic research:

The following question was used as a guide to this section:
Should there be prior informed consent, from the people donating genetic material, to patents being sought for that material or products derived therefrom?

Genetic material is a special case for the patent system in many ways. The information is personal; knowledge of which conveys information about the person as well as of family members and other people who share the genetic characteristics. More importantly for the patent system, is the dual nature of the material. It is both tangible material as well as intangible information. The patent system while protecting the information in the genetic material dissociates the human source of the material from the invention itself. Hence, critics who speak of the rights of the human source of genetic material, and the proponents of the patent system seem to speak past each other.

The relationship between the person and her genetic material that may become part of an invention can be viewed from personal rights as well as a property perspective. Both seem to imply informed consent of the participants in genetic research as essential, which process, it may be argued, is incomplete without information about possible commercialisation of the results of the research. Informed consent of a research participant is a well-recognised international principle. It is recommended that further steps should be taken to make this an unambiguously binding legal principle. Such a step would increase the confidence of developing countries and ease international collaboration in genetic research. Article 3 of the European Charter, is a step in the right direction, but this too, falls shy of mentioning informed consent in the context of patenting.

III. The relevance of community consultation and consent:

The following question was used as a guide to this section:
Is it sufficient to obtain the consent of the person donating the genetic material or should consent be obtained from others sharing characteristics of the material?

Group consent has been recognised as necessary in case of certain genetic studies by some international bodies, including the International Bioethics Committee of UNESCO. It is a complex requirement that is compounded by the heterogeneity of the groups that could potentially take part in a genetic study. Communities should have a chance to assess the benefits and risks of taking part in such research; this process is necessary for their self-determination, much like an expression of personal autonomy in individuals. Community consent is particularly significant because of the negotiating point it represents for the community. But group consent is not a substitute for individual consent.

This section describes various international and national efforts to ensure community participation in an informed way in genetic research. If compliance with such guidelines is essential to conduct the research, then there is every reason to include the process of commercialisation within the scope of this process. Linking ethical guidelines with commercialisation of research will strengthen protection of community rights. One way of doing this is to initiate international guidelines that researchers and patent systems must respect.

IV. Benefit sharing with the research participant:

The following question was used as a guide to this section:
What provisions should there be to ensure that donors of the original material or a group to which they belong share in any of the benefits arising from any patents on that material or product derived therefrom?

The international guidelines and national regulations in this context highlight certain core tensions. Promising a share of the benefits to a potential participant in a genetic study seems to contravene ethical principles that the body or the human genome in its natural state should not give rise to financial gain. The ethical validity of consent that is given under the promise of benefits to be gained is also questionable. Given this, many guidelines specify a gratuitous model for use of human genetic tissue. However, such a model, as evidenced by developing country regulations is not a model of choice for many reasons. Many developing countries' regulations specify benefit sharing in the form of technology transfer, medical benefits or a share in intellectual property rights. This finds support in the UNESCO Declaration on the Human Genome. In this context it is recommended that international measures of benefit sharing should be undertaken in addition to the national regulations. One such measure was suggested by the Ethics Committee of the Human Genome Organisation; that commercial entities that benefit from biomedical research in developing countries should consider contributing 1-3% of their profits towards humanitarian measures. It is recommended that the bioindustry should be consulted on the feasibility of such measures.

V. Patent laws in developed countries with respect to informed consent and benefit sharing

The following question was used as a guide to this section:
Should the patent laws in developed countries play a role in enforcing any requirements relating to prior informed consent or benefit sharing?

The question of whether the patent system should be concerned with matters external to actual patentability criteria is a deeply divisive one. There are those who feel that certainty in patentability standards is crucial for the maintenance of the bioindustry's prospects and additional requirements like informed consent or benefit sharing will entail high transaction costs and are not called for, given the nature of a patent grant. On the other hand, the patent is the fulcrum of the process commercialisation of biological and genetic resources, and critics have expressed concern that the patent system may be rewarding unethical behaviour on the part of patent applicants.

There are two main reasons, as evidenced by the literature, why it may be argued that informed consent should be enforced via patent laws. The Convention of Biological Diversity is a binding legal document and it calls for such measures. If informed consent is required for the taking of plant and animal genetic material or traditional knowledge, there is reason to believe that informed consent should be necessary for taking of human genetic material as well. International regulations and the wide acceptance of informed consent in national legal systems add weight to the argument that informed consent should be regarded as a binding norm in international law. No state can license an agency (the patent office) to reward inventors who may have violated such a norm in developing their invention.

A certificate of compliance as part of a patent specification that all national laws regarding informed consent and benefit sharing where applicable were obeyed, may be one way of incorporating such norms. It is generally accepted that research without informed consent is unethical. Where such consent has been taken, the information maybe inserted into the patent without great additional cost. Where informed consent was not taken it will act as a deterrent to unethical behaviour.

VI. Post grant control over use of a patent:

The following question was used as a guide to this section:
Should the original donors of genetic material on which patents are based have any influence on how those patent rights are exploited?

Some commentators draw arguments from notions of human dignity to maintain that a person continues to have a strong interest in how human genetic material taken from her is used, handled and commercialised. From this flows the position that the original source of genetic material on which patents are based should have an influence on how patent rights are

exploited. If such a claim is recognised, it could lead to uncertainty in how patent rights are exercised. However, if informed consent to commercialisation has been taken and benefits sharing agreements entered into, then this question of post grant control over patents may not arise. This is can be seen as another reason why it would be in the interests of patent applicants to comply with such regulations at the time of conducting the research itself. It is recommended that institutions like Medical Research Councils should encourage researchers to follow ethical standards comparable to the researchers country of origin while conducting research overseas as well as follow regulations at the site of research.

VII. Developing countries and patent protection for human genetic material:

The following question was used as a guide to this section:
Do any developing or least developed countries provide or plan to provide patent protection for human genetic material. If so, what is the rationale for providing such protection?

A study of patent laws in many countries shows that no country allows for the patenting of human gene sequences, unless technical contribution has gone into it. Information collated from a WIPO questionnaire on the subject shows that this is true for most developing countries as well. Colombia, Cuba and Brazil have indicated that human gene sequences may not be patentable in their countries. There is a wide variation among developing countries as to the impact of human genome studies. India, China, Brazil and South Africa for example have the infrastructure to make use of freely available genome sequence information for their own priority research areas. The question whether developing countries will be able to exclude patents on human gene sequences at all under the TRIPS agreement is discussed in this section.

In this context it is recommended that where patents are taken out on human gene sequence information that is of particular public health relevance in developing countries, a research exemption should apply in a way that is broader than that applied in developed countries. This would allow those with the means to carry out such research in developing countries to continue to do so. Also, public health needs of developing countries maybe best met by technology transfer to the more advanced developing countries who can then prioritise resources for this.

VII. Other issues raised by the intellectual property protection for human genetic resources:

The following question was used as a guide to this section:
Do current practices in the developed countries in relation to the patenting of human genetic resources raise any other issues for the people of developing countries?

There are three significant effects of patenting of human genetic resources described here that may impact on developing countries. The first is that the secrecy and strategic behaviour associated with patenting of such knowledge may undermine the norms under which academic information is freely exchanged. The basic science infrastructure in developing countries, which is very important for the biotechnology industry, may suffer as a result of this. Secondly, it should be recognised that the human genome project has the potential to widen the 'apartheid' in health care between rich and poor countries by leading to greater individualised care for those who can afford it. The relevance of the scientific advances represented by the mapping of the human genome must be maintained for both developed and developing countries. This requires that medical researchers be encouraged to seek interventions that are population based and emphasis is put on developing inexpensive drugs and vaccines that prevent disability and disease in populations. Thirdly, there is a likelihood that some laboratories maybe conducting research into the genetic resources of poor populations in places akin to 'experimental havens' by analogy with 'tax havens' because of inadequate regulations on ethical research or difficulty in overseeing compliance in the case of foreign research collaborations. International initiatives may be need to prevent such a situation. It is recommended that the country of origin of the researcher should also enforce ethical standards comparable to such country's standards when overseas research has been authorised.

Recommendations

The link between intellectual property rules and ethical regulations over genetic research should be institutionalised. Human genetic research is highly international and interactive in character, hence agreeing on standards for informed consent and benefit sharing present a regulatory challenge akin to those that deal with genetic resources under the Convention on Biological Diversity.

Specifically, it is recommended that steps be taken to recognise informed consent of individuals and groups where appropriate, as a legally binding principle that should be appropriately complied with during all human genetic research.

A certificate to the effect that informed consent was taken from participants, that local laws and regulations were obeyed, as well as specifying their origin and location, where appropriate, should be appended to all patent applications that describe inventions that comprise human genetic information and the products derived therefrom. Such a certificate of compliance can be included with relative ease where informed consent has been taken, and will act as a deterrent to unethical research. Such a measure would increase the confidence of developing countries to initiate greater research collaboration with foreign and international entities.

Where such compliance cannot be assured, there should be provision for sanctions within the patent system.

There are circumstances when samples are anonymised or informed consent is not possible because samples were collected previously. Allowance for such cases should be made. In this regard national bodies like Medical Research Councils or Genetics Commissions should be consulted.

It should be recognised that the biomedical advances represented by increased knowledge about the human genome must be shared between all peoples in developing and developed countries.

One way to do this is to recognise the need for benefits sharing agreements when people from developing countries participate in genetic research. Such measures may include technology transfer, medical services or a share in intellectual property rights for the collaborating site in the developing countries. It is recommended that profit making entities, including academic institutions, be encouraged to commit a percentage of their profits from genetic research to humanitarian work in the developing countries involved.

The benefit sharing should extend to public health advances. Special measures should be taken to identify diseases and disabilities that are the largest afflictions in developing countries. It is possible that the human genetic sequence or the sequence of the pathogen involved may already be patented. In such cases, the possibility of providing special research exemptions under patent law for such studies should be explored.

It is possible that basic science in developing countries is adversely affected by failure or delay in publishing of scientific papers because they describe results or ideas that could give rise to a patentable invention. Given that basic science infrastructure is essential for biotechnology industry, it is recommended that this issue should be investigated further. Supporting scientific advancements in developing countries will help in developing biotechnology that is specific to their needs.

It is recommended that, once a patent has been granted, the original sources of the human genetic material should not have control over how it is exercised under patent law itself, as this would bring about uncertainty of control. Such control may be exercised through contractual agreements, and should be decided before the research is conducted.

In order to help in evidence based policy making, it is recommended that patent information services be developed that index the location and people from which human genetic material was taken, keeping in mind requirements of confidentiality of such participants where appropriate. Patent applicants should be asked to provide such labels for their research that can then be used to gauge what kind of research is being commercialised, and where it is being done.

International initiatives are required to evaluate the relevance of the notion that human genome sequence information should be made freely available to all. If this information is not regarded as pre-competitive information, then global health advances may slow down, and become too expensive to be of real benefit to peoples in the developing world.

The way in which national patent systems in developing countries impinge on the international consensus that human genome sequence should remain accessible, should be investigated. One way of reversing the trend is not to allow product patents on the DNA sequence itself, but only *use claims* on resulting end products. It would be detrimental to useful research to allow the patentability of human gene sequences whose function is known only through use of bioinformatic tools. It is recommended that one possibility is to put in place subject matter limitations that were an important part of patent law till recently. Specific subject matter inclusions or exclusions will allow for policy based decisions on what may be patentable and what may not be. The current system whereby the scope of what is patentable changes incrementally and in undirected ways is too problematic. It is recommended that industry and academic institutions be consulted on a continuous basis, as to what their reasonable expectations in this respect are.

National patent systems are dealing with human genome information which is a finite resource and is the common heritage of humanity, albeit in a ‘symbolic sense’. Given the international nature of genetic research and its global relevance, the role of domestic patent systems should be seen as one that is of significance for both developing and developed countries. Public health interests, should ideally transcend national boundaries, and should be taken into account when evaluating the pros and cons of any action taken by national patent systems.

Commission on Intellectual Property Rights

Workshop 10: Research Tools, Public Private Partnerships and Gene Patenting

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Summary: The workshop discussions covered the most relevant aspects of the research tools debate. There were presentations on the US approach the RTs developed by the NIH, and the perspectives of the CGIAR and the MVI, both international public sector research organisations. Case studies indicating the complex layers of patents surrounding RTs, highlighted the problems such institutions face in accessing RTs for pro-poor research. There was a presentation and discussion on the strengths, weaknesses and potential collaboration between the public and private sectors. One session was devoted to a presentation and discussion on issues concerning RTs in the field of human genetic research; informed consent, benefit sharing, and access to RT information. The final session comprised of a 'tour de table' in which the attendees suggested key issues and recommendation for the commission to consider.

Session 1: What's the problem with research tools and what should we do about it?

Presentation by Maria Freire
Access to Intellectual Property Rights: The Research Tool Issue

The source of funding for development of a research tools (RTs) is of crucial significance in intellectual property management. Publicly funded research is subject to government regulations and public scrutiny and includes the obligation to share access to the invention. Privately funded research usually has greater IPR/publication restrictions. Although the NIH has no direct control over private entities, the NIH guidelines on access and control rules for

RTs were meant for both public and private bodies. RTs are defined as unique research platforms such as cell lines, animal models, reagents, or databases, which may or may not be patented. They are not usually final products available to the public, although they may be 'end products' for research firms.

The NIH working Group on research tools, convened in 1997 found that access to RTs was severely constricted and proposed the framing of guidelines for all the grantees of government funds. The Final NIH Research Tools Guidelines sets out the following core principles in the first part:

- Ensure academic freedom and publication, especially when importing RTs.

- Appropriate implementation of the Bayh-Dole act. The letter of the Act clearly seeks to move technology forward and enable economic development, but it was widely misinterpreted to imply a compulsory mandate to patent as much and as often as possible. The objectives of the Bayh-Dole Act may be achieved through publication of research results or licensing as well.

- Minimise Administrative burdens: The negotiation for Material Transfer Agreements on average took 6-8 months.

- Ensure dissemination of NIH-funded RT. The NIH backed by government regulation would decide the terms of access to RT as a pre-condition of funding.

The salient features of the NIH Guidelines focus on the following.

- In case of importation of RT from other sources for use in an NIH funded project, the IPR obligations agreed on will have to be consistent with the NIH Guidelines.

- The possibility of exclusive licenses was maintained with the qualification that the exclusivity be limited to particular 'fields of use'.

- In those cases where the RT owner is in the private sector, the possibility of 'Restricted Options' and/or 'Grant Back of intellectual property rights' is allowed although NIH grantees will have to ensure that research enterprises are not blocked by such clauses.

- A simple 'Letter Agreement Model' replaced the complicated Universal Biological Material Transfer Agreement (UBMTA).

Case Study: Access to Stem Cells

The NIH funded stem cell primate studies at the WARF (Wisconsin Alumni Research Foundation) which by law allowed them some claim to the human stem cell patents as the 'conception' of the invention in the context of primates

was made using NIH funds. This claim proved important in subsequent negotiations for access to the stem cell technology and exemplifies the importance of the origin of funding in the case of Research Tools.

Geron, a private company funded the human stem cell studies. WARF obtained broad patents on the primate stem cells and methods as well as the human stem cell studies and licensed 6 cell types to Geron. The license carried a stipulation that such cell lines would be distributed to the academic world for research purposes. WiCell was created for scale-up and distribution of the stem cells. These developments raised concern that access to stem cells for the purposes of academic research was being restricted and NIH had to draft guidelines to ensure academic access based on the following principles:

- Research and Commercial Uses were segregated.
- Intellectual property was to remain with inventors – no automatic 'grant back' or 'reach through' provisions.
- Materials received from third parties were also be subject to the same terms and conditions.
- These were to be the same terms for MOUs between WiCell and all Universities that are NIH grantees.

The NIH-WiCell MOU therefore stipulated that cells would be transferred under an MTA, for non-commercial purposes, and re-distributed only with WiCell consent. The use of stem cells could only be as provided under law (as this is a restricted area of research under US law). Further, there were to be no costs in the form of paybacks. As quid pro quo for these terms, it was agreed

(a) that all publications by NIH scientists would acknowledge the source of the stem cells
(b) a yearly compliance certification would be sought from WiCell, to rule out unauthorised use of the stem cells
(c) it was agreed that for commercial uses, scientists would have to go back to WiCell for a separate license. If direct benefit of a private sector organisation was entailed, a separate license would have to be negotiated with WiCell
(d) No third-party 'reach through' agreements can be entered into by NIH grantees.

Presentation by Victoria Henson-Appollonio
The Intellectual Property Concerns of CGIAR

A number of case studies were presented to address the question 'is there an effect on CG research or dissemination of products due to IPR on research tools?'. The main intellectual property concern of the CGIAR arises out of the need to ensure access to the centre's products, to benefit subsistence level farmers, particularly those in developing countries.

Case 1: Positech technology covered by US Patent 5767378 awarded to Novartis (now Syngenta). This is a patent covering a process of selecting transformed plant cells. The patent claims include compositions needed to carry out the method. Syngenta made it known that the material would be available to the Centres, but this was to be only under Material Transfer Agreements (MTAs) that contains a 'research only' license with 'reach through' implications regarding new inventions. A 'research exemption' is insufficient because CGIAR needs to be able to distribute the materials. The fact that the material itself was covered by claims of the patent did not cause problems as such but the licensing agreement was the source of the dilemma.

Case 2: 'Golden rice' involves the use of gene sequences that result in the production of Vitamin A precursors in plants. Many pieces of intellectual property were involved in the hybridisation process. The negotiations to obtain a license for the central patents required enormous effort and ongoing research was made difficult by the publicity.

Case 3: The case of Xa21; use of a gene sequence to confer resistance to rice blast infection. The centre spent several years negotiating a license to use this sequence because an exclusive license had already been granted to a company by the patent owner.

Case 4: 'Rice genome database access' and use of proprietary information regarding the sequence of the rice (*O. japonica)* genome. One rice genome database is generated by the International Rice Sequencng Consortium, and is due to be completed by the end of 2002. The second is the proprietary database owned by Syngenta which is a much more detailed product than the one in the public domain. The licensing terms for use of this database is unacceptable to the CGIAR.

Case 5: 'Spatial/GIS Information access and distribution'. This comprises geographical, meteorological and other information incorporated into spatial information databases and then displayed in a graphical format. The data includes information from many countries, with security implications for those countries. Public and private institutions have restrictions over datasets that are available, many of which are very expensive. The licensing policy differs between manufacturers. New database legislation in EU countries has increased the difficulty in the centres being able to use the data and distribute the results.

Case 6: The Micro-arrayer: Top of the line equipment brand has 'reach through' and 'use' restrictions in the licensing agreement.

Recommendations:

- Encourage liberal licensing policies without 'reach through' provisions. Tax incentives that encourage liberal licensing, benefit sharing provisions (for exclusive licensing deals) might help towards this.

- Encourage public disclosure and enablement. This may take the form of patenting in keeping with the original intent of patent law.

- Discourage the keeping of trade secrets, especially commercial trade secrets. Use every opportunity to weaken enforcement of regulations that protect trade secrets.

- Encourage broad interpretation of the implied 'research license'.

- Strengthen enablement provisions of patent law.

- Support the US CAFC's decision in *Festo.*

- Encourage public institutions to disclaim (copy and database) rights over information generated with public funding.

Discussion

Direct government intervention often proves detrimental to making RTs available to the public sector, and negotiation between the public sector and the RT patent holder works best. The threat to patents, (because they can be challenged or worked around) can be used as a very efficient negotiating tool. Anti trust legislation should also be considered in the case of access to RT on reasonable terms.

The definition of what is commercial is central to the NIH guidelines, although the demarcation is difficult to make. If a private entity is in a position to get 'direct benefit' from the licensing of a tool to an academic user funded by that private entity, then a university is likely to regard that use as 'commercial'. It has been recognised that 'funding arrangements' in Universities may be used to circumvent negotiations for a legitimate 'commercial use' license. The mere fact that research can result in information that may be patented or licensed does not in itself make the endeavour commercial. Recently, 'social benefit' within an American context has become central to the issue of use of public funds. This can be extrapolated to social benefit to people in the developing world as well.

Given the dubious patentability of some RTs, particularly with respect to industrial applicability, it was debatable whether third world countries are obliged under the TRIPS agreement to allow patents on RTIs. It was suggested that developing countries are required under TRIPs to provide patent protection for human gene sequences and there are no special exclusions for RTs. The central question seems to be that of what amounts to an invention. In a European context an 'invention' is patentable, but a 'discovery' is not. Under US law, an invention includes a discovery. In practice there is no difference in effect between the two positions.

MTAs and licenses under which the material is made available are often more problematic than patents on RTs. Considerable resources are spent negotiating for broader and 'customised' research exemptions. It was

recommended that ways of institutionalising or codifying this process in law should be investigated. For example, under the American Inventors Patent Act passed in 1999, a researcher working independently on something that is subsequently patented by another entity can continue to use that technique and such use will not amount to infringement of the patent. It was pointed out that any resolution on access to RTs would have to take note of the distinction between intellectual property rights and tangible property rights. The right to use the patent without infringing it does not extend to access to the actual material, which is subject of a separate contract. Both kinds of rights are reflected in the NIH Guidelines.

The RTs question may resolves itself as commercial enterprises stop bothering to negotiate 'use licenses' unless there is a real prospect of a commercial product. However many CGIAR scientists feel thwarted by the lack of access to RTs, specifically, 'Geographical Information System' and 'database rights' could potentially cause severe difficulties for the functioning of CGIAR. Centres like CGIAR should be situated in parts of the world where the reach of US patent law is minimal. CGIAR is a special case as they provide a lot of material to farmers. In this context it was agreed that the specifics of the legislation being introduced in developing countries in accordance with the TRIPS agreement is crucial. Strong rights to compulsory licenses scope for research must be maintained. To ensure access to RT, unreasonable valuation of RT by small private companies and inflation of what is allowed within the claims of the patent itself are two particularly insidious problems.

Session 2 – What are the IPR issues in public-private partnerships?

Presentation by Richard Mahoney
Intellectual Property, R&D, Public-private partnerships

The specific question addressed was 'Can better management of IP in product R&D have an important impact on health in developing countries?'.

The two prominent inequities in health, are that of 'cost' of new products, that acts as a barrier to the poor, and 'availability', as products needed predominantly by the poor receive much less attention. The use of IP in the public and private sectors is lopsided. The private sector has highly sophisticated abilities to manage IP, and uses IP effectively for their corporate objectives. In the public sector there is little clarity on the importance of IP and how it can be used to realise public sector objectives.

These findings led to the specific question of why and how better public sector IP management can address problems of cost and availability? The private sector has limitations and cannot be expected to assign high priority to products for the poor in developing countries. Conversely, a lack of such products indicates that the public sector has not fulfilled its responsibilities.

Intellectual property is important because it provides opportunity for reward to risk capital in the private sector. Regulation is pervasive, affects all aspects of R&D, and is expensive to comply with. The prospect of reward acts as incentive for the investment for the private sector.

The following high priority needs were identified:

- Identification and codification of 'best practices' for licensing to achieve the goals of the public sector. These include:
  - Fields of use – reserve options for products likely to be for the poor.
  - Territory – reserve options for developing countries
  - Price – help ensure affordable price for the poor.
  - 'White Knight' – specific benefits for the public sector and/or poor.
  - Royalties – maximise benefit for the licensor; minimise burden on the poor.
- Training for scientists and administrators of universities, research institutes and product-specific groups in both developed and developing countries.
- Consulting services (delivery of best practices) to developing and developed country groups concerned with research and product development.

Other needs that have to be fulfilled include the establishment of IP databases, policy analysis and research, information collection and dissemination, brokering, patent pooling (for platform technologies, for example), and IP value assessment. The interim conclusions of the study proposed that an independent centre (MIHR) be set up as a consultative organisation that would work in collaboration with existing or emerging organisations. It would function as an IP management initiative addressed to developing country health needs. Expanded consultation is being currently provided, and it is hoped that the entity is created in early 2002.

The aims and objectives of the International Vaccine Institute is a case in point. The IVI is an autonomous international organisation under the Vienna Convention and is hosted by Korea. The IVI is a non-profit research centre that carries out many of the same research activities as private industry. However, unlike industry, the IVI accords highest priority to vaccines for the poor in developing countries. Its purpose in collaborating with industry is to assume a significant portion of the risk of vaccine development to meet the needs of the poor in developing countries. The major research programs span DOMI (Diseases of the most impoverished, bacterial diseases of Asian children, Vector borne diseases, and other enteric infections funded by various bodies. In the context of the IVI, and given these major research initiatives, IP is a matter of high priority. Some of the points of special protection are international agency access, and the need to maintain incentives for the private sector.

Presentation by Melinda Moree
Intellectual Property and Neglected Diseases: Help or Hindrance?

The mission of the Malaria Vaccine Initiative (MVI) is to accelerate the development of malaria vaccines and ensure their availability and accessibility for the developing world. While the clinical and preclinical expenditure in the development of a malaria vaccine is similar to that of any other vaccine, the profitability of malaria vaccines is significantly lower than the normal profitability of a vaccine. The strategic approach of MVI is to pull together various entities working in an academic, government or biotechnology firm into an 'industrial model of management' towards vaccine manufacture. Time is of utmost importance, thousands of children die every day due to malaria, and negotiating MTAs takes time. The major players in the field are complicated entities with multiple stakeholders in academia, government and biotechnology companies. These stakeholders moreover, are distributed all over the world. Each of the patent stakeholders individually are entitled to small pieces of royalty that cumulatively make up about 30% of costs.

The case of one antigen (MSP-1) was used to illustrate the complexity. There are currently 34 MSP-1 patent 'families' that describe and claim the antigen, process the fragments and constructs, as well as deal with production and delivery of the antigen. The patent landscape that establishes the value of patents and the 'freedom to practice' risk for a product or technology in this case is very complicated. Within the MSP-1 patents there is little IP heritage to be found; there are very limited backward or forward citations. Most importantly, qualitative questions are raised about the validity and enforceability of the MSP-1 'patent families'. This case illustrates that although IP ownership is critical for commercialisation and investment, it can also prevent access for research into neglected diseases. High transaction cost in terms of time and money for access to the use of the subject matter of these patents leads to 'avoidance'.

The Malaria Vaccine Initiative's approach to the problem is based on the following:

- Vaccine developer retains 'ownership' of the project and the IP.
- In some cases an up-front license is requested.
- In all cases 'back-up rights' are requested if the vaccine developer ceases development of the malaria application.
- The MVI plays the role of a neutral broker and advises on IP strategies.

Discussion
Compulsory licensing is irrelevant at the R&D stage where most of the hindrance exists. Although publicly embarrassing the groups that thwart important research maybe an effective way of dealing with the situation, it is often the cumulative effect of patents that is detrimental to further research. An effective solution may be to locate such research in the developing world where such patents may not have been taken out.

Any viable solution to the problem will have to take account of the following

- Doing away with the patent system in health research may prove counterproductive as the cost of regulations in the field and the resultant need to ensure return on investment could lead to such information being guarded as trade secrets.

- Special exemptions for 'neglected diseases' technologies may not be effective as in many cases technologies are developed for another use and then its use in 'neglected diseases' is realised.

The dubious quality and validity of some of these patents, called for guidelines on 'appropriate patentability' that patent examiners should enforce. The re-examination of patents is a very useful process and it should be applied liberally as it is easier to challenge the validity of a patent at the re-examination (or application stage) rather than at a later (infringement stage). The American system does not adopt a re-examination procedure prior to the granting of the patent. It was pointed out that the problem is spread over various regulatory bodies and hence more difficult to solve.

Session 3 – What is the problem with human gene patents and what can we do about it?

Presentation by Sivaramjani Thambisetty
Informed Consent and Benefit Sharing in Patent Law: Incompatible or Necessary?

Four central issues were raised.

1. How is informed consent related to patent law?

Firstly, informed consent may include explicit consent to patenting of a resulting invention that arises out of or comprises human genetic material. Truly 'informed' consent protects the autonomy of the human subject, and in some cases 'conveys' property rights where limited property interests in genetic material are recognised. Secondly, patent law may play a role in enforcing requirements relating to prior informed consent for many reasons. Patents are a form of property and many developing countries have established 'sovereign rights' over human genetic material making authorisation for research necessary. The patent system affords an opportunity to put in place minimum requirements as to informed consent as oversight of compliance is difficult any other way. On the contrary, a major reason for not introducing such requirements in patent law is that this body of law is particularly unsuited to take morality into account. The increased costs and uncertainty in patentability may be detrimental to the bio-industry.

International Declaration that codify informed consent requirements are, UNESCO Declaration on the Human Genome and Human Rights, 1997, The

Charter of fundamental rights of the European Union, 2000, The Convention on Biological Diversity, 1992 and recital 26 of the European Biotechnology Directive, 1998. National access regulations in India, China, the Andean Pact nations, and the Organisation of African Unity, also require informed consent. Many Indigenous peoples declarations also articulate this. It was pointed out that 'Peer pressure' within academia and industry can also act as an enforcement mechanism.

Recommendation: A 'certificate of compliance' to the effect that local laws and regulations were obeyed and that informed consent was taken from participants, whose origin and location are specified should be appended to all patent applications that describe human gene sequences and products derived therefrom.

2. Is 'benefit sharing' important in commercialisation of human genetic research?

Two propositions were discussed in relation to 'Benefit sharing'. Firstly, that it may be a viable alternative to 'direct financial gain' to participants in genetic research. Secondly, the possibility that it may be made a component to patent law. Remuneration or 'direct financial gain' for participants in genetic research is prohibited. Given that developing countries may not have the financial or technological resources to undertake genetic studies themselves, but are however keen to use biotechnology as a spur for economic development, the question of 'returns' for participation in genetic studies assumes great importance. Access legislation in developing countries describe mechanisms for 'equitable sharing of benefits' such as technology transfer, humanitarian development work, immediate medical benefits, share in intellectual property etc. (for example, India, China, Tonga). In contrast, many developed country policy documents articulate a 'gratuitous model' of 'donation' of human genetic material to pre-empt any subsequent claims on the commercial benefits of the research. There are some documents like the HUGO statement on benefit sharing in 2000, that suggest that 1-3% of profits out of genetic research should be donated towards humanitarian work in developing countries. The Human Genome Diversity Project's Model Ethical Protocol suggests three principles of benefit sharing – legality, honesty and appropriateness of scale.

Recommendation: Development of an international consensus on the need for and mechanisms of benefit sharing. Profit making entities (patent holders) are actively encouraged to commit a percentage of profits from genetic research to developmental activity in participating target countries.

3. What does it take to keep 'genomic information freely available to scientists everywhere'?

The most obvious way to keep gene sequences freely available is to deny their patentability. But genomic information in various forms is increasingly coming under monopoly control via patents. So far the internet has played a

very important role in making genomic information available but empirical data shows that access by scientists in developing countries is substantially lower than those in the west. Data was collected on the number of times the 'ensembl' website was accessed from different locations to show this. Given that genomic information is in fact patentable in most developed countries means that most gene sequences will be patented by entities in the developed world, leading to a loss of access to discoveries for further research in the developing world.

Recommendation: Patents granted for application of genomic information should be limited to 'use claims' and should not extend to the gene sequence itself.

4. Does special legislation for pharmacogenetics raise any issues?

Special legislation for 'Orphan drugs' is to be found in the US, Japan, Singapore, Australia and most recently in Europe that provide for broader protection than patents. Pharmacogenomics offers the opportunity to 'genetically profile' patient populations and predict the therapeutic value of drug(s). This information can in turn be used to render a 'conventional' drug 'orphan'. This could lead to monopolies on drugs that are already in the public domain because of expired patents or to extend existing monopoly of patented drugs.

Recommendation: Careful scrutiny of market exclusivity provided to conventional drugs under the orphan drug legislations is called for.

Discussant

Informed consent in patent law is 'necessary but not sufficient' and cannot be a substitute for fairness in all dealings between countries and individuals undertaking research. Benefit sharing should be incorporated into a mandatory scheme. It is unfair to expect corporations to be socially responsible and put the onus of voluntary compliance on them. An international regulatory framework should therefore replace notions of corporate responsibility towards benefit sharing.

In terms of keeping genomic information freely accessible, three remedies were suggested. Firstly, there was no justification for patents on gene sequences to cover all uses of the sequence. Secondly, discoveries of gene sequences should not be granted patents. Thirdly, more can be done to disseminate technology, especially to spread the use of bioinformatic tools. Such a need was 'desperate' as developing countries should have the capacity to study the genetic bases of diseases that concern them the most.

All gene databases, not just human, should be kept in the public domain. An insidious aspect of proprietary databases is that re-distribution of the information is prevented. This unreasonably inhibits research by restricting communication between researchers and publications. The need for public

databases is absolutely necessary not only for developing countries but also researchers everywhere.

Discussion

There were three central questions raised. Firstly, whether informed consent in developing countries should be regarded differently than in developed countries. Secondly, whether informed consent should be looked at within the ambit of patent law at all, rather than looking at it from the completely different perspective of protection of human subjects of research. Thirdly, in what way is the wider debate on informed consent and the need to specify sources in the case of patents on traditional knowledge different or similar to the requirement of informed consent in human genetic studies where it works as protection of the human subjects of research?

Most policy documents deal with traditional knowledge differently from human genetic material. The principles behind both are quite different. The notion of protection of the human subject is key to informed consent directed at the individual or community. The International Convention on Biological Diversity does not directly refer to human genetic material, and at the second meeting of the conference of parties, it was decided that the CBD should not apply to human genetic material. This in itself makes the two issues separate. This was put in place because of the apparent repugnancy to the idea that one could trade in human genetic material. It was pointed out that the use of CBD-like arrangements in developing countries for access to human genetic material is contradictory to what was agreed at COP. Perhaps what can only be borrowed from CBD is a framework of arriving at an international consensus and then leaving it to national laws to implement a broad agreement.

The idea of ‘moral rights’ in copyright might provide a model to implement similar rights in patent law to do with protection of the human source of genetic material. Such a measure might be effective as there is theoretical precedence for it within Intellectual property law itself. But to term these as ‘moral’ requirements may undermine them as the patent system has shown itself to be averse to arguments based on morality.

Informed consent, is an indeterminate doctrine in itself and notoriously difficult to implement. The provider of the consent has an opportunity to negotiate some benefit sharing although there are often circumstances that cannot always be foreseen at the point at which informed consent is given. In such cases, other laws like anti trust legislation on consumer protection should be brought into effect. Because of the moral position that the body should not be subject of ‘direct financial gain’, the community gains prominence as a focal point for benefit sharing. Community consent can take many forms. In Iceland and Tonga, for example, population gene databanks have been set up under law. This may be construed as ‘political consent’.

The question of compatibility of additional requirements like origin of the source, and informed consent with TRIPS, Art 27 (3) (b) was met with the

possibility that it could be interpreted to fall within the public order and morality exception. There is no internationally agreed precedent for interpreting this clause and this may well work in favour of developing countries and 'local' interpretation. It was suggested that under TRIPS this was only applicable to 'commercialisation of the invention' and not grant of the patent itself. It was pointed out that the legal status of recital 26 of the European Biotechnology Directive which requires that 'informed consent' should be taken wherever possible is a source of disagreement between European countries.

Possible commercialisation via patents, as well as through exclusive licensing, should be disclosed to the provider of informed consent upfront. 'Inappropriate licensing' was a cause for concern for example, when the lung cancer vaccine, including the gene sequences, that were taken originally from two lung cancer patients were subsequently licensed exclusively to Japan Tobacco. It was pointed out that many people do not understand the implications of the patents. In such a case the efficacy of explaining the notion of patents to research participants is doubtful.

Genes can be used a diagnostic tools as in the case of the breast cancer genes, there are also patents on therapeutic proteins that incorporate the gene sequences itself as in the case of EPO, and there is also the case of RTs where subsequent research can be done on the gene sequences. It was suggested that given that the European Biotech Directive is already in place, there is scope only to suggest incremental changes. Some of the aspects that require changes are the distinction between inventions and discoveries, the unjustified breadth of some of the patents, overlap of patent rights leading to huge transaction costs for useful research, patenting of RT that is a matter of concern for many pharmaceutical companies, the emphasis on protection of investment rather than invention, and other ethical concerns.

A number of remedies emerged during the discussion. It was strongly emphasised that the commission has an opportunity to improve the situation with respect to the invention-discovery distinction. This could take the form of guidelines. Inventions or discoveries happen as a process, and guidelines would help to characterise the process. This could extend to the function/utility aspect as well.

A distinction has to be made between the undesirable subject matter of the patent itself and the breadth of the patents (which may be solved by enablement doctrines, for example). In the specific context of the BRCA patent, the question of whether a narrower patent that would maintain the incentive effect while allowing further inventive activity around it, would be acceptable was posed. A more appropriate BRCA patent would be one that would not prevent development of a cheaper or more appropriate diagnostic device.

With respect to the discovery – invention dichotomy the theoretical basis of patents was raised. It was also strongly recommended that any guidelines aimed at corporate behaviour should be mandatory as anything else in

unlikely to be effective given the lobbying power of MNCs and their objective to make profit.

There is a need to clarify that legislation under TRIPS can specifically exclude gene sequences from being patentable. Anglo-American patent terminology used in recent legislation in developing countries could in effect make such sequences patentable. The alleged contradiction between developing country rhetoric and practice was pointed out. Many developing countries seem keen to patent their own biodiversity in first world countries including the US, precisely because there is a market for it and there are profits to be made. At the same time many of these countries would not allow such patents in their own jurisdictions. It was suggested however, that this was due to the pressure of a lopsided system, similar to the way universities have been driven to aggressive patenting undermining their own academic objectives in the process.

Session 4: Tour de table - Key issues and themes for the Commission

- Commission has a key and timely opportunity to influence thinking about intellectual property rules and practice.

- Developing countries need institutional capacities to design appropriate IP regimes under TRIPS to take note of specific concerns dealt with in this workshop.

- Licensing of IPRs often has unintended consequences in limiting access. Undesirable clauses like ‘exclusive rights in all fields of use’ should be identified.

- Negotiating licenses and of access takes inordinate time and resources. Compulsory licenses should be considered as a viable alternative, irrespective of industry sensitivity to it. On the downside use of compulsory licenses can also be counter-productive, barring many potential partnerships with IPR owners.

- Inclusion of mechanism for pre-grant opposition periods in national patent laws should be considered. Bad patents may be prevented by greater attention to the role of patent examiners. Review of patent examination practice and possible audit of patent grants to look for overly broad or incorrect claims should be considered.

- There is need for greater transparency about how patents function. Misunderstandings can be particularly detrimental when consent is required from research subjects and licensing agreements for use of technology are being negotiated.

- A ‘best practice’ approach for licensing should be developed.

- Public-private partnerships have a negative affect on the IP policies of the public sector. There is a need to re-articulate the objectives of these institutions. IP policy for publicly funded research should maximize access to the knowledge generated.

- The correct mandate and obligations of developing countries with respect to gene patents under TRIPS should be clarified.

- The Commission should consider special measures for technology transfer to those countries suffering pandemic diseases in terms of public health related products.

- The commission should be wary of emphasising the Consent issue, as this is largely based on the mistaken belief that potential windfall benefits are to be gained from genetic information.

- Patent law and ethical concerns should be kept separate. The latter is better dealt with elsewhere, as patent law is designed to reward innovation. Tampering with this objective can be ineffective and raise transaction costs.

- Rather than target big pharmaceutical companies as the cause for the plight of public health of poor people, it would be more constructive to deal directly with neglected diseases. There are many good aspects of the current system that can be exploited through public-private partnerships.

- Although the case of MVI exemplifies the problems of licensing the enormous and (overlapping) range of different IPRs, it also means the necessary knowledge has already been created and exists as intellectual property because of the patent system. The patent system cannot be condemned in entirety as detrimental to developing platform technologies.

- The Commission should consider broadening research exemptions in patent law, by making these unambiguous (in the EU), or making a case for their inclusion where they are not currently incorporated (in the US)
- Commission should look at the UNESCO Declaration on the Human Genome and Human Rights (1997), as this already reflects a minimum level of international consensus on issues like consent, benefits sharing and technology transfer.

- Commission should consider recommending that countries stop a minimum level of international consensus. giving product patents on (human) gene sequences and restrict this to granting of ‘use’ claims.

- The commission should consider both sides of the invention-discovery dichotomy. The distinction appears irrelevant as the social purpose of the patent system is to encourage the development of useful technologies and their availability for use by people. And whether these are invention or discovery makes no difference. But patents on the discovery of human genes can fundamentally restrict future competition in (possibly better/cheaper) application technologies by restricting 'inventing around'.

- Patenting of research uses needs to be addressed by narrowing the scope of claims.

- Commission should consider the serious problem of the growing use of 'reach through' clauses in patent claims and in IP license agreements.

- Natural altruism is the expected norm (by ordinary people) in terms of benefit sharing of the use of human genetic material in commercial research, this should be institutionalised as a core part of the notion of 'consent'.

- The commission should use evidence and case studies as far as possible to inform debate and point to what the real issues are.

- Strengthening regulations requiring informed consent for use of human genetic material in medical research could have the undesirable effect of increasing costs and slowing the delivery of treatments and vaccines for neglected diseases in developing countries.

SESSION 8: INTERNATIONAL INSTITUTIONS, RULES AND PRACTICES AND CAPACITY BUILDING

Paper 7. Executive Summary – Implementation of the TRIPS Agreement by Developing Countries

(Workshop 7. Minutes – there was no workshop on this study area)

Paper 8. Executive Summary – Developing Countries and International Intellectual Property Standard-setting

(Workshop 8. Minutes – the workshop on this study area took place on the 19th February and the minutes are not yet completed)

Paper 9. Executive Summary – Institutional Issues for Developing Countries in Intellectual Property Policymaking, Administration & Enforcement

(Workshop 9. Minutes – the workshop on this study area took place on the 18th February and the minutes are not yet completed)

Commission on Intellectual Property Rights

Study Paper 7

Implementation of the TRIPS Agreement by Developing Countries

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Executive Summary

An analysis of the current intellectual property laws of about 70 developing and least developed countries was undertaken. The majority of these laws have recently been amended to take account of the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).

The analysis centred primarily on the implementation of Section 5 of TRIPS which covers patents since this is the area where most concern has been raised. The study does however explore issues relating to other categories of intellectual property including copyright, plant breeders' rights and protection of undisclosed information.

The analysis shows that very few developing countries are still denying patent protection for pharmaceutical products. The analysis also revealed that all but three of the 30 Least Developed Countries (LDC) in Africa are apparently already providing patent for such products despite not having to do so until 2016 at the earliest. This protection is available in a large number of these countries through the two African regionally based intellectual property IP organisations.

An analysis of patents issued by these two regional African IP organisations shows a high proportion to be related to medicines. Indeed in some years more than 50% of patents issued appear to be related to medicinal products.

It would also appear from the analysis that developing countries are to a large extent fully aware of the legislative possibilities provided under TRIPS, although only a few appear to have taken advantage of all of the possible flexibilities. Numerous examples now exist of national legislative provisions seeking to give effect to these flexibilities.

These provisions cover the more obvious and more legally certain flexibilities such as providing for international patent exhaustion and the use of a patented product without the consent of the patent holder for regulatory approval purposes (Bolar type exception). Of the countries analysed, over 30% now specifically provided for international exhaustion. At least 8 developing countries now also include specific Bolar type provisions in their legislation.

Specific provisions are also included in the legislation of at least 9 developing countries requiring patent applicants to disclose the source of any biological material used in the invention. This provision extends in some cases also to any associated traditional knowledge.

Despite being able to exclude animals and plants from patentability under TRIPS, over 75% of developing countries still provide patent protection for at least some inventions covering plants and animals. A significant number of

countries analysed (over 60%) also provide patent protection for new uses of known or previously patented subject matter.

All of the countries analysed provided some form of compulsory licensing to prevent against abuses of IP rights.

In respect of other categories of intellectual property, it was noted that a significant number of developing countries have taken advantage of the flexibilities provided by TRIPS by providing for example sui-generis systems of plant variety right protection including fairly broad exceptions to enable farmers, especially small farmers, to save and exchange seeds. In the field of copyright some countries have also provided fairly generous exceptions to the rights particularly for educational purposes.

Commission on Intellectual Property Rights

Study Paper 8

Developing Countries and International Intellectual Property Standard-setting

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and
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EXECUTIVE SUMMARY

The report examines the extent to which developing countries influence outcomes in the international intellectual property standard-setting process. It concludes that developing countries have comparatively little influence. The main reason lies in the continued use of webs of coercion by the US and EU, both of which remain united on the need for strong global standards of intellectual property protection.

Analytical framework

The study draws on the analytical framework developed by Braithwaite and Drahos in *Global Business Regulation* (GBR).[9] GBR ranged across more than 15 different areas of business regulation, including intellectual property. It found that regulatory globalisation is a process in which different types of actors use various mechanisms to push for or against principles.

More than 500 people were interviewed for GBR. The study also draws on a forthcoming book by Drahos and Braithwaite (*Information Feudalism: Who Controls the Knowledge Economy?*) dealing with the globalisation of intellectual property rights. Further interviews were undertaken for the purposes of the study, including interviews at WIPO and the WTO.

Standard-Setting Pre-TRIPS

The study briefly describes the impact of developing countries in the international standard-setting process pre-TRIPS. The main conclusion is that as developing countries came to be influential within fora such as WIPO by virtue of their number, the US embarked on a strategy of forum shifting.

The TRIPS negotiations

The paper evaluates the TRIPS negotiations using a theory of democratic property rights. The theory argues that efficiently defined property rights are more likely to emerge if at least three conditions are met. Firstly, all relevant interests have to be represented in the negotiating process (*the condition of representation*). Secondly, all those involved in the negotiation must have full information about the consequences of various possible outcomes (*the condition of full information*). Thirdly, one party must not coerce the others (*the condition of non-domination*). The study concludes that the TRIPS negotiations did not meet these conditions of democratic bargaining.

[9] J. Braithwaite and P. Drahos, *Global Business Regulation*, Cambridge, Cambridge University Press, 2000.

Bilateralism in Intellectual Property Post-TRIPS

The study details continued US bilateralism on intellectual property rights. It compares TRIPS with the provisions on intellectual property in bilateral trade agreements and bilateral investment treaties that the US has signed with developing countries. The study concludes that bilateral intellectual property and investment agreements are part of a ratcheting process that is seeing intellectual property norms globalize at a remarkable rate. The role of WIPO in this process is examined.

The Global Politics of TRIPS

The paper looks at the impact of civil society on the intellectual property standard-setting process. NGOs, after states and business, have become a third force in the global politics of intellectual property rights. NGOs function as an analytical resource for developing states and as possible partners in a global coalition of minority factions on international intellectual property standard-setting issues. But these kinds of coalitions are difficult to put together, are issue specific and predominantly rely on a crisis of some kind to be truly effective. They do not threaten the standard-setting dominance of the US and EU, especially when these two states are united on the direction in which global regulation should travel.

The study makes the following recommendations:

SUMMARY OF RECOMMENDATIONS

1. Developing countries should use the Council for TRIPS to create a practice of asking states to explain bilateral departures from multilaterally agreed IP standards.
2. Developing countries should use the WTO Trade Review Policy Mechanism to review distortions in trade being caused by excessively high intellectual property standards.
3. Trade policy bodies/institutes within developing countries should investigate the feasibility of forming a developing country Quad along the lines suggested in the paper.
4. An independent review of WIPO's current private sector income and development spending should be undertaken with a view to assessing the possibility of WIPO playing a role in the UN Programme Of Action For The Least Developed Countries For The Decade 2001-2010.

5. (i)Developing countries should review their participation in the WIPO standard-setting process with a view to increasing their participation in the expert groups and broadening the range of experts they send to WIPO meetings to include, for example, experts in health, environment and agriculture. (ii) Developed countries could assist by funding aid projects aimed at establishing structures for cooperation amongst ministries/regulators which have expertise to contribute on development aspects of intellectual property issues within a given developing country.
6. Developed countries should review the operation of the policy advisory committees that advise their patent offices with a view to significantly increasing the participation of members of civil society in those committees.
7. Developed countries should assess their conduct of trade negotiations with developing countries with a view to ensuring that development objectives remain a priority during those negotiations.

Commission on Intellectual Property Rights

Study Paper 9

Institutional Issues for Developing Countries in Intellectual Property Policymaking, Administration & Enforcement

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&

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This report has been commissioned by the Commission as a background paper. The views expressed here are those of the authors and do not necessarily represent those of the Commission.

EXECUTIVE SUMMARY

The study examines the institutional capacities for intellectual property policy making, administration and enforcement which exist in poor countries and the recent technical co-operation programmes which have sought to re-enforce them. It is based on a review of available existing literature, the preparation of a number of case studies, interviews with representatives of both developed and developing countries, and the creation of an institutional model for national IP administration in low income countries.

Designing IP regimes in poor countries: points of departure

The study is based on a set of assumptions and criteria that: (a) attempt to balance incentives for IP rights holders with access for the users of subject matter covered by IPRs; (b) recognize the relative low levels of domestic creation of intellectual property in poor countries; (c) accept that benefits may flow from IPRs through adoption of a "holistic" approach to the design of relevant institutions, (d) address the institutional implications of viewing IPRs as private rights; and (e) acknowledge the need for compliance with international obligations in the national administration and enforcement of IPRs.

Institutional challenges in developing countries

The study examines current levels of institutional capacity for addressing the challenges related to (a) formulating policy and legislation on IP; (b) participating in international rule making through organizations such as WIPO and WTO; and (c) administering and enforcing IPRs at the national level in line with international obligations.

The study highlights the lack of IP expertise in the national academic institutions of developing countries. This in turn results in a serious shortage of domestic legal professionals and a lack of policy development capacity in the area of IP. Secondly, the study notes that there tends to be a low awareness and understanding of IP among key stakeholder groups, including the business sector, the scientific community and public officials, as well as the public (consumers) at large. Further, the study concludes that institutional capacity of developing countries for policy coordination across government, and participatory processes for IP policymaking (including active participation of poorest groups) vary widely and may, in some countries, be one of the weakest areas of the IP system. The study also notes an undesirable discontinuity in the continuum from the development of policy and legislation to the implementation of the latter through regulations, new institutional arrangements and modernization of office operating procedures.

In terms of participation in international rule making, the study concludes that there exists a duality among developing countries. Some, including 20 LDCs, have no permanent representation in Geneva, have limited or no travel resources to permit experts to attend from capitals and are often little more

than spectators in WTO and WIPO. Others are active and influential participants in the international rule making processes.

The study examines the institutional arrangements and capacity for both administration and enforcement of IPRs. In the area of administration, the study concludes that arrangements vary widely but that, in general, most developing countries face serious financial and human resource constraints in implementing new legislation and modernizing (including computerizing) office procedures. With regard to enforcement of IPRs, the study confirms the view that institutional weaknesses are likely to be greatest in the poorest countries, and examines options that may be viable to strengthen enforcement. The study also considers some institutional issues for developing countries in the regulation of IPRs in relation to matters of special public interest, including compulsory licensing and prevention of anti-competitive practices.

Finally, in this section the study examines cost, revenue and expenditure issues and options for IP institutions and proposes the rationalization of operations and increased participation in regional and international cooperation agreements.

Technical co-operation programmes 1996-2001

The study proposes that technical assistance programmes in very poor countries should be accelerated and increased, with emphasis on institutional reforms and capacity building. The financing of these should be increased. The paper reviews the major donors and the types of activities that have been undertaken, and offers some observations on the apparent effectiveness and impact of such programs. The study concludes that coordination among donors should be strengthened in order to improve the effectiveness of technical assistance programmes.

Recommendations

The study makes the following recommendations to address the issues and problems discussed.

a. Developing countries should establish a single institution responsible for IPR administration, either as semi-autonomous agency or government department operating on a trading account basis, under the supervision of a suitable government ministry. As well as IPR administration, the institution should be responsible for providing policy and legal advice to the government on all matters relating to intellectual property (in conjunction with other concerned ministries and agencies); liaison with the enforcement agencies and competition regulators (including providing training and advice as required); expert representation in international organisations and rule-making; and co-ordination of public awareness and consultation programmes regarding intellectual property subjects.

b. Developing countries should ensure that their intellectual property legislation and procedures emphasize, to the maximum possible extent, enforcement of IPRs through administrative action and through the civil rather than criminal justice system. To address the enforcement of copyright infringement in particular in low-income countries, responsibility should lie with rights holder organisations to increase their co-operation with the enforcement agencies and to agree with national governments appropriate cost-recovery mechanisms for any large-scale anti-counterfeiting operations and public awareness campaigns undertaken by government agencies.

c. Developing countries should aim to recover the full costs of upgrading and maintaining all aspects of the national intellectual property infrastructure through national IPR registration and administration charges. A tired-system of fees should be employed and fee levels regularly reviewed. IPR administration agencies should generally only offset one-time and recurrent expenditures with revenues from such charges, but a fixed percentage of revenue income should be returned to the government's consolidated fund each year as a contribution towards IPR enforcement costs.

d. Developing countries should seek to exploit the maximum possible benefits in terms of cost reduction and administrative efficiency from existing regional and international co-operation mechanisms (such as the PCT and the Madrid system). LDCs and small developing countries in particular should adopt a patent registration regime and should make use of the verification systems offered by the international search and examination authorities such as the EPO and others. Countries within the African region, particularly the LDCs, should give serious consideration to becoming full member states of ARIPO or OAPI.

e. Like-minded countries and donors should also re-double their efforts to support high-level dialogue on new regional and international co-operation initiatives in IPR administration, training and IPR statistical data collection involving developing countries. Donors should stand ready to provide substantial technical and financial assistance to support such initiatives, particularly over the short term as cost-recovery mechanisms are developed, not least because they offer excellent opportunities for scale economies in the delivery of region-based technical assistance, training and IPR statistical data collection.

f. Developing countries should encourage policy research and analysis on intellectual property subjects in the national interest (eg protection of plant varieties; traditional knowledge and folklore; technology transfer etc) within academic organizations, policy think-thank institutes and other stakeholder organizations in civil society that can contribute to the intellectual property policy and legislative development processes. To support these efforts and channel technical and financial assistance, a Preparatory Group of donors and developing countries should be formed to examine the feasibility of

establishing a Foundation for Intellectual Property and Development Research, either as a new entity or under an existing non-governmental organisation, based in Geneva. The UK Government should initiate discussion with like-minded countries and donor organisations such as WIPO and the World Bank on the formation of the Preparatory Group and should provide funding for the completion of a feasibility study and other preparatory work.

g. Delivery of technical and financial assistance to IPR administration institutions in low-income countries should be through multi-year, broad-based programmes. They should cover support for one-time expenditure such as premises, automation, equipment, communications, staff training, consultancy support, international travel, public awareness raising programmes, patent information systems, website development (linked to WIPONET), policy research and legislation development. Financial sustainability of such institutions should be a key objective from the outset. Where a recurrent budget deficit is projected before sufficient revenues from cost-recovery come on stream, non-staff recurrent cost support should be provided for an agreed period under enhanced monitoring arrangements.

h. In order to meet the special needs of LDCs in developing the modern intellectual property regime and wider institutional infrastructure they require, WIPO, EPO and developed countries should plan to commit US$100 million in technical and financial assistance specifically to LDCs over the next 5 years, raised though income from IPR service user-fees. To facilitate better integration with national development plans and donor assistance strategies, the planning, delivery and management of this assistance should be fully incorporated within the Integrated Framework for Trade-Related Technical Assistance to LDCs.

i. To take forward recommendation (h) above, the UK Government should quickly move to propose that WIPO and EPO be formally invited to join as donor agencies of the Integrated Framework alongside the World Bank, UNDP, UNCTAD, WTO, and ITC. Developed countries should also review their participation as donor agencies in the Integrated Framework, with a view to increasing the contribution of their national IPR offices. Both EPO and WIPO (and ideally developed country national IPR offices also) should then each make an initial contribution of US$1.5 million to the Integrated Framework Trust Fund as soon as possible to enable consideration of intellectual property-related capacity building needs within those pilot country diagnostic studies that have already been prepared and for the next wave of pilot country diagnostic studies to be undertaken.

j. To streamline donor co-ordination, UNDP, the World Bank and UNCTAD should co-operate with EPO, WIPO and developed country agencies in implementation of intellectual-property related programmes under the Integrated Framework. To facilitate effective management between the agencies and national governments on the ground in LDCs, a portion of

the WIPO and EPO contributions to the Integrated Framework Trust Fund should be used to fund the provision of up to 6 Field Managers, to based in selected UNDP or World Bank missions in Africa (4), Asia (1) and the Pacific (1).

k. WIPO should make funds available to cover the travel, accommodation and subsistence expenses of two representatives from all LDC Member States or Observers of WIPO or WTO to participate in all WTO TRIPS Council meetings and in those meetings at WIPO which such countries are eligible to attend. In addition, along with other donors, WIPO should make a commitment to contribute through technical support and financial aid to initiatives being planned or undertaken by other international organisations for developing countries without permanent representation in Geneva (eg AITEC). To complement these initiatives, the UK Government, through the Department for International Development (DFID), should expand its current support to UNCTAD's TRIPS-related capacity building project to include provision for a full-time post of Intellectual Property Adviser to developing countries' delegations in Geneva (the funding should also cover associated resources along the lines of DFID's support for the UNCATD GATS Adviser post).

l. To improve monitoring of technical co-operation provided to developing countries under Article 67 of the TRIPS Agreement, all developed countries and the relevant international organisations should include summary financial information and evaluation results in their annual submissions to the WTO TRIPS council. Based on this data, the WTO Secretariat should prepare and update a summary matrix showing technical co-operation activity for all developing countries and LDCs.

m. WIPO should strengthen the present systems for monitoring and evaluation of its development co-operation programmes. A rolling programme of external impact- evaluations should be undertaken and published, commencing with a review of WIPO training activities including the WIPO Worldwide Academy. At the same time, the structure and organization of WIPO's Permanent Committee on Development Co-operation should be examined, with a view to enabling it to provide more effective strategic oversight of development cooperation. As initial tasks for a re-organised Committee, Working Groups under its auspices should be established to steer the evaluation programme and to develop detailed due-diligence and procedural guidelines for the Secretariat in the provision of assistance to developing countries for reform of domestic intellectual property legislation.

n. With a view to encouraging best-practice and better co-ordination amongst donors, a work programme on Guidelines for Modernising Intellectual Property Systems for Development should be established under the auspices of the OECD Development Assistance Committee, commencing 2003. The work programme would be undertaken by the OECD Secretariat in conjunction with a Steering Group of experts from donors

and developing countries and should be based on a series of case studies on different developing countries/regions. The output of the work programme would be a set of detailed DAC guidelines for improving the delivery of intellectual property-related technical co-operation but the process in itself would also be useful in improving dialogue and information sharing. The UK and other countries should contribute funding for this initiative and should offer to send suitable representatives to the Steering Group.