TOWARDS DEVELOPMENT-ORIENTED INTELLECTUAL PROPERTY POLICY:

SETTING AN AGENDA FOR THE NEXT FIVE YEARS

1. A group of specialists, government experts and members of international and non-governmental organizations, met in their personal capacity, from 30 October to 2 November 2002, in the context of the Bellagio Series on Development and Intellectual Property Policy sponsored by the Rockefeller Foundation.

2. The meeting was convened out of concern that certain trends in the formulation of international intellectual property (IP) policies may be detrimental to economic, technological, social and cultural development as well as poverty alleviation. The dialogue focused on strategic discussions to identify concrete recommendations that could contribute to the formulation of development-oriented IP policies.

3. The discussion covered the following four themes: the future of IP in the multilateral trading system; the challenge of new treaty development and harmonization; promoting effective national policy formulation; and integrating IP policies in development strategies.

4. Participants acknowledged the important findings of the Report of the UK Commission on Intellectual Property Rights including its conclusion that the international IP system in its present form does not adequately further the interests of the poor.

5. The Group expressed its concern that developing country members of the World Trade Organization (WTO), through the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), no longer have the range of policy options developed countries had to support their national development. In addition, a strong concern was expressed concerning the significant new developments that are taking place at the international, regional and bilateral levels that build on and go beyond the TRIPS standards.

6. The Group had extensive discussions on the issues and the considerable challenges ahead. It highlighted, inter alia, the following:
    a. IP policy could contribute to development if properly formulated to respond to national needs and stages of development. It should promote innovation, creativity and contribute to the integration of developing countries in the multilateral trading system;
    b. The problem is that the opportunities for tailoring national IP systems to promote sustainable development are being rapidly foreclosed;

c. The need to rebalance IP policies, at all levels, by taking into account the interests of producers, creators, local communities, consumers and the society at large;
d. One single IP model does not respond to the development concerns of low and middle-income countries;
e. Mastering technology is key to a fair integration and participation in the multilateral trading system. All developing countries face a major challenge in this respect requiring the urgent attention of the international community;
f. The TRIPS Agreement, its evolution and jurisprudence, should continue to recognize existing flexibilities and the need for their adaptation to national conditions, taking into account the findings and recommendations of the UK Commission on Intellectual Property Rights and other empirical evidence;
g. The trend towards harmonization of IP policies is driven by industrialized countries concerns. The meeting felt that this process should accommodate a diversity of approaches. Developing countries should not be forced to forgo stages of development by adopting inappropriately high standards of protection not commensurate with their level of development.

7. The Group discussed a set of priorities areas for future action to pursue the goal of integrating development objectives in the formulation and implementation of IP policy. The priority areas include:
    a. The promotion and protection of public health;
    b. Evaluating and addressing the institutional framework in which IP policy is developed and implemented including assessment of the WIPO process;
    c. Precluding the possibility of non-violation nullification or impairment actions in the TRIPS dispute settlement context;
    d. Assuring that competition rules are developed and applied to IP in a manner that promotes the interests of developing countries;
    e. Addressing aggressive unilateralism and the promotion of TRIPS-plus standards;
    f. Developing and implementing effective and concrete short and long term policies on the transfer of technology;
    g. Pursuing a development-oriented approach to traditional knowledge, issues surrounding genetic resources and the Article 27.3(b) review;
    h. Reviewing harmonization efforts in the fields of patent and copyright to address concerns that developing country interests are not being adequately addressed;
    i. Establishing the best means for capacity building in developing countries.

8. In each of the above areas, different actors in the Group identified short, medium and long-term actions that could be carried out at different levels and by different actors, including priority areas in negotiations, policy analysis and research. This set of priority actions should be updated regularly. In this respect it was agreed to initiate a process of follow-up and monitoring.

9. A session to review progress and other changes in the identified areas will be convened in 2003.

Summary of deliberations

Intellectual property rights (IPRs) have never been more economically and politically important or controversial than they are today. Patents, copyrights, trademarks, industrial designs, integrated circuits and geographical indications are frequently mentioned in discussions and debates on such diverse topics as public health, agriculture, education, trade, industrial policy, traditional knowledge, biodiversity, biotechnology, the Internet, the entertainment and media industries, and increasingly the widening gap between the income levels of the developed countries and the developing, and especially least-developed, countries. An understanding of IPRs is indispensable to informed policy making in all areas of human development.

Developing country members of the World Trade Organization (WTO) no longer have the policy options and flexibilities developed countries had in using IPRs to support their national development. The Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) imposes minimum, relatively high, standards, which all WTO members must follow. But TRIPS is not the end of the story. Significant new developments are taking place at the international, regional and bilateral level that build on and strengthen the minimum TRIPS standards. The challenges ahead are considerable.

The Dialogue consisted of strategic discussions to identify concrete recommendations that could contribute to the formulation of development-oriented IP policies. The recommendations were directed not only to the Council for TRIPS and the Doha Development Agenda but other important national, bilateral and regional initiatives and processes relating to IP and development. The four themes covered were (i) the future of IPRs in the multilateral trading system; (ii) meeting the challenge of new treaty development and harmonization; (iii) promoting effective national policy formulation; and (iv) integrating IP policies in development strategies.

1. The future of IPRs in the multilateral trading system

There are seven issues that developing countries should pay special attention to for the forthcoming Ministerial Conference of the WTO, scheduled to take place in September 2003 in Cancun, Mexico.

Public health: The Council for TRIPS is instructed by Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health to report to the General Council before the end of 2002 regarding an expeditious solution to the problem of members facing difficulty in using compulsory licensing due to insufficient manufacturing capacity. Prospects for a favourable result are enhanced by seeking an "early harvest" agreement. Without agreement on a comprehensive, expeditious and permanent solution maximally supportive of developing country interests, developed country members will offer the solution as a major "concession" to developing members for which additional concessions will be demanded. It should be clarified here that public health measures are far too important to be treated as a subject for reciprocal trade bargaining.

Resolution of the technical and legal issues will not resolve the basic economic problem. After 2005, generic industries making substitutes for new products on patent will begin to disappear completely. Hence, for production under compulsory license firms must learn how

to produce the particular product, conduct the necessary quality control, and scale up a production facility. This issue must be promptly addressed and resolved before 2005 so that generic standby production capacity to supply medicines remains available after that date. Given the lives at stake, the "sanctity" of the 1 January 2005 deadline may need to be re-evaluated. The WHO and UNDP could serve as sources of political and intellectual support for generic capacity building and compulsory licensing implementation.

Measures must be taken to promote the establishment and maintenance of developing country capacity to supply products in the pharmaceutical sector. This will require significant expense that must ultimately be covered by users of the product or by the world public sector. In addition, research and development on medicines relevant to developing countries must be promoted, supporting the efforts of Medicins sans Frontieres, including its Drugs for Neglected Diseases Initiative, WHO, Oxfam and others. A number of other measures should be considered, such as to support the creation of regional medicines supply centres.

Maintaining the freedom to use the flexibilities of TRIPS would be strengthened by such measures as developing model best practices in developing country intellectual property legislation affecting medicines (e.g. model compulsory licensing, government use and parallel importation provisions), and establishing consumer alliances between NGOs and consumer groups in the North and South. In addition, unreasonable demands for data protection, regulatory barriers, and other obstacles should be opposed.

In the longer term, it would be worthwhile to carefully rethink the relationship of patents to public health. The need to generate R&D of relevance to developing countries, while providing medicines at affordable prices, should be a focal point. The public sector may be reinvigorated as a source of R&D. The reintroduction of licenses of right as part of the compulsory licensing arsenal might also be considered. In addition, means for promoting constructive socially responsible action by the pharmaceutical industry should be considered.

Non-violation causes of action: Developing countries have a substantial and immediate interest in resolving the question whether and under what conditions non-violation nullification or impairment (NVNI) causes of action may be initiated under TRIPS. It seems more likely that developed member IP holder interest groups will seek to expand the scope of TRIPS actions through this mechanism. If the de facto moratorium on NVNI actions is lifted, it may be very difficult to re-engage in limiting such actions. For this reason, it is important that the issue be addressed now, rather than as a longer term agenda item. Ideally, non-violation causes of action should have no place in the context of TRIPS.

Transfer of technology: Transfer of technology must have a broad scope, taking into consideration the contexts in which it applies. Modalities of technology transfer should include firm-to-firm transfers, foreign direct investment, capacity building, private-public partnerships, and technical assistance. Developing country members may press for concrete proposals on technology transfer, which would necessarily include funding commitments. Assistance under TRIPS has largely consisted of technical programmes to implement IP laws. Developing country members might agree on one or two specific proposals, rather than continuing to address this subject matter in the abstract.

With respect to implementation of Article 66.2, developed countries should make specific commitments such as providing immediate capacity building for the LDCs including additional funding, while addressing also the concerns of developing countries.

The Working Group on Trade and Transfer of Technology (WGTTT) should become the main forum to discuss technology transfer and coordinate current debate under other WTO and non-WTO agreements such as multilateral environmental agreements (MEAs). The Working Group should examine new mechanisms for technology transfer including a new international treaty on technology exchange, explore the potential of South-South cooperation, and make recommendations on the above to the WTO Ministerial Conference in Cancun. Based on studies that identify cases where second-best or obsolete technologies are transferred to developing countries in the context of investment promotion or FDI, the Working Group should find out how international rules could ensure that companies invest and transfer state of the art technologies.

Environmentally sound technology should be transferred on a fair, most favourable or preferential and non-commercial basis. The WGTTT should: (i) examine the mechanisms to implement those provisions; (ii) identify those technologies and products that could help developing countries implement environmental obligations; and (iii) examine how this process interfaces with TRIPS obligations and what kind of clarifications are needed from TRIPS, if any.

An independent group should be set up to prepare studies on capacity requirements in the poorest and in the middle income countries and the mechanisms to be used.

Convention on Biological Diversity and Article 27.3(b): A large number of organizations and groups are currently working on issues related to the protection of traditional knowledge, genetic resources and the relationship between TRIPS and the CBD (although some consider that the review of Article 27.3(b) should be distinct from discussions on TK and genetic resource protection). Expert dialogues between IPR experts and environmental groups should be encouraged to build cooperation and strategic alliances for purposes of coordination as well as formulating proposals in the multilateral setting.

The main components of protection, thus far, have been prior informed consent (PIC), regulation of access and benefit sharing (ABS), and the introduction of disclosure of origin (DO) requirements in national and international IP laws. The proposal that patent applicants be required to disclose the source of genetic material or traditional knowledge relating to the invention is reasonable. The arguments offered so far in opposition are weak. Even so, sound and credible research is needed on the economic benefits of having a disclosure of origin requirement and how countries can design a system to appropriate such benefits. Such a paper should also consider the effects of such a request in the multilateral setting of administrative treaty harmonization. While some developing countries may be keen to insist that the introduction of a DO provision be included in negotiations on patent law harmonization, they should ensure that such insistence is not taken as an endorsement of the fairness, legitimacy or appropriateness of the harmonization process undertaken at WIPO.

Issues have been raised by certain developing countries regarding Article 27.3(b) and the patenting of life forms, including genetic material. It might at least be clarified that such materials do not constitute "micro-organisms" and therefore are excludable. Interested developing countries might wish to state a position on the record, and let the matter be put before a panel at some stage. Developed country members arguing that the 1991 version of UPOV is the only effective sui generis system for plant varieties have a very weak case. Given the flexibility provided by Article 27.3(b), the most appropriate tactic may be to resist further elaboration of its language, leaving the matter to member discretion.

Traditional knowledge (TK) and folklore: It may be useful to pursue rules against "biopiracy" prior to attempting to define positive ownership rights in TK, which involves a far more complex set of issues. It seems doubtful that rights in traditional cultural expressions will have a material impact on development. While the protection of such expressions is important on cultural grounds, and will have an impact in certain micro-economic settings, it may be preferable to pursue such protection at WIPO or another UN affiliate, where cross-concessions are less likely to be demanded.

There is a need for capacity building in the least-developed and some developing countries to assist in the identification of TK and genetic resources, providing information on optional models for protection with identification of benefits and costs, to implement their chosen mode of protection. It might be helpful to undertake a development analysis including cultural aspects and perspectives of various models of protection recommended in existing literature.

There is a need for coordination and monitoring of efforts to promote TK protection and genetic resources for the purpose of ensuring coherence, consistency and for achieving better cooperation between countries. Developing countries with sui generis systems for TK and genetic resources should consider an international agreement that includes reciprocal recognition for the protection of TK and genetic resources.

Geographical indications (GIs): This is a very difficult area for the developing countries because of the difficulties inherent in predicting whether there will be net advantage to them if greater general levels of GI protection are afforded. The European Community asserts extensive rights in GIs that developing countries might be required to recognize if more extensive protections are provided. This could affect developing country producers and consumers. Certainly there are some important areas where developing countries consider their interests are being neglected. However competing claims among developing countries may need to be resolved before profitable advantage of strengthened GI protection can be taken. Before prioritizing the GI subject matter, it might be best to await further identification of specific developing country economic benefits.

Pandora's Box: The question inevitably arises whether opening TRIPS to any amendment is opening a "Pandora's box" in that the developed countries have demands of their own that will be used to counter-balance any gains that developing countries may seek to achieve. There is certainly a risk that if TRIPS is reopened, bilateral pressures will be applied toward achieving higher levels of protection.

For developing countries, the most successful negotiations in the TRIPS Council to date involve access to medicines. The first important lesson is that the developing countries shared not only a common interest, but also a compelling public interest. The second is that the developing countries led the pre-Doha negotiations.

Developing countries would benefit by attempting to calculate in advance the extent to which elements more likely to lead to success will be present. Developing countries may serve their interests better by prioritizing negotiations in areas where they can identify strong common interests, public support and NGO participation.

As for the evolved jurisprudence on TRIPS, the totality of Appellate Body (AB) decisions indicate that the AB is not isolated from its political/public context. In a case involving a

compelling public interest like access to medicines, the AB may be sympathetic to policy claims. But attempting to predict the responses of a quasi-judicial body in ambiguous cases may be a "fool's errand". It may thus be preferable to obtain agreement diplomatically, rather than resort to the judiciary's discretion.

Strategizing to deal effectively with the TRIPS review process

Historical experience suggests that solutions based on better or more sophisticated policy analysis of developing country interests will run into a wall of countervailing power. The formulation of common negotiating positions is inherently problematic. Developing countries do not share uniform characteristics in terms of level of overall economic development, technology infrastructure, or trained research and development personnel, and so forth. It might be worth trying initially to identify countries that share characteristics from the standpoint of IP, and perhaps consider policy options, initially at least, within subgroups of countries.

It would seem highly desirable that a relatively stable policy analysis group be established on a subgroup or issue level. This would address the problem confronting developing countries in Geneva of the rotating nature of diplomatic positions. At the point when a diplomat has spent a number of years on a particular subject matter and become adept with it, he/she may be transferred to a different negotiating arena. For the EC and US, rotation is less of a problem.

Another problem is that developing countries are in economic competition with each other, and each may perceive that its advantage would lie in accepting incentives from developed countries, rather than working on a common position.

Effectively strategizing for TRIPS Council review and negotiations may thus involve: (i) building toward a developing country common position through stages that first identify the interests of subgroups, then attempting to reconcile potentially competing interests (ii) creating a stable policy analysis group with a longer term memory, and (iii) overcoming the desire to maximize individual gains at the potential expense of a common objective.

But no matter how reasonable from a public welfare policy standpoint a developing country negotiating demand is, the demand may not be accepted unless the developed countries do not perceive their interests as adversely affected, or the developing countries amass a sufficient amount of leverage to overcome resistance. The "easiest" way to achieve negotiating objectives would be to identify positions that are aligned with developed country interests. This is plausible in some cases. A second but more costly way to achieve objectives is by offering reciprocal concessions. In some cases, the developing countries may decide that they would not be adversely affected. A third way is through public relations offensives, perhaps in common cause with NGOs.

Whether the developing countries could plausibly threaten a general market access boycott in a way comparable to a US Section 301 threat of market access restriction is debatable, but at least worth considering at some level. The central problem is one of establishing a disincentive for breaking ranks, and overcoming the problem of the availability of multiple potential sites for investment and exports. One alternative to a general developing–developed country market access restriction strategy would be to offer favourable treatment to one developed country or region over another based on favourable treatment in TRIPS negotiations. Developing and implementing a strategy of this nature would be highly complex.

The problem of insufficient data and evidence for effective policymaking

The problem of indeterminacy in the economic analysis of TRIPS-related issues arising, *inter alia*, from the lack of adequate objective data is likely to persist for the foreseeable future. However, while the tools of economic analysis may not provide concrete answers to questions facing TRIPS negotiators, these tools are useful in identifying factors that may play a role in determining whether the introduction of new and higher standards of IP protection will benefit or harm consumers and producers in developing countries. This problem might be addressed by framing the matter as a burden of proof issue. That is, demanding empirical proof of a positive effect of the introduction of higher levels of IP in the particular contexts faced by developing countries. But not too much emphasis should be placed on this. Developed country policy researchers are adept at manipulating information, including data and statistics, to suit their objectives.

2. Meeting the challenge of new treaty development harmonization

The prolonged negotiation of TRIPS might have suggested that international efforts in regulating IP would abate for some time. Instead, however, two significant treaties in the area of copyright were negotiated in 1996, not long after the obligatory implementation of TRIPS in developed countries. The WIPO Copyright Treaty (WCT) and the WIPO Performances and Phonograms Treaty (WPPT), deal with a new and very much unsettled frontier in copyright law, namely the application of copyright in the digital economy. In addition to these treaties, WIPO has recently commenced work on advancing a Substantive Patent Law Treaty to facilitate greater harmonization.

The momentum to harmonize IPRs is likely to continue well into the foreseeable future. First, because there are numerous *perceived* gains from harmonization. These include: (i) efficiency gains from the standardization of rules; (ii) the economies of scale uniformity offers such as the relative ease of administering/enforcing the rights from country to country; (iii) consistency in interpretation of terms; and (iv) the development of a common culture oriented towards similar levels of IP protection. Second, harmonization is considerably easier since countries now share a substantive common baseline established by TRIPS. Further, it should be noted that one of WIPO's fundamental activities *is* to initiate new negotiations in areas where it believes member countries will benefit from harmonized rules. Thus, as a regulatory matter, it is likely that harmonization will continue to play a central role in international IP development.

However, harmonization also has very definite costs for developing countries. Historically, countries joined the harmonization process only when their own levels of development and domestic priorities were in alignment with the objectives of the harmonizing treaty. As members increase and the subject matter becomes more complex due to changes in the market place (whether related to labour costs or technological developments) there is typically a corresponding increase in the scope of the treaty. As a result, additional rights are negotiated by members to deal with these new challenges and to give creators opportunities to exploit their works in new media and in new markets.

The integration of developing countries into the international IP system has historically taken place through the harmonization process. The evidence is clear that harmonization generally tends to tilt the balance of interests in favour of IP owners and, de facto, developed countries. Harmonization means that developing countries negotiate new standards and rules without necessarily having had the benefit of experience in that area. In general, harmonization exerts an upward force on national laws and policies. Correspondingly, the scope of limitations or exceptions tends to be narrower. The standardized approach of harmonization makes it difficult for developing countries to tailor domestic laws to address local problems regarding the structure of domestic IP laws. Where developing countries are concerned, harmonization has been a means of introducing higher standards of IP into the domestic economy. Empirical evidence does not support the assumption that such higher standards attract foreign direct investment and encourage technology transfer.

In addition to the increased difficulty of shaping national IP policy for development objectives, harmonization directly affects local inventors. Higher standards mean that domestic innovators and investors assume higher risks in the creative process than the level of development indicates should be the case. This observation is particularly important when one considers that in developed countries, young industries and new technologies generally enjoy lower IP standards in order to encourage innovators to engage in optimal levels of creativity. All this suggests that harmonization has facilitated greater gains for creators in developed countries at the expense of those in developing countries, with no significant corresponding increase in welfare for the developing world.

Given that harmonization will continue to dominate the international regulation of IPRs, several questions must be evaluated for development purposes. These include: How does harmonization aid or detract from development objectives? How can harmonization efforts be structured to ensure that development objectives are clearly incorporated into the main text of the agreement? What mechanisms exist in international law to allow developing countries to strategically implement the harmonized terms of a treaty? How does the digital environment alter the fundamental assumptions that inhere in the classical justifications for IP? How can/should developing countries engage in the harmonization process? At what stage in the process should they engage? What role does/can regional harmonization play in efforts to implement IPRs in a manner consistent with development objectives? What are some ways that developing countries might more fully benefit from and participate in the harmonization process?

To effectively think about these issues, it is helpful to distinguish between types of international IP treaties and how these categories affect development priorities and efforts. There are substantive treaties, which purport to harmonize substantive doctrines of IP protection. Examples of such treaties include the Berne Convention, the Paris Convention and to a lesser extent, TRIPS. The proposed Patent Law treaty also falls into this category. And

there are administrative treaties, which coordinate the practices and activities related to the administration of IPRs. Examples of these include the Madrid Agreement concerning the International Registration of Marks and the Patent Cooperation Treaty. They are treaties that establish taxonomies for IP to facilitate the organization of information regarding different kinds of IP.

In general, administrative treaties have the potential to facilitate development goals in a more direct manner than substantive treaties. For example, administrative treaties provide a rich source of information for developing countries: they can constitute avenues to participate in the generation of data, and may be a source to identify owners of IP. One immediate concern may be that such classification can be artificial and problematic for certain kinds of creative works in developing countries, e.g. traditional knowledge products which are not easily amenable to rigid categorization. There has been a tendency to treat these two types of treaty in a uniform fashion. However, each category functions quite differently and has different effects on development strategies.

Points of action

All participants agreed that the harmonization process conducted by WIPO is dangerous for developing countries and it may be important to stop it. All recognised that allowing the construction of a globalized system may mean the end of IP as a tool to promote development of national interests unless the terms of the harmonization agreement are consistent with development needs.

But how we can achieve a favourable outcome if in the political context the pressure to advance harmonization is very high and the development representatives at Geneva are not clearly opposing the process yet?

Bother direct and indirect ways were discussed by the Dialogue participants. Direct ways entail suggesting that developing countries not accept the WCT or the WPPT. In addition, work is needed to ensure that the current patent harmonization negotiation recognize developing countries' interests in such areas as disclosure of origin of genetic materials, inventive step standards, patentable subject matter, and industrial applicability. Negotiations for a patent enforcement treaty should only be entered into if there is a promise that the outcome will be fair to developing countries with respect to such issues as compulsory licensing and the research exemption.

There is strong support for a "just say no" campaign to harmonization. This can be carried out by a consortium of NGOs based on the dissemination of credible information about the adverse development consequences of harmonization along patterns that reflect the developed country intellectual property communities. Such a campaign will be important as increasing pressure to harmonize continues to be applied through bilateral and multilateral agreements. The campaign will have the benefit of facilitating the participation of civil society in the dialogue about IPR as a development tool, as well as generating pressure favourable to development interests.

With respect to indirect methods, ways should be developed to slow the harmonization process by proposing an end to the single package approach by allowing reservations to the respective treaties, including development concerns in the treaty objectives, proposing limitations and exemptions (such as an international fair use doctrine; reverse engineering exceptions, etc.), introducing special or differential treatment provisions, and linking any proposed initiatives for harmonization to capacity building.

A paper should be undertaken that considers the regionalization of administrative issues to explore if this would be a better option for developing countries building on existing regional institutions (e.g. Mercosur, Andean Community, etc.). Such a paper might discuss the essential elements of such a regional office/structure. Regionalization is also a dangerous mechanism but there are ways to provide some security.

An important undertaking is to identify how the major treaties under each category interact with development goals of member states generally, and in specific industries targeted for purposes of exploiting comparative advantage. Over 50 treaties affect international IP regulation. The time has come to begin a synthesis of these treaties to help developing countries identify development losses due to multiple memberships in overlapping, conflicting or superfluous agreements. Streamlining these treaties will also allow for more effective planning, allocation and use of scarce resources.

The structure of international IP treaties must be considered very strategically. Where, in a treaty, should development objectives be integrated? Questions about the operational and legal force of the TRIPS preamble, where most of the development objectives of TRIPS were placed, and the fact that at least several WTO dispute panels have had the opportunity, but have not referred to the development-oriented objectives of TRIPS, suggest that the placement of such clauses is indeed a matter that should be carefully revised for future negotiations. There is also the recent practice of negotiating Agreed Statements to complement the treaty. What is the legal effect of these Agreed Statements? Is the practice of making exceptions for developing countries still a viable model for a world economy with open markets? Should such welfare enhancing limitations be construed as "developing country exceptions" or more broadly as consumer exceptions?

There has been little use of developing country exceptions in existing treaties. Some developing countries have stronger IPRs than some developed countries. It is important to understand what social, economic and political/institutional pressures may be creating this situation and how to reverse it as a matter of law.

In other areas of international harmonization, there has been success with the use of "soft law" agreements. These are agreements that focus on normative principles that guide the behaviour of member states, as opposed to explicitly stated obligations. It will be increasingly important to explore such agreements in areas such as standard setting, exceptions to proprietary rights, technical cooperation and new subjects of treaty negotiations.

Papers should be commissioned to show and relate the consequences of a global system with impact in developing countries (brief, primarily for the use of diplomats/politicians who do not have time to read long academic papers). Another study is needed that considers the development concerns and options for developing countries in the copyright and trademark areas. Information and assessment should be provided to delegates of developing countries regionally and in Geneva through a centre of excellence or a consortium of experts to

counterbalance WIPO's "one size fits all" "our way alone" machinery. A further study should be conducted that considers the different kinds of exceptions and limitations in the international IP treaties and how developing countries can integrate them in their domestic laws.

Context, considerations and problem spotting

In addition to the need for a more precise identification of existing treaties and corresponding development goals, there remain some important points of focus for future consideration, reform and other action. These include: (i) regional harmonization and regional institutions; (ii) involvement in negotiations of the new treaties; (iii) integration of treaty language in national laws; (iv) the relationship between old treaties and new treaties; (v) the problem of "piggy-backing"; (vi) the use of information technology; and (vii) preemptive/advance identification of issues.

Although there are several regional IP institutions for developing countries, evidence for the pro-development role/benefit of these institutions is, at best, mixed. Regional institutions have historically served primarily as outposts for foreign IP owners seeking regional recognition/protection of their creative works.

The relatively successful experience of developing countries during negotiation of the WIPO digital treaties demonstrates the importance of getting involved in the early stages of negotiations. These negotiations were helped by the alliance built between developing countries and public interest groups from developed countries. As a result, the WIPO digital treaties were more balanced than might otherwise have been the case. Developing countries should be involved in the negotiations of new treaties, first with other developing countries to identify common grounds of interest and/or concern, and then in the broader negotiating forum. Early introduction of issues of concern for development objectives should be an integral part of the discussions, particularly in WIPO-led treaty initiatives.

Developing countries increasingly incorporate, verbatim, treaty language into domestic laws. This practice may have some adverse consequences for development purposes, particularly since treaty language often reflects a particular understanding of the treaty and this tends to be viewed in a strong protectionist light. It is important to evaluate which countries have done this, and to suggest ways of incorporating treaty norms into domestic laws in ways that are sensitive to development concerns.

The legal relationship between TRIPS and the WIPO treaties, or TRIPS and the CBD is complex and unsettled. Often, developing countries do not know how to comply with their obligations in a consistent and complementary fashion. There needs to be a thorough review of the legal relationship between new and old treaties and how this relationship may affect development concerns. Further, evidence of state practice has important ramifications for how a treaty-based obligation may be based against them. Developing countries need to understand what constitutes state practice. Regional state practices may also be developed to strengthen a pro-development construction of treaty obligations.

Increasingly, treaties are being subsumed/incorporated in new negotiations. For example, membership in the WTO is a de facto membership of the Berne Convention and the Paris Convention; membership in regional organizations like OAPI requires membership in the PCT, and so on. The result is that membership in a new treaty often entails joining several

other treaties. For developing countries that are already lagging behind in many respects, this means their economies must absorb *all at once* what developed countries absorbed over many years, sometimes over centuries.

One of the primary issues here is to understand how information technology can be used to enhance the knowledge base in developing countries, particularly in the administration of IPRs. Information technology can play a critical role in upgrading human resource capacity through distance education, expanding databases of information pertaining to IP in developed countries, protection and use of information technology in administering local IP offices, enhancing quality and quantity of interaction between developing countries and Geneva-based trade offices, and building institutional alliances with public sector organizations involved with IP issues in developed countries.

Developing countries are typically caught unawared or unprepared when issues for new treaty negotiations are submitted. As a strategic matter, it is important for developing countries to think ahead about issues that developed country priorities/interests may later suggest as the appropriate subject of multilateral negotiations. To this end, it will be helpful to identify what domestic structures are on the ground in key developing countries that might be used as focal points for identifying possible issues that may be introduced in a multilateral context. An immediate starting point is the new Patent Law Treaty.

In conclusion, not every development concern can be addressed for each IP treaty that exists. An integral part of development strategy in the immediate future is to identify global-specific, region-specific and some country-specific development needs. Strategies should concentrate heavily on areas where these three converge. A working list of these areas of convergence and relevant sectors implicated should be developed for preparations to negotiate common positions between developing countries. There should also be some consideration given to creating alliances with some developed countries in areas where those countries mat share similar concerns. This was a strategy that worked very well during the TRIPS negotiations as well as during the WCT/WPPT negotiations.

3. Promoting effective national policy formulation

Developing countries face significant challenges for formulating IP policy compatible with their production structure, cultural values and development needs, and for translating such policy into laws and regulations consistently with international obligations. The purpose of IP policy is often described, in a simplistic way, as a means to reward inventors and creators for their contributions to the state of the art. IP, however, has been designed to benefit society by providing incentives to those that introduce new inventions or creations. Its purpose is not the exclusive benefit or advantage of individuals or corporations, but of the public or community at large through the activities of inventors and creators. IP is an instrument for achieving specific objectives, which have historically evolved and varied across countries. The available evidence clearly suggests that the role of IP varies significantly according to productive structures and levels of development.

Ideally, an IP policy should be designed in any particular country having in view its broad impact on society, both in the short and long term. There is no universal model of IP policy that suits all countries; different industrial structures, modes of agricultural production, availability of natural and human resources, and development strategies, call for different

types and extent of IP protection. The objectives that an IP policy may aim to include, *inter alia*: (i) promoting the disclosure and exploitation of innovations; (ii) fostering R&D activities; (iii) promoting foreign direct investment and the importation of foreign technology; (iv) inducing local manufacturing (e.g. through compulsory licensing in cases of non-working); (v) providing incentives for the transfer and commercial exploitation of knowledge (e.g. in the case of university R&D results and traditional knowledge); and (vi) protecting investments made (e.g. databases and protection of undisclosed data submitted for approval of agrochemical and pharmaceutical products). What objectives are pursued and how possible tensions among them are to be dealt with, should be a matter of national policy in the context of broader development strategies.

Designing IP policy in developing countries

A major challenge for developing countries is to effectively integrate development policies into IP policies. A development assessment of different components and levels of IP protection needs to be undertaken for that purpose. This is not a simple task since, on the one hand, there are several components of IP which play different roles. Moreover, IP differently affects firms and consumers across sectors and even within a given sector. Therefore, any generalization about the impact of IP is of very little practical value.

Assessing the development impact of IP requires a deep understanding of IP institutions and appropriate knowledge about strengths and weaknesses in different sectors. It also calls for a forward looking approach and the capacity to foresee possible scenarios. There are, in fact, no easy-to-apply methodologies for this purpose. This task is particularly difficult in developing countries.

A vast array of IP agreements has been negotiated without any development assessment, and ties the hands of developing countries who are parties to them. Due to the application of the Most-Favored-Nation clause, in addition, those countries who are WTO Members are bound to grant the same level of IP protection to other WTO Members who are not parties to said agreements. Thus, TRIPS plus standards established under agreements with the USA also benefit right holders in the EC, while US right holders benefit from the standards negotiated by the EC.

Assessing needs and priorities

Assessing the development impact of IP is not a simple task. Relevant data need to be collected and analyzed at the national level. An IP development assessment should examine the possible impacts of IP on local production and the development and diffusion of technologies in different sectors. The implications of IP will substantially depend on what kind of IP rights are involved and what the nature of the covered activities is. It is well documented that R&D intensity significantly varies across sectors. In a country where high-intensity R&D sectors are significant, an IP policy may provide powerful incentives to undertake costly R&D. But in countries where the dominant sectors are agriculture, textiles and other low-intensity R&D industries, and where minor or incremental innovations prevail, IP may have little or no effect on innovation while reducing the diffusion and increasing the cost of foreign products and technologies.

Another important aspect is firms' size. Small and medium enterprises (SMEs), particularly in developing countries, may benefit little from the IP system. Their innovations often concentrate

on products/processes with a short life cycle, while obtaining patent protection often takes a long time. In addition, obtaining a patent and maintaining it in force, are generally quite costly, unaffordable to most SMEs. Most importantly, defending a patent against validity challenges by third parties or enforcing it against infringers are extremely expensive and risky operations.

A comprehensive development assessment cannot be limited to the impact on production and innovation. It also needs to consider other crucial dimensions, such as public health, nutrition and food security. There exists a tension between high levels of IP protection and public interest in those fields. While many developing countries are likely to benefit little, if at all, from the dynamic efficiency effects of IP protection, they will surely suffer losses in static efficiency. Therefore, a sound IP policy should evaluate and try to minimize the short term social costs of introducing or increasing IP protection.

Drafting IP laws

Several difficulties also arise in relation to the *drafting* of IP legislation in developing countries. Government officials in the executive branch and lawmakers generally lack expertise in IP law. Such expertise can only be domestically provided, in some cases, by lawyers who have been trained in foreign universities and represent or advise foreign IP right holders. There are often conflicts of interests that are not apparent to policy makers. There is anecdotal evidence about policy makers being grossly misled in the process of drafting IP laws.

IP is a cross cutting issue involving several government departments. Quite often, however, departments with a substantial interest in the matter do not participate in decision making. This has typically been the case of health authorities, which were absent in the Uruguay Round negotiations. Moreover, due to limited domestic capacity, developing countries are strongly dependent on technical assistance, and rely on WIPO and WTO for expert advice and commentary to confirm the consistency of draft legislation with international obligations.

WIPO has had a prominent role in providing technical assistance to developing countries for drafting IP laws. WIPO's advice has emphasized the benefits and largely ignored the costs of IP protection, and has generally failed to present the range of options that developing countries may have to pursue their own interests, including the flexibilities allowed by TRIPS.

Developing countries have received significant support to "modernize" their IP administration systems, including activities by police and custom authorities. These actions directly benefit IP applicants. They generally involve training in industrialized countries, and transmit the concepts and values prevailing in those countries. In some cases, advice has also been provided by industrialized countries' international cooperation agencies for drafting IP laws. It may be necessary or convenient to reconsider WIPO's Mandate "to promote intellectual property". Alternatively, its mandate could be interpreted to include the notion of development. WIPO's activities in this regard could be made more sensitive to the needs of developing countries by such measures as the following:

- Change the composition of the Policy Advisory Commission to include a more representative constituency.
- Improve transparency regarding the technical assistance provided by WIPO.
- Ensure that technical assistance programmes are conducted in ways that incorporate the interests of all WIPO members. This is a responsibility not just for WIPO but also

for government agencies receiving the assistance. Specifically, officials dealing with health, trade, environment, education, agriculture, amongst others, need to be brought into these discussions and activities.

- Establish an Independent Commission (outside of WIPO) to evaluate/monitor WIPO's technical assistance programmes.
- Seek alternative and more independent sources of technical assistance. This competition could also help improve the quality of technical assistance provided by WIPO.
- In order to avoid conflicts of interest, the activities of technical assistance and funding should be separated from the norm-setting and policy making processes.
- Increase the participation of developing country friendly and public interest NGO's at WIPO to counter-balance the influence of organizations that represent the interests of industry.
- Establish rules and procedures for the participation of NGO observers in WIPO in order to preserve its inter-governmental character.
- Improve the governance of the WIPO Secretariat.
- Empower developing country participation in WIPO.

Can constraints for designing IP policies be overcome?

The design of IP policy and drafting of IP legislation in developing countries has largely failed to consider their productive structures, cultural values, and development needs. Such legislation has been generally based on the models applied in industrialized countries, with little or no adaptation to the circumstances and development needs of developing countries. Moreover, developing countries have been coerced to adopt standards of IP protection in the context of bilateral and regional agreements that go even beyond TRIPS.

Though industrialized countries did enjoy freedom to design their IP regimes as they developed, the room left to developing countries has been significantly limited, though not totally suppressed, by the TRIPS and other bilateral and regional agreements. IP policy can be modeled, to a certain extent, to respond to different social and economic conditions prevailing in developing countries. But room to do so is limited and is continuously narrowing down as new agreements on IP are negotiated.

The constraints that developing countries face to formulate pro-development IP policies may be addressed by a number of actions. They may, for example, include actions to increase the "freedom to operate", as well as to improve policy making and drafting of legislation. Such actions include: (i) avoiding new IP commitments under bilateral and regional agreements; (ii) carefully considering the implications of accession to IP existing treaties and of other current negotiations; (iii) promoting the revision of bilateral and regional agreements that establish TRIPS-plus standards; (iv) undertaking the review of national legislation from a development perspective in the light of the flexibilities allowed by TRIPS; and (v) reviewing national legislation in the light of the Declaration on TRIPS and Public Health.

Freedom to operate depends largely on successful resistance to aggressive unilateralism on the part of the United States and Europe. This would benefit from an assessment of the economic costs of accepting TRIPS plus agreements and concessions in negotiations, and in making representations of these costs at the WTO. Independent academic centres should be

engaged where necessary in providing such assessments. Public interest NGOs could try to get involved in dialogues with trade policy makers and negotiators in regional and bilateral agreements, and submit counter representations to the USTR on Special 301 cases.

Improving policy making and drafting

A national IP policy that integrates development objectives should not only be *defensive*, that is, aimed at minimizing the costs of introducing IP protection in different areas. It should also actively explore whether new modalities of IP protection may be established to respond to development needs. For instance, the possible impact of a second-tier form of protection for non-patentable innovations needs a deeper consideration. The issue of TK protection also requires careful analysis. However, such analysis should not only include the possible benefits for right-holders, but the possible implications of protection for public health, food security and other public interests.

The implications of IP are too important to leave policy and drafting in the hands of IP lawyers, foreign consultants or officials in international organizations. Actions to be taken to improve policy-making and drafting may include: (i) establishing inter-agency governmental committees to address IP policy issues, including bilateral, regional and international negotiations, with the participation of the private sector *and* civil society; (ii) undertaking interdisciplinary studies on the implications of IP on different sectors and activities; (iii) training government, academy and NGOs in IP policy-making and drafting; (iv) redirecting technical assistance on IP on policy formulation rather than on administration; and (v) monitoring technical assistance activities of international organizations, such as WIPO, so as to ensure unbiased advice that presents all options available to developing countries.

4. Integrating IPR policies in development strategies

The Commission on Intellectual Property Rights report identified two IPR issues of great importance to developing countries that are on, or very close to, the current international agenda. The first of these is the move to harmonize patent law. This negotiation is strongly supported by the EC and the US as a way to avoid duplication of the costs of patent searching and granting. A harmonized treaty would probably leave significantly less flexibility than does TRIPS. This is a problem if the harmonized structure ends up, as is likely, as a compromise between the US and the European systems. The question is, what is the right strategy for the developing nations?

The second is a negotiation over appropriate arrangements for the digital environment. Here, the driving force is the concern of the entertainment industries that digital material can be readily copied, thus making impossible an adequate return on the investment in content production – but the principles involved will almost certainly affect computer programs and perhaps scientific information as well. These concerns have led to a desire to provide "technological protection," such as encryption, for such material, and to seek international treaties and statutes to prohibit circumvention of such protection. This may interfere with fair use rights and thus not be in the interests of the developing world. There will certainly be an effort to extend such anti-circumvention legislation and treaties to the entire world, and the developing nations will need to consider how to respond.

But it may be possible for the developing nations to think more boldly. The new technology can permit a fundamentally new approach to the economics of information. If information can be reproduced at zero cost, a system of incentives based on charging for the making of copies seems unlikely to be successful in the long run. Is there a way for developing nations to take the lead in designing ways to take advantage of this ease of dissemination while also maintaining incentives for development and creation of digital material?

Making the current IPR system work as well as possible

A second set of tasks is to find ways to make the current IPR system work as well as possible for developing nations. This is particularly an issue for the patent system, for it is an especially expensive system, but also an issue for other areas. And there is the obvious question of who should pay for the strengthening of developing nation IPR systems. In some cases, the costs may be appropriately borne by the World Bank or national donors. In other cases, they may not properly be high-priority development areas; the funding should rather come from the international IP community, such as through fees by patent applicants or support from WIPO.

The obvious first example is the creation of model laws and grant of technical assistance in drafting national laws. The laws most adapted to developing nations are not the same as those currently used by developed nations. Additional studies may be useful, as may a series of working level meetings among IP offices and practitioners from the developing world. The development of workable TRIPS-compatible compulsory license procedures is particularly important. And it may be desirable to strengthen regional IP systems, in order to save costs and create larger markets that may be more likely to attract research investment.

In the face of strong political pressure and building on substantial technical assistance that is generally based on a developed world model, most developing nations have adopted the basic IP legislation needed to protect global IP rights holders. They have been much slower, however, in adopting the legislation that might help them in meeting their own specific needs. The obvious examples are the legislation needed to help transfer public sector technology into the private sector. For some nations, there may be a need for legal arrangements to manage genetic resources or traditional knowledge. There may also be a need to elaborate price control procedures. Another possible need is to develop antitrust principles that can complement IP legislation.

None of these areas of law is useful without human resources, nor can developing nation concerns be effectively represented in specific transactions or in general national and international policy making without such resources. This requires people who understand the formalities of the law *and* the way to operate effectively in the international arena on behalf of developing nation clients.

Another need is to enable developing country scientists to use the IP system in the developed world. The international legal system provides for reciprocity. But since the developing world scientist usually lacks the funds to have the application prepared, this is often meaningless in practice.

Beyond the current IPR agenda – toward real technology policy

All the points so far are essentially about making IP systems as useful as possible. But the crucial issue is not IP but technology for development. IP systems can play only a slight role in actually encouraging the creation of that technology. It seems essential to move the debate beyond a reactive one focusing on IP to a proactive one focusing on technology. We know that technology was extremely important to the development of the US and probably of other developed nations as well. We know much less about how to shape the technological input to development in developing nations today. The needs differ from case to case, so the appropriate strategies must be thought out nation-by-nation, and sector-by-sector, if not firm-by-firm. But it is especially important to think further about the needs of the technologically more advanced developing nations. For these more advanced nations, unlike the poorest nations, IP systems may encourage domestic innovations, and for the larger ones, or those in appropriate regional groupings, such systems may even encourage outside innovation focused on the special needs of those countries. But these nations face a new problem beyond poverty of how to enable their firms to participate in the global business community. In today's world, the leading firms in that community hold strong IP positions that may be used to defend their existing oligopolies against new entrants. Certainly, firms within these nations can start as licensees or strategic allies of global majors, but can they become more independent industrial competitors? The difficulty of entering markets dominated by multinational oligopolies is thus compounded by the international IP system. What can reasonably be done in response? Are there international antitrust approaches that might be helpful? National antitrust arrangements in the developing world alone may well be inadequate, for a license created under national IP-antitrust principles does not necessarily permit export of products to major markets with different antitrust principles.

Programmes are emerging to provide global public goods oriented toward the developing world, such as medical and agricultural research. At this point, these are fundamentally public programmes, although there are many efforts to integrate the public sector with the private sector. The fundamental problem in these areas is persuading the taxpayers in wealthy nations that the programmes are worth funding. But there are also IP problems being faced by almost all these institutions, because of the variety of patents held by both universities and the private sector on fundamental research technologies. Might there be value in more legislative solutions, such as creating an international analogue of the public use provision of US patent law, which allows use of patents by or for the government without license?

For the developing nations a critical component is the creation of a scientific and technological human resource infrastructure. There are already many bilateral and regional agreements to encourage the cooperative development of new technologies that, in general, provide a framework within which specific public sector collaborations can be negotiated. Why not expand this network into a global process through an international treaty designed to strengthen commitment to science and technology, to education in it, and to its sharing, particularly with developing nations?

Many questions must be explored in designing such a treaty. The focus might be more on science and education or it might be more on technology and entrepreneurial activity. The former would concentrate more on human resources and basic research; the latter would recognize the importance of the private sector in much technology flow, but might raise greater concerns about threats to trade secrets and industrial competitiveness.

Moreover, the focus might be more on encouraging the flow of technology generally or more on specifically benefiting developing nations. The exchange of scientific and technological ideas among nations accelerates the progress of science and technology and makes it possible for the benefits of free trade to be expanded. Thus, a global treaty is in the interests of the developed nations too. But a global treaty would particularly benefit developing nations, by providing the prerequisites for real technology transfer to these nations.

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