FORMULATING EFFECTIVE PRO-DEVELOPMENT NATIONAL INTELLECTUAL PROPERTY POLICIES

Developing countries face significant challenges for formulating an intellectual property (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. This paper reviews those challenges and makes preliminary suggestions about ways in which developing countries can deal with human, institutional and financial constraints to ensure the coherence, sustainability and effectiveness of their policies.

IP as a policy instrument

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. CITA

IP is an *instrument* for achieving specific objectives, which have historically evolved and varied across countries. How the rationale for IP protection has changed over time in developed countries is well documented, particularly in the area of patents[1]. The available evidence clearly suggests that the role of IP varies significantly accordingly with productive structures and levels of development. As the World Bank has noted, in the area of IP "one size does not fit all"[2].

In the United States, for instance, weak copyright protection during the nineteen century was deliberately aimed at promoting the development of the domestic printing industry. One century later, the promotion of domestic industry is still present in US law. Under section 204 of the Bay-Dole Act a preference for United States industry for the exploitation of publicly funded inventions is granted. Similarly, many European countries only strengthened patent protection (particularly for pharmaceuticals) as they industries developed, or until they were forced (like in the case of Spain and Portugal) by other partners in trade agreements.

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*,

-Promoting the disclosure and exploitation of innovations
-Fostering R&D activities
-Promoting foreign direct investment and the importation of foreign technology
-Inducing local manufacturing (e.g. through compulsory licensing in cases of non-working)
-Providing incentives for the transfer and commercial exploitation of knowledge (e.g. in the case of university R&D results and traditional knowledge)

[1] See, e.g. CIPR, Integrating intellectual property rights and development policy , London, 2002.
[2] See World Bank (2001), Global Economic Prospects and the Developing Countries 2002, Washington, D.C.

-Protecting investments made (e.g. data bases 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 (in the area of industrial development, public health, food security, education, etc.) 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 (patents, trademarks, copyright, designs, etc) which play different roles. Therefore, any generalization about the impact of IP is of very little practical value. Thus, patents impose significant losses in static efficiency by diminishing access to medicines, seeds, etc., while patents' dynamic efficiency effects may be insignificant or inexistent in poor countries. At the same time, they may benefit from the use of trademarks to identify and promote quality products. Some countries also have considerable expectations about the use of some components of IP, such as geographical indications,

On the other hand, IP differently affects firms and consumers across sectors and even within a given sector. For instance, in India some domestic pharmaceutical firms, which have reached significant productive and technological capacity, are reported to be potential beneficiaries of the introduction of pharmaceutical patents, while smaller pharmaceutical firms may face substantial problems to survive in the new legal context. Similarly, copyright protection may favor authors and artists (e.g. musicians in the Caribbean) while adversely affecting access to educational materials, especially by the poor.

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 for various reasons.

First, developing countries have little analytical capacity to undertake a sound cost-benefit assessment of the impact of IP protection in different productive sectors and on consumers. Unlike the situation in developed countries, firms and consumers in general lack in developing countries the organization to articulate their interests in the area of IP (an important exception may be the domestic pharmaceutical industry where it exists). Moreover, the design of IP policy (including the participation in international negotiations on the matter) is often left in the hands of trade departments and industrial property offices, without or with limited participation of representatives from public health, agriculture and other areas of government.

Second, developing countries have been strongly lobbied or subject to political pressures to adopt IP legislation that responds to the interests of industries from industrialized countries. Some of such industries -as illustrated by pharmaceuticals and computer software- have a significant capacity to lobby developing countries' as well as their own governments. Industrialized countries' governments have championed the cause of their industries in bilateral, regional and multilateral agreements involving IP. In contrast, developing countries' governments often lack sufficient knowledge on and interaction with their domestic industries.

Third, in many instances the adoption of high IP standards of protection by developing countries has been the price paid in return for expected trade benefits in other areas (such as agriculture and textiles). This was notably the case in the Uruguay Round, though it is questionable whether such benefits have actually materialized. There are also indications that FTAA negotiations may follow a similar pattern.

Fourth, even if developing countries had the expertise to design their IP policy and draft their own IP laws accordingly, many of them face the constraints imposed by over-protectionist bilateral or regional treaties that include obligations on IP. Examples of agreements which impose "TRIPS plus" obligations are the US bilateral agreements with Cambodia, Laos and Jordan, the cooperation agreements established between the EC and Bangladesh, Nepal, Laos, Cambodia and Yemen, and the "Cotonou Agreement" -which replaced the Lomé Convention- between the 77 countries of the African, Caribbean, and Pacific region and the European Community. Another example is provided by the "Bangui Agreement" entered into between the sixteen French speaking African countries (eight of which are LDCs) that make up the African Intellectual Property Organization (OAPI), under which the contracting parties declined their right to use the flexibilities that the TRIPS Agreement recognizes in relation, for instance, to parallel imports, compulsory licenses, farmers' right to save seeds, and the protection of data submitted for the registration of pharmaceuticals and agrochemical products.

This vast array of agreements has been negotiated without any development assessment, and ties the hands of developing countries who are parties to them to design IP policies more suitable to their own levels of development. 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 USA also benefit right holders in the EU, while US right holders benefit from the standards negotiated by the EU.

Assessing needs and priorities

As mentioned, assessing the development impact of IP is not a simple task. Relevant data need to be collected and analyzed at the national level. Box 1 presents *some* of the issues to be addressed.

Box 1. MAPPING NATIONAL INTERESTS

1.1 Industrial structure (contribution to GNP and trade of different sectors, productivity indicators, firms' size, etc.)

1.2 National innovation system (scientific capacity; industry-academy linkages; main areas of research; technological performance of various sectors, patterns of innovation, etc)

1.3 Current and potential role of FDI (resource-oriented; domestic/export market oriented) and technology licensing

1.4 IP-sensitivity of foreign trade

1.5 Public health situation (access to medicines, coverage of social security systems, epidemics, etc)

1.6 Supply of seeds (formal and informal systems), systems of exchange and distribution, farmers' practices

Supply of and access to educational materials, software and other copyrightable works

Traditional knowledge, extent of its use and commercialization

Importance of regional production

An IP development assessment should examine the possible impact of IP on local production and the development and diffusion of technologies in different sectors. For instance, the analysis of item 1.1 may lead to important conclusions for framing an IP policy. As noted, the relevance of different kinds of IP significantly varies according to the types of industries involved, and the rate and nature of their innovative activities (see Table 1).

Table 1. SUBJECT MATTER AND MAIN FIELDS OF APPLICATION OF INTELLECTUAL PROPERTY RIGHTS.

Types of intellectual property right	Subject matter	Main fields
Patents	New, non-obvious, indigenous applicable inventions	Chemicals, drugs, plastics, engines, turbines, electronics, industrial, control and scientific equipment
Trademarks	Signs or symbols to identify goods and services	All industries
Copyright	Original Works of authorship	Printing, entertainment (audio, video motion pictures) software, broadcasting
Integrated Circuits	Original layout designs	Microelectronics industry
Breeder's rights	New, stable, homogeneous, distinguishable varieties	Agriculture and food industry
Trade Secrets	Secret business information	All industries
Industrial Designs	Ornamental designs	Clothing, automobiles, electronics, etc.
Geographical Indications	Geographical origin of goods and services	Wines, spirits, cheese and other food products
Utility Models	Functional models/designs	Mechanical industry

As this table suggests, 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 the R&D intensity significantly varies across sectors[3]. In a country where high-intensity R&D sectors (e.g. aerospace, computers, pharmaceuticals) 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 -derived from the routine exploitation of existing technologies- 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, as illustrated by the case of patents. Their innovations often concentrate in product/process with a short life cycle, while obtaining patent protection often takes a long time (from 2 to 6 years depending on the country). 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

[3] See, e.g., OECD (1992), Technology and the economy. The key relationships, Paris.

infringers are extremely expensive, and risky, operations. This explain why the patent system has been found to be "at best an irrelevancy" for SMEs even in industrialized countries[4].

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. The normal effect of IP is to allow the title holder to charge prices above marginal cost, thus reducing the diffusion of the protected innovations and reducing access thereto. 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[5].

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. WHO has actively promoted in the last three years awareness on IP issues among such authorities, but their actual influence in decision making is still limited[6].

Due to its limited domestic capacity, developing countries are strongly dependent on technical assistance, and rely for expert advice and commentary on new draft legislation on WIPO and WTO, especially to confirm consistency of draft legislation with international obligations.

WIPO has had a prominent role in providing technical assistance to developing countries for drafting IP laws. This is reflected in WIPO Secretariat' reports as well as in the extensive use by developing countries of the "model laws" developed by WIPO. 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

[4] See Coleman, R. and Fishlock, D. (2002), Background and overview of the Intellectual Property Initiative, available at www.info.sm.umsit.ac.uk

[5] In one country, for instance, health authorities claimed that a "Bolar exception" has been introduced into their patent law. However, a more careful analysis of the adopted law indicated that registration procedures before expiration of the patent had been exempted from *criminal* sanctions, but not from the ordinary civil or commercial legal actions that the patent holder could exercise.

[6] As noted in the CIPR Report, there is evidence indicating that "some countries have established mechanisms to improve the co-ordination of policy making and advice, with the main participants being the key ministries most involved i.e. health, justice, science, environment, agriculture, education or culture (for copyright and related rights). However, these mechanisms are often only embryonic and their degree of effectiveness is yet to become apparent – particularly in respect of integration of IP issues with other areas of economic and development policy. In many cases, this may reflect the fact that such co-ordinating bodies are not able to draw readily on a supply of the necessary technical advice and expertise, but it also reflects divergent interests within government (CIPR, op. cit. p. 139).

developing countries may have to pursue their own interests, including the flexibilities allowed by the TRIPS Agreement[7].

Developing countries have received significant support from WIPO, EPO and other agencies 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. For instance, USAID has had a relevant role in shaping IP legislation (not surprisingly encompassing high levels of IP protection) in some Arab and Central American countries. A law adopted in Guatemala provided for a fifteen years exclusive protection of data submitted for the registration of pharmaceutical products, three times the period available in the USA.

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 structure, 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 the TRIPS Agreement.

Though (as history shows) 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.

There are outstanding examples of the design of IP policy that reflects national conditions and needs, developed with the active participation of different branches of government and civil society. The adoption of the Indian Plant Varieties Protection (2001) provides one of such examples. This law established a regime to ensure equitable sharing of benefits arising from the use of biological resources and associated knowledge. It incorporated a clause (article 39 (1) (iv)) which allows the farmers to save, use, sow, re-sow, exchange, share or sell his farm produce including seed of a variety protected under the Act, provided that the farmer is not be entitled to sell branded seed of a variety protected under the Act.

Hence, IP policy can be modeled, to a certain extent, to respond to different social and economic conditions prevailing in developing countries. There is some room to do so, but it has already been limited and it is continuously narrowing down as new bilateral and regional 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, which are only presented here for further discussion. They may include actions to increase the "freedom to operate", as well as to improve policy making and drafting of legislation

Increasing the freedom to operate

(a) Avoiding new IP commitments under bilateral and regional agreements (including as trade-off for concessions in other trade areas);

[7] See, e.g. the recently published WIPO's model laws, available at www.wipo.int.

(b) Carefully considering the implications of accession to IP existing treaties and of other current negotiations[8];

(c)Promoting the revision of bilateral and regional agreements that establish TRIPS-plus standards;
(d) Undertaking the review of national legislation from a development perspective, in the light of the flexibilities allowed by the TRIPS Agreement;

(e) Reviewing national legislation in the light of the Doha Declaration on TRIPS and Public Health.

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 the protection of traditional knowledge 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 so as 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:

(a) Establishment of 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;

(b) Undertaking interdisciplinary studies on the implications of IP on different sectors (e.g., pharmaceuticals, software) and activities (e.g. education);

(c) Training government, academy and NGOs' professionals (including but not limited to lawyers) in IP policy-making and drafting;

(d) Redirecting technical assistance on IP on policy formulation rather on Ip administration

(e) Monitoring technical assistance activities of international organizations, such as WIPO, so as to ensure unbiased advise that presents all options available to developing countries.

[8] In particular, the proposed harmonization of substantive patent law under the auspices of WIPO may severely limit the room to design IP policies in the future.