

Since the early 1990s, Intellectual Property (IP) policy has become one of the most economically and politically contentious issues in the international arena, whether in discussions on public health, food security, education, trade, industrial policy, traditional knowledge, biodiversity, biotechnology, the Internet, or the entertainment and media industries. For many policy makers working in these specific areas, IP policy is an entirely new subject. Indeed, historically, it was the exclusive domain of legal specialists and the owners and producers of intellectual property. In the same vein, few developing countries have had much direct experience with IP policy. And for those that have introduced some IP policies, the relevant laws and agencies have been marginal to discussions on national development.

Over the past decade, IP has joined fiscal, monetary, trade and industrial policies, and overseas development assistance, as a key area in which developing countries have come under pressure to identify their interests and define public policies. In the context of a global economy increasingly propelled by knowledge-based industries, the protection of ideas and innovations has become a priority in the competitive strategy of powerful economic industries and countries. Ownership and distribution of these assets has become a high-stakes issue in international negotiations.

This paper discusses the relevance to developing countries of the various debates on IP, with a focus on the implications of IP policy for economic development, poverty alleviation and sustainable human development. The policy paper is not prescriptive, nor does it pretend to be exhaustive. Rather, the goal is to support informed, constructive debate among policy makers and relevant stakeholders by clarifying key policy issues, reviewing the major policy-making processes, drawing attention to evidence, or the lack thereof, on controversial issues, and providing guidance on relevant information sources.

As one of the main outputs of the joint UNCTAD-ICTSD Project on Intellectual Property Rights and Sustainable Development, this paper is complemented by a series of separate studies analysing specific issues of particular relevance to developing countries such as compulsory licensing, geographical indications, traditional knowledge, transfer of technology and indicators of the relative importance of intellectual property rights (IPRs) in developing countries. The joint UNCTAD-ICTSD Project has also produced a *Resource Book on TRIPS and Development* to serve as an authoritative, practical guide to the TRIPS Agreement. For each

provision of the TRIPS Agreement, the Resource Book analyses the negotiating history, possible interpretations, existing jurisprudence, and the relationship with other international instruments, as well as the potential social and economic implications.

This policy paper contains three parts. Part One provides a general introduction to the underlying assumptions and rationale underpinning IP policies. It reviews the historical evolution of IP rules, noting the varying views of governments and industry regarding the appropriateness of the objectives, nature and role of IP policy to their specific economic and political contexts. The key agreements and international institutions, which together comprise the global intellectual property regulatory system, are also presented here.

Part Two focuses on three cross-cutting issues and potential opportunities offered: creativity and innovation, access to and use of new technologies, and technology transfer. Debates about the relationship between IP policies and each of these cross-cutting topics are a constant feature not only of the general IP policy landscape, but also of debates on a range of specific areas of concern for developing countries. Part Three explores challenges arising from each of these specific areas of concern for developing countries with regard to IP policy in the fields of: health; food and agriculture; traditional knowledge, folklore and cultural property; and access to knowledge and scientific information.

This Overview presents the highlights of the discussions contained in each of the sections of this paper. It begins with a brief look at why and how intellectual property has emerged as a key development policy issue.

What is intellectual property policy?

Intellectual property policy is concerned with the design, implementation and enforcement of a system of legal devices commonly referred to as "intellectual property rights". These legal devices take a number of different forms, including patents, copyright and related rights, industrial designs, trademarks, trade secrets, plant breeders' rights, geographical indications, and rights to layout-designs of integrated circuits. Of these, patents, copyright and trademarks tend to attract the greatest attention.

A survey of the goals stated in existing national and international laws reveals a generally shared understanding that, at the broadest level, intellectual property policies exist to contribute to the enrichment of society by helping to promote:

- (a) the widest possible availability of new and useful goods, services and technical information that derive from inventive activity; and
- (b) the highest possible level of economic activity based on the production, circulation and further development of such goods, services and information.

Beyond this broad view, there is considerable debate as to what kinds of IP policies will best help advance these goals. The specific objectives and provisions of IP policy have varied greatly as governments have worked to balance various goals.

Most IP laws and devices share common conceptual foundations and assumptions, namely that the provision of legal rights to those who invest their resources (e.g. creative energy and financial capital) in innovation will spur further knowledge development, creativity and the availability of new products for society. IP rights (IPRs) usually provide investors with a monopoly privilege, for a specified length of time, to exploit their innovations and turn them into commercial advantages. After a certain time, these legal rights terminate, whereupon these now unprotected inventions and works become part of the public domain and can be freely used by others.

Depending on their existing priorities, governments place differing emphases on the goals of rewarding and promoting innovation, protecting industrial investment and international competitive advantage, rewarding importers of foreign technologies, promoting diffusion of new knowledge, creating incentives for future innovation, and affordability of technologies. In countries where little inventive activity takes place, encouraging easier flow of technical information may generate more technological capacity building than providing stronger exclusive rights.

Similarly, stakeholders present a range of different goals and interests that they believe should be served by IP policies. For holders of intellectual property rights, for example, the primary purpose of IP may be to recoup investment costs, but also to develop and maintain market power and dominance. One of the main challenges for IP policy makers is to balance the interests of creators and investors on the one hand, and other potential users of IP, including researchers and consumers, on the other. Because of the economic stakes involved, the design of IP systems is not just a matter of economic calculation, it is also an inherently political exercise.

Why has IP policy become such a topical development issue?

IP policies are not new. They have existed in developed countries, and in many developing countries, for decades and in some instances centuries. Yet, one of the most distinctive features of IP policy has been its relative insulation from the kind of public debate common in most areas of public policy. One reason for this is the arcane and complex legal nature of IP policies.

Clearly, much has changed in recent years. IP policy has acquired a global dimension and as such it has become an issue that is hard to ignore for several reasons.

First of all, significant changes in the international regulatory system for IPRs have in themselves stimulated greater attention to IP policy. Perhaps the most significant change is the entry into force of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (see discussion below).

Second, the pressure on developing countries to implement national TRIPS-compliant IPR policies has generated, sometimes for the first time, national debates in those countries about the appropriateness of IP protection.

Third, the IP policy arena is now one of the most dynamic areas of international law. Beyond the TRIPS Agreement, significant new agreements are being forged at the international, regional and bilateral levels that build on and strengthen the minimum TRIPS standards. There is a common tendency in these agreements for protectable subject matter to be expanded, for new rights to be created, and for the basic features of intellectual property rights to be standardized. Consequently, national IPR regimes throughout the world are becoming increasingly pressured to harmonize their regimes in line with standards of protection that follow the standards of the technologically advanced countries.

For developing countries, these changes in the IP policy framework generally represent a considerable strengthening of the protection offered to IP holders. The intense pressure from developed countries to implement policies to strengthen IP protection has generated increased interest in the intersections of IP policies and other development policies and goals.

Opinions on the impacts on developing countries of strengthened IP policies vary widely. On the one hand, proponents of strong IP protection and enforcement claim these are indispensable for developing countries. They argue that strengthened IP laws help developing countries create the incentives structure and institutional framework necessary for knowledge generation and diffusion, technology transfer and private investment flows. In the face of constant pressure to maintain international competitiveness, businesses are increasingly concerned about the prospect of "free- riding" where other, foreign companies may benefit economically from the technological investments of one company, and potentially undercut its competitiveness. IP policies are being harnessed as a way to preserve private appropriation of rents from investment in innovation in the context of international trade and investment.

On the other hand, a spectrum of dissenting voices remains sceptical of claims used to justify stronger protection. Some critics argue that current trends in the global IP system will have a range of deleterious short- and long-term effects on developing countries, including raising the prices of essential drugs beyond their affordability by the poor, limiting the availability of educational materials for developing-country school and university students, legitimising the piracy of traditional knowledge, and undermining the self-reliance of resource-poor farmers.

Some critics, concerned that greater IP protection could reinforce the concentration and market power of large economic actors, emphasize the need for strong competition policies to address anti-competitive behaviour. If TRIPS were fully implemented, estimates indicate that annual transfers to major technology-creating countries - particularly the United States, Germany and France - in the form of royalties and licensing fees for pharmaceutical patents, computer chip designs, and other IP, would amount to more than \$20 billion. Stated baldly, this means that TRIPS represents a \$20 billion-plus transfer of wealth from the technology-importing nations (many of which are developing countries) to the technology exporters (few, if any, of which are developing countries) that may or may not be outweighed by future gains. For example, potential benefits such as foreign direct investment (FDI) may take quite a long time to accrue, and their scale is difficult to predict, particularly in light of the variety of policy issues and economic conditions that influence FDI decisions. Moreover, they note that IPRs can inhibit, rather than enhance, the flow of trade by limiting market access opportunities for foreign competitors.

Most fundamentally, some critics question the assumption that IPRs are necessary for innovation and commercial investment in new technologies. Most commonly, those who have doubts about the impact of existing IPR regimes, are not pro or anti intellectual property rights *per se*. Rather, they call for a more careful analysis of which IP policies will serve what goals and whose interests, and under what conditions.

For developing-country members of the WTO, the core concern is that they no longer have the policy options and flexibilities in the IP policy arena that developed countries earlier relied upon to serve their national development. The historical evidence confirms that several of today's developed countries readily exploited the absence of agreed international standards in the past, adapting their level of protection according to national needs. The evidence also suggests that while patent systems, for example, may indeed have helped to stimulate the development and diffusion of new technologies that were the foundation for industrial development, countries benefited from freedom to choose from a variety of possible national systems.

In short, for developing countries, the emerging global IP regulatory regime appears to place severe constraints on the policy "space" available to them to devise and implement IP policies that are supportive of development goals. Far more relevant data is needed in order to fully understand the range of possible benefits and losses to developing countries of the introduction of stronger IPR regimes. At present, it is far from evident that stronger IP protection will generate the presumed gains in terms of economic transformation in developing countries to the level anticipated by proponents. Arguably, the harmonized IPR regime that developing countries currently encounter is far better suited to the interests of technological leaders than technological followers.

The global intellectual property rights regime

As discussed in chapter 2, the expansion of international IP protection is a process that has evolved steadily over the past few decades to the point that, today, most countries of the world are now involved in what can best be described as a global system of intellectual property regulation. This system comprises a series of intersecting international agreements and several powerful international institutions, the most important institutions being the World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO). The global IPR regime is very much a work in progress.

The TRIPS Agreement

The substantive obligations and disciplines set forth in the TRIPS Agreement are now widely accepted as the centrepiece of the international IPR regime. This policy paper reviews the history and the concept of "trade-related" intellectual property. For those seeking higher standards of IP protection, compliance and enforcement, the incorporation of IPR issues into the General Agreement on Tariffs and Trade (GATT)/WTO has presented an attractive opportunity to include all IPRs in a *single* agreement. It has also meant that, for the first time, WTO Members risk action under the WTO Dispute Settlement Understanding if they fail to implement and enforce the minimum TRIPS standards. In addition, by placing IP issues within the scope of the WTO, Members are obliged, for the first time, to implement IP laws consistent with the most-favoured-nation and national treatment principles. This means that a Member's IP protection and enforcement system must be non-discriminatory as to the nationality of rights holders. That Member must also extend any advantage it grants to the nationals of one country to the nationals of all other WTO Members.

While the supporters of the TRIPS Agreement were quite clearly developed countries and industry, the Preamble to the Agreement notes the importance of broad public policy priorities, including developmental and technological goals. It also highlights the need for a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods. The formal objectives of the Agreement include: the protection and enforcement of IPRs, the promotion of technological innovation and the transfer and dissemination of technology. The Agreement specifies that countries may adopt measures to protect public health and nutrition, and promote public interest in sectors of vital importance to their social, economic and technological development.

TRIPS also places considerable emphasis on enforcement, obliging countries to make available fair and equitable procedures that "permit effective action against any infringement of IPRs", and which are not unnecessarily complicated, costly or time-consuming." The judicial authorities must be granted the power to require infringers to pay adequate damages and to provide for criminal procedures and penalties (with the possibility of imprisonment or monetary fines as remedies). For many developing countries, particularly the least developed

countries, the cost of implementing and maintaining an effective IP administration and enforcement system presents a significant economic burden. The cost is particularly high for the least developed countries, because regulators and courts lack experience in this area. Consequently, relevant legal expertise must be developed or imported, forcing countries to depend on external financial, legal and technical assistance from bilateral and multilateral aid agencies.

Within the WTO, the Council for TRIPS is the forum in which Members monitor compliance with the Agreement. Importantly, the TRIPS Agreement is not set in stone. The TRIPS Council has the possibility to review implementation of the Agreement at two-year intervals and can undertake additional reviews in the light of any relevant new developments, which might warrant modification or amendment of the Agreement. At the 2001 Doha Ministerial Conference, for example, Members agreed to: negotiate the establishment of a multilateral system of notification and registration of geographical indications for wines and spirits; examine the relationship between TRIPS and the Convention on Biological Diversity (CBD) and the protection of traditional knowledge and folklore; establish a Working Group to examine the relationship between trade and technology; and reaffirm the mandatory nature of the obligation for developed country Members to provide incentives to entities and institutions within their territories for the purpose of promoting and encouraging technology transfer to least developed country Members. Members also agreed upon the Doha Declaration on TRIPS and Public Health, designed to ensure that the TRIPS Agreement did not hinder the capacity of developing countries to provide access to medicines in their countries in cases of public health emergencies.

Beyond TRIPS

The TRIPS Agreement is just one part of a broader system of multilateral, regional and bilateral agreements and treaties relating to IPRs.

Standard-setting treaties define agreed basic standards of protection for the different IPRs; they include: the Paris Convention for the Protection of Industrial Property, the Berne Convention for the protection of Literary and Artistic Works, the Rome Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organisations, and the 1996 Internet Treaties, all of which are administered by WIPO.

In addition, multilateral treaties include agreements on global protection systems, which facilitate filing or registering of IPRs in more than one country (e.g. the Madrid Agreement Concerning the International Registration of Marks and the Patent Cooperation Treaty). Finally, classification treaties (e.g. the Strasbourg Agreement Concerning International Patent Classification) organize information concerning inventions, trademarks and industrial designs into indexed manageable structures for easy retrieval.

Regional and bilateral agreements take several forms and can set global precedents, which are sometimes incorporated into global agreements. In addition, trade agreements, rather than stand-alone IP treaties, govern bilateral IP relationships. Like other regional agreements, they can include provisions that go beyond TRIPS obligations, such as extending patents to new subject matter, eliminating certain exceptions, and requiring the introduction of protection at a faster pace and higher standard than what TRIPS requires. In addition, these agreements can require contracting parties to accede to certain international conventions.

The global IPR regime also encompasses several sector-specific actors and institutions. For example, the World Health Organization (WHO) is actively involved in providing advice and technical assistance to governments in the area of health and IP policy. There are three international treaties which form part of the framework for IP protection related to plant varieties and genetic resources: the International Union for the Protection of New Varieties of Plants Convention (UPOV Convention); the Convention on Biological Diversity; and the Food and Agricultural Organization's International Treaty on Plant Genetic Resources for Food and Agriculture.

In sum, over the past decades, the following major trends have characterized the evolution of the global system on intellectual property rights: the widening of protectable subject matter; the creation of new rights to accommodate technological advances; and the progressive harmonization and standardization of the basic features of IPRs.

The multiple negotiations under way in a wide range of fora means that countries are under considerable pressure to identify their national IP interests in each area. The development of coherent, effective and sustainable policies and negotiating strategies on IPR policy at the multilateral, regional and bilateral levels is becoming increasingly difficult, particularly for countries with poor resources. Many developed countries hope to raise and strengthen standards for IPRs. Some developing countries, while acknowledging the TRIPS Agreement's weaknesses from a development perspective, are working to creatively take advantage of the flexibilities it can provide. Others are working to lower the mandated standards. At present, the evolving international IPR system continues to raise the floor of minimum standards for IPRs above and beyond the TRIPS Agreement. This TRIPS-plus environment represents a significant narrowing of the policy options available to developing countries.

Cross-cutting issues: opportunities for developing countries to develop policies appropriate and responsive to their local conditions.

Fostering creativity and innovation in developing countries

Developing countries are the hosts of significant creative activity, particularly in the areas of textile design, plant cultivation, medicines, software and music. Much of this activity has flourished in the absence of an effective IPR regime. A critical question facing developing countries is what kinds of IPR policies may effectively foster more creativity and innovation

while transforming these into commercially viable products that generate productive employment and export opportunities.

As discussed in chapter 3, several components of IPR policy can be usefully harnessed to help promote the development of industries in specific sectors of interest to developing countries (e.g. software, textiles and music).

Patent and second-tier patent systems: utility models

Countries with a weak technological base can adopt carefully defined exceptions and limitations to the patent regime. They should examine the possibility of adopting a secondtier patent system such as utility models. While TRIPS is silent on this type of IPR, many countries have adopted second-tier regimes. Their characteristics vary considerably. Usually, they exist along with traditional patent regimes. Rights are generally accorded to inventions that show local or regional novelty, and the requirements for inventiveness are usually low. The duration of protection varies from 6 to 20 years, and the invention may not necessarily require either examination or registration. There is persuasive evidence that cheap and rapid second-tier patent protection can assist small and medium-sized businesses, particularly where local industrial or production sectors are engaged not so much in major inventions, but in incremental innovation or improvement (e.g. toy manufacturing, clock and watch making, optics, micro-technology, and micro-mechanics). For small, local firms, the second-tier patent systems can provide a much cheaper opportunity to process applications (largely because of the absence of examination). That said, second-tier patent regimes still rely on a broader incentives structure to ensure that there are innovations to protect; they also require patent lawyers capable of filing applications. In addition, the fact of non-examination can result in the granting of overly broad claims, which in turn can provoke uncertainty for other inventors and loss of confidence among their holders in the security of their rights.

Industrial design protection

Industrial designs protect the outward appearance of a product, as opposed to its technical functions. Most, but not all, industrial design laws are registration-based. In designing such a system, policy makers need to consider the range of potential challenges to designers and artists (e.g. ensuring that the registration formalities are not too onerous). In the context of short-lived design products such as those made by the toy, fashion, household and furniture, and textile industries, which are fast-moving, quickly imitated and in need of immediate protection, the most common forms of protection are unregistered design rights or copyright (see below, concerning the textile industry), rather than registered design right.

Trade secrets

Trade secrets provide inventors with a method for protecting themselves against unauthorized exploitation of their inventions (particularly those which are either unpatentable or for which the costs of patenting are too high). They also help to protect

against disclosure of information. For developing countries, features of a pro-competitive trade secrets law could include provisions to eliminate obvious forms of industrial espionage and permit reasonable restraints on the use of technical secrets by professional employees who leave employment. These laws could also provide other researchers and inventors with an absolute right to reverse-engineer products covered by trade secrets and to independently discover, duplicate and patent undisclosed research. Trade secrets can, however, create absolute and long-lasting barriers to entry in some sectors. This is why governments often prefer the patent system, with its emphasis on disclosure of technological breakthroughs in exchange for fixed-term exclusive rights.

Trademarks

Trademark protection can provide a valuable tool to help develop brand recognition and commercialisation of high-quality crafts, clothing and music products from developing countries. It can also help firms differentiate products by quality and increase their value-added.

Chapter 3 reviews some IP policy options relevant to several industries of particular interest to developing countries.

Software

In the realm of software, developing countries face the challenge of balancing several objectives and policy options. Copyright law provides a case in point. For countries that wish to expand the average size and value-added of local software development, copyright protection may be of interest. The appropriate scope of protection depends, however, on the nature of the software being produced. While some software companies may want protection to help them to recoup their investment, others may also wish to save costs by reusing pre-existing work or elements of those works. Indeed, it is often the same firms that want to protect their software, but also to build on pre-existing works. Hence the need for a copyright law that adequately preserves a balance between the innovations of today and those of tomorrow.

Textiles

The textile, fashion and garment industries of developing countries may also benefit from improved IP protection. Under the TRIPS Agreement, countries can use either copyright or design laws as a means to protect the design of such goods. Copyright may be more attractive for short-lived production that can be quickly imitated and which is in need of immediate and automatic protection (particularly where industries rely on incremental rather than massive design improvements). This is because design law has tended to be more cumbersome and expensive than copyright given its relatively higher thresholds for protection (e.g. in terms of originality or novelty) and registration procedures.

The music industry

In the music industry, developing countries are endowed with abundant music talent. While the scope for development is great and the export of music has been increasing rapidly, relatively few countries are able to record compositions and make money in either domestic or export markets. Copyright protection policies are one means of helping to nurture and protect the music industries of developing countries. Even where copyright protection is in place, policy makers need to provide efficient, transparent and fully accountable royalty collection and distribution regimes among the key parties concerned (e.g. composers, performers, publishers and recording companies). There has been considerable discussion about how to design collective management systems in ways that maximize benefits to local artists and producers (rather than serving as collection agencies for large foreign firms). Clearly, the development of an internationally competitive music industry will also rely on a broader range of public policies to support technological restructuring processes, marketing strategies, joint ventures, local content requirements, deregulation of the local radio industry, and synergy between local and international musicians.

New technologies

Over the past decade, the potential of new technologies, particularly biotechnologies and information and communications technologies (ICT), to contribute to development has attracted considerable attention and debate. The capacity of developing-country research centres, universities and the business sector to generate inventions in new technologies varies considerably. These issues are examined in chapter 4.

Biotechnology

There is growing interest in the potential applications of biotechnology to a range of different activities in developing countries, in the hope of generating new industrial and trade opportunities. To date, however, the most visible and profitable industrial applications, such as pharmaceuticals, have remained largely beyond the affordable reach of most developing countries, both in terms of research contributions and access to final products.

In the coming years, a number of practical factors could lower the barriers to entry for developing countries and increase the possibility that some developing countries may become sources of innovations in this field. After determining whether, to what extent, and how they wish to harness biotechnology for development, developing countries need to formulate an IP policy as a critical component of their overall policy framework. For a country to become an active contributor to biotechnological research, a solid national system of innovation should be in place (e.g. basic R&D, skilled personnel and a strong education system). Clearly, IP policy cannot be separated from other policies and institutions touching upon growth and development of a country.

The TRIPS Agreement makes no explicit reference to biotechnology. There are, however, important provisions relevant to biotechnology in the Agreement, particularly in Article 27.3 (b), which addresses the issue of patentability. Countries are provided a series of obligations and options with regard to how they define a patentable invention in the context of biotechnology. The policy paper reviews the various requirements in detail and emphasizes the considerable flexibility countries have in terms of defining a patentable invention, depending on their objectives with respect to biotechnology development. Broadly speaking, countries can choose to offer broad, strong patent protection in the field of biotechnology, or, for example, they can take advantage of the options to exclude certain products (e.g. plants and animals) and processes (e.g. essential biological processes for the production of plants or animals) from patentability. They can also pursue the option of a sui generis alternative to patents for the protection of plant varieties.

In some developed countries, laws and courts allow patenting of isolated DNA sequences so long as a credible use is disclosed. Other jurisdictions include novelty standards so that isolation of a naturally occurring substance is insufficient to demonstrate novelty. The extension of patent protection to genes and gene fragments has attracted considerable controversy within the scientific community of developed countries. There are concerns that patents in this field raise the cost in conducting research and could have the adverse effect of slowing down innovation. Some critics raise objections, on moral and religious grounds, to patents not only on genes but also on plants, animals and other so-called "life forms".

Information and Communication Technologies (ICT)

Information and communication technologies (ICT) is a field in which tremendous advances have been achieved in a very short time. The main sources of innovation in the ICT field are the software, hardware, semiconductor and telecommunications industries. Many other industries involved in the fields of electronic information processing and communications also have an interest in IP regulation, namely Internet service providers (ISPs), content providers, content creators, World Wide Web browsers and e-commerce businesses. Each of these players has a distinctive view on IP protection. Content providers, for example, tend to favour levels of copyright protection even stronger than those for the print environment. ISPs, on the other hand, tend to argue against stronger protection, especially given the possibility of finding themselves liable for the copyright infringement of their users.

Although some developing countries are important sources of ICT innovation, access is likely, overall, to be a greater priority than the promotion of innovation. Innovative firms in developing countries are already finding it hard to grow in the context of highly concentrated ICT markets. Even where developing countries are critical centres of production, it is their partners in developed countries that usually capture most of the value for the design and sale of products.

The ICT revolution is pushing the boundaries of IP policy in several ways. The TRIPS Agreement requires countries to protect software through copyright law. Software and database developers favour this copyright protection as a way to protect both expressions and limited access to information. In the United States, for example, software developers can copyright the code of their programs without having to fully disclose it (they can also secure additional protection by keeping the source code secret through trade secrets laws). While TRIPS does not explicitly state that countries must provide for the patenting of software, some countries are required to do so under the terms of bilateral trade agreements. In the EU, patents are not officially permitted on computer programs, yet several have been issued. TRIPS also obliges countries to implement a *sui generis* system for the protection of semiconductor chip designs.

For developing countries, key priorities to consider in this regard are to ensure that users of information on the Internet are guaranteed "fair-use" rights, such as making and distributing printed copies from electronic sources in reasonable numbers for educational and research purposes, including the use of reasonable excerpts in commentary and criticism. Countries also need to pay attention to particular methods employed by suppliers of digital information and software to restrict fair use. These include the use of overly restrictive, non-negotiable licensing contracts (e.g. for software or for access to electronic journals) and the use of technological devices and barriers to prevent copying. These new "anti-circumvention" measures not only seek to restrict access to works, but may also allow owners of IPRs to deny users their lawful rights of fair use. Governments may, for example, want to ensure that efforts to circumvent technological protection for purposes of fair use should not be made illegal. As such, it should not be illegal to produce, use and disseminate technologies which aim to circumvent these barriers.

Technology Transfer

Most developing countries remain net importers of new technologies and products and technology transfer is thus a critical element of their strategies to promote technical improvements in production processes and diversification into new productive activities. The vast majority of modern technological innovations are owned by companies, research institutes, universities or individuals in developed countries. Patent ownership, for example, is heavily skewed in favour of the developed countries. The vast majority of international applications continue to be filed by companies based in North America, Western Europe or Japan.

Chapter 5 points out that technology transfer is a complex process with several core components, including the sharing of physical technologies, codified knowledge, know-how and management techniques. The literature on technology transfer distinguishes between informal and formal aspects of technology transfer. Informal technology transfer generally

refers to the practice of "imitation", which served as a powerful instrument for technical change and learning for such economies as Japan and the Republic of Korea. Formal technology transfer, on the other hand, is generally a commercial operation that takes place through firm-to-firm arrangements and involves flows of knowledge, be they embodied in goods (as in the sale of machinery and equipment), or in ideas, technical information and skills (through licensing, franchising or distribution agreements), and movement of experts and skilled labour.

A core assumption underlying the TRIPS Agreement is that the "protection and enforcement of intellectual property rights" will contribute "to the transfer and dissemination of technology". The Agreement stipulates that developed countries shall provide incentives to their enterprises and institutions for the purpose of promoting and encouraging technology transfer to the least developed countries. Proponents of stronger IP protection in developing countries assert that the combination of stronger IP laws and more stringent enforcement will also enhance flows of FDI to developing countries, and greater innovation through research and development.

The empirical evidence concerning the links between stronger IP protection and technology remains inconclusive. However some studies have shown that the relationship between IP policies and technology transfer depends on the level of development of a country, the specific technological fields involved, and the behaviour and absorptive capacity of individual firms. They also suggest that the impact of stronger IPR regimes on informal and formal modes of technology transfer can be expected to differ.

In terms of formal technology transfer, it is possible that the combination of stronger laws and enforcement in the areas of patents, trademarks and trade could build greater confidence among foreign companies that they will be able to retain control over their technologies, and would thus effectively make them more willing to increase formal technology transfer and FDI. In terms of informal technology transfer, implementation of TRIPS could take the form of putting in place a series of disincentives (e.g. the threat of trade sanctions) to pursue traditional practices of imitation. Again, the evidence here is not conclusive. Increased protection and domestic legal rights for foreign IP owners may simply reinforce their ability to block access to their technologies or to charge licence fees that are too high for domestic firms. In addition, it must be borne in mind that it is not simply patent information or access to a patented product that is important for technology transfer. Equally important is the associated "know-how" which most companies continue to guard carefully. Indeed, in many cases of FDI in developing countries, companies maintain their core design knowledge and tasks in the host or other developed countries. Moreover, the data available so far are hardly conclusive, and suggest that FDI decisions may depend on a host of factors beyond the status of IP policies, including the general investment climate.

In sum, it is clear that countries should not simply accept the assumption that strengthening and enforcing IPRs will induce much more innovation, FDI and technology transfer. Experience from other countries suggests that a number of other factors are at least as important for establishing and benefiting from these processes. Therefore, it becomes evident that the effect of strengthened IP protection is often dependent on its relationship with other factors, such as the size of the domestic market, the specific technological fields involved, the behaviour and absorptive capacity of individual firms, the structure of factor supply, productive infrastructure, the level of development of the country, and the degree of stability of the macroeconomic environment. It may be the case for certain products and contexts, but the oft-repeated assertion of a positive correlation for developing countries between IP policy on the one hand, and innovation, FDI and technology transfer on the other, should be approached with caution.

Specific areas of concern: Challenges for developing countries in the implementation of new IP standards

Health

The relationship between IP policies and access to medicines has emerged as one of the most controversial policy debates in the IP field, as discussed in chapter 6. Access to affordable medicines is a key priority for many developing countries, particularly the least developed countries. A range of obstacles, including inadequate public health infrastructure, inefficient marketing and distribution networks, insufficient funding, cumbersome regulatory procedures and high prices of medicines, frustrates access to medicines. The issue of high prices has generated increasing criticism about the existence of powerful patent monopolies in the health sector. In particular, pharmaceutical companies have been condemned by many NGOs and several governments for failing to do enough to assist the millions of people dying from HIV/AIDS for lack of access to anti-retroviral drugs. They are also criticized for deploying an extremely low proportion of their R&D to diseases affecting poor people; and for putting pressure on developing-country governments to prevent the local manufacture or import of cheaper, copied version of the drugs produced in countries where patents are not available or respected.

Exclusive rights afforded by patents enable companies that hold them to set and maintain prices at high levels. Pharmaceutical companies argue that patents are a vital means for them to capture returns from their R&D, and that they are a critical tool for providing incentives to invest, particularly in risky, expensive new drug development. From a developing country perspective, a key policy priority is to help ensure that drugs are available to doctors, hospitals and individuals at lower, more competitive prices. Promoting early competition from generic medicines is one important way to foster competition, stimulate price reductions and expand access to drugs. In recent years, attention has focused on the patents

and public-health-related provisions of the TRIPS Agreement. The TRIPS Agreement obliges all WTO Members to grant patents for pharmaceutical products. Prior to TRIPS, no similar obligation existed in international law, meaning that more than 50 countries did not grant any protection for pharmaceutical products, and many more provided much weaker protection than that called for by TRIPS. In addition TRIPS requires Members to provide for product patents as well as protection against unfair commercial use of the information submitted for the marketing and approval of drugs. New obligations in TRIPS include: granting patent protection for at least 20 years from the date of patent application, limiting the scope of exemptions from patent rights and obligations, and effectively enforcing patent rights through administrative and judicial mechanisms. Together, these rules have dramatically changed the global framework for the commercialisation of drugs and affordable access to them in developing countries.

Nevertheless, TRIPS allows countries to implement their obligations in a manner necessary to meet human health priorities. In order to promote competition, the TRIPS Agreement does provide leeway, through a number of important flexibilities, for Member countries to adopt measures that mitigate the exclusive rights conferred by patents. Developing countries have several options to reduce the costs of the obligation to grant patents on pharmaceutical products. First, in the case of a national emergency or other circumstances of extreme urgency, TRIPS permits countries to pursue compulsory licensing (or authorization for public non-commercial use) even without prior negotiation with the title holder. The Agreement specifies that this authorization must be "predominantly for the supply of the domestic market" thereby limiting the ability of countries to issue a compulsory licence with the goal of supply the third countries in need of patented medicines. In many instances, the threat of compulsory licensing has also served as a useful tool that developing countries can use. The very possibility of compulsory licensing tends to strengthen the bargaining position of governments and third parties, even if such licences are never actually granted. Second, the TRIPS Agreement also permits countries to pursue parallel imports of patented products when they are obtainable in a foreign country (where a patent also exists) at lower prices. Third, countries can pursue the option of establishing exceptions to exclusive rights, such as the early-working exception (also known as the Bolar exception), which allows generic firms to initiate and obtain marketing approval of patented drugs before the expiration of their respective patents.

In response to concerns by governments and civil society, in 2001, WTO Members adopted the Declaration on the TRIPS Agreement and Public Health. The Declaration affirms that TRIPS should not prevent Members from taking measures to protect public health, and reaffirms the right of countries to use, to the full, provision in TRIPS that allow each Member to "grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted." It also allows WTO Members to establish their own regime for "exhaustion" of intellectual property rights. The Declaration does not, however, address the problem of countries lacking the capacity to produce drugs, and which find it difficult to take effective

advantage of compulsory licensing. Paragraph 6 of the Declaration instructs the TRIPS Council to "find an expeditious solution to this problem".

Food and agriculture

Over the past decade, the potential impact of new IP rules and legislation on food security, agriculture and biodiversity has been one of the primary IP policy concerns for developing countries. Chapter 7 examines some of these concerns.

Plant variety protection, access and benefit-sharing

A range of policy instruments is relevant to the issue of plant variety protection, and the policy landscape is continuing to evolve. Most significantly, the TRIPS Agreement requires all WTO Member countries to provide IP protection for plant varieties, either in the form of patents, or through a "sui generis" (i.e. of its own kind) system, which, in principle, allows countries to develop their own system for protecting plant varieties. While some countries are doing so, others have elected to adopt model legislation formulated by the Union for the Protection of Plant Varieties (UPOV).

There has been considerable debate about UPOV's model legislation. Many developing countries have expressed discomfort with the plant-breeder-rights (PBR) approach, arguing that it is designed to accommodate the specific characteristics of capital-intensive, large-scale commercial agricultural systems that prevail in developed countries. Concerns about PBR-style protection, discussed in this policy paper, suggest that it fails adequately to account for the interests of poor farmers, that it inadequately acknowledges the historic contributions of traditional farmers to the development of plant varieties, and that it will diminish the availability of genetic resources for further breeding. There are also concerns that the process of protecting plant varieties diminishes the prospects for sharing of plant varieties, and may contribute to genetic erosion. Finally, there is concern that the PBR regime encourages greater centralization of research, rather than research tailored to respond to local environmental and socio-economic conditions.

Beyond the specific debates about PBR, there are concerns that strengthened IP protection to plant varieties (whether through patents or plant variety protection) contributes to further privatisation of the genetic material needed for research, privatisation of agricultural research itself, an increased concentration of breeding materials, research tools and technologies in the hands of a small number of giant corporations, and the shrinkage of non-proprietary public sector research. But regardless of their concerns, many developing countries find themselves under pressure or obligations in bilateral and regional trade negotiations to adopt UPOV-style plant variety protection. The Organization of African Unity has, for example, developed a model law for the protection of the rights of local communities, farmers, and breeders, and for the regulation of access to biological resources.

In 2001, the Indian parliament adopted the Protection on Plant Varieties and Farmers' Rights Act.

Chapter 7 also notes the relevance of the Convention on Biological Diversity (CBD) (and its Bonn Guidelines on Access Legislation) and of the new International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) of the FAO to the task of implementing IP policy in this area. In practice, the relationship between TRIPS and these two agreements has proved complex. Whereas the TRIPS Agreement legitimises IP protection and thus the monopolization of plant genetic resources, the FAO and CBD treaties both recognize national sovereignty over them. Whereas the CBD suggests bilateral arrangements for facilitating access to genetic resources, the FAO Treaty aims to create a multilateral system and provide a framework for sharing benefits and burdens among countries. A key issue in the FAO Treaty is whether it should be possible to claim IP rights that limit access to the plant genetic resources covered by the Treaty. Under the CBD, IP is only explicitly referred to in the context of technology transfer, yet IP policy is frequently discussed with respect to such topics as access to genetic resources, benefit-sharing and the knowledge, innovation and practices of indigenous and local communities.

Geographical indications

A second area of IP policy relevant to food, agriculture and biodiversity is geographical indications (GIs). The TRIPS Agreement defines GIs as "indications, which identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation, or other characteristic of the good is essentially attributable to its geographical origin". In other words, geographical indications can help to identify and differentiate products on the market. They can also help establish a special link between the origin of a product and its quality, reputation or special characteristics, all of which can make a significant difference to the profitability and long-term commercial viability of a particular product. The TRIPS Agreement makes a distinction in term of the protection offered to wines and spirits and that provided to other products.

At the Doha Ministerial, Members agreed to pursue discussions regarding the extension of GIs to new products. The European Union and the Swiss Governments are among those that are keen to promote GIs; they highlight a range of potential benefits for developing countries, particularly for rural economic development. For some developing countries, there is also a strong interest in expanding the scope of geographical indications so that protection can apply to a broader range of products. There is hope that the ability to market products based on their geographical origin (and preventing others from using reference to that same geographical region) will allow some commercial producers from developing countries to differentiate some of their agricultural and other products on international markets. In particular, there is a hope that the use of GI protection will help those communities that maintain long-standing, collective production practices to reap greater economic returns for their efforts.

On the other hand, some countries, including developing countries, fear the extension of Gls. They are concerned that requirements such as "authenticity" and "origin" may become barriers to entry into niche sub-markets for particular classes of their exports. Some developing countries argue that, compared to developed countries, they have a smaller number of Gls that could benefit from the extension of Gls, in part because so many of their local products are deemed generic in developed countries. Some developing countries already involved in free and fair product imitation also fear that they will suffer losses from market closures due to the extension of Gls.

At present, however, the potential of geographical indications for developing countries is somewhat speculative because this type of IPR has been used only in a few countries outside Europe. Many Gls have only small markets and relatively few are traded internationally. Evidence from Europe suggests that successful commercialisation and use of Gls depends on coordination between firms within the products' supply chains and on effective public support for establishing and monitoring product quality standards. In addition, there is considerable need for product marketing and promotion as well as market information, particularly for the foreign markets to which the products are to be exported.

Traditional knowledge and folklore

Traditional peoples and communities in developing countries are responsible for the discovery, development and preservation of a wide range of medicinal plants, health-giving herbal formulations, and agricultural and forest products. Traditional knowledge (TK) is also used as an input into modern industries such as pharmaceuticals, botanical medicines, cosmetics and toiletries, agriculture and biological pesticides. While estimating the full monetary value of TK is extremely complex, there is no doubt about its contribution to food security, employment, livelihoods and exports in developing countries. In addition, a great deal of TK has a cultural or spiritual value that cannot be quantified in any monetary sense.

As discussed in chapter 8, in general, intellectual property policies fail to account adequately for traditional knowledge. Since the early 1990s, developing countries and holders of TK have pushed for greater acknowledgement in international IP policies and laws of its value and origin. Frequently, multinationals and researchers in developed countries use TK without the permission, consent or knowledge of local traditional communities and fail to share the subsequent economic benefits on fair terms with them. Others neglect to ask permission to use the cultural expressions of indigenous communities and fail to acknowledge the source of the creativity, even passing off productions and works as authentic expressions or products when they are not. Some communities complain that knowledge and/or cultural expressions of special sacred or religious significance are commercialised in ways that they find offensive or morally wrong. Several developing-country governments have launched challenges to patents granted in developing countries on "inventions" which have been in the public domain in their countries for centuries.

TK is now a specific topic in international discussions. In Doha, WTO Members agreed to examine the relationship between TRIPS and the protection of traditional knowledge and folklore. Similarly, in 2000, the WIPO General Assembly established an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. The CBD has work under way on TK and IP-related issues under the auspices of its Working Group on Article 8j. This article requires, among other actions, that the Parties respect, preserve, and maintain knowledge, innovations and practices of indigenous and local communities, and encourage the equitable sharing of the benefits arising from their utilization. The FAO's new ITPGR also refers to measures governments should take regarding the protection of TK. Lastly, UNCTAD has conducted work aimed at improving the protection of traditional knowledge, and WHO has a programme promoting traditional medicines, and the fair and equitable sharing of benefits that derive from them.

Several specific issues are under discussion at the international level. The first issue concerns prior art. While precise provisions vary from country to country, most national IP systems consider traditional knowledge, no matter where it is from in the world, as the property of nobody. That is, they assume that traditional knowledge is in the public domain. One potential remedy is to enable patent offices to conduct more effective prior art searches. To this end, some developing-country governments are working to establish national and/or local databases of TK. Some are collaborating with WIPO to improve the accessibility of information held in those databases. Many indigenous groups agree that databases can help patent examiners to filter out spurious inventions. However, they argue that registration of TK must not proceed without the consent of the TK holders, and that databases must be maintained locally and remain under the control of indigenous communities. A related policy priority for many developing countries is for all countries to require disclosure of information in patent applications regarding the geographical source of genetic resources from which the invention is derived.

While most indigenous and local traditional communities appear to support efforts to improve intellectual property laws to better protect them against the misuse and misappropriation of their knowledge, efforts to use existing laws or to design new laws to advance new positive protection of their knowledge have been attracting more controversy. Past experience of misappropriation, means that many indigenous communities tend to be hostile towards patent regimes and feel powerless to challenge invalid patents. For many indigenous peoples, the idea that one group or company, even their own community, could claim exclusive rights over inventions derived from genetic resources violates their value systems and customs. Communities that are interested in pursuing protection for their inventions often encounter problems relating to compliance with the traditional standards of patentability; they also lack sufficient resources for applying for patents and for enforcement of their patents.

Conceivably, a considerable amount of TK could be protected under trade secrecy law. While the sharing of knowledge is common in many traditional societies, healers and other specialist knowledge holders as well as clans and lineage groups are likely to have knowledge that they would not wish to share with anybody. If desired, the trade secret could, for example, be stored in a close-access database, and then be disclosed to companies with benefit-sharing guaranteed through a standard contract, enabling the economic benefits to be shared appropriately with the community.

Some governments have called for *sui generis* systems for the protection of TK that would take adequate account of its distinctive nature. Most indigenous peoples argue that *sui generis* systems can and should draw from customary laws. The customary laws that indigenous peoples possess typically include local systems of jurisprudence regarding classification of different types of knowledge, proper procedures for acquiring and sharing knowledge, and the rights and responsibilities which attach to possessing knowledge, all of which are embedded uniquely in each culture, its language and the environment. In general, most countries fail to acknowledge customary laws, let alone with respect to indigenous knowledge and IP matters, but some countries are increasingly (and successfully) taking customary laws into account. While there are many common principles and values that indigenous communities share, the intricacies and sheer diversity of traditional customary laws makes it unlikely that any single form of collective IP or international law on traditional knowledge could be effectively designed.

Access to knowledge and educational, technical and scientific information

For developing countries, IP policy considerations are emerging as important variables in public education, and also in the capacity to conduct technical and scientific research and development. In the education and scientific sphere, developing countries rely on information in the form of foreign publications, academic journals (digital and non-digital), teaching and research software, electronic databases and Internet access. From a development perspective, there are concerns that recent trends in IP policy are constraining access to knowledge and to educational, scientific and technical information vital for building local capacity for scientific R&D and innovation in developing countries. Companies are also employing controversial new technological and contractual strategies to strengthen the traditional protection of their investment provided by IP policy. Developing country governments are in the difficult position of striking an appropriate balance between their need to ensure access to information and knowledge and their commitments to comply with international treaties. Chapter 9 explores a range of copyright policy options and exceptions developing countries could consider, and also draws attention to the contribution that differential pricing might make.

On the education front, a critical IP-related issue for developing countries is the ability to copy and distribute texts that are beyond the reach of most developing-country pupils and public school systems. Price is not just an issue with regard to access to foreign publications, but also for local publications for schools, universities and research in general. The growing

interest in distance education in many developing countries, as a way of reaching rural and poor communities, has also drawn attention to IP policies associated with the Internet, teaching software and other related communication technologies.

For developing countries, it is important that concepts such as "fair use" (as it is called in the United States) or "fair dealing" (in United Kingdom and other Commonwealth jurisdictions) are fully utilized. These provisions establish exceptions to copyright, authorizing the use of protected works under certain conditions (notably copies for private, non-commercial purposes, and for public archives and libraries). Recent trends in national legislation around the world, however, reveal pressure to reduce or exclude the possibility of fair use, even though it is permitted in international copyright instruments such as the Berne Convention and the 1996 WIPO Copyright Treaty (WCT). In addition, an appendix to the Berne Convention includes some special provisions targeting developing countries, to facilitate ease of translation for the purpose of teaching, scholarship or research, and reproduction for use in instructional activities. However, owing to the many restrictions and qualifications in these provisions, only a few developing countries are currently availing themselves of the options available.

Along with efforts to maintain fair use opportunities for developing countries, there is growing attention to the need to reconsider the design of "collecting societies" (these organizations are practical instruments to collect fees from rights users and to distribute the revenues to rights holders) to ensure that they do not act in an anti-competitive manner, and that the costs of establishing and operating such agencies are borne by copyright holders, particularly *foreign* copyright holders, who have proven to be the main direct beneficiaries of these societies.

The WCT obliges parties to implement laws that will provide protection against the circumvention of technological measures used by authors and producers to prevent the unauthorized copying of their works or access to their works. These provisions were developed in response to concerns from both authors and publishers arising from the growing difficulties they face in controlling the dissemination and use of their works over the Internet, and to enforce their exclusive rights. The Digital Millennium Copyright Act (of the United States) (DMCA) goes beyond the WCT to make illegal any act circumventing encryption technologies; even in cases traditionally considered legal under the "fair use" provision. Interestingly, the DMCA also provides several examples of exceptions that developing countries may want to consider for their national implementation laws, such as for non-profit libraries, law enforcement, reverse engineering to make software inter-operable, encryption research, and technology used to control Internet access by minors.

Finally, scientific research and technological advancement depend on the free exchange of knowledge across national boundaries. However, access to such knowledge is increasingly restricted by a combination of IPRs and regulations to enhance national competitiveness in

the developed countries. Copyright policies, for example, are implemented in ways that make scientific publications and journals for developing-country scientists and engineers increasingly unaffordable. In particular, the hard copies of scientific journals are being replaced by expensive, subscription-based electronic formats, which creates difficulties for many researchers in accessing cutting-edge knowledge, data and ideas.

Similarly, new efforts to develop IP protection for databases of information also jeopardize affordable access to a vast range of data potentially contained and organized in protected databases. The introduction of the EU's *sui generis* database protection regime, for example, provides database creators the right to prevent extraction of the whole or a substantial part of the contents of the database for a period of 15 years (the term of protection is renewable whenever substantial changes to the database are made, e.g. by adding new data. While the precise implications remain unclear, developing-country research institutions and universities could face further constraints on affordable access to knowledge, particularly as more and more information is converted into electronic databases and made accessible only through Internet channels.

* * *