CHAPTER 11
TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS

'If nature has made any one thing less susceptible than all others of exclusive property, it is the action of the thinking power called an idea.... that ideas should freely spread from one to another over the globe, for the moral and mutual instruction of man, and improvement of his condition seems to have been peculiarly and benevolently designed by nature'.

—Thomas Jefferson, 1813

The contentious introduction of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement into the framework of the multilateral trade regime has probably aroused more controversy than any outcome of the Uruguay Round. This stems from the far-reaching implications of TRIPS for human development in the spheres of technology, public health, education, and conservation, stewardship and ownership of traditional knowledge and biological resources.

THE TRIPS AGREEMENT

The TRIPS Agreement aimed at establishing minimum standards of intellectual property rights (IPR; see annex 11.1 and box 11.1). The agreement has three broad components. The first sets out the content and overall direction of the goals and objectives. Member nations agree to provide minimum standards of protection for all intellectual property applied to all technologies in products and processes. Intellectual property includes copyrights, trademarks, geographical indications, industrial designs, integrated circuits, patents and trade secrets. The aim is to balance innovation and dissemination of technology to the mutual advantage of producers and users so as to promote social and economic welfare (Parts I and II, articles 1–40).

The second component defines the broad civil and administrative procedures for enforcement of IPR (Part III, articles 41–64; Parts IV and V), with details on state obligations, provisional measures and remedial measures under the dispute settlement mechanism. The third component focuses on the needs of technology consumers. In return for the rights provided in the first section, it recognizes the

BOX 11.1 TRIPS: A HISTORICAL PERSPECTIVE

The first attempt at a multilateral agreement on intellectual property rights (IPR) protection began with the Paris Convention of 1883, where 14 countries agreed on broad principles on equality of treatment, right of priority, independence of patents, general principles on compulsory licensing and revocation of patents and rules of unfair competition. By 1998, 155 countries were signatories to the Paris Convention. It played an important role in the spread of national patent legislation, though the patterns of legislation differed depending on country circumstances and requirements.

In the late 1960s and 1970s, a group of developing countries, led by the Andean Group, began a reassessment of intellectual property, its implications for development and the need to revise the Paris Convention to make it more compatible with developing country interests. As part of this revisionist movement, many developing countries that already had patent legislation tried to make it more balanced and flexible. This trend towards weakening IPR protection in developing countries and the increasing importance of new knowledge-based technologies were major considerations for the US in pushing for IPRs to be on the multilateral trade agenda. The US and the EC introduced IPR protection in the General Agreement on Tariffs and Trade (GATT) negotiations during the Tokyo round of 1978 in a draft proposal in connection with anti-counterfeiting measures. As no agreement was reached, the US circulated a new draft in 1982 and raised it in a GATT experts meeting in 1985.

Meanwhile, the US Trade and Tariff Act of 1984 linked intellectual property protection to the application of the generalized system of preferences. In 1988, the Omnibus Trade and Competitiveness Act extended this further by authorizing the US trade representative to list countries that had been given deadlines to improve their IPR protection; threatening them with sanctions if compliance did not follow. Developing countries, meanwhile, were only willing to discuss the clarification of existing GATT rules such as articles IX and XX(d) on measures to restrict trade in counterfeit goods. They treated any discussion of substantive IPR norms as beyond the competence of GATT and within the exclusive jurisdiction of the World Intellectual Property Organization (WIPO). After two years of analysis, at the senior officers' meeting in Geneva, the GATT mandate was clarified with explicit reference to standard setting, dispute settlement and transitional arrangements.

The first draft proposal was submitted by the European Economic Community, followed by proposals from the US, Switzerland and Japan and was based on the assumption that inadequate, discretionary or excessive protection of intellectual property could distort and impede trade and should as such be dealt with within the GATT framework as part of a single undertaking. Fourteen developing countries responded with detailed proposals on trade in counterfeit and pirated goods and the principles for the use of intellectual property rights. These proposals also included detailed discussions of scope of patents, compulsory licensing, control of anti-competitive practices and the like. This allowed the chairman of the negotiating group to consolidate various texts and prepare a comprehensive proposal for discussion at the ministerial meeting in 1990 that led to the successful conclusion of the negotiations on TRIPS in December 1993. In its final form, TRIPS built on earlier agreements at the Paris, Berne, Rome and Washington conventions but was the first that explicitly linked IPRs to trade sanctions.

Source: UNCTAD, 1994; Roffe, 2000.

need for transitional arrangements, technology transfers and technical cooperation for the least developed countries (Parts VI and VII, articles 65–73).

The provisions in the agreement that protect intellectual property are specific, binding and actionable. These include the scope of IPRs (all products and processes in all technologies), the length of patent protection (20 years), the scope of exceptions allowed (limited to very specific cases) and the legal compliance required from domestic patent laws in member countries. Non-compliance can be challenged under the World Trade Organization's (WTO) dispute settlement mechanism. By contrast, provisions with the potential to benefit technology consumers (mainly developing countries), such as technology transfer and technical cooperation, while also binding in theory, are vaguely worded, making them difficult to enforce. Non-compliance with these provisions is hard to prove and, on a practical level, subject to no penalty. Attempts to develop a code of conduct for technology transfer have also failed (Roffe, 2000).

The Doha Declaration, as discussed later, is an important step towards making the TRIPS Agreement more development friendly. It has clarified the need to interpret TRIPS from a public health perspective and, in accordance with articles 7–8 (social and economic objectives), is a useful guideline for interpreting not just TRIPS, but also other agreements.

TRIPS has important human development implications for public health, technology and knowledge and biological resources. Developing countries are likely to be worse off under TRIPS if it is viewed from a human development perspective, and alternate models of IP protection should be designed. The bargaining framework of the WTO is inherently inappropriate for an asymmetric agreement such as TRIPS, and intellectual property protection issues should be delinked from trade sanctions.

In the interim, countries should use the flexibilities available in the TRIPS Agreement to interpret and implement it in a manner that furthers human development goals. This requires using compulsory licensing provisions in a systematic and efficient way, setting the correct precedents in disputes, adopting alternative *sui generis* systems that balance rights and obligations where mandated and using the review mechanism of the agreement to provide additional assistance to developing countries.

TRIPS IN THE CONTEXT OF DEVELOPMENT

The economic rationale for protection of intellectual property stems from market failure. Like other public goods, knowledge is non-rival (so quantity does not shrink with consumption), is non-excludable (and is therefore easy to reproduce) and its original costs of production are high. In the absence of intervention, therefore, it is likely to be underproduced. Intervention can take various forms. The government can produce or finance the production of knowledge, it can subsidize the private

BOX 11.2 EMPIRICAL EVIDENCE ON INTELLECTUAL PROPERTY RIGHTS

Patents. Ginarte and Park (1997) find that patent laws have became stronger in the 1990s. Maskus and Penubarti (1995) find a U-shaped relationship between patents and per capita income, indicating that at low levels of income, patents fall as income rises and, beyond a threshold level, patents rise with per capita incomes. The World Bank puts this threshold at US$7,750 in 1985 prices. Maskus (2000) also infers that effective patent rights are likely to remain limited unless income levels in developing countries rise well above current levels.

Trade. Maskus and Penubarti (1997) also postulate that stronger patents have ambiguous effects on trade; they can increase imports (due to the lower deterrence costs and the increased effective demand due to the exit of local imitators) or can decrease imports if the host country firms hold the patents.

Ability to engage in imitation. Smith (1999) finds that as patent laws become stronger, countries with strong imitative capabilities see the greatest increase in manufacturing imports, while countries with weak imitative abilities see deterioration in their terms of trade.

Technology diffusion. Models that try to measure the impact of IPRs on technology diffusion have given mixed results. Helpman (1993) and Glass and Saggi (1995) find that once a strong patent regime is adopted, the rate of innovation slows, which leads to a slowdown of the global rate of innovation as well.

Foreign direct investment. Lee and Mansfield (1996) find that weak IPRs have a significant negative impact on the location of US foreign direct investment and on R&D facilities. Maskus (1998b) estimates the joint impacts of the activities of transnational corporations and finds that foreign direct investment measured by the asset stock reacts positively to patent strength. Question marks remain, however, on robustness. Braga and Wilmore (1991) and Gould and Maskus (2000) show that IPRs are by themselves insufficient to promote foreign direct investment.

Quality of technology transfer. Davies (1977) and Contractor (1980) show that weak IPRs reduce the quality of technology transferred. However in conjunction with an overall hospitable framework of regulation (taxes, investment rules), the IPR regime influences a firm's perception of its returns on knowledge-based assets. Further, the likelihood that the most advanced technologies will be transferred rises with the strength of the IPRs. Also, rapidly growing developing countries are likely to strengthen their IPRs as they move up the technology ladder.

Access to specific technologies. Sharing of data, scientific research, information, genetic materials and research tools affects knowlege building and scientific enterprise, particularly in developing countries.

Source: Maskus, 2000a (chapter 4 and others). All sources cited here are listed in Maskus.

costs of producing knowledge or it can grant temporary ownership rights to knowledge producers. Normally, some combination of these interventions is used to increase the pool of knowledge. Granting temporary rights requires a legal IPR system that provides and regulates these rights. The TRIPS Agreement is an attempt to reinforce this system at the international level.

Appropriate intervention strategies depend on perceived benefits and costs. The potential benefits from an intellectual property regime are increased innovation and technology transfer. An intellectual property regime also creates temporary

monopolies and restricts access to technology for imitators. The empirical evidence on the role of IPRs is inconclusive precisely because it is difficult to isolate the impact of IPRs from that of other factors that affect innovation, promote investment in research and create markets for intellectual property (see box 11.2).

TRIPS in an unequal world

TRIPS and its expected impact on rewarding knowledge creation need to be seen against the backdrop of the world as it exists today. In 1998, the high-income countries of the Organisation for Economic Co-operation and Development (OECD) accounted for 86 per cent of total patent applications filed and 85 per cent of scientific and technical journal articles published worldwide, earning over 97 per cent of worldwide royalties and license fees (UNDP, 2001; World Bank, 2002). In contrast, the least developed countries earned 0.05 per cent of worldwide royalties and license fees in the same year. In this context, TRIPS works against latecomers or imitators by increasing the price of technology and restricting their options for technological catch-up. Further, it affects future economic development, which is likely to increasingly rely on the power of ideas and information, threatening to leave behind countries that lack research capacity.

Empirical research has also shown that weak IPRs have been used by countries with low levels of technological capacity until they reached a level of development at which their industries could benefit from intellectual property protection (see box 11.2). The history of intellectual property protection in developed countries confirms this trend. As Chang (2000) points out, most developed countries allowed the patenting of imported inventions by their nationals. The Netherlands abolished its 1817 patent law in 1869, treating patents as other monopolistic practices, and reintroduced it in 1910 under pressure from its neighbors. Other examples are Britain before 1852 and Austria and France. Even though the nature of technology has changed, this historical evidence is telling about the relevance of a standardized intellectual property regime for countries at hugely varying levels of income and technological capability.

Further, the World Bank (2001) estimates that (of a sample of 26 developed countries) TRIPS will lead to rent transfers to 9 of them of US$41 billion (in 2000 dollars).[1] These transfers are a natural outcome of the unequal distribution of technology and technological capacity and raise the overall cost of the TRIPS Agreement for countries with already scarce resources.

Today, the main beneficiaries of intellectual property protection are largely transnational corporations, which can use intellectual property laws to own and control research and development, while the world's poorest people face higher prices and restrictions on access to new technologies and products. Intellectual property protection on educational material, essential drugs and medical equipment is likely to hurt poor consumers. Yet, the true impact of TRIPS is variable. Producers in countries with fledgling technological capabilities can benefit from TRIPS.[2] At the same time, intellectual property protection on sunrise technologies

and R&D-intensive industries is likely to stymie developing country efforts to acquire, imitate and learn from them.

Within the developing world variation is also high. As pointed out by the 2002 Commission on Intellectual Property Rights (CIPR) report, in 1994 China, India and Latin America contributed to nearly 9 per cent of research expenditure worldwide, while sub-Saharan Africa contributed to only 0.5 per cent and all other developing countries contributed only 4 per cent. Also, as the report argues, apart from differences in technological capabilities, developing countries are also vastly different in their socio-economic conditions. It is difficult, therefore, to justify the imposition of an across-the-board, one size fits all approach to intellectual property protection. Ultimately, the impact of TRIPS must be measured by whether it allows poor countries to close the technology (and therefore income) gap or helps widen it or by whether it helps poor people and national development.

TRIPS and the multilateral trade regime

The asymmetric relations of developed and developing countries in the context of TRIPS do not fit with the mutual bargaining framework of the WTO. The WTO agreements are negotiated agreements, and concessions are traded to make all members better off. In the case of TRIPS, low-income countries are predominantly technology consumers and have little to bargain with. The expected gains from TRIPS are unlikely without a range of complementary policies such as investment in tertiary education and research capabilities, reward mechanisms in research sectors and an appropriate investor climate—all of which depend on different government policies.

The negative implications of TRIPS meanwhile are clear and immediate in the form of restricted access and higher prices for protected goods. Enforcement of TRIPS through the dispute settlement mechanism allows for retaliation against non-compliance through trade sanctions. For countries already hurt by TRIPS, this means fewer exports and less income for producers. Despite developed country arguments to the contrary, TRIPS itself is trade restricting since it creates monopoly rights and prevents the entry of cheaper, generic versions of products.[3] It is therefore at odds with the aims of the WTO of furthering economic development through increased trade. TRIPS does not necessarily assist in either and is both inappropriate and potentially harmful as part of the WTO framework.

IMPLICATIONS FOR DEVELOPING COUNTRIES: LINKS WITH HUMAN DEVELOPMENT

The TRIPS Agreement has not been fully implemented in most developing countries, since they have an extended transitional period of up to 2005. The least developed countries have, in general, until 2006 to implement TRIPS and until 2016 to implement the patent provisions of TRIPS dealing with pharmaceutical products. However, most developing countries have national intellectual property systems of

various types, and the potential implications of TRIPS are clear.[4] This section examines the links of TRIPS with human development in greater detail with a focus on public health, technology and knowledge creation, and food security, biological resources and traditional knowledge. It highlights the implications of TRIPS, the flexibilities it offers and the challenges it raises for meeting human development goals.

Public health

The research-based pharmaceutical industry, characterized by high initial investment in R&D and ease of imitation of final products, is a prime candidate to benefit from TRIPS. articles 27–34 of the TRIPS Agreement deal with patents (for provisions, see annex 11.1) and are particularly relevant for public health and human development.[5]

TRIPS affects access to drugs and medical equipment in the following ways:

- *Increasing prices.* The most common private finance mechanism for health care in the majority of developing countries is out-of-pocket payment, since governments cannot provide large scale subsidized health care. Out-of-pocket payments in developing countries exceed 90 per cent of total payments, much higher than the 20 per cent in developed countries (WHO, 2000). Other important determinants include the presence of trained medical personnel, well-functioning healthcare infrastructure, comprehensive reach and adequate medical supplies—all of which require resources. However, all these determinants (including access to drugs) need to be addressed simultaneously. Notwithstanding this, drug prices are a critical determinant of access to health care. Patented drugs are substantially more expensive than generic versions. According to the Federal Trade Commission in the US, generic drugs cost 25 per cent less than their patented counterparts and, after two years, the price differential is 60 per cent. Several studies for developing countries have estimated the impact of patents on drug prices (Fink, 2000; Watal, 2000; Lanjouw, 1997; and Subramanian, 1995). Their estimated increases range from 12 per cent to 68 per cent once TRIPS is implemented.[6] In the case of anti-retroviral drugs for HIV/AIDS, patented drugs that cost US$10,000–$12,000 per patient per year are available for US$200–$350 in their generic form (see box 11.3).
- *Producing generic versions.* Some developing countries have the technical capacity to produce generic versions of drugs. Others have the capacity to produce formulations but not active ingredients. Still others rely almost completely on imports. For those with production capacity, TRIPS restricts reverse engineering and increases the waiting time for generic versions of patented drugs to the length of protection (20 years). For countries that rely on imports of patented drugs, the implications are as yet unclear. As the next section shows, articles 30 and 31 can be interpreted to permit generic production, but implementation problems remain.
- *Fuelling Research.* Patents have clearly fuelled the pharmaceutical industry in the developed world, creating incentives for further research. The Pharmaceutical Research and Manufacturers of America estimated research costs at US$30.3 billion for 2001 compared to US$8.4 billion in

BOX 11.3 BRAZIL'S EXPERIENCE WITH IMPLEMENTING TRIPS

Brazil's experience with patent protection in the pharmaceutical sector is instructive. Before implementing TRIPS, Brazil did not afford protection to products nor pharmaceutical processes. This policy needed to be altered as a result of the Uruguay Round. Brazil, at the same time, has created one of the most ambitious anti-retroviral drug programs among developing countries through imaginative legislative and administrative procedures. By 2000, Brazil had more than 536,000 cases of HIV infection. Since 1996, the Brazilian Ministry of Health has implemented a policy of universal access to anti-retroviral drug therapy and by December 2000 had treated some 95,000 patients. This represents US$300 million in expenditure to buy the 12 drugs that make up the anti-HIV cocktail. Simultaneously, the government encouraged a strong generics industry that supplied 40 per cent of all anti-retroviral drugs used nationwide.

This combination of free access to drugs with an extensive health infrastructure was supported by national legislation. The Brazilian intellectual property law of 1996 (article 68[1]) requires the patent holder to manufacture the product in Brazil. If this does not happen, the government can issue a compulsory license to another producer, unless the patent holder can show that local production is not feasible. Both these provisions are well within TRIPS parameters. However, the US challenged the provisions of article 68(1). Brazil insisted that the law was central to the country's public health policy and its threat of compulsory licensing has been instrumental in its negotiations with pharmaceutical companies to reduce prices on imported anti-retroviral drugs. On June 25, 2001, the US government withdrew its WTO Panel against Brazil and, in turn, Brazil agreed to hold talks with the US before applying article 68. More recently, Brazil threatened to use the provision when its negotiations with Roche over lowering prices of nelfinavir (marketed as Viracept by Roche) broke down. Eventually, Roche agreed to lower the price by another 40 per cent; article 68 was not invoked.

The Brazilian AIDS program has shown significant results. There has also been a 60-80 per cent reduction in AIDS-related opportunistic infections, a four-fold reduction in hospitalization rates and an overall savings to the government of more than US$490 million during 1996-2000 in procurement costs alone. And finally, between 1996-2000, average locally produced drug prices fell by 72.5 per cent, while imported drug prices fell by only 9.6 per cent.

Source: UNDP, 2002.

1990 and US$1.97 billion in 1980. In the developing world, some countries are also beginning to develop research-based pharmaceutical industries. But private research is driven by the promise of patent rents. The Global Health Forum (2001) estimates that of the US$70 billion spent globally on health research, less than 10 per cent is spent on diseases that comprise 90 per cent of the world's health burden — despite the fact that most of the poorest countries of Africa have offered patent protection since at least 1984 and, in some cases, since 1977.[7] In the last 25 years, scientists have developed only two new drugs for tuberculosis, while research outlays for malaria are only US$100 million.[8] Clearly, patent systems like TRIPS do not ensure pioneering research into the diseases of the poor.

THE DOHA DECLARATION. The Doha Declaration on TRIPS and Public Health reaffirms the right of developing countries to interpret the TRIPS Agreement through a public health perspective. Specifically, the declaration states that 'the

TRIPS Agreement does not and should not prevent members from taking measures to protect public health.' It explicitly recognizes the flexibility within TRIPS to grant compulsory licenses and the right of countries to determine the grounds on which these are granted. Paragraph 6 of the Doha Declaration also recognizes the problems for countries with 'insufficient or no manufacturing capacity in the pharmaceutical sector' and instructs the Council to find a solution regarding compulsory licensing for them 'expeditiously' (by the end of 2002).

The Doha Declaration is an important milestone in the TRIPS debate. It paves the way for a more public health-friendly interpretation of TRIPS by explicitly recognizing that intellectual property rights are subservient to public health concerns.[9] It is a political, rather than a legal statement and should be used as a reference point for more public health-friendly interpretations of TRIPS if disputes arise.

Opportunities and challenges for public health under TRIPS. TRIPS is a broad framework and contains several flexible provisions that developing countries need to use. At the same time, several challenges remain in ensuring that TRIPS articles are interpreted and implemented in a public health-oriented manner. Some of these are illustrated below.

- *Articles 7 and 8, and the Doha Declaration.* The objectives and principles in these articles and in the Doha Declaration affirm that IPRs should be 'conducive to social and economic welfare' and members may adopt measures that are needed to 'protect public health and nutrition….provided [that they] are consistent with the provisions of the Agreement'.

  Articles 7 and 8 are guiding principles and should be used for a pro-public interest interpretation of TRIPS. The Doha Declaration extends the transitional period available to least developed countries until 2016.

- *Article 6 and parallel imports.* TRIPS does not explicitly address the issue of international exhaustion of property rights, leaving individual member countries to decide whether to recognize that the right of patent is exhausted at sale, and consequently, if parallel imports are legal.

  TRIPS allows countries to use parallel imports to source patented products legally from anywhere in the world. Countries like Argentina, Japan, Australia and the US have adopted the international exhaustion principle. At the same time, South Africa's attempt to use the principle for parallel imports led to a lawsuit from 39 pharmaceutical companies (later withdrawn) and pressure from the US, illustrating implementation problems under TRIPS.

- *Article 30 and exceptions to rights.* TRIPS allows for exceptions to rights under article 30. Members can provide 'limited exceptions' to patent rights for legitimate interests of third parties, as long as they do not unreasonably prejudice the interests of the patent holder, are limited and do not conflict with the normal exploitation of the patent.

  Article 30 can be interpreted so that members may authorize the production, sale and export of public health-related products without the consent of the patent-holder as a limited exception, especially in the case of countries that do

not have the capacity for generic production. For this to happen, the TRIPS Council needs to adopt a liberal interpretation of article 30. In the only dispute on article 30, (Canada-Generic Pharmaceuticals), the panel followed a much more restrictive interpretation of 'limited exception'. While article 30 has the potential to resolve the access to drugs problem, it has not been interpreted in a development friendly manner as yet and is open to legal challenge.

- *Article 31 and compulsory licenses.* Article 31 allows for authorization for use without the consent of the patent-holder. Compulsory licenses can be provided based on individual merit; such licenses should be issued only after efforts have been made to secure voluntary licenses on reasonable terms and have failed (exceptions are allowed in the case of a national emergency). They are predominantly for use in the domestic market, are non-exclusive and temporary. Specifically, TRIPS allows for compulsory licensing in cases of emergency, anti-competitive practices, public non-commercial use and dependent patents (Correa 1999).

  Article 31 allows production of generic versions of patented products. Countries like Canada and the US have used compulsory licenses extensively for pharmaceutical companies, biotechnology and chemicals. But the Brazilian case (see box 11.3) highlights the difficulties faced by developing countries in implementing article 31. The Doha Declaration categorically states that countries have the right to grant compulsory licenses and the freedom to determine the grounds on which they are granted. Yet, several outstanding issues remain.

  For adequate access, the definition of countries with 'insufficient manufacturing capacity' needs to include countries that lack capacity to produce active ingredients as well as formulations. It should also include countries that may have the capacity to produce generics, but have markets that are too small to justify production.

  Import of generic drugs by these countries under article 31 requires clarification on compulsory license requirements by the importing country as well as by the country in which the drugs are produced. Article 30 is a simpler, administratively easier and more direct mechanism for achieving the same and can be a solution to the access problem, if clarified by the TRIPS Council.

Technology and knowledge creation

The raison d'etre of the TRIPS Agreement is the commercial exploitation of ideas. Notwithstanding its serious implications for public health, its most profound implications lie in the areas of research and development and diffusion of technology. Developing countries are net technology importers; consequently, the first impact of an international patent regime that they experience is a rise in the cost of purchasing technology.

Technology and human development. Technology is critical for enhancing productivity and spurring economic growth. Investments in research and development correlate positively with high levels of income. High-income countries

invested 2.4 per cent of their GDP in 1998 compared with 0.9 per cent for low-income countries. Innovation is central to a strong technological base, which in turn allows countries to build high value-added products and remain 'ahead of the curve'. Lall (2001) has developed an index of 'domestic capabilities' by combining two separate indices: an industrial performance index and a technology effort index.[10] He has classified countries based on their capabilities. Not surprisingly, the world's poorest countries fall into the bottom quintile. The causality operates both ways: lack of resources inhibits the ability to invest in research, and the low investment in research contributes to continuing poverty.

Technology and TRIPS. The complex relationship between technology and intellectual property is mediated by industry characteristics, the rate of technological change, local economic circumstances and the distribution of market power.

- *Restricting absorption of technology*. From an economic viewpoint, innovation can be encouraged through either subsidies or patents, though the use of patents has increased significantly during the last decade.[11] Viotti (2001) points out that technical change for 'latecomer' developing countries comes through diffusion and incremental innovation, which begin with absorption and imitation in active learning systems that eventually evolve into innovation systems. TRIPS increases the costs of purchasing, and thereby of absorbing, patented technology. Patents also restrict access to the original technologies, opening incremental innovation to litigation based on claims of infringement.
- *Inhibiting innovation?* For industries in which innovation is cumulative and complementary, patents can reduce overall innovation and social welfare (Bessen and Maskin, 2000; Garfinkel and others, 1991; Stallman, 2002).[12] The software, computers and semi-conductor industries of the US are such examples. Strong protection began only in the 1980s.[13] A number of small firms had built on the common pool of ideas in the public domain to produce new ideas and products. Stronger patent rights parceled out that common pool under patents and cross-licensing agreements and forced new entrants to 'reinvent the wheel'. In many cases, inventing around software patents was difficult, raising the cost and time of innovation. Consequently, stronger patents have correlated with a period of stagnancy in R&D among firms that patented the most. TRIPS extends these stronger patents to fledgling software and semiconductor industries in developing countries, making it more difficult for them to catch-up.
- *Making acquisition of technology more difficult.* Developing countries acquire technology in four broad ways: through embedded technology in capital goods imports, through direct foreign investment, through purchase or foreign technology licensing, or through technology transfer through assistance. Empirical evidence shows that the relative importance of intra-firm technology flows has increased since the mid-1980s as a way of transferring technology (Kumar, 1997). This was spurred by the emergence of new technologies in information, electronics and biotechnology. Companies see these technologies as key to long-run competitiveness and

are keen to preserve their monopoly. TRIPS consolidates knowledge ownership and reduces opportunities for learning and imitating for new entrants.[14]

- *Impeding the spread of knowledge.* TRIPS raises the cost of copyright-protected educational material. In the software industry, only a small segment of developing country populations can afford copyright-protected software, and non-compliance can be penalized through retaliatory measures. TRIPS can also reduce the quality of software that comes into a country. In the case of hardware, a few large firms own significant blocks of patents and under TRIPS can control the terms on which technology is distributed. Finally, developed country firms also control the information industry. Technology has made it possible both to permit inexpensive copying and access to information and to control and, to some extent, restrict this access (encryption, licensing, online subscription). In 1998, for example, the US Congress passed the Digital Millennium Copyright Act on anti-circumvention measures, which are far more restrictive and, if internationalized, will render TRIPS flexibility on fair use irrelevant and widen the technology gap (Correa, 1999).

Developing countries also lack the legal infrastructure to deal with abuse of monopoly power as effectively as developed countries (CIPR, 2002). This makes it more important for developing countries to design an IPR regime that is the right mix of incentives and access to meet their needs.

Finally, patent enforcement incurs significant costs. Domestically, apart from the initial costs of establishing the institutional structures, training personnel and building mechanisms for filing and examining and enforcing patents, enforcement also varies greatly by industry characteristics. In high-innovation industries, the cost of patent searches to check the existence of 'prior art' can be prohibitive. Internationally, TRIPS brings with it the threat of litigation with high costs. For developing countries, this raises the question of opportunity costs and priorities—whether developing countries should invest in patent litigation and search infrastructure or use the resources to address more important development objectives. The cost of setting up the institutional structure for TRIPS (estimated between US$250,000 and US$1.2 million[15]) could instead be used towards more urgent development expenditures such as achieving the Millennium Development Goals.

Opportunities and challenges for technology under TRIPS. At the same time, TRIPS offers opportunities and challenges for technology acquisition and use. Among them:

- *Articles 66 and 67.* Developed countries are expected to provide incentives to their enterprises to encourage technology transfer to least developed countries to help them create a 'sound and viable technological base'. They are also expected to provide, on request, technical and financial cooperation on legal and institutional issues for countries to help them become TRIPS compliant.

Articles 66 and 67 have not been implemented even as symbolic measures. Technology transfer has not occurred in any recorded, coherent or consistent manner. Technical Assistance has been narrowly limited to TRIPS compliance, without reference to implications for human development.

- *Copyrights and the software industry*. TRIPS reflects the current international ambiguity of the 'expression' dilemma. It treats software programs as 'expressions' protected by copyright. To the extent that these programs merely codify ideas or laws of nature, they cannot be patented, though on proof of industrial application, many are routinely patented in the US. TRIPS is not explicit on software codes as being 'industrial applications' or merely 'codification of laws of nature'. Some argue that national laws can therefore legitimately provide for reverse engineering and deny protection to user interfaces, but the current debate on this is unresolved.[16]

  Strict enforcement of copyright laws under TRIPS can reduce access to computer programs unless balanced with fair-use provisions for educational and research purposes.

- *Bolar Provisions*. This provision allows for the use of an invention without the patentee's authorization so that approval for the generic version can be obtained before the patent expires. This permits marketing of a generic version as soon as the patent expires. Since generic competition lowers prices, the Bolar exception increases the affordability of off-patent products. Since the commercialization of the product does not take place while it is on patent, this early working provision is compatible with article 30.

  While TRIPS does not explicitly refer to this exception, the WTO in the dispute between Canada and the EU ruled that an early working exception is consistent with TRIPS even in the absence of an extended period of protection for the patent. So developing countries can use the Bolar Provision to speed up the production of generics. However, the right to manufacture and stockpile before the expiration of the patent was not deemed consistent.[17]

- *Experimental use*. TRIPS does not explicitly prevent countries from providing exceptions to patents for experimentation.

  Several countries have built experimentation provisions for scientific or academic purposes into their national legislation. These include Argentina, Brazil, Mexico, the Andean Group and the U.S.

- *Applicability of patents, scope of claims and patentability requirements*. As a framework, TRIPS sets international standards and parameters for what constitutes a patent regime but leaves their detailed articulation to the national level. For example, TRIPS requires nations to award patents on the basis of 'novelty' but leaves them to define 'novelty'. If drafted carefully and flexibly, national patent laws could disallow patents for certain chemical categories and still leave them TRIPS-compliant.[18]

  Many developing and least developed countries lack the capacity to design legislation appropriate to their development interests and to defend their domestic legal policies in the face of international pressure. The freedom to set appropriate standards in novelty, prior art and the like is important to build into legislation and needs to be actively used by developing countries.

Food security, biological resources and traditional knowledge

Article 27.3(b) of the TRIPS Agreement allows members to exclude plants and animals and biological processes for the production of plants and animals, other than microorganisms and non-biological or microbiological processes, from patentability. It also requires member nations to extend intellectual property protection to plant varieties through either patents or a *sui generis* system or any combination thereof (see annex 11.1).

The TRIPS Agreement does not explicitly prevent or promote the formulation of additional measures that provide for farmers' rights, or the sharing of benefits in genetic resources or traditional knowledge with countries or communities, as long as these measures do not violate the minimum standards laid down under the Agreement. Most of these measures lie outside the scope of TRIPS though some TRIPS provisions can be used (see annex 11.2) in some cases.

Article 27.3(b) and human development: farmers' rights and food security. The issue of protection for plant varieties is central to the world's food supply. Plant breeding can generate higher yields and lead to seed varieties with stronger resistance to drought, pests and disease.

Many plant varieties come from seeds that farmers in developing countries have selected and sown for many years; these practices form the basis of food security and livelihoods for communities throughout the developing world. Where subsistence-based production is dominant, it is critical to maintain farmers' freedom to save, exchange and replant their own seed.

However, as the biotechnology industry has expanded, it has sought to demand protection for genetically modified seed varieties in order to guarantee returns for high R&D investment costs. Similarly, as developing countries build their industrial seed production capabilities, their views on the utility and shape of a patent and plant variety protection system will also change. 'In areas with good access to urban markets, even small-scale farmers may see a shift to modern hybrids as an attractive option because of their high yield potential. In this case, private sector companies are the main seed suppliers' (FAO, 2001, p. 37) and private breeding companies may wish to seek greater protection.

But with large numbers of farmers engaged in subsistence farming for at least part of the time, a *sui generis* system that protects the rights of farmers to exchange and replant protected seeds is critical to ensuring food supply and livelihoods. This was also acknowledged internationally, at the UN Food and Agriculture Organization Conference-approved International Treaty on Plant Genetic Resources on Food and Agriculture 2001, which established a multilateral system of access to plant genetic resources for food and agriculture, as well as of fair and equitable sharing of the benefits obtained from their use. It also included provisions on farmers' rights.

Several international efforts to create such systems have already occurred. The Union for the Protection of Plant Varieties (UPOV) models of 1978 and 1991 are

two such examples. The 1978 model allowed farmers to save seeds for their own use and breeders to freely develop new seeds.[19] The 1991 convention restricts these exceptions; farmers' privilege is optional but the breeders' exception is preserved. It also implements a *sui generis* system of plant variety protection through which the commercial interests of plant breeders are protected.[20]

The implications of plant variety protection are uncertain and vary according to circumstances (Rangnekar, 2001). A preliminary study in the US showed that it led to increased seed prices for farmers, a falling role for public investment in plant breeding and reduced information flow from the private to the public sector. It also did little to stimulate plant breeding (Butler and Marion, 1996). Further, genetic modifications increase gene uniformity, and this can affect biodiversity in the long run. Developing countries need to encourage incentives for new seed development without restricting the rights of farmers to save and replant seeds through an appropriate *sui generis* system.[21]

However, TRIPS is essentially an inappropriate model for property rights that do not follow the conventional Western model (based on individual rights), and TRIPS mandates countries to deal with the requirements of these community rights through the creation of appropriate *sui generis* systems.

The gender dimension of the impact of IPRs on biodiversity is often overlooked. TRIPS affects women's reproductive health, agriculture, food security and traditional knowledge in health care and medicines. Women are affected in many direct and indirect ways by IP since they are the primary users and protectors of biodiversity. They produce 50 per cent of all food in the world and are also responsible for collecting food, fodder, fuel and water. In the poorest rural households in developing countries, traditional diets often consist of a finely balanced mix of cultivated crops and plants and fruits found in the wild. Women, more than men, tend to use the forest as a source of a wide variety of insects, plants and plant products to supplement the basic diet, especially during food shortages.

Common property resources have been used as grazing lands for animals, communal sources of water and forest resources for food and income. The protection of agricultural biodiversity and common property resources is therefore crucial to the livelihood and food security of poor people in rural areas, particularly women and girls, who are responsible for family welfare but tend to fare worse than the male members in food intake and nutrition. Privatisation of biological resources directly affects women, who lack resources to purchase them and are left relying on shrinking and increasingly degraded common property resources.

Traditional knowledge and benefit sharing. The 1992 Convention on Biodiversity promotes the need to 'respect, preserve and maintain' traditional knowledge for 'the conservation and sustainable use of biological diversity' and encourages the 'equitable sharing of benefits arising from the utilization of such knowledge' (article 8(j)). Many developing countries have lobbied for an expansion

of IP concepts to enable more effective 'protection'[22] of traditional knowledge. In recent years, there has also been increasing attention to the importance of greater recognition of the value and contribution of traditional knowledge to public health and community development.

Traditional knowledge and indigenous knowledge are not the same. Traditional knowledge can refer to knowledge that is in some way nationally held (such as ayurvedic medicine and Chinese herbal medicine), while indigenous knowledge is often associated with groups that are or have historically been marginalized or are trying to pursue a traditional lifestyle. Both traditional and indigenous knowledge have been used for generations by local communities and have contributed to the development of crop varieties, food security and medicines, as well as the emergence and continuation of artistic work in the form of music, handicrafts and artisanship.[23] Traditional knowledge tends to be passed down over generations and held collectively (at the community or national level). It provides legitimacy, as a first step towards benefit sharing of the knowledge and the resources that these communities possess. Further, it is important for the economic development of indigenous communities, since recognition of traditional knowledge protects them against misappropriation or loss, and compensation can also help in broadening its use (Correa, 2001). But, as Correa also points out, protection could also reduce access to and sharing of this knowledge. Many indigenous communities express concern about traditional knowledge being in the 'commons' because that exposes it to private interests that could steal from this commons and use the knowledge as a tool for their future exploitation. Governments need to design protection systems that balance out these costs and gains for their communities' futures.

Unlike other intellectual property, protection for traditional knowledge is not a prerequisite for encouraging future innovation. It is aimed at preserving ownership and sharing the benefits from the commercial exploitation of this knowledge rather than rewarding its creators. From a human development perspective, it is important to prevent corporate misappropriation of knowledge that is already in the public domain. It is also important to codify this knowledge and place it in the public domain with the cooperation of the communities to which it belongs and to clarify rules for benefit-sharing following the same principles that apply to all other sectors—that of balancing the rights of owners and consumers. Indigenous peoples have their own ways of managing and sharing their knowledge, and this will require an acceptance of different models of property rights (collective, customary, community-based rights as opposed to individual rights).

Sui generis systems. Several models of *sui generis* legislation have been proposed and enacted by various countries (see box 11.4). They demonstrate the heterogeneity of developing country intellectual property requirements for best preserving the interests of their populations. Specifically, these systems depart from (but do not conflict with) TRIPS in one of the following manners: they explicitly recognize

BOX 11.4 ILLUSTRATIVE SUI GENERIS SYSTEMS

'Community rights are natural, inalienable, pre-existing or primary rights. The rights of local communities over their biodiversity leads to the formalization of their existing communal control over biodiversity. This system of rights, which enhances the conservation and sustainable use of biological diversity and promotes the use and further development of knowledge and technologies is absolutely essential for the identity of local communities and for the continuation of their irreplaceable role in the conservation and sustainable use of this biodiversity'.

—African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders and for the Regulation of Access to Biological Resources, African Union

'The collective intellectual property of indigenous knowledge, technology and innovations is guaranteed and protected. Any work on genetic resources and the knowledge associated therewith shall be for the collective good. The registration of patents in those resources and ancestral knowledge is prohibited'.

—Article 124, Constitution of the Bolivarian Republic of Venezuela, 1999

'The State expressly recognizes and protects, under the common denomination of *sui generis* community intellectual rights, the knowledge, practices and innovations of indigenous peoples and local communities related to the use of components of biodiversity and associated knowledge. This right exists and is legally recognized by the mere existence of the cultural practice or knowledge related to genetic resources and biochemicals; it does not require prior declaration, explicit recognition nor official registration; therefore it can include practices which in the future acquire such status. This recognition implies that no form of intellectual or industrial property rights protection regulated in this chapter, in special laws and in international law shall affect such historic practices'.

—Article 82, Biodiversity Law, The Republic of Costa Rica 1998.

collective or community rights; they establish different criteria for different product forms and services (separate systems for traditional knowledge, plant varieties, artistic creations) and they define rights in terms of remuneration and benefit sharing. TRIPS provides the flexibility for countries to adopt appropriate *sui generis* systems depending on their specific needs.

TRIPS 'PLUS'

Apart from TRIPS, there are several other regional and bilateral IP agreements that have troubling implications for human development. Many of these agreements are more stringent than the TRIPS Agreement and considerably diminish the room for maneuver for developing countries. Countries that have signed onto these agreements cannot take advantage of the flexibilities in TRIPS discussed above either.

Stricter IP provisions that set the wrong precedents

These agreements go beyond TRIPS in terms of IPR protection. The revised Bangui Agreement of 1999, for example, recognizes regional exhaustion of IPRs and therefore restricts parallel importing to countries that are part of the agreement (see box

BOX 11.5 THE REVISED BANGUI AGREEMENT, 1999

The Organisation Africaine de la Propriété Intellectuelle (African Intellectual Property Organization) has regulated intellectual property in 15 countries of Francophone Africa since the Bangui Agreement in 1977. In 1999, the Bangui Agreement was revised to bring it in line with the TRIPS Agreement. This was important because four of the member nations (Cameroon, Côte d'Iviore, Gabon and Senegal) expected to be TRIPS compliant by January 1, 2000. The Bangui Agreement is equivalent to the national patent law in each of these 15 member countries, and in its revised version goes well beyond the TRIPS Agreement.

The Bangui Agreement recognizes the regional principle of exhaustion of rights, limiting parallel imports to member countries only. Further, compulsory licenses can no longer be granted if the product can be imported; in other words, the lack of locally available patented products is no longer valid reason for compulsory licenses. Licenses to meet special needs can also be granted only for local use and not for imports, leaving unresolved the problem of countries with no production capacity. The revised Bangui Agreement has not yet been ratified by all its members and is therefore not yet in effect. However, its binding conditions make it harder for these countries to source cheaper generics through imports and to promote generic production domestically, leaving few options for access to cheaper drugs.

11.5). The Bilateral Free Trade Agreement between the US and Jordan limits the scope of compulsory licensing to remedies against anti-competitive practices, for non-commercial, governmental use, or in the case of an emergency when the licensee is either a government agency or a government designee, and for failure to meet working requirements (where imports are included in the definition of 'working'). By signing these treaties, developing countries are restricting their policy options without adequate evidence on the impact of these higher standards on human development outcomes.

Other such bilateral agreements that go beyond TRIPS include US agreements with Cambodia, Ecuador and Singapore; EU agreements with Morocco, Palestine and South Africa; and the Swiss-Vietnam treaty (GRAIN, 2001). These agreements are setting a dangerous precedent. By committing to higher standards of protection than mandated under TRIPS, these countries become unable to take advantage of the flexibilities offered under TRIPS. Any attempts to make TRIPS more human development friendly, therefore, will be meaningless for these countries unless they can ensure that their commitment to TRIPS overrides their bilateral and regional commitments.

Harmonization of intellectual property laws

Some agreements seek to harmonize intellectual property laws; the EU-Tunisia agreement requires Tunisia to join the Budapest Treaty by 2002 and binds it to UPOV 1991 as the model *sui generis* system for protection of plant varieties.[24] The EU-Bangladesh Treaty obliges Bangladesh to make 'best effort' to join UPOV 1991 by 2006. The US-Vietnam treaty has similar conditions on UPOV and extends protection to encrypted program-carrying satellite signals apart from the IPRs covered under TRIPS.

Setting the agenda

TRIPS is clearly the most controversial of WTO agreements because of its scope and nature. Despite its exceptions and flexibilities, it has the potential to restrict access to medicines, technology and knowledge, with disturbing implications for indigenous knowledge and food security. An alternative to TRIPS, either within or outside the ambit of the WTO, ought to be debated at the highest level. In the interim, TRIPS can be made more development friendly through key changes to the design of the agreement and in its interpretation and implementation.

Alternative models of intellectual property rights

The relevance of TRIPS is highly questionable for large parts of the developing world. Its asymmetric nature makes it unsuitable to be included in a trade bargaining and negotiation context. While benefits can arise from protecting intellectual property, certain preconditions need to be in place before the gains can be expected. The underlying issue is deeper: countries at low levels of human and technological capability cannot benefit significantly from TRIPS. The experience of developed countries has also shown that strong patents follow industrial development rather than lead it. In Pareto optimal welfare terms, the preceding analysis shows that developing countries are not likely to be even *at least as well off* under TRIPS as they would be outside it. From a development perspective, therefore, TRIPS should be revisited as a required agreement in the multilateral trading regime.

While there has been substantial thinking on alternative models for intellectual property in the last few decades, clearly much more research is required to generate models relevant to the development context of different countries.[25] A related question is how the intellectual property discussions, even if they are to remain a part of the WTO, can be delinked from trade sanctions. This is particularly important because WIPO, which should be the appropriate organization for this function, has an extremely narrow and technical mandate that restricts it to 'promoting protection'. It needs to do much more to help countries design development friendly regimes. Member nations need to begin dialogues to replace TRIPS—and equivalent top-down schemes of substantive IPR harmonization—with alternate intellectual property paradigms that are unrelated to trade sanctions and may include, but are not restricted to:

- An intellectual property ladder, where more stringent laws apply to countries at higher levels of income and technology use, and countries progress from one level of protection to another with improvements in their Human Development Index/Millennium Development Goal indicators.
- A TRIPS-minus model that significantly reduces the length of protection and scope of coverage and increases national decision-making authority on standards and coverage of protection while maintaining a minimalist agenda at the international level.

- An IPR regime with specific opt-out clauses for certain kinds of property rights and specific industries.
- Separate IP regimes for collective and individual rights.

To strengthen the case for replacing TRIPS, there is an urgent need to undertake extensive research and monitoring programmes to measure the potential welfare implications of TRIPS (and alternative intellectual property regimes) on different sectors and segments (consumers, small farmers, large entrepreneurs) of the population.[26]

Admittedly, replacing or fundamentally altering TRIPS will not be easy or sudden, given the differences in national positions on this issue. However, it is critical to begin serious thinking about it at an inter-governmental level.

In a parallel vein and in the interim, governments will need to use TRIPS as best as they can to further their social and economic development objectives. This requires modification in the way the agreement is interpreted and implemented.

Interpretation and implementation of TRIPS

There is little indication, apart from the Doha Declaration, that TRIPS has really been interpreted in the true spirit of balance between rights holders and users. From a legal perspective, the generalist language employed in TRIPS has worked both ways for developing countries; it has allowed for flexible interpretation, but also left the text open to dispute. The latitude in the text requires tremendous specialized legal capacity, which most developing countries lack. Moreover, the experience of Brazil (see box 11.3) has shown that efforts to use this flexibility provoke strong opposition from the developed world.

Finally, the enforcement mechanism—the cross-retaliation mechanism of the dispute settlement process—takes little account of differences in capacity to retaliate. This is costly and harmful for developing countries. Exceptions are limited and specific, and the burden of proof falls on the alleged violator. In practice, this considerably reduces the power of the exceptions.

TRIPS has not been implemented fully in most developing countries, and its future will depend on the decisions taken by the dispute settlement body, which will determine to what extent the agreement is implemented in line with the social and economic development objectives of member nations. On a priority basis, member nations need to:

- Facilitate implementation of exceptions to rights. Compulsory licensing procedures need to be simplified, made easier to invoke and made broader in scope. *Human Development Report 2001* (UNDP 2001) specifies five features of a suitable legal structure (administrative approach, strong government use provisions, production for export, reliable rules on compensation and dispute demand disclosure), which should be used as parameters to determine the ease of implementation of articles 30 and 31. There is also talk of countries invoking broader exceptions, for example, with respect to research tools, life forms,

particular technologies of interest to poverty reduction in developing countries and indigenous knowledge.

- Set the correct precedents in disputed cases. Much of the impact of TRIPS will depend on how the dispute settlement body interprets the agreement with reference to its social and economic objectives, the first test being the use of the Doha Declaration. Although the text is clearly ambiguous, the manner in which decisions will be taken will indicate the actual latitude that the agreement allows. The multilateral trade regime has a responsibility to ensure that interpretation is in line with human development concerns so that further disputes, retaliation and litigation are minimized.
- Create alternative protection regimes as allowed under TRIPS. *Sui generis* regimes to protect plant varieties and integrated circuits need to be designed as appropriate, and there should not be multilateral pressure to promote a particular system (such as UPOV 1991) in countries in which it is not appropriate.
- Under the mandated review mechanism, extend the transition periods for compliance for all developing countries, not just the least developed countries. In addition, strengthen articles 67 and 66.2 to establish time-bound, concrete and measurable parameters for technical assistance and technology transfers in accordance with the development needs of different countries.

Additional policy interventions

Finally, no multilateral intellectual property regime in itself can guarantee that human development objectives will be met. Active government policy intervention is needed in:

- Designing national legislation that addresses human development needs in terms of access to health care and the resources and opportunities for technological progress.
- Ensuring that products are priced to market and, irrespective of their patent status, are affordable to consumers. Part of this strategy should aim at encouraging growth of the generic drug industry and promoting a competitive market structure.
- Investing in research and development, which is critical to developing technological competence. Results of publicly funded R&D, in developed and developing countries, including patents, could then be voluntarily licensed to producers in developing countries.

Any multilateral agreement should reflect a balance of interests among countries and their constituents. An agreement will not be sustainable if the interests of one or more constituents are under- or overrepresented. TRIPS as well as any equivalent system of top-down harmonization needs to better balance the interests of its largest constituency: the poorest sections of the world population. Until the TRIPS Agreement allows their concerns to be adequately addressed—or, at the very least, not actively harmed—it will run counter to its own stated objectives.

ANNEX 11.1

Main provisions of the TRIPS Agreement

Aspect of agreement	Main provisions
Type of protection	
Copyright and related rights (performers, recordings, broadcasting organization rights)	Protection to expression (as in the Berne Convention) Computer programmes (source or object code) treated as literary works Term of protection: minimum term of 50 years from publication or creation (if publication was not made within 50 years from creation) for works not belonging to natural persons
Trademarks	Inclusion of trademarks for goods and services Term of protection: seven-year periods, renewable indefinitely Compulsory licensing not allowed
Geographical indications	Protection of geographical indicators that identify a good as originating from a certain place where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin Special protection for wines and spirits
Industrial design	Term of protection: 10 years
Patents	All fields of technology, for products and processes for 20 years Patentability of plants and animals excludable (other than microorganisms); however, members are required to protect plant varieties through patents or a *sui generis* system Exceptions to exclusive rights: Article 30, limited exceptions allowed Article 31, compulsory licensing allowed under specific conditions Burden of proof reversed to the infringer of a process patent rather than the right-holder
Integrated circuits	Protection to layout designs for a minimum of 10 years No trade in protected layout designs; an integrated circuit containing a protected design or a product containing an integrated circuit that contains a protected design Exceptions in cases where the traders are unaware, and had no reasonable way of knowing, that the article contained a protected layout design, in which case, they are required to pay the right holder 'reasonable royalty'
Undisclosed information	Protection of commercial trade secrets Provision for protection of data for new chemical formulations needed for pharmaceutical or agricultural products against unfair commercial use, unless disclosure is necessary for public interest
Anti-competitive practices	Freedom to restrict rights in case of anti-competitive practices due to abuse of intellectual property rights, and due consultations with other member nations

Enforcement	Fair, transparent procedures Review by judicial authority, no obligation to establish separate judicial system dedicated to IPR resolution Provisional measures and measures at the border need to be made available Provision for criminal procedures and penalties (imprisonment or monetary fines) in the case of trademark and copyright violations Dispute settlement moratorium until 2000 for non-violation cases
Transitional arrangements	Transition periods for developing countries (2000) and least developed countries (2005) subject to extension Members that do not recognize patent rights in pharmaceutical and agricultural products as of date of entry need to provide mechanisms for filing patent applications and provide exclusive marketing rights for five years or provide patent protection, whatever is earlier
Review and amendment	Biennial review mechanism established Amendments based on consensus subject to WTO general rules for amendments to an agreement

Source: Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1C, WTO Agreement.

ANNEX 11.2

TRIPS and traditional knowledge

Options under TRIPS	Interpretation and implementation issues for developing countries
Patents—novelty and inventive requirements	
Latin American countries have argued that processes to use this knowledge and resources may still be protected if their application fulfills the novelty requirement.	Traditional knowledge is not, according to TRIPS language, 'new, does not involve an inventive step and is not necessarily capable of industrial application'. Novelty and inventive requirements are hard to fulfill, since this knowledge has often been in use for generations and is community-based, which means that no effort has been made to keep it confidential.
Copyrights and trademarks	
Artistic expressions of traditional knowledge-holders in the form of literary works, theatrical or pictorial works, textiles, pottery, sculptures, tapestries, carpet designs and the like can be copyright-protected. Further, all goods and services that belong to native communities, different guilds and the like can be identified through trademark protection, which will differentiate and brand them for commercial purposes.	Copyrights and trademarks are also inappropriate because of the collective ownership of this knowledge. National legislation needs to clarify the communal nature of traditional knowledge and specify that it be deemed eligible for copyright protection. This has been done by Bolivia, China, and Morocco.

Geographical indications

Identifying certain products or services as belonging to the particular region from which the product or service derives its characteristics is a powerful way of protecting native industry. Geographical indications currently used primarily for wines and spirits could be extended by developing countries to protect traditional products.	Geographical indications currently cover only wines and spirits. Many developing countries are keen to extend coverage to products that are of special importance to them. Geographic indications do not protect knowledge or technology; they only prevent the misleading use of certain indications by other parties.

Protection of undisclosed information

Traditional secrets of native and indigenous communities that have potential technical or economic value can be protected under Article 39 of the TRIPS Agreement as protection against unfair competition. Control over such information can allow for its regulation in terms of formulating contractual agreements, licensing it and earning remuneration from it.	Most important, TRIPS leaves details of guidelines, classification, and benefit sharing to the countries, which has generated controversial patent grants. Examples include the Ayahuasca plant from Brazil, turmeric from India, and quinoa from the Andean region. Some of these patents were revoked on appeal (turmeric, for example), but these examples illustrate the inability of the TRIPS Agreement to deal with the consequences of Article 27.3b.

NOTES

1. The nine countries are the US, Germany, Japan, Switzerland, UK, Australia, Netherlands, France and Ireland. It should also be noted that some of these transfers come from developed countries. However, given that developing countries are net technology consumers, the bulk of the transfers can be assumed to come from them (World Bank, 2001, p. 133, table 5.1).

2. These include Brazil, China, India, Republic of Korea, Mexico and South Africa (UNDP, 2001).

3. Developed countries have argued that in the wake of increased trade in knowledge-intensive goods, IPR protection is necessary across markets. However, this argument is flawed on several grounds. One, the choice to sell or not depends primarily on the purchasing power of the local populations, not the kind of IPR regime in place as seen in the case of emerging markets like China. Two, increased trade does not imply IPR protection for *all* products in *all* countries and depends on the relative weights different societies place on the rights of sellers versus consumers. Poor countries simply cannot afford the monopoly pricing consequences of TRIPS. Further, since trade occurs in the context of these widely different socioeconomic conditions, the harmonization of laws will not by itself create effective demand for patented products. It is possible, however, that the absence of property rights in other markets can reduce the incentive for full disclosure by patent holders in developed markets because of fears of imitation, and this may affect innovation in the long run. However, this can be balanced through other more appropriate policy interventions in disclosure regulation, research incentives and related areas.

4. Several least developed countries have strict IPR laws through regional or bilateral agreements and are de facto TRIPS compliant already.

5. According to WHO estimates for 1998, infectious diseases accounted for 13.3 million of a worldwide total of almost 54 million deaths. For low- and middle-income countries, one third of the deaths were due to treatable conditions of communicable diseases, shortfalls in maternity care or nutritional deficiencies. These include HIV/AIDS, malaria, tuberculosis, diseases that increase infant mortality (such as diarrhea, diphtheria, tetanus and measles) and the varied causes of maternal mortality. Among these, HIV/AIDS has probably become the most dangerous disease faced by the world today. Since its emergence nearly 20 years ago, over 60 million people have been infected; it is now the leading cause of death in Sub-Saharan Africa and the fourth largest killer worldwide (UNAIDS and WHO, 2001).

6. This was based on increases in the patentable segments of drug markets for select countries. These specific studies were conducted for Argentina and India using detailed price data (WTO, 2001).

7. The Organisation Africaine de la Propriété Intellectuelle (African Intellectual Property Organization) members, comprising 15 countries of Francophone West Africa, have offered a system of pharmaceutical product and process patents since the *Bangui Agreement* of 1977, and the African Regional Industrial Property Organization members, comprising 14 Anglophone countries, have offered pharmaceutical patent protection since at least 1984 (www.ohadalegis.com/anglais/intell per cent20property.htm# membership and www.aripo.wipo.net/protocol.html).

8. This is equivalent to US$2.2 per disability-adjusted life year (DALY), 1/20 of the global average (WHO, 2002, p. 79). DALY measures the number of life years lost due to premature mortality and the number of life-year equivalents lost due to chronic disability.

9. The Doha Declaration was also significant because for the first time, developing countries, led by the African group, and others such as Brazil and India decisively negotiated for a development friendly outcome.

10. The technology effort index is based on two variables: the R&D financed by productive enterprises and the number of patents taken out internationally (in the US) and then standardized and averaged to give a technological intensity index. The industrial performance index is based on manufacturing value added per capita, exports per capita, medium- and high-technology products as proportions of exports and manufacturing value added (Lall, 2001).

11. From an economic point of view, subsidies are a first-best option, since they directly reward innovators; at the same time, they require that the cost of innovation be estimated ex ante and are therefore difficult to implement. By contrast, patents are a second-best solution, since they distort prices and create monopolies. But they are easier to implement because the cost of innovation has already been incurred.

12. Cumulative as in 'each successive innovation builds on the previous one', and complementary as in 'each potential innovator takes a somewhat different research path and enhances the overall probability of reaching a particular goal' (Bessen and Maskin 2000).

13. For more details, see Bessen and Maskin (2000).

14. In some cases, capacity constraints are the impediment. The *sui generis* regime on integrated circuit designs under TRIPS does not prevent reverse engineering. However, few developing countries possess the requisite knowledge or resources to do so.

15. The UN Conference on Trade and Development (UNCTAD, 1996a) estimates these costs for upgrading, training and administration for selected countries.

16. This is primarily because of differing interpretations by US and European courts. Recent rulings in Europe, however, are moving closer to the US position of higher protection, which may imply more stringent implications of TRIPS under case law.

17. WT/DS114/R, 17 March 2000, EU vs. Canada, where the EU challenged a Canadian law that allows for a similar exception to not only allow tests, but also produce and stockpile for release immediately after the patent expires.

18. Detailed illustrations of these forms and conditions can be found in Correa (2000) for the pharmaceutical industry.

19. Members of the 1978 Convention are Australia, Austria, Argentina, Bolivia, Brazil., Chile, China, Colombia, Czech Republic, Ecuador, Finland, Hungary, Japan, Kenya, Mexico, Norway, Panama, Paraguay, Poland, Portugal, Slovakia, Trinidad and Tobago and Ukraine.

20. Members of the 1991 Convention are Belgium, Bulgaria, Canada, Denmark, France, Germany, Ireland, Israel, Moldova, Netherlands, New Zealand, Russia, South Africa, Spain, Sweden, Switzerland, UK and US.

21. The 1978 UPOV version offered one such model, though it is by no means the only model that combines these goals.

22. The term *protection* is the subject of much confusion and contention. On the one side are groups that seek protection of traditional knowledge through IP to enable its commercial exploitation. Some see it as a way to use IP tools to protect traditional knowledge and biological resources from misappropriation and misuse. Some see the possibility that IP protection could be used as a tool for enhancing recognition of the value of traditional knowledge. And some see IP protection as a way to secure certain knowledge as privately held assets that can be commercialized for economic development. There is strong debate about the extent to which IP can advance any of these objectives and the role of IP among a range of other possible policy instruments for advancing these goals. On the other side are those who argue against protection through IP and for the protection of traditional knowledge through investments in communities and their livelihoods. Some groups want to contain the scope of IP, preventing its application to traditional knowledge in any way, to guard against the danger that foreign corporations could appropriate local knowledge through IP tools. And some argue against the commodification of knowledge that comes with the assignment of ownership rights. There are also concerns that governments will appropriate traditional knowledge for national benefit or for elites to benefit.

23. WIPO defines traditional knowledge as 'tradition-based literary, artistic or scientific work; performances, inventions, scientific discoveries, designs, marks, names and symbols, undisclosed information and all other tradition-based innovations and creations resulting from intellectual activity in the industrial, scientific, literary or artistic fields' (WIPO, 2001, p. 25).

24. The Budapest Treaty obliges countries to recognize the physical deposit of a sample of a microorganism as disclosure of an invention for the purpose of patent

protection. For this, the treaty—which has 49 member states, 47 of them from developed countries—relies on a network of recognized international depository authorities which operate special rules on access to the biological samples, especially to avert potential patent infringement. There are 31 depository authorities in 19 countries, all but 2 of them being developed countries (GRAIN, 2001).

25. UNCTAD did significant research in this area in the 1970s (UNCTAD, 1996b).

26. As is being carried out as part of the WHO Essential Drugs Monitor program.

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