CHAPTER 8

PROTECTION OF INTELLECTUAL PROPERTY

MULTILATERAL cooperation in the field of intellectual property rights (IPRs) dates back more than a century. Although certain IPR-related issues were a matter of long standing concern under the GATT—in particular trade in counterfeit goods—it was not until the creation of the WTO that enforceable rules regarding ownership rights to intellectual property were embedded in the trading system. The Agreement on Trade-related Intellectual Property Rights (TRIPS) is unique in the WTO-context in that it imposes obligations upon governments to adopt a set of substantive rules in an area that traditionally has been the purview of domestic regulation. It is an example of what Tinbergen (1954) has called positive integration. This contrasts with the 'negative' integration that is the basic principle underlying GATT disciplines, which involves agreement not to use certain policies that directly affect (distort) trade flows—such as export subsidies or quotas—or if used, imposes constraints on when and how they may be applied.

This chapter provides an overview of the economic rationale for protection of IPRs and the forces behind moves to bring IPRs into the trading regime, the basic elements of the substantive disciplines imposed by TRIPS, and implementation-related questions and conflicts to date.

8.1. Intellectual Property Rights and International Trade

Intellectual property can be defined as information that has economic value when put into use in the marketplace (Maskus, 2000). Ownership rights to intellectual assets span those ideas, inventions and creative expression on which there is a public willingness to bestow the status of property (Sherwood, 1990). Examples of legal expressions of IPRs include industrial property, copyrights and so-called neighbouring or related rights. Industrial property principally concerns protection of inventions through patents and trademarks. The subject matter of copyright is usually described as literary and artistic works. All these ownership rights are territorial in nature, so that the level and conditions of protection are a function of national laws and enforcement institutions.

The rationale for government protection of IPRs depends considerably on the characteristics of the knowledge that is involved. As a first cut, it can be noted that patents, copyrights and neighbouring rights, industrial secrets and industrial designs have one broad commonality: they all fall within the broad category of knowledge goods. They are the result of research and development (R&D)—invention and innovation. In contrast, trademarks and marks of origin are not knowledge goods. Instead, their aim is to allow product differentiation through the creation of brands and to provide information to consumers. Although not knowledge goods, the importance of trademarks and geographic indications of origin in trade—and as potential protectionist devices—is significant. The issues that arise from an economic perspective are analogous to those that result from the use of technical barriers to trade (see Chapter 5). The following discussion therefore focuses primarily on IPRs for knowledge goods.

Knowledge has the characteristics of a public good in that the stock of knowledge does not diminish with consumption: the marginal cost of distributing an additional unit of a knowledge good is zero. Consequently, from a static efficiency perspective the optimal allocation of resources requires that such goods have a zero price. However, this does not take into consideration that inventions have to be produced and that technological innovation can require considerable investment. With a zero price for knowledge goods, investors have no pecuniary incentive to invest in R&D activities. A zero price is therefore socially suboptimal in a dynamic sense, as it discourages innovation and technological progress. Of course, in practice many types of knowledge cannot be diffused at zero cost. Moreover, investments may need to be made to use and adapt knowledge to fit local circumstances. There are costs to imitation, including fixed costs, and many production techniques require tacit knowledge (knowhow) that is difficult to obtain. Thus, creators of many types of inventions are often able to benefit even

in the absence of legal IPRs. The empirical evidence suggests that IPRs are needed not so much to promote inventions (many of which would occur anyway) but to provide an incentive to engage in costly R&D activities, which turn inventions (pure knowledge) into innovations (products or production processes that can be used in industry). The degree of protection afforded to innovations has an impact on inventor's profits and therefore on investment in R&D.

Patents or copyrights grant an inventor or author a temporary monopoly over the use of the invention or the reproduction of a work. They prevent competitors from using their knowledge without permission and/or payment. The rents resulting from the reduction in competition (and thus the ability to charge prices that exceed marginal costs) enable the owners to recoup their investments in R&D and profit from their creation, thus creating an incentive for the production of knowledge. Intellectual property rights also contribute to more rapid public disclosure of inventions, as a necessary condition for the grant of a patent is full disclosure and description of the technology for which protection is being sought. This provides competitors with useful information that can be employed in an effort to 'invent around the patent'—in practice a major source of innovation and technological progress (Maskus, 2000). In the absence of IPRs certain types of industrial inventions and the associated technical information would be kept secret much longer, with detrimental consequences for diffusion.

Governments are generally concerned with establishing an optimal mix between the need for a temporary monopoly to create incentives for the innovation needed to realize dynamic gains (growth driven by technical progress) and the benefits of free access to knowledge. In formulating their IPR policies they must reconcile static efficiency considerations (which imply that knowledge goods should be free or available at very low cost) with the longer term objectives of encouraging innovation and technological progress. There is no unique solution to this problem. Whether a given regime is optimal depends on the objectives and circumstances of countries and the economic sectors involved. Conflicts of interest between countries can easily occur. A priori, the case for harmonization of intellectual property regimes is weak—the type of regime that is most appropriate will vary with the level of development of a country.

Intellectual property rights became a trade issue for a number of reasons. Knowledge-based industries in industrialized countries have grown in relative importance. International trade in goods embodying IPRs increased substantially in recent decades as the share of manufactures in total merchandise trade has expanded, and within manufactures, the share of 'high-technology' goods has increased. Starting in the 1980s, a number of industrialized country governments began to perceive that inadequate enforcement of IPRs in importing countries reduced the competitive advantage of their exporting firms. Although trade in

counterfeit goods had been an irritant for the multilateral trading system for a long time, as technologies for duplication became both more advanced and cheaper, trade in goods embodying 'stolen' knowledge became an increasingly contentious issue.

Examples of counterfeit include imitations of premium goods such as 'replica' Cartier or Rolex watches available on numerous Internet sites, Lego toys and Dunhill handbags, as well as pirate copies of compact discs, software and video films. Resulting disputes were frequently addressed through bilateral channels, with the threat of trade sanctions to induce action by importing country governments. The US played a prominent role in using unilateral threats of trade sanctions to deal with alleged IPR infringements in foreign countries. The two main instruments employed were Section 337 of the 1930 US Tariff Act, and Section 301 of the 1974 Trade Act, as amended by the 1988 Omnibus Trade and Competitiveness Act. The former was used against imports into the US, the latter against foreign governments (Box 8.1.).

The EU has instruments similar to those used by the US to address foreign trade practices, but has traditionally been much less activist than the US (Blakeney, 2004). In part, the recourse to unilateral 'self-help' instruments by major traders reflected the fact that the International Court of Justice, the main dispute settlement forum in this area prior to the creation of the WTO, requires agreement between the interested parties to submit a case to it. Moreover, many of the countries targeted under instruments such as Special 301 were not signatories of the relevant international conventions in this field, so that recourse to international dispute settlement was simply not available. Of course, these reasons did not justify the use of unilateral, threat-based approaches. The appropriate response to the problem would be to seek to negotiate a multilateral agreement that would make all parties better off. Eventually this was attempted in the Uruguay Round.

The use of US trade law provisions was challenged under GATT dispute settlement provisions on a number of occasions. In a 1981 case concerning invocation of Section 337 against Canadian exports of certain automotive springs assemblies, the dispute settlement panel found that the application of US law could be justified under GATT Article XX:*d* (General Exceptions—see Chapter 9). The panel's findings were endorsed by the GATT Council on the understanding that this did not preclude future examinations of the use of Section 337. A subsequent panel considered an EEC complaint concerning a Section 337 action against exports of Aramid fibres by Akzo, a Dutch chemical firm. This panel concluded that Section 337 was inconsistent with Article III:4 (national treatment), because it discriminated against imported products alleged to infringe US patents. Another GATT case was initiated by Brazil, after a decision by the US—following a Section 301 investigation—to increase tariffs on a range of Brazilian products in retaliation against perceived inadequate patent protection

Box 8.1. Sections 301 and 337 of US trade law

Section 301 of the US Trade Act of 1974 gives the President authority to retaliate against foreign trade practices that are deemed to restrict US exports. What such practices were was not spelled out and it was left to the discretion of the President whether or not to retaliate. A Section 301 action is initiated by private parties (in the US), and initially involves pressure being exerted on the foreign government to adopt different policies. If the response is deemed to be insufficient, attempts to negotiate agreements may be made. If negotiations fail, the US may retaliate by restricting access to its market.

The Omnibus Trade and Competitiveness Act of 1988 introduced changes to 301, rendering it much more threatening for foreign countries. Because Congress perceived the President to be insufficiently vigorous in pursuing foreign unfair trading practices, the 1988 Act called for formal investigations of private complaints. It created a new procedure—'Super 301'—that required the US Trade Representative (USTR) to create an inventory of unfair practices in foreign countries, to select priority targets from that list, set deadlines for action to be taken and to restrict the exports of these countries if the governments concerned did not act. Super 301 was complemented by a new 'Special' 301 provision that pertained to the identification of countries where protection of IPRs was deemed to be inadequate. It is Special 301 that is relevant to this chapter.

Section 337 of the US Tariff Act of 1930 allows for investigations to be initiated to determine whether foreign producers of goods imported into the US are supported by unfair trade practices and are injuring an efficiently operating US industry, act to prevent the establishment of such an industry or are anticompetitive (restrain trade). What these practices are is again not defined precisely, but many of the cases brought against imports under Section 337 have involved claims of infringement of US-held IPRs. The Omnibus Trade and Competitiveness Act of 1988, subsequently renewed in 1991 and 1999, eliminated the need to demonstrate that the unfair practice had injured a domestic industry if the allegation concerned a violation of IPRs.

The successful negotiation of the TRIPS Agreement precludes such unilateral action, as allegations of violations of the agreement must be pursued through WTO dispute settlement mechanisms. Requiring the US to use a multilateral rather than a bilateral approach to conflict resolution constituted an important motivation for developing countries to agree to the creation of TRIPS. However, Section 301 is still relevant as it is the instrument through which the US may retaliate if authorized to do so by the Dispute Settlement Body in the case of dispute that has gone through the WTO process.[1]

for pharmaceuticals and fine chemicals in Brazil (see Hudec, 1993, for more on these cases).

Business communities in OECD countries maintained that infringements of IPRs constituted a straightforward matter of piracy and theft, and called for

[1] In November 1998, Sections 301–10 of the US Trade Act of 1974 were the basis of a dispute settlement case in the WTO. The panel concluded these provisions of US trade law were not inconsistent with the GATT because of US undertakings—articulated in the Statement of Administrative Action approved by the US Congress at the time it implemented the Uruguay Round agreements—that it would abide by its obligations under the WTO in the invocation of the law. The DSB adopted the report in January 2000.

multilateral rules and enforcement of IPRs. Many developing countries opposed this strongly, arguing that protection of IPRs was a domestic policy matter, that lack of protection of IPRs on their part had a negligible impact on producers in OECD countries, and that adoption of stronger IPRs would be detrimental to their welfare and development prospects. For example, patent protection was held to be potentially detrimental to food security by raising the costs of inputs (seeds, fertilizers) and to the health of poor segments of the population (which would have to pay more for patent-protected pharmaceutical products). However, opposition was not universal. Some interest groups in developing countries favoured stronger IPRs. Examples were industries that depend on inward FDI and licensing for technology, and producers of indigenous and traditional knowledge.

The eventual acceptance of TRIPS in the Uruguay Round by developing countries reflected a package deal of sorts, comprising a mix of carrots and sticks. The stick was represented by the fear that if they did not agree they would be increasingly vulnerable to unilateral arm-twisting by the US and the EU. Carrots included the (implicit) quid pro quo that was offered by OECD countries in the form of agreeing to the phase-out of the MFA, agreeing to outlaw VERs and to bring agriculture back into the GATT. A growing perception that IPRs could be beneficial also played a role. Examples included protection of indigenous knowledge and cultural heritage, fostering innovation, and giving domestic industries better access to new technologies.

8.2. International Conventions and the GATT

Several international conventions exist that lay down standards for protection of intellectual property. These include the Paris Convention (on patents), the Berne Convention (on copyright), the Rome Convention (on sound recordings and music), the Performance and Phonograms Treaty and the Treaty on Intellectual Property in Respect of Integrated Circuits (Table 8.1). These and other conventions are administered by the World Intellectual Property Organization (WIPO), a Geneva-based UN body. Both the Paris and Berne Conventions were first negotiated over a century ago, and have been periodically updated and expanded. The need for international cooperation on IPRs arose over a century ago because IPRs are country-specific, created by national legislation. As creators of innovations must file for IPRs in each jurisdiction where they want protection, they have an incentive to push governments to adopt similar procedures and standards. Little

Table 8.1. IPRs: instruments and related international agreements

Type of IPR	Instruments of Protection	Subject Matter	Main Fields of Application	Major International Agreements
Industrial property	Patents, utility models	New, nonobvious inventions capable of industrial application	Manufacturing, agriculture	Paris Convention, Patent Cooperation Treaty (PCT), Budapest Treaty, Strasbourg Agreement, TRIPS
	Industrial designs	Ornamental designs	Manufacturing, clothing, automobiles, electronics, etc.	Hague Agreement, Locarno Agreement, TRIPS
	Trademarks	Signs or symbols to identify goods and services	All industries	Madrid Agreement, Nice Agreement, Vienna Agreement, TRIPS
	Geographical indications	Product names related to a specific region or country	Agricultural products, foodstuffs, etc.	Lisbon Agreement, TRIPS
Literary and artistic property	Copyrights and neighbouring rights	Original works of authorship	Printing, entertainment (audio, video, motion pictures), software, broadcasting	Berne Convention, Rome Convention, Geneva Convention, Brussels Convention, WIPO Copyright Treaty 1996, WIPO Performances and Phonograms Treaty, Universal Copyright Convention, TRIPS
Sui generis protection	Plant breeders' rights	New, stable homogenous, distinguishable plant varieties	Agriculture and food industry	Convention on New Varieties of Plants (UPOV), TRIPS
	Database protection	Electronic databases	Information processing industry	European Council directive 96/9/EC
	Integrated circuits	Original layout designs of semiconductors	Microelectronics industry	Washington Treaty, TRIPS
Trade secrets		Secret business information	All industries	TRIPS

Notes: All international treaties except TRIPS, the Universal Copyright Convention and the European Council Directive 96/9/EC are administered by WIPO. Indices calculated using the Hoekman (1996) methodology; see Section 7.3 above.

Source: Braga, Fink and Sepulveda (2000).

harmonization occurred, however, and many international conventions did not go much beyond agreement to apply the national treatment principle.

Most net exporters of knowledge-intensive goods were not fully satisfied with the existing conventions and sought to fill certain gaps through the GATT. For example, the Paris Convention does not stipulate the minimum duration of patents or define what should be patentable. No international agreements existed on proprietary business information (trade secrets). Standards of protection for computer software and sound recordings were deemed to be too weak by the industries concerned. Many countries considered that existing agreements dealt inadequately with counterfeiting and that national laws on trademarks were often too weak or poorly enforced. Finally, producers sought an effective multilateral dispute settlement mechanism to deal with IPR-related issues. Existing conventions did not contain binding, effective procedures in this regard. A major attraction of the GATT was that it had an enforcement mechanism.

The General Agreement on Tariffs and Trade 1947 provisions related to IPRs were quite limited. Among the GATT provisions referring specifically to IPRs are those on marks of origin (Article IX)—which require that these not be used to restrict trade—and Articles XII:3 and XVIII:10, which state that a condition for using QRs for BOP purposes is that these not violate IPRs legislation. The general exceptions provision of the GATT (Article XX:*d*) states that measures necessary to protect IPRs are not subject to GATT as long as they are nondiscriminatory (see Chapter 9). Although GATT rules such as national treatment (Article III), MFN (Article I), transparency (Article X) and nullification and impairment (Article XXIII) applied to actions taken in connection with national enforcement of IPRs, the general relevance of GATT for IPR regulations was limited. In effect, no substantive disciplines applied in this area. Moreover, GATT rules such as national treatment related to products, whereas those of the IPR conventions also concern persons.

Intellectual property rights-related matters raised in the GATT before the Uruguay Round mainly concerned trade in counterfeit goods, and involved trademark and design infringement, access to and misuse of certification marks, appraisal of the value of IPRs in connection with goods being imported, and use of marks of origin. Informal negotiations on trade in counterfeit goods were held during the Tokyo Round, and led to the tabling of a draft code on the subject by the United States. However, no agreement proved possible on this question (Winham, 1986). The subject was first put formally on the GATT agenda in November 1982, when ministers asked the Council to determine whether it would be appropriate to take joint action in the GATT framework on trade in counterfeit goods and, if so, what this action should be. In 1985, a Group of Experts established to advise the Council concluded that trade in counterfeit goods was a growing problem that needed multilateral action, but could not agree on whether the GATT was the right forum for this. This question was resolved at the 1986 ministerial meeting at Punta del Este that launched the Uruguay Round.

8.3. The Uruguay Round Negotiations

The negotiation on TRIPS was one of the more difficult of the Uruguay Round, both politically and technically. The issue was relatively new to GATT and involved a North–South split. Industrial countries, led by the US, sought an ambitious and comprehensive agreement on standards for protection of IPRs of all kinds. They argued that negotiations should consider a wide range of IPRs and that enforcement through the dispute settlement system as well as through domestic laws and customs procedures was a necessity. Led by the same countries that opposed comprehensive discussions on services—India, Brazil, Egypt, Argentina and Yugoslavia—developing countries sought to draw a firm distinction between work on trade in counterfeit goods and IPRs more broadly defined. They were willing to cooperate on the former, but opposed the latter. The first order of priority for poor countries was to ensure that unilateral measures to protect IPRs did not cause barriers to legitimate trade. There was a general concern that greater protection of IPRs would strengthen the monopoly power of multinational companies, and detrimentally affect poor populations by raising the price of medicines and food.

The first two years of negotiations were dominated by disagreements over the mandate of the negotiating group. Areas of disagreement included standards of protection, use of unilateral sanctions, the reach of competition law, and the need for—and length of—transitional periods. One of the most difficult questions was how far new rules could go to protect intellectual property. Was it acceptable for GATT contracting parties to draft substantive standards on intellectual property and embody them in an international agreement? Some developing countries, led by India, argued that GATT or its successor organization was not the right place for setting and enforcing IPR standards. They felt that this was a task for WIPO—which already administered some 20 multilateral conventions—and for individual governments themselves. As far as unilateral sanctions were concerned, developing countries wanted industrialized nations to renounce the option of unilateral trade sanctions. They called for a credible commitment to multilateral dispute settlement procedures. This aspect of the negotiations was complicated by the initial US refusal to change its legislation (Section 337), which a GATT panel had found to be discriminatory in nature (see above). The US linked modifying its laws to conform with the panel recommendations to satisfactory progress in the TRIPS discussions. In the event, at the end of the day the US agreed to comply with the panel's findings, although implementation was problematical (Hudec, 1993).

In contrast to the rest of the Uruguay Round, the TRIPS negotiations were not about freeing trade, but about getting developing countries to implement existing international IPR conventions (and in a number of areas, to go beyond them). The agenda essentially centred on the establishment of minimum standards for IPRs in all countries. The talks divided developed countries—the major net exporters of

knowledge and knowledge-intensive products with high levels of IPR protection that would find it easy to meet whatever minimum standards were adopted—from many developing countries, invariably net importers, many of which did not have IPR legislation. Although the final outcome went beyond existing international conventions in a number of respects, the major implications were for developing countries.

As discussed further below, from an economic perspective a good case can be made that the TRIPS talks were zero-sum in the short run, as stronger enforcement of rights in developing countries could result in large transfers from the South to the North. But gains from trade across IPR issues were clearly available. Developing countries wanted to control US trade policy (301), maintain sufficient discretion to safeguard national interests, and minimize the adjustment costs of strengthening IPRs protection. They were also keen to see stronger disciplines on the use of contingent protection, agricultural support in OECD countries and improved access for exports of labour-intensive manufactures. The objectives of the high-income industrialized countries centred on stronger IPR standards, multilaterally agreed, with multilateral enforcement. Incentive structures also differed over the course of the Uruguay Round.

Important in this connection is that developing countries were not really a cohesive bloc on the TRIPS issue. Some of the poorer nations that had tightened their domestic protection of IPRs unilaterally so as to attract FDI and technology or as a response to the threat of US action, feared being undercut by competitors in other developing countries without legal protection. Many also came to the view that stricter IPR protection was in their interest in the longer run, not only because it was a necessary component of a more general move towards a market economy, but also because of the link between IPRs and FDI and related access to knowledge. But it was the scope for cross-issue tradeoffs that ultimately created the pre-conditions for a successful conclusion of the negotiations. In exchange for agreeing to TRIPS, developing nations obtained the prospect of better market access for their textile, clothing and agricultural exports. Without a deal on IPRs it is unlikely that the Agreements on Textiles and Clothing, on Agriculture and on Safeguards could have been concluded.

8.4. WTO Rules On Intellectual Property Rights

The TRIPS agreement is an integral part of the WTO—its provisions apply to all members. It is a complex agreement—with seven major parts and 73 articles—that

covers copyrights and related rights (rights of performers, broadcasters and phonogram producers), layout-designs of integrated circuits, geographical origin indications, trademarks, industrial designs and patents (Table 8.2). The agreement:

(1) establishes minimum substantive standards of protection for the above rights;
(2) prescribes procedures and remedies that should be available to enforce these rights; and
(3) extends basic GATT principles such as transparency and nondiscrimination to IPRs (although allowance is made for the fact that a number of international conventions permit departures from MFN or national treatment in certain circumstances).

The agreement builds upon the main international conventions administered by the WIPO. In a number of instances TRIPS established disciplines that go beyond existing international norms. With respect to copyrights, WTO members are required to comply with the substantive provisions of the Berne Convention for the protection of literary and artistic works, except regarding protection of moral rights. Computer software is to be protected as a literary work under the Berne Convention, and copyright is to extend to computerized databases—something that was not part of the Berne Convention. As of 1994, 57 developing countries and two industrialized nations had not provided protection of computer software (Braga, 2004).

Another significant addition to international rules on copyrights are the provisions on rental rights, giving authors of computer programs and producers of sound recordings the right to authorize or prohibit the commercial rental of their works to the public. A similar exclusive right is also applicable to films. Performers are to be given protection from unauthorized recording and broadcast of live performances (bootlegging). Here again TRIPS goes beyond existing IPRs disciplines as the Rome Convention on rights of performers, producers of sound recordings and broadcasters has few signatories, particularly among developing countries. The TRIPS agreement requires governments to allow recording companies from one country to attack unauthorized reproduction and sale of its products within another country. The protection for producers of sound recordings and performers is to be for at least 50 years, whereas broadcasting stations are granted a 20-year period during which use of their programs requires their authorization.

The agreement defines the types of marks eligible for protection as a trademark or service mark. It also specifies the minimum rights that members must grant to mark owners, subject to certain reservations. Marks that have become well known in a particular market enjoy additional protection. For example, owners of foreign marks may not be forced to use their marks in conjunction with local marks. Governments must provide means to prevent the use of any geographical indications that mislead consumers as to the origin of goods and are required to

Table 8.2. Major provisions of the TRIPS agreement

Article	Comments	Subject
Cross-cutting provisions		
3.	National treatment	Applies to persons
4.	Most favoured nation treatment	Reciprocity exemptions for copyright; grandfathering of existing regional and bilateral agreements
6.	Exhaustion	No rule imposed except nondiscrimination
Copyright and related rights		
9.	Apply Berne Convention	Does not require moral rights
10.	Programmes and data	A significant change in global norms; compilations protected as literary works
11.	Rental rights	A significant change in global norms
12.	Term of protection	Minimum 50-year term. Clarifies corporate rights
14.	Neighbouring rights protection for phonogram producers, performers	
Trademarks and related marks		
15.	Protectable subject matter	Confirms and clarifies Paris Convention
16.	Rights conferred	Deters use of confusing marks and speculative registration; strengthens protection of well-known marks
19.	Requirement of use	Clarifies nonuse. Deters use of collateral restrictions to invalidate marks
21.	Licensing and assignment of rights	Prohibits compulsory licensing
22–4.	Geographical indications	Definitions; additional protection for wines and spirits
Industrial designs		
26.	Protection	Minimum term protection: ten years
Patents		
27.	Subject matter coverage	Patents to be provided for products and processes in all fields of technology. Biotechnology covered. Exceptions allowed for plants and animals, as long as a system is in place to protect plant varieties
28.	Rights conferred	Exclusive rights on sale and importing of patented product or process
30.	Exceptions to rights conferred	Allows limited exceptions to patent rights as long as this does not unreasonably prejudice the right holder
31.	Other use without authorization of right holder	Specific disciplines on use of compulsory licences
		Domestic production can no longer be required; nonexclusive licenses with adequate compensation
33.	Duration of protection	Minimum 20-year patent length from filing date
34.	Burden of proof for process patents	Defendants must prove their process differs from the patent
Integrated circuits designs		
36.	Scope of protection	Protection extends to articles incorporating infringed design. Significant change in global norms

(*cont.*)

Table 8.2. (Continued)

Article Comments	Subject
38. Term of protection	Minimum ten years
Protection of undisclosed information	
39. Trade secrets protected against unfair methods of disclosure	New in many developing countries
Abuse of IPRs	
40. Control of anticompetitive practices	Wide latitude for competition policy to control competitive abuses, subject to other WTO disciplines
Enforcement of IPRs	
41–64. Requires civil, criminal enforcement	Detailed provisions on minimum standards for enforcement Agreement not to bring nonviolation cases until TRIPS Council determines the scope and modalities for such complaints
Transitional arrangements	
65–6. Transition periods round to 2016	5 years for developing and transition economies; 11 for LDCs, extended during the Doha.
70. Pipeline protection for pharmaceuticals	Not required. Provision for maintaining novelty and exclusive marketing rights
Institutional arrangements	
71. Review and amendment	TRIPS Council to monitor and review the agreement on expiration of the transitional period

Sources: Adapted from WTO (1994); Maskus (2000); and Hoekman, Mattoo and Sapir (2007).

discourage any use that would constitute unfair competition. Trademarks containing a geographical indication that could mislead the public on the true origin of the product are to be refused or invalidated. Geographical indications for wines and spirits are given specific protection. The agreement calls for a multilateral system of registration and notification of geographical indications for wines to be negotiated.

The protection of industrial designs under TRIPS was also strengthened relative to existing international norms. Designs are to be protected for a minimum period of 10 years. Owners of such designs may prevent the importation, sale or production of products bearing a design that is a copy of the protected one. World Trade Organization members must comply with the substantive provisions of the Paris Convention (1967) on patents. At least 20-year patent protection is to be provided for almost all inventions, including both processes and products. The 20-year lower bound implies harmonization toward the standards maintained by industrialized countries. It was an important rule because certain countries, including OECD members, that provided for shorter patent terms had to lengthen that protection—an issue that led to a WTO dispute settlement case brought by the US against

Canada (Box 8.2.). The provisions of the TRIPS Agreement on protection of patents required profound changes in many countries. In 1994 some 25 developing nations and four industrial nations did not recognize patents for pharmaceutical products, and 31 developing and six industrialized countries provided no protection for plant varieties (Braga, 2004).

The permitted exclusions from patentability comprise plants and animals (other than microorganisms), computer programs, and biotechnological processes. However, plant varieties must be given protection, either through patents or a *sui generis* (special or more specific) system. Inventions may be excluded from patentability for reasons of morality, public order or because of therapeutic, diagnostic or surgical usefulness. As a general rule, rights conferred in respect of patents for processes must extend to the products directly obtained by the process.

There is substantial flexibility in defining the conditions for awarding patent protection, including recognition of narrow claims, provision of utility models and pre-grant opposition procedures. Maskus (2000) notes that such elements of IPRs systems helped generate Japanese productivity gains after the Second World War by encouraging local entrepreneurs to pursue process innovations. There are no restrictions on the grounds that may be used to impose compulsory licensing to correct for anticompetitive practices (abuse of IPRs—Article 31 TRIPS) or for reasons of a national emergency. Thus, WTO members retain broad scope for compulsory licensing, including for nonworking of rights (Watal, 2000). This reinforced developing countries bargaining power vis-à-vis large drug suppliers

Box 8.2. Do new WTO obligations apply retroactively?

The TRIPS Agreement specifies that patent duration should be at least 20 years. However, Section 45 of Canada's Patent Act provided a 17-year term to patents granted prior to 1 October 1989. The US considered that this violated the TRIPS Agreement (invoking Article 33 TRIPS). Canada held that a WTO member should not be required to extend the duration of protection for existing patents that were granted for a shorter period prior to the existence of TRIPS, invoking the basic principle of nonretroactivity of treaty obligations. Canada referred to Article 28 of the Vienna Convention on the Law of Treaties, which provides that a treaty's provisions do not operate to bind a party in relation to any act, fact or situation which predates the treaty's entry into force for that party. Both the Panel and AB rejected Canada's claim on the basis of the TRIPS Agreement provision (Article 70.2 TRIPS), which created obligations in respect to all existing subject matters and decided that Canada was required to afford the mandated minimum of 20 years protection to patents that existed when TRIPS entered into force. The Appellate Body considered that Canada's interpretation would preclude the application of virtually the whole of the TRIPS Agreement (WT/DS170/AB/R, 18 September 2000).

in international markets, providing them with an additional instrument to lower the cost of medicines.

Once patents approach expiry, generic manufactures can step in and compete for market share. A standard tactic of holders of valuable patents is to try and maximize the length of protection by seeking to make it more difficult for competing firms to ramp up production before the patent expires so that they can flood the market once it has ended. Another early WTO dispute brought by the EC against Canada clarified what type of activities by competitors are permitted before the patent expires. The Canadian law in question allowed generic manufacturers to test patented products before the expiration of the patent. This practice was upheld by a 2000 WTO panel (WT/DS170/AB/R), but a companion provision allowing production and storage of such products before the patent expiration was declared in violation of TRIPS. The panel found that Article 30 TRIPS (allowing limited exceptions to the exclusive patent rights as long as these do not unreasonably prejudice the legitimate interests of patent holders) covered the regulatory excepting for testing but not the storage exception.

The Treaty on Intellectual Property in Respect of Integrated Circuits (1989) provides the basis for the protection of layout designs of integrated circuits. The TRIPS Agreement goes beyond this treaty by requiring a minimum protection period of ten years and extension of rights to products incorporating infringing layout designs.

Trade secrets and know-how of commercial value are protected against acts that conflict with honest commercial practices such as breach of confidence. However, the relevant provision of TRIPS (Article 39), does not define what acts are unfair, leaving governments free to allow for reverse engineering (Maskus, 2000; UNCTAD-ICTSD, 2005). Test data on agricultural or pharmaceutical chemicals submitted to the authorities in order to obtain marketing approval must also be protected against unfair commercial use.

World Trade Organization members are obliged to provide procedures and remedies under their domestic law for effective enforcement of IPRs by right-holders (both foreign and national). Such procedures should be fair and equitable, entail reasonable time limits and not be unnecessarily complicated or costly. Requirements on the civil and administrative procedures and remedies include provisions on evidence of proof, injunctions, damages and other remedies. In cases when delay is likely to result in irreparable harm to the right-holder, prompt and effective provisional measures must be available. The Agreement also deals with measures to be taken at the border by customs authorities against pirated or counterfeit goods.

Article 40 TRIPS recognizes that some licensing practices or conditions pertaining to IPRs may have adverse effects on trade or impede the transfer and dissemination of technology. It allows for members to specify in their legislation practices or conditions that constitute an abuse of IPRs and give rise to intervention by the

government. The TRIPS Agreement provides some flexibility by leaving it to the discretion of governments how to regulate 'exhaustion' of IPRs. In legal parlance, IPRs are exhausted once an invention or a product embodying the IPRs has been sold, allowing the purchaser to make fair use of the product for private purposes and to re-sell. Under an international exhaustion rule, a protected product, once introduced in a market anywhere in the world, can be imported into the country without permission of the IPRs holder. Under a national exhaustion rule the goods may only be re-sold to buyers that are resident in the country—that is, 'parallel imports' are prohibited. International exhaustion allows buyers to purchase patented and branded products wherever they find the most favourable prices.[2] An intermediate approach is to apply a regional exhaustion rule—which is the case under EU law. Countries with large knowledge industries tend to apply a national exhaustion rule, reflecting the interests of industry, whereas those that do not frequently adopt international exhaustion.

All members had one year following the date of entry into force of the WTO to implement the agreement. Developing countries were entitled to a delay of an additional four years for all provisions of the agreement with the exception of MFN and national treatment. If a developing country had to extend product patent protection to areas of technology that were not protected before TRIPS (for example, pharmaceuticals or agricultural chemicals), it could delay the application of the provisions on product patents to such areas for an additional five years. Least developed countries were granted a 12-year period to conform to the agreement (until 1 January 2006), with the possibility of requesting a longer period if deemed necessary. They did so during the Doha Round and obtained an extension through 2016.

These transition periods are all rather arbitrary in that they do not reflect careful assessments of likely implementation costs. Instead, they reflect issue linkage considerations: the transition period for the abolition of the MFA was ten years, and liberalization under the ATC was heavily back-loaded. This helps explain why developing countries (non-LDCs) insisted on a ten-year transition for implementation of the key part of the TRIPS agreement—patent protection of pharmaceuticals. Although the TRIPS agreement may be too riddled with holes as far OECD right-holders are concerned, developing countries committed themselves to doing more on the IPRs front than OECD countries did with regard to traditional issues such as contingent protection and market access. Indeed, many TRIPS disciplines applied with immediate effect, including in the patent area the requirement to provide for exclusive marketing rights during the transition period (Watal, 2000). Simulation studies and other types of economic analysis of the outcome of the Uruguay Round discussed later in this chapter suggest that on balance the costs of

[2] The term parallel signifies that the transactions take place alongside sales by the IPRs owner through its own distribution channels. See Abbott (2007).

TRIPS for developing countries may have outweighed the benefits obtained in other areas of the negotiation.

8.5. Implementation and Disputes

Implementation of the TRIPS agreement involved substantial adjustments and costs for many developing countries. Bringing legislation into conformity in a way that best reflects the interests of a country takes time and scarce human resources. Creating or strengthening the domestic institutions required to enforce the new laws costs money. Such costs did not need to be incurred by OECD countries, as they were already largely in compliance with TRIPS standards and had the necessary enforcement infrastructure in place. Developing countries had to revise or adopt new legislation, ensure that judges were trained in the application of IPR law, and educate customs and other enforcement authorities so that they understood the new rules and had the tools and resources to apply them. Efforts needed to be made to educate the business community and civil society as well.

Designing an intellectual property regime that is relevant for the situation and characteristics of the economy of a developing country is not straightforward. Simply copying the regime that is in place in an OECD country will not do. The type of intellectual property that needs to be protected varies across countries, as does institutional capacity. Rather than develop a patent office along European or US lines it may be more important to develop mechanisms to protect the fruits of indigenous culture such as music or crafts. How to do this in a cost-effective manner requires research and trial and error experience. At the time the TRIPS agreement was being negotiated, insufficient knowledge existed to allow such concerns to be embodied in the drafting of the agreement.

Finger and Schuler (2000) reviewed World Bank projects in the area of IPRs and concluded that the costs of implementing the TRIPS agreement could be substantial. In large part this is because required reforms go beyond drafting new legislation. What matters are the administrative structures needed to apply the new norms (for example, bolstering the capacity to review applications, including investments in computerized information systems and extensive training for staff) and buttressing enforcement capacity. Although developing countries were granted a transition period to implement the agreement, in many cases the time required for upgrading IPR regimes spans a longer period than was granted. Many countries did not have the resources available to undertake the comprehensive reforms and institutional strengthening that was required. Little analysis exists of

the actual costs that are associated with full implementation of TRIPS. However, a feature of IPRs is that they are valuable assets. Thus, firms and investors are therefore ready to pay for the costs of obtaining a right, be it a patent, trademark or copyright. In practice, patent offices—once up and running—can pay for themselves from fees. The implication is that the lion's share of the implementation costs are likely to be associated with training of officials and the potential 'diversion' of scarce administrative capacity to an agenda that is may not be a priority from an economic development perspective.

During the first ten years of the WTO over two dozen cases referring to TRIPS were submitted for dispute settlement. Given that many of the major substantive provisions of the agreement did not yet apply to developing countries, most of these cases involved the major OECD countries. However, India was one of the first countries to be subjected to a complaint, following separate cases filed in 1996 by the US and the EC against Japan's copyright regime for sound recordings (Box 8.3).

The US was the most active early user of dispute settlement, with the majority of cases brought against the EU. It complained, inter alia, of an alleged lack of protection of trademarks and geographical indications for agricultural products and foodstuffs in the EU, failure to grant copyright and neighbouring rights in

Box 8.3. Early TRIPS disputes: music royalties in Japan and the 'mailbox' provision in India

The first dispute settlement cases brought under TRIPS were against Japan, brought by the US and EC (WT/DS28 and WT/DS42). They were similar to the dispute between the US and Canada regarding length of patent protection: Japan did not provide at least 50-year copyright protection for sound recordings. The case never went through the panel process. Japan reached a mutually agreed solution with the complainants, agreeing to revise its legislation to bring it into conformity with TRIPS.

The first case under TRIPS to go through both the panel and AB stages was launched by the US in late 1996 (WT/DS50). (Here again the EU followed the US example, bringing its own case a few months later.) The US challenged India's implementation of the so-called mail box provision (Article 70 TRIPS) with respect to patent protection for pharmaceutical and agricultural chemical products. This specifies that a developing country delaying implementation of TRIPS obligations in an area of technology that was previously unprotected must secure the legal security of patent applications. This was meant to ensure that no subsequent claimant would be able to assert the same patent once the transition period for implementing the TRIPS obligation expired. The panel and AB found that India had failed to establish a mechanism that adequately preserved novelty and priority in respect of applications for product patents for pharmaceutical and agricultural chemical inventions, and was also not in compliance with Article 70.9 of the TRIPS Agreement by failing to establish a system for the grant of exclusive marketing rights. Two related cases were subsequently brought against Argentina.

certain EU member states, nonenforcement of IPRs in Greece (allegations that TV stations in Greece regularly broadcast copyrighted motion pictures and television programmes without the authorization of copyright owners), Denmark's alleged failure to make provisional measures available in the context of civil proceedings involving IPRs, and Portugal's term of patent protection under its Industrial Property Act. The EU in turn has taken the US to task on legislation that precludes registration or renewal in the United States of a trademark if it was previously abandoned by a trademark owner whose business and assets were confiscated under Cuban law (Section 211 of the US Omnibus Appropriations Act) and a law that permitted commercial entities such as bars and restaurants to play music and television without payment of royalties (Section 110:5 of the US Copyright Act). The latter two cases are illustrative of the types of disputes that have been brought under TRIPS: on the one hand addressing a conflict where specific commercial interests are at stake, and on the other seeking to ensure that general legislation complies with TRIPS—even if the law in question appears to be quite reasonable.

At issue in the trademark case (WT/DS/176) were the rights to the name Havana Club. The EU filed the complaint on behalf of a French company, Pernod-Ricard, which sold Cuban-produced rum under the Havana Club trade name (as part of a joint venture with a Cuban state-owned enterprise) but could not do so in the US because Bacardi, a Bermuda-based firm, had obtained the US rights to this name from the original Cuban owners whose assets were nationalized by the Cuban government in 1960.[3] The Cuban family that had the original trademark in the US had let it lapse in 1973, and in 1976 the Cuban state export company registered the name in the US. However, 20 years later, Bacardi sought out the original family members and obtained their agreement to use the name and began to distribute rum in the US market under the Havana Club label. This led Pernod to sue in the US courts. Williams (2005) notes that part of the Bacardi response to the Pernod threat was to lobby successfully to revise existing US law by including specific language on trademarks that had been confiscated by Cuba into the general spending bill that was being considered by the US Congress at the time (the US Omnibus Appropriations Act).

The end result of the WTO panel and AB process was to find that Section 211 of this Act violated national treatment and MFN (because it denied trademark owners access to US courts by not giving them legal standing). However, the US was free under TRIPS to establish the criteria to determine ownership of IPRs such as trademarks and trade names, including the right to refuse registration of confiscated marks. As a result of the case, the US agreed to revise its legislation to bring it into compliance, but the commercial dispute between Bacardi and Pernod on the trade name continued to be pursued in the US courts. As in other, more

[3] What follows draws on the discussion in Williams (2005).

high-profile cases such as *Bananas* and *Gambling*, this dispute illustrates that the ultimate or even proximate commercial interests that are at stake may not involve firms headquartered or based in the country that brings it to the WTO.

The second case concerned nonpayment of royalties for music or programmes broadcasted in bars and similar retail spaces (WT/DS160), permitted under Section 110 of the US Copyright Act. This dispute revolved around the 'minor exception' doctrine—that the violating practice only has a minor effect on the rights-holder. The case was brought by the EU on behalf of a complaint lodged by the Irish Music Rights Organization. The genesis of the complaint was an amendment by the US of its copyright law (introduced via the Fairness in Music Licensing Act of 1998) that expanded the coverage of exemptions for certain retail establishments to pay royalties for music.

The 2000 WTO panel distinguished between the 'business exemption' applying to a very large percentage of bars and restaurants and 'home-style exemption' applying to a limited set of cases where the music (not recordings) was being broadcast by means of a single, standard TV set or radio of a kind commonly used in private homes. It concluded that 'business exemption' could not be considered 'defined and limited' in the sense of TRIPS Article 13 because of the large percentage of establishments to which it applied. It considered, however, that the 'home-style exemption', which applied to 13–18 per cent of small establishments, was not a major potential source of royalties and that in any event royalties would be difficult (costly) to collect. Therefore, the 'home-style exemption' was considered not to violate the TRIPS Agreement. The US did not appeal the report.

This case illustrates both how the TRIPS agreement is more intrusive than the traditional GATT disciplines, and how international disciplines pertaining to domestic regulatory regimes may have unintended and unanticipated consequences (the *Gambling* case is another example). Surely US negotiators had not foreseen the implications of TRIPS for the legislation that was contested in this case. In effect, the Irish musicians' organization was able to contest a US domestic political economy equilibrium that was reflected in a US law that balanced the interests of IPRs holders and buyers/users. Given that the practices that the EU complained about were put in place by the legislature of the country with the strongest music and broadcasting industry in the world, presumably the provisions of the US law were acceptable to US producers. After all, the proprietors of the bars and restaurants will have bought or otherwise paid for the music they play in their establishments.

An obvious question is how much was at stake in this case. Because the US was not able to revise its legislation within the reasonable period established by an arbitrator, the US and the EC notified the DSB in 2001 of their agreement to pursue binding arbitration under Article 25.2 of the DSU to determine the magnitude of the loss incurred by the EU rights-holders (the level of nullification or impairment of benefits). The arbitrator determined that the loss amounted to

€1,219,900 per year or US$1.1 million at the then prevailing exchange rate—a rather trivial amount. As part of the Wartime Supplemental Appropriations Act, signed into law on 16 April 2003, the US Congress approved a US$3.3 million appropriation—to cover three years of payments—which was subsequently paid to the European Grouping of Societies of Authors and Composers, at the request of the European Commission. This was the first time that WTO members made use of arbitration (invoked Article 25 of the DSU) to establish the level of compensation to be paid in a case.[4]

Developing countries have also become more active in safeguarding their IPRs interests. For example, in 1998 Thailand asked the US to revoke registration of the 'Jasmati' rice trademark of a US firm. Objections have also been raised to the use of variants of the name Basmati for rice, with India taking steps to protect 'Basmati' as a geographical indication. Tea plantations in the region of Darjeeling launched a campaign to protect the 'Darjeeling' brand from foreign imitations, with a Belgian watchdog agency asked to identify the use of the name 'Darjeeling' in international markets.

8.6. The Doha Round

In the run-up to—and during—the Doha Round, IPRs continued to remain among the more controversial areas of trade and business regulation, reflecting a sharp North–South divide. Despite their success in putting in place the TRIPS Agreement, IPRs lobbies continued to push for expanding and strengthening rights. They favoured extending the reach of the patent system, reinforcing protection of copyrights and neighbouring rights and extending rules on geographical indications. Advocates of expanding TRIPS pointed to increasing R&D and positive effects of trademarks and geographical indications for value added in developing country business, and noted ways in which the system might be beneficial to developing countries in terms of protection of traditional knowledge and biodiversity. The critics raised concerns about higher prices and access to essential medicines, limited availability of new seed varieties, and risks of abusive licensing practices.

Concerns about the implications of TRIPS became an integral part of the anti-WTO message propounded by many NGOs. The Doha Round offered an opportunity for the two camps to pursue their different visions of what constitutes

[4] The funds were used for combating piracy on the Internet and supporting actions for copyright strengthening and enforcement in Europe and the United States. The details of the arbitration award are discussed in Grossman and Mavroidis (2003).

appropriate regulation of IPRs. Proponents of stronger disciplines were mostly on the back foot during the Doha period, devoting much of their energy and resources defending what they had negotiated in the Uruguay Round. Critics conversely were more successful in addressing some of their major concerns as regards the TRIPS agreement, which included access to essential medicines and protecting traditional knowledge and biodiversity.

Essential medicines

Among some 10 million people who pass away each year due to infectious diseases more than 90 per cent live in developing countries (WHO, 2005). The most dangerous infectious diseases in low-income countries of Africa, Asia and Latin America include HIV/AIDS, respiratory infections, malaria and tuberculosis. The TRIPS Agreement (Article 31: f) recognizes that IPRs should not come in the way of action by governments to address pressing public policy needs. Thus, in a case of an important public health emergency, if local drug manufacturers are unable to produce enough to satisfy the demand for the medicines protected by patents, a WTO member government can require the producer to licence the medicine to other firms to address any (expected) shortage. The TRIPS rules negotiated in the Uruguay Round stipulated that production under compulsory licensing must be predominantly for the domestic market. This created a problem for developing countries with no production capacity as they would need to import the drugs.

The question of how to produce 'global public goods' in a world where countries have divergent norms and preferences, in part reflecting differences in economic development, is increasingly prominent on the international policy agenda. The TRIPS Agreement raised concerns regarding at least three public (or quasi-public) goods: the generation of new knowledge, the maintenance of rules fostering open trade and competition, and the provision of public health (Shaffer, 2004). Many developing countries viewed the TRIPS Agreement as an impediment in their efforts to combat public health emergencies by restricting availability of patented medicines and by transferring scarce resources to patent-owners and producers in high-income countries. As developing economies are often overwhelmed by infectious diseases, access to affordable medicines was a vital concern.

The TRIPS Agreement became part of the equation insofar as the relevant drugs were protected by patents. Fixing the imbalance between countries with and without local production capacity as regards their ability to invoke compulsory licences for pharmaceuticals came to be perceived as a test as to whether the WTO could address development concerns.

The most publicized aspect of the debate has been over HIV/AIDS in Africa. As access to low-cost drugs is increasingly recognized as a key component of treatment strategies, the patent status (and resulting high cost) of the new antiretroviral drugs

were perceived as a barrier to prevention and treatment.[5] The pharmaceutical industry argued that the HIV/AIDS problem in Africa resulted from poverty and should be treated as such, suggesting for example that the appropriate solution was for high-income governments to provide subsidies to pay for the drugs. They maintained that serious limitations on patent protection would be counterproductive, resulting in less R&D on products of particular interest to the developing world. A leading role in this campaign was assumed by one of the most influential Washington industry associations, representing some 48 pharmaceutical companies: the Pharmaceutical Research and Manufacturers of America (PhRMA).

The industry's stance resulted in severe criticism of the TRIPS Agreement by a broad constellation of nongovernmental groups as well as some governments and international bodies. In August 2000, the UN Sub-Commission for the Protection and Promotion of Human Rights adopted a resolution that recognized 'the apparent conflict' between the TRIPS Agreement and international human rights law. The resolution underlined that the implementation of TRIPS did not adequately reflect the fundamental nature and indivisibility of human rights, including the right of everyone to enjoy the benefits of scientific progress and its applications, the right to health, the right to food, and the right to self-determination (Article 2).

Another influential critical voice was a report by the UK Commission on Intellectual Property Rights, sponsored by the UK Department for International Development (DFID) and chaired by a distinguished Stanford University Law Professor, John Barton. The report expressed serious doubts concerning the benefit of the current IPR regime for the poor segments of world population and pointed to the system's shortcomings in the area of public health and development (Barton et al., 2002). Numerous NGO campaigns echoed such comments and the possible adverse impact of IPRs on access to medicines became a high profile matter of public debate.

At the same time, the pharmaceutical industry sought to enforce TRIPS through action in national courts as well as through their governments in the WTO. The highest profile such effort occurred in South Africa and attracted worldwide attention and opprobrium (Box 8.4). Another instance of such pressure centred on Brazil's decision to increase supplies of generic medicines to address the HIV/AIDS epidemic, which prompted the US to initiate a WTO dispute case in 2000. At issue was a requirement for 'local working' for patents. The US held that the Brazilian law violated TRIPS Articles 27–8 and the national treatment principle by stipulating that a patent was subject to compulsory licensing if the subject matter of the patent was not 'worked' in the territory of Brazil (Abbott, 2002). The

[5] In 2003 the triple combination of drugs that was most effective in combating AIDS cost over US$10,000 a year in developed countries, compared to US$200–300 in India, where they were produced without patent protection (Subramanian, 2006). The disparity in prices was even larger in practice if account is taken of the fact that most developing country citizens are not insured and must pay medical expenses privately.

Box 8.4. The South African Medicines Act

Faced with the HIV/AIDS crisis in the early 2000, South Africa passed the Medicines Act, which included a provision that allowed for fast track compulsory licensing of medicines and authorization for parallel importation of drugs. Both provisions were motivated by a desire to give South Africans access to the lowest priced sources of supply of vital pharmaceutical products. The Act permitted the importation of patented medicines that had been commercialized in another market by the patent owner (i.e. South Africa adopted an international exhaustion rule). Pressured by its pharmaceutical industry, the US, with support from the EU, pressed the South African authorities to modify the Act and remove the offending provisions. One of the arguments was that the law breached South Africa's obligations under the TRIPS Agreement. In 2001 a number of major drug corporations brought their case to the Pretoria High Court. Several months later, following a mass media campaign supported by NGOs such as Oxfam and Médecins sans Frontières, the litigation was withdrawn in order not to deteriorate even further the public image of the pharmaceutical companies concerned.

Source: Braithwaite and Drahos (2006). See www.cptech/ip for more on the history of the dispute.

case was settled with an agreement to create a bilateral 'Consultative Mechanism' under which Brazil will notify the US government in advance in the event that it finds it necessary to issue a compulsory licence. There is nothing in the WTO that would require such bilateral notification, and arguably the outcome was a face-saving exercise that is not enforceable.

The widespread criticism of the TRIPS Agreement eventually resulted in the November 2001 Doha Declaration on TRIPS and Public Health. This reaffirmed the right of all countries to protect public health and stated that TRIPS should be implemented in a manner supportive of rights 'to promote access to medicines for all'. The Declaration also recognized the problem confronting countries without industrial or technical capacity to produce drugs in being able to benefit from invoking compulsory licensing provisions and instructed the TRIPS Council 'to find an expeditious solution to the problem of the difficulties that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement' (WTO/MIN(01)/DEC/2) and to do so before the end of 2002.

Several possible solutions were proposed by WTO members: amending the TRIPS agreement; adopting a broader interpretation of Article 30 to authorize third parties to produce and sell drugs without the consent of the rights-holders; promising not to initiate dispute settlement proceedings in case of departure from Article 31(f)—which requires that a compulsory licence must be authorized 'predominantly for the supply of the domestic market of the Member authorizing such use'; and introducing a 'waiver' for Article 31(f) in the sense of Article IX(3) of the WTO (Bourgeois, 2008). It was the latter approach that was eventually adopted

following highly contentious negotiations on the scope of—and eligibility for invoking—a provision to facilitate the use of compulsory licensing. A 2003 WTO General Council Decision allowed WTO members to grant compulsory licences with a view to exporting pharmaceutical products to countries with no or insufficient manufacturing capacities (WT/L540). The 2001 Doha Declaration on TRIPS and Public Health, which was outside the single undertaking, was practically the only area in which results had been obtained in time for the review of progress made in the Doha Round during the Cancun ministerial meeting in 2003.

The above process of negotiation was accompanied by significant pressure by the US and a number of other developed countries aimed at minimizing the impact of the 2001 Declaration. There was a strong effort to limit the number of eligible diseases (drugs) and to obtain agreement on a specific list of countries to which the modalities of operationalizing the 2001 Declaration would apply. In the end, the 2003 Council Decision simply states that the drugs concerned address the public health problems, including those mentioned in the 2001 Declaration, which emphasized HIV/AIDS, tuberculosis, malaria and other epidemics, but does not define a limited set of diseases. It also does not limit the country eligibility except through a requirement that the country concerned have insufficient or no manufacturing capacities. In December 2005, at the Hong Kong ministerial meeting, the Decision was made permanent through adoption of an amendment to the TRIPS Agreement that transposes the Decision into an Article 31 *bis* TRIPS. (This was the first ever, and to date only, amendment to a WTO agreement). Under the WTO (see Chapter 2) general entry into force of an amendment requires acceptance by two-thirds of the membership. As of August 2008, counting the EU-27 as one, 18 WTO members had ratified—including the US (the first to have done so).[6]

The Decision (and Article 31 *bis*) waives the obligations of Article 31(f) by allowing WTO members to export pharmaceutical products under a compulsory licence to another country that has invoked the provision to address a public health need (national emergency or other circumstances of extreme urgency or in cases of public noncommercial use are mentioned as examples). It requires importing country governments to put in place mechanisms to prevent re-export and parallel trade—a matter of great concern to the industry. Medicines traded under the regime should be packed, labelled and coloured differently to ensure that they can be identified by Customs if they were to enter into parallel trade, and special reporting requirements are imposed. Over 30 WTO members indicated that they would not use the system set out in the 2003 Decision as importers—the result of efforts by the EU, Japan and the US to limit the extent to which the original TRIPS discipline in this area might be weakened (General Accounting Office, 2007).

[6] The 2003 waiver applies to countries that have not yet formally accepted the amendment.

The media debate on patents for medicines contributed significantly to the legitimacy woes of the TRIPS Agreement and the WTO. Concerns by the pharmaceutical companies regarding their public image and support resulted in a change in the hard-line stance taken by the pro-IPR lobby. As a result of the opposition and skilful advocacy by economic development NGOs, patent-holding multinationals began to shift from a strategy that put significant emphasis on litigation to one that began to do more to capture the moral high ground. A number of firms decided to provide developing countries with affordably priced retroviral drugs (that is, engage in differential pricing strategies) or to donate drugs.

The shift coincided with a growing awareness that the drug industry had to rethink its business model, ranging from innovation and patent strategy to marketing and advocacy. A new business model that went beyond the industry's traditional and substantially vertical integration in R&D, production and marketing medicines began to gain popularity. It involved, in particular, a move towards more offshore outsourcing, increased interest in generic drug production, and a convergence of drugs, devices and diagnostics that promised new opportunities for growth and escape from low-margin market segments subject to commodity pricing. The trend towards business modernization combined with public pressure to soften the industry's position with respect to the health matters governed by the TRIPS Agreement resulted in a more flexible approach on these issues by OECD countries. These changes in strategy and positions facilitated agreement on the 2003 Council Decision on TRIPS and Public Health.

How important is the relaxation of the TRIPS disciplines in this area? To date, use of compulsory patent licences by developing countries has been limited. Examples include Taiwan in 2005 for the Avian flu (Tamilflu—a substance owned by Roche),[7] Thailand in 2006 and 2007 for HIV/AIDS and heart disease drugs, and Brazil in 2007 for a HIV/AIDS treatment. The first use of the provision established by the Council by an LDC was a compulsory licence for export of an antiretroviral drug (TriAvir) from Canada to Rwanda in 2007. To implement this Canada issued a compulsory licence allowing a firm based in Canada, Apotex, to use nine patented inventions for manufacturing and exporting TriAvir to Rwanda. Apotex specified that it would sell and export 15.6 million tablets at the cost of its production (about US$0.40 per tablet) and obtained a royalty-free two-year-compulsory licence on the nine Canadian patents to do so in late 2007. Hestermeyer (2007) argues that this was not a good test case as Rwanda could have imported a similar combination drug from India, which was available at US$0.14 per tablet. (Not yet being under patent in India, Rwanda could simply have imported the drug from India.) He also notes that the Canadian firm concluded

[7] Other countries such as Indonesia, the Philippines and Thailand threatened to follow suit. Roche responded by stating that these countries are free to manufacture generic versions of Tamiflu because it was not patented in their markets.

that a generic manufacturer has few incentives to go through the WTO process for markets as small as Rwanda and that the two-year maximum term for a compulsory licence in Canada was not enough to recoup the investment associated with producing the drug from scratch (the compound was not sold in Canada).

In practice the compulsory licensing mechanism and the TRIPS flexibilities more generally appear to have had only a limited effect on the availability of medicines for the poor (see e.g. Sihanya, 2005). One reason for this is that many drugs are *not* patented—that is, there are generics already on the market. Another reason is that many developing countries first need to incorporate the possible provisions on compulsory licensing, parallel imports, limits on data protection, use of broad research and other exceptions to patentability into their legislation (Abbott and van Puymbroeck, 2003). Factors such as inadequate distribution systems, the lack of trained personnel to administer the drugs, weak incentives for generic drug manufacturers to supply small quantities to LDCs with no production capacity, and the necessity to use distinctive packaging and notification requirements, all limit the benefits of the compulsory licences (Correa, 2004). According to then-EU trade negotiator, Pascal Lamy, the compulsory licensing arrangement resolved 'about 10% of the problem of access to medicines by developing countries' (*Wall Street Journal*, 2 September 2003). Many public health experts will agree—clearly the public health challenge in poor countries extends far beyond access to low-priced patented drugs. Effective and efficient delivery and distribution mechanisms are also needed, as are infirmaries and hospitals, health-care providers, etc.

Notwithstanding these arguments, the indirect effect of the attention devoted to this matter was undoubtedly significant. Although it is the case that lowering prices of drugs is only part of the answer to public health needs in developing countries, from an economic perspective the approach pursued in the TRIPS and Public Health discussion makes a lot of sense. The countries that cannot afford high-priced drugs are not important in generating the R&D incentives needed to induce investment in the development of new drugs. Thus, pricing drugs at marginal cost in these markets will not have adverse dynamic effects on innovation. As long as re-exports can be precluded, firms—whether generic producers or those that invented the compounds—will be able to cover the costs of servicing these markets by pricing at levels that cover marginal costs while charging higher income markets (much) more, in the process recouping R&D costs. The required market segmentation is critical for developing countries to be able to benefit from this differentiated pricing. The alternative of a uniform pricing rule would be far inferior to low-income markets.

One result of the TRIPS decision was to strengthen the already existing incentive confronting pharmaceutical firms to engage in beneficial price discrimination by establishing a 'price ceiling' for the drugs concerned—defined by the cost of producing and shipping drugs to the markets concerned without having to pay royalties.

The pharmaceutical industry responded by reducing prices for antiretroviral drugs for developing countries, although it should be stressed that this reflected more than just the WTO Decision—the whole episode was a public relations disaster for the industry that it sought to address in part by a willingness to provide drugs at low or zero cost. Greater resources are now also being devoted to accelerate the development and promote the distribution of vaccines for other diseases such as malaria and TB. The fact that these countries are poor means that diseases which predominantly occur there will not be the focus of R&D without public subsidy of some kind. This problem has been recognized by OECD governments and major foundations that are committed to investing substantial resources in such diseases.

That said, conflicts between the industry and governments and regulators will persist, and pharmaceutical companies will continue to defend their rights and base business decisions in part on the strength of IPR enforcement in any given market (Box 8.5).

Traditional knowledge, life forms and biodiversity

Traditional knowledge covers a variety of assets, including genetic resources, indigenous medicinal knowledge and designs. Traditional medicinal knowledge relies on plant treatment, which being obvious or in the public domain, is usually not patented or not patentable. But, a medicine derived from plants that use traditional know-how may be patented by a pharmaceutical company. This raises two types of potential problems for developing countries: (1) IPRs may be acquired by such companies, precluding use by local communities; and (2) holders of the traditional knowledge may not be adequately compensated, if at all.

Finger and Schuler (2004) have noted that TRIPS is mostly about knowledge that rich countries own and want to sell to poor countries. They suggest that the as yet unwritten part of the TRIPS Agreement should be about knowledge that poor people in poor countries generate and might want to benefit from. This in turn suggests asking questions such as: how could one prevent inappropriate patenting of traditional knowledge? What could be done to ensure that providers of traditional knowledge are not excluded from benefits resulting from interventions based on that knowledge? One result of developing country interest in addressing these types of questions was that protection of traditional knowledge became an item on the agenda of a review TRIPS called for in the Doha Ministerial Declaration (para. 19). Technical issues requiring solution included agreeing on an operational definition of traditional knowledge, determination (identification) of 'right-holders' and establishing the legal basis for protection of those forms of traditional knowledge that were in the public domain.

The Doha agenda included a review of TRIPS Article 27.3(b), which allows plants and animals other than microorganisms and essentially biological processes for the

Box 8.5. Business interests and patent protection of drugs

The Indian Patent Act prohibits the granting of patent protection to inventions involving a new form of a known substance that does not result in the enhancement of the known efficacy of the substance (Section 3(d)). A Swiss-based multinational company Novartis applied in 2006 for patent protection of its cancer drug Clivec in India. The Indian Patent Office rejected the patent application on the grounds that the subject matter was anticipated and obvious in the light of prior art and that Clivec could not demonstrate sufficient improvement in treatment efficiency over the molecule imatinib, on which the drug was based.

Novartis disagreed with the decision and filed a case with the Madras High Court in Chennai alleging that Section 3(d) of the Indian Patent Act was incompatible with the TRIPS Agreement and the Indian constitution. The court upheld the constitutionality of India's restrictions on 'ever greening' pharmaceutical patents and declined to rule on the compatibility of the Indian national law with the TRIPS Agreement. Novartis decided not to appeal the decision to the Indian Supreme Court. In such circumstances, the only way to determine the compatibility issue would be for Switzerland to initiate a WTO dispute—a move that was unlikely given the political sensitivity of public health issues and patent protection in developing countries. The Novartis court case had already drawn much attention worldwide, with some 420,000 people signing a petition urging the company to drop the case. One of the signatories, Anglican Archbishop Emeritus Desmond Tutu, commented that the court's decision reflected 'what we know in our hearts: that our society's priority must be people's health, not extra profits from patents for rich corporations'. The Paris-based NGO 'Médecins sans Frontières' referred to the High Court's verdict as 'critical for us doctors, who now feel confident that we will be able to continue to rely on India as a source of affordable medicines for our patients'. In August 2007 Novartis announced that it was shelving its investment plans in India, stating that the High Court's ruling was not an invitation to invest in India's R&D. The CEO of the pharmaceutical giant was quoted as saying 'We will invest more in countries where we have protection'.

Source: *Bridges* 11 May (2007); *Financial Times*, 22 August (2007).

production of plants and animals (other than nonbiological and microbiological processes) to be excluded from patentability as long as a system was put in place to protect plant varieties. At issue here were questions on such issues as how to define *sui generis* protection of plant varieties and how to deal with ethical questions relating to the patentability of life-forms. Could biological and genetic resources in their natural state be protected by IPRs? Should these resources be protected as intellectual property so that developing country local community or farmers could benefit from their conservation?

The TRIPS Council became the forum for negotiations on the protection of traditional knowledge and folklore as well as the question of the relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD). A group of developing countries, including Brazil and India, proposed

that TRIPS be amended to preclude bio-piracy, i.e. uncompensated and unauthorized appropriation of genetic resources, and to ensure fair and equitable sharing of benefits obtained from traditional knowledge or folklore. A proposed amendment to TRIPS would impose conditions for patents based on biological material or traditional knowledge, including disclosure of their source and evidence of benefit-sharing and prior informed consent. It was also suggested that IPRs could be an instrument for implementing the Convention on Biodiversity, e.g. by providing for sharing of benefits resulting from the use of genetic resources and the disclosure of the geographical source and origin of genetic material (Llewelyn, 2003).

Prior to the July 2008 mini-ministerial meeting in Geneva, proponents of the CBD-related amendment to TRIPS pushed for a disclosure requirement in order for patent applications to be processed, and proposed that members agree to define 'the nature and extent' of prior informed consent and access and benefit-sharing. The biotechnology industry opposed these proposals and raised concerns that the disclosure of origin requirement would result in an undue burden on patent applications, given also that the concept of 'sufficient disclosure' remained subjective. They also considered that any requirements to go ever further in pinpointing the source of genetic material could result in such specificity as to make satisfying the requirement impossible. With respect to biodiversity, the WTO clearly cannot go beyond the creation of rights. This is obviously not sufficient. Maintaining biodiversity requires incentives to ensure that developing country farmers and communities have a self-interest in maintaining diversity stocks. This suggests a need to align the WTO with the CBD to provide a global solution to biodiversity concerns.

Geographical indications

The TRIPS Agreement (Article 22) defines geographical indications (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'. It requires GIs to be protected in order to avoid misleading the public and to prevent unfair competition; establishes a higher standard of protection for GIs for wines and spirits (Article 23), and provides for exceptions in instances when a name has become generic (e.g. 'cheddar cheese') or is protected through a trademark.

The TRIPS definition of GIs goes beyond the related and long standing concept of *appellations of origin*. The latter require a quality linkage between the product and its geographical origin to be established, with the geographical name designating the product (e.g. *Bordeaux* or *Jerez*) (Maskus, 2000). Appellations of origin were already incorporated in the Paris and other IPR conventions and thus covered by TRIPS. Geographical indications were a new form of IPR that was embodied in TRIPS, although they had been talked about in the context of the EU and WIPO.

The EU has long favoured stronger global protection of its regional food names by extending the TRIPS rules on GIs to go beyond wines and spirits to include food and other products. In the EU view, 'cheddar' may be generic, but names such as Black Forest ham and Parmesan cheese should be reserved for food products actually produced in those regions of Europe. The EU has implemented a regime within its member countries that does so. For example in 2003, Denmark's cheese producers were required to stop using the Greek name 'feta' for their version of that type of cheese, even though Danish producers supplied more feta cheese to European consumers than did Greece. In line with its own regime, the EU has proposed that the TRIPS Agreement be extended to include a system of 'registered geographical indications' that would require both proof of geographical origin and compliance with applicable product standards.

In response to the EU pressure, the Doha ministerial declaration (para. 18) called for negotiations on the establishment of a multilateral system of notification and registration of GIs for wine and spirits. Two issues were the focus of negotiation: creating a multilateral register for wines and spirits, and strengthening the level of protection for products other than wines and spirits.

The EU efforts to widen the scope of the WTO rules on GIs were actively opposed by a number of countries, including Australia, Brazil, Canada, South Africa and the US as well as other non-European agricultural exporters. These countries took the view that many of the names for which the Europeans wanted protection had become generic. Indeed, many well-known foods have their origin in Europe and many European-origin names have been widely used in the marketing of these foods on world markets. The matter has been a source of conflict for many years, including a number of GATT and WTO disputes (Box 8.6). For example, some US wine producers have used the name 'Champaign' to market sparkling wine—a practice that infuriated the vineyard owners from the Champagne region in France. In the opinion of the opponents of EU strategy, stronger protection of GIs would simply be yet another form of protectionism for the already overprotected EU farm sector.

The subject is not one that divides developed and developing countries—as noted, opponents included the US and other OECD countries such as Australia, and proponents included a number of developing countries such as India, Kenya and Thailand. Proponents regard GIs as an instrument that can be used to help them in marketing their products and to establish and defend market shares and create niches. Opponents take the view that consumers can be informed of the origin of goods through labelling—and already are—and that quality can be assured through trademarks.

The EU made the matter a major negotiating objective in the Doha round, especially after the removal of most of the Singapore issues from the table. There is little doubt that protection through GIs can result in significant increases in profits for producers through premium pricing. Econometric studies have found

Box 8.6. Disputes over food names: scallops and ham

Indications of geographic origin are helpful to both producers and consumers because they reduce information (search) costs. However, national regulations concerning the description or geographic origin of a product may also be used as a protectionist device. A case in point was a 1993 French regulation concerning the description of scallops (a shellfish), which reserved the use of the expression 'Noix de coquille de St. Jacques'—under which scallops are sold in France—to shellfish originating in France. As a result, Canadian scallops—which are identical to French scallops in size, texture and use–could not be labelled as coquille de St. Jacques. Canadian exports of scallops to France dropped, as distributors were confronted with the need to re-label the product under another name. This significantly weakened the competitive position of Canadian scallops on the French market. Canada requested a panel on this issue in 1995 (WT/DS/7), alleging that the nondiscrimination provisions of the WTO had been violated. Peru and Chile, two other producers, followed with a similar case. The panels were suspended after the parties came to a settlement.

Geographical indications are particularly contentious for alcoholic beverages. For example, domestic distributors in Chinese Taipei have sold spirits labelled 'bourbon', cognac' or 'scotch', there being no legal framework setting rules for claims concerning content, age or origin. Some consumers also found it difficult to differentiate between brand name products and imitations. Thus, 'Chimas Teacher Extra Old Whisky' produced in India was aimed at those who had heard of Chivas or Teachers, two well-known international brands. Such examples are found in many countries, and have been brought to WTO dispute settlement panels. For example, the EU successfully contested the distribution of 'Chimas Teacher' whisky in India.

Two opponents to the EU approach towards regulation and protection of GIs and marks of origin—the US and Australia—brought a case against the EU in 2003 (WT/DS/174 and WT/DS/290). In its 2005 report, the panel ruled against the EU because it did not allow the registration of non-European food products. The report pointed out that the EU cannot stop producers of Florida oranges or growers of Idaho potatoes from protecting their food names in the EU simply because the US has not put in place a system equivalent to that in Europe for protecting such geographic indications. (The EU refused to recognize such trademarks unless other countries granted similarly broad protection to all European food names—i.e. by seeking such reciprocity it violated the national treatment rule.) The panel finding implied that an EU list of some 600 protected foods and 4,000 wines would have to be opened up to non-European products. However, the ruling partially backed the EU argument that GIs should not be superseded by pre-existing trademarks, and concluded that both forms of IPRs should coexist.

This case has many practical implications. For example, it may be seen as a setback for attempts undertaken by Anheuser-Busch, the US brewery, to ban a Czech beer producer from using the Czech equivalent of the Budvar brand as a rival to the company's trademarked Budweiser beer. However, the ruling also limited the rights of the Czech company, which had registered three geographical indications related to the Budvar name. The Czech company cannot attempt to assert its control over the Budweiser name worldwide, because of another part of the panel report that concluded GIs cannot be extended to include translations into other languages.

Source: WT/DS290/R (2005); *Financial Times* 18 November (2004).

that consumers are willing to pay more for GI products. Fink and Maskus (2006) survey some of the literature, which includes a study of Bordeaux wines that found certain regional designations command a large price premium—as much as US$15 per bottle in the case of the 'Pomerol' designation; a study of the Spanish market for meat products that found products bearing the 'Galician Veal' label commanded a premium of US$0.21 per kilogram; and a study that concluded wines with a 'Napa Valley' designation commanded prices that are 60 per cent higher than wines with simply a 'California' designation. Surveys of consumers have also demonstrated that many buyers—although not necessarily a majority—would pay a premium for origin-guaranteed products. The role of GIs is substantially greater in international trade than in domestic commerce, because informational problems are more pronounced when consumers and producers are located in different countries.

As noted by Maskus (2003), in many respects GIs are similar to trademarks in terms of their economic effects: they increase the incentives to invest in enhancing quality in a region (including control of free riding or shirking by some suppliers in the region, as this would harm the investment in reputation) and reduce consumer search costs and uncertainty regarding the quality or other characteristics of a product by making it more difficult for 'imitators' to sell similar products, which even if not of lower quality have not contributed to the collective investments in creating the 'brand' or market. Geographical indications are also similar to trademarks in that they do not protect the underlying production technology or knowledge used to make the product: Australian wine makers are free to adopt the techniques used in the Bordeaux or Bourgogne regions of France.

The major difference between GIs and trademarks is that the latter are owned by firms, whereas GIs almost by definition will benefit many producers located in a certain area. As a result, exploitation of GIs can be associated with high coordination and other costs. This helps to explain why there are hundreds of thousands of registered trademarks in the world (Baroncelli, Fink and Javorcik, 2005), but fewer than 1,000 registered GIs. An implication is that small regions in low-income countries may not be able to mobilize the resources required to create and exploit GIs as a competitive tool. However, GIs are a potentially useful instrument to define and protect certain forms of traditional knowledge, as GIs can be designed to provide collective right to such knowledge insofar as it is produced or exists in a specific region (Maskus, 2003).

Economic effects of patent protection

In addition to direct administrative compliance costs, implementation of the TRIPS Agreement also gives rise to economic costs and benefits for a country and has cross-country distributional implications. As noted above, IPRs essentially

act to create a temporary monopoly for innovators to recoup their investment in inventive activity. As a monopoly, IPR holders can be expected to extract some proportion of consumer surplus by equating marginal revenue to marginal cost. This will generate a static deadweight loss for the products that benefit from protection. Nations that have producers of knowledge will profit, the more so the greater the net export position is. If the industry can exert market power on world markets, not just at home, because of the IPR, the equation becomes even more beneficial. For countries without production, IPRs can only generate a loss. The only source of potential gain for these countries is if global IPR enforcement raises R&D and innovation incentives. This is rather unlikely to be significant given their small markets.

The extent to which prices will rise in response to the exercise of stronger market power is a function of several variables (Maskus, 2000). First, market structure matters crucially. The number of firms (home and foreign) competing with rights-holders, the nature of that competition, the ease of market entry and exit, quality differentiation among products, openness to trade and the feasibility of arbitrage (parallel imports), and wholesale and retail distribution mechanisms are all factors that determine the impact of IPRs. Oversimplifying for purposes of discussion, the more competitive the market for a product before the introduction of IPRs, the lower the substitutability of protected for generic products, and the more concentrated the industry producing protected varieties, the greater the impact of IPRs on prices is likely to be. Second, the less elastic is demand, the greater the price-increasing effect of enhancing market power through IPRs. Third, the strength of competition policy and the willingness to intervene directly through regulation will determine outcomes. For example, policies towards exhaustion of rights (discussed previously) can have a substantial impact. Finally, much depends on the wording of IPRs legislation, including the scope of protection, the provisions for reverse engineering as a means of fair competition and fair-use exemptions in copyright.

In economies that are significant net importers of technologies and knowledge-intensive goods and services, the rents paid by consumers to producers (right-holders) are transferred outside the country. This implies that in an international context, IPRs are not simply a mechanism to redistribute income among different groups in a given society, with an associated static efficiency deadweight loss. They involve significant transfers across countries. Net importers may experience a reduction in national welfare (a terms-of-trade loss) as foreign producers extract rents from domestic consumers.

Maskus and Penubarti (1995) conclude that the strength of national IPRs regimes exerted a statistically significant positive effect on imports of manufactures. That is, stronger protection leads to more trade. Smith (2001) found that strong foreign patent rights increase bilateral exchange on average across all countries, with the positive market expansion effect being particularly pronounced

for countries with strong imitative abilities. There is also empirical evidence for US multinationals to suggest that strong foreign patent rights confer a locational advantage that increases affiliate sales and licences relative to exports of goods embodying the IPR-protected knowledge and results in increased flows of knowledge to affiliates of the US multinational corporations (Smith, 2001).

A series of studies, both theoretical and empirical, undertaken after the Uruguay Round generally conclude that the net transfers from South to North will be positive and may be large. Theoretical analyses consistently suggest that incentives and thus optimal policies differ across countries depending on level of development, which in turn affects key variables such as innovative capacity (which affects whether a country is going to focus more on imitation and acquisition of existing knowledge); preferences for types of innovation (e.g. Diwan and Rodrik, 1991, argue that IPRs may be in the interest of developing countries as a way of encouraging investment in technology that that is more relevant to their needs/preferences); and the locational choices of multinationals and the importance of FDI as a channel for knowledge transfer relative to trade or licensing, which in turn depends on many variables, but includes the level of human capital and the strength of IPRs (Yang and Maskus, 2001; Glass and Saggi, 2002). In general, there is a consensus supporting the early conclusion by Deardorff (1992) that uniform standards for IPRs will not maximize world welfare or be in the interest of developing countries. At the same time there is also a consensus that IPR protection will be too weak when policies are set independently by individual governments, because governments will ignore the effects of national IPR policies on consumers and firms in the rest of the world (Grossman and Lai, 2004). Empirical research on the effect of IPRs on economic variables generally finds that stronger IPRs—often measured on the basis of an index of IPRs constructed by Ginarte and Park (1997)—tends to have negative impact on variables such as welfare, growth and innovation in developing countries (e.g. Schneider, 2005; Chaudhari, Goldberg and Jia, 2006; Falvey, Foster and Greenaway, 2006).

A noteworthy attempt to estimate the magnitude of the potential transfers associated with TRIPS is McCalman (2001). He incorporated information on the volume and price of technology transfers through patents, including the likelihood of local imitation across markets, to estimate the net present value of patents if countries were to broaden the coverage and enforce TRIPS-type standards of protection. Estimates of the transfers that could arise are reported in Table 8.3 (results for only a subset of countries are replicated). The first column of Table 8.3 reports estimated net transfers associated with the TRIPS Agreement, which are defined as the increase in the value of patent rights held by residents of a country minus the increase in the value of patent rights granted to nonresidents by that country. (Both figures increase due to the higher patent standards agreed upon in the TRIPS Agreement.) Among the winners are US, Germany, France and Switzerland. Most countries experience a net static loss from (stronger) patent

Table 8.3. Estimated transfers associated with the TRIPS Agreement

	TRIPS Net Transfer (US$ Million) (1)	Net Transfer (% of GDP) (2)	TRIPS Gross Transfer (US$ Million) (3)	% of Gross Transfer Due to Broader Coverage (4)
US	4,553	0.09	73	0.00
Germany	788	0.07	384	0.00
France	568	0.06	0	0.00
Switzerland	22	0.01	288	0.60
Netherlands	−96	−0.04	313	1.00
South Africa	−113	−0.13	123	0.40
Belgium	−224	−0.15	293	0.64
South Korea	−326	−0.18	328	0.92
Spain	−345	−0.10	367	0.45
Japan	−439	−0.02	896	0.00
Mexico	−444	−0.26	445	0.29
India	−526	−0.19	526	0.34
UK	−541	−0.06	1,044	0.00
Brazil	−926	−0.28	930	0.11
Canada	−1,023	−0.21	1,107	0.41

Source: McCalman (2001).

protection. The US stands out as the main winner with benefits that are almost six times greater than those of the second largest beneficiary. Among the most significant predicted losers—some of them unexpected— are Canada, Brazil, the UK, India, Mexico, Japan, Spain and South Korea. Canada's ranking is consistent with the country's alignment with developing countries in the Uruguay Round negotiations on TRIPS. The position of the UK and Japan largely reflects a substantial increase in the value of both countries' patent protection, a rise that is not matched by the increase in value of foreign patents held by the countries' citizens.

The second column puts the size of the net transfer into perspective by comparing it with the country's GDP. It shows, first of all, that the relative size of these transfers is rather small given the size of the national economy. Columns 3 and 4 permit one to distinguish between the transfers associated with a broadening of the sectoral coverage of patent protection and those associated with increasing enforcement effort. They suggest that the transfers from developing countries are mainly due to an increase in enforcement rather than extended coverage of protection, and that for advanced countries the transfer source tends to be equally divided. McCalman points out that this breakdown might imply that, in the future, developing countries will favour the extension of the coverage of patent protection rather than improving enforcement.

Comparing the figures in Table 8.3 with the results of one of the best quantitative assessments of the Uruguay Round commitments to liberalize trade in

goods—Harrison, Rutherford and Tarr (1997)—suggests that the net TRIPS transfers increase the short (long) run gain for US by 40 (20) per cent. Conversely, developing countries see their net gains diminished as the result of the TRIPS Agreement, especially in the short run. For some countries, such as Mexico, the overall net static effect is actually negative—implying a loss from the round, reflecting not just TRIPS but the loss in preferential access to its major export market, the US, as a result of the MFN tariff concessions made by the United States. Of course, all these calculations must be considered illustrative only, as they pertain only to patents and are dependent on the type of model used for estimation purposes and the accuracy with which the results of the Uruguay Round commitments, and, more generally, the WTO are captured (Lybbert, 2002). Much of what the WTO is all about—certainty, rules, tariff bindings, transparency, etc.—is not captured by the empirical models. However, the model-based analyses do serve to illustrate that the TRIPS Agreement involves a sizeable transfer to the primary producers of knowledge—the US and various EU member states in particular.

In the politically sensitive context of medicines, Chaudhari, Goldberg and Jia (2006) argue that if foreign patents are enforced as required by TRIPS, local producers will exit the market causing large welfare losses on consumers in developing countries. Using detailed product-level data from India, they estimate that the withdrawal of the four domestic product groups in the fluoroquinolone subsegment in India would have inflicted welfare losses of US$305 million upon the Indian economy, some 80 per cent of which would fall on the shoulders of Indian consumers.

However, Branstetter and colleagues (2007) note that rent transfers and static welfare losses are only one part of the story. They argue that the level of FDI will respond to changes in the strength of IPRs protection. Stronger IPRs protection in developing countries may increase the share of global manufacturing undertaken there as well as the pace at which production of recently invented goods shifts to them, leading to an overall enhancement of industrial development. They analyse the response of US multinationals to IPRs reforms in 16 countries in the 1980s and 1990s and find that these firms expand the scale of their activities in countries after IPRs reforms. Using industry-level data, they show that industry value added increases after reforms, particularly in industries that are technology-intensive and where US FDI is concentrated. Moreover, using an annual count of 'initial export episodes'—the number of ten-digit products for which US imports from a given country exceed zero for the first time—as an indicator of the rate at which production of goods shifts to the reforming countries, they find that this rate of production transfer increases sharply after IPRs reforms. The Branstetter and colleagues (2007) analysis illustrates that the possible effects of stronger IPRs on the global allocation of production, industrial development and longer run global innovation and growth need to be considered in any assessment of TRIPS. Gould and Gruben (1996, 2004) discuss the relationship between IPRs, innovation and economic growth more generally.

Policy implications and options

Given the negative impact effect of TRIPS on importers, very much depends on creating the conditions that maximize the potential for beneficial dynamic effects of IPRs, and on obtaining compensation in other areas that is of sufficient value to offset the short-run loss. The latter is of course what the Uruguay Round was about and the Doha Round might be about. On the former, a variety of policies can be pursued that can reduce the magnitude of the transfer. Examples include taxation of imports of those IPR-intensive goods where foreign producers have significant market (pricing) power, facilitating the absorption and diffusion of know-how, vigorous enforcement of competition law, and direct regulation. The TRIPS Agreement allows significant latitude for governments to draft implementing legislation that attenuates the ability of right-holders to abuse their market power.

Regulation of prices is common in many countries, especially of pharmaceuticals. Although this can result in firms pricing closer to cost, it can have unintended consequences. If prices are set too low, firms may choose not to sell. Firms will also have an incentive to try to circumvent price regulations by inflating costs. One way they may do this is by setting high transfer prices on imported ingredients (Lanjouw, 1998). Another policy option is an active competition regime that ensures that markets are contestable and that there is vigorous inter- as well as intra-brand competition. One element of such a competition policy could be a liberal parallel import regime that limits the ability of right-holders to segment markets.[8] The economics of this issue are complex. Many experts argue that as long as a producer faces competition from other brands, exclusive distribution arrangements do not matter. But in many developing countries inter-brand competition may be weak because only a few distributors control the market. National exhaustion and legally enforceable exclusive distributor arrangements can then have a detrimental impact on welfare.[9] However, preventing parallel imports can also be beneficial if it results in lower prices than would arise under uniform pricing. The decision of whether to adopt international exhaustion is a matter for national authorities to decide independently. Hong Kong's experience illustrates the importance of adopting competition legislation to control 'overshooting' on

[8] As noted above, parallel imports involve traders buying goods protected by IPRs in one market and importing them into another market. Such trade does not involve a violation of IPRs of the type that occurs when goods are counterfeited or copied illegally.

[9] An anecdote recounted to one of the authors in the late 1990s is illustrative. Lebanon has an exclusive distribution ('sole agency') law that gives licence holders (agents) the right to request Customs block entry of goods that have not been authorized by the licence holder (distributor). On a visit to Germany, a businessman buys a batch of second-hand Siemens-made dentist chairs from a university, which had used them for training purposes. On import into Lebanon, clearance of the shipment was blocked because it had not been authorized by the Siemens agent. The businessman was obliged to pay the agent a large fee and was forced to pay customs duty on the chairs on the basis of the value of new chairs, in effect wiping out his anticipated profit.

IPRs. Reportedly, the vigorous enforcement of IPRs has led to the exclusion of grey market, parallel imports and to allegations of abuse of a dominant position, which the Hong Kong government has generally argued to be impossible given its free trade stance. The Director-General of the Department responsible for enforcing IPRs recognized that the absence of a competition law creates problems, but noted that his job was to protect the interests of rights-holders; 'someone else must protect the others' (*Financial Times*, 8 January 1999).

At the end of the day, it is impossible to generalize regarding the effect of the TRIPS Agreement on individual WTO members. The design of the IPR legislation and complementary policies will play an important role. Much depends as well on the impact of IPRs on FDI, on the incentives to innovate, and on the effectiveness of IPR regimes in developing countries in protecting indigenous culture and knowledge. A case study of an Indonesian pharmaceutical firm illustrates that the responses of firms in developing countries will also play a major role (Box 8.7). Konan and La Croix (2006) sum up the basic thrust of the economic literature on

Box 8.7. Kalbe Farma of Indonesia

Kalbe Farma PT is an Indonesian pharmaceutical company. The firm produces and markets medicaments for therapeutic use. Under the pre-TRIPS Indonesian patent law the firm was able to copy and sell pharmaceutical products that were protected by international patents. Such products were sold by Kalbe Farma in Indonesia and in other developing country markets, including Bangladesh, Malaysia, Myanmar, Nigeria, Sri Lanka and Vietnam. Once the government began drafting legislation to bring its IPRs regime into conformity with TRIPS, management reviewed its product development strategy. Kalbe Farma production consisted of drugs that were no longer protected internationally as well as pharmaceuticals that were still under patent protection outside the country, but for which a valid patent had never been filed in Indonesia. The company was free to supply the latter to the Indonesian market, but had to exercise restraint in exporting to markets in which the patent protection was still in force. It also imported a range of products, preparations and ingredients from third-party suppliers that were protected. Such imports were expected to become illegal unless acquired from the right-holder or a licensee.

Management decided not to wait for the new TRIPS-consistent law to be passed. Kalbe Farma developed a new marketing and partnership strategy involving both foreign companies and Indonesian firms. It focused on securing marketing rights in Indonesia for foreign patented products and to develop and sell generic drugs no longer under patents. The company also initiated negotiations with international pharmaceutical suppliers to acquire licensing rights for a range of products in Indonesia with a view to establish a leadership position in the domestic market. Kalbe Farma also expanded its R&D, recognizing that competition in the pharmaceutical industry was likely to intensify, including through entry of foreign companies attracted by stronger patent protection. As of 2008 it was the largest publically listed pharmaceutical firm in Indonesia.

Source: Kostecki (2001).

this subject as follows: (1) harmonization is not optimal for the world as a whole—for example, they note that US history provides a clear case of a country that used strong patent rights and weak copyrights in the nineteenth century to enhance its growth prospects; (2) the theoretical literature suggests that there is a strong case for welfare gains to developing countries from patent harmonization (i.e. 'TRIPS') if developed countries pay lump-sums to offset higher royalty payments by developing countries; and (3) although there is a case for IPRs to support innovation, the appropriate scope, depth and enforcement of IPRs will differ across countries according to their economic and political institutions, their per capita income and their capability to engage in and disseminate the fruits of R&D.

These conclusions from the economic literature raise serious concerns about efforts by the EU and US to further strengthen IPRs disciplines in the WTO. Given the difficulty of agreement on these matters in the WTO (in turn a reflection not so much of the arguments of the economists as those of the NGOs!), what is of greater concern are the efforts by OECD nations to introduce 'high standards' of IPR protection in preferential trade agreements with developing countries. As of late 2007 the US had pursued new and expanded (TRIPS-plus) commitments on IPRs in more than 16 bilateral and regional trade treaties, including free trade agreements with Chile, the Dominican Republic and Central American countries (DR-CAFTA), Columbia, Panama and Peru. These treaties, not all of which have been ratified, encompass standards that go beyond the TRIPS Agreement and limit the flexibilities established in that agreement (General Accounting Office, 2007). We discuss these matters further in Chapters 10 and 13.

It should be noted, however, that both the EU and US have at times demonstrated flexibility in this area. Thus, the US has relaxed certain health-related IPRs provisions in some of its PTAs with developing countries, including on technical issues such as patent extension, linking drug approval to patent status and data exclusivity (General Accounting Office, 2007). Similar developments have occurred in the stance taken by the EU in the Economic Partnership Agreements (EPAs) it is negotiating with ACP countries. The European Parliament adopted two resolutions on the matter, expressing concern over the inclusion of TRIPS-plus rules in EU trade agreements stipulating that the European Commission should not include such provisions in EPAs.

8.7. Conclusion

The GATT and the GATS are similar in that the focus is primarily on market access liberalization, complemented with general rules and principles relating to the

application of trade policies. Both agreements aim at reducing discrimination against foreign suppliers of products. However, as noted previously, the GATS created disciplines on certain domestic regulatory regimes that apply equally to domestic and foreign providers. An example is the requirement that an independent regulatory authority be established for the basic telecommunication industry for signatories of the Reference Paper (see Chapter 7). Similarly, the GATT has also begun to move down this track. An example are the two agreements on product standards, which require WTO members to adopt international standards if these exist and requires a 'defence' in cases where this is not the case. To date, however, the emphasis of multilateral disciplines pertaining to domestic regulatory policies is overwhelmingly on procedure or process—little substantive harmonization is imposed. Insofar as harmonization disciplines apply—as in the case of standards—the substantive norms are not developed by the WTO but by the competent international bodies, such as the UN (e.g. the Food and Agricultural Organization) and the Codex Alimentarius Commission. This is not the case with the TRIPS Agreement, which establishes minimum, common standards for IPRs that must be satisfied in all WTO members. Although many of these standards were developed under WIPO auspices, TRIPS goes beyond existing conventions in a number of important areas.

The approach taken in the TRIPS Agreement is somewhat analogous to a Directive in the EU context: it sets minimum standards, but leaves it to signatories to determine how these requirements will be implemented. Article 1 TRIPS states: 'Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice'. Nonetheless, the TRIPS Agreement obliges governments to take positive action to protect IPRs in specific ways. Both the GATT and the GATS are essentially limited to disciplines that apply ten members if they choose to pursue certain policies.

With the TRIPS agreement, OECD-based pharmaceutical, entertainment and software industries, which were largely responsible for getting TRIPS on the agenda, obtained much of what they sought when the negotiations were launched. Their objective was multilaterally agreed minimum standards of IPRs protection in all GATT contracting parties, an obligation to enforce such standards and the creation of an effective multilateral dispute settlement process. It is fair to say that developing countries agreed to substantially more than even an optimist might have predicted in 1986 when the round began.

There are no definitive empirical estimates of the impact of the TRIPS Agreement on developing countries. Although the dynamic effects of the agreement are clearly vital in this regard, the conclusion by Dani Rodrik before the Uruguay Round was finalized continues to hold:

> all evidence and arguments... point to the conclusion that, to a first-order approximation, TRIPS is a redistributive issue: irrespective of assumptions made with respect to market

structure or dynamic response, the impact effect of enhanced IPR protection ... will be a transfer of wealth from [developing country] consumers and firms to foreign, mostly industrial-country firms (Rodrik, 1994: 449).

The estimates of McCalman (2001) cited above suggest that the transfer to OECD countries is not trivial and they show that including TRIPS in the equation significantly reduces the net gains from the Uruguay Round.

The TRIPS agreement was signed because it encompassed a tradeoff between IPRs and the rest of the Uruguay Round agenda. The deal to abolish the MFA and reintegrate agriculture into the trading system, the acceptance of a positive list approach to coverage in the GATS, a stronger dispute settlement mechanism, and the agreement to outlaw VERs were all elements in the final equation. Although it is not possible to identify specific issue linkages, it is very suggestive that the transition period for the phase-out of the MFA was similar to that for developing countries to fully implement the TRIPS Agreement. There was also recognition that without TRIPS, ratification of the Uruguay Round package by the US Congress was unlikely given the political weight of the US industries supporting stronger IPR disciplines. The regime shift that occurred among many developing countries in the 1980s in attitudes towards inward FDI also played a role. Attracting FDI in certain higher tech sectors requires enforcement of IPRs. Finally, there is little doubt that the threat of continued unilateral action on the part of the US (but also the EU) played a role.

Although the US and the EU pushed to enforce the TRIPS Agreement vigorously, including not just against major developing countries, but against each other and other OECD nations, in more recent years they have also demonstrated willingness, especially with respect to LDCs in Africa suffering from the HIV/AIDS epidemic, to show forbearance. The US government issued an Executive Order in May 2000 to help make HIV- and AIDS-related drugs and medical technologies more affordable and accessible in Sub-Saharan African countries. The order prohibits the US government (USTR) from using Section 301 to seek the revocation or revision of IPRs policies of beneficiary Sub-Saharan African countries that regulate HIV or AIDS pharmaceuticals or medical technologies (for example, by allowing parallel imports or regulating prices) if such policies promote access to antiretroviral drugs or medical technologies for affected populations. At about the same time as the Executive Order was issued, the pharmaceutical industry announced an initiative to reduce prices for antiretroviral drugs for developing countries. G8 leaders also announced efforts to devote greater resources to accelerate the development and promote the distribution of vaccines for HIV and AIDS, malaria, TB and other infectious diseases. Developments during the Doha Round negotiations also illustrates a more general acceptance of the need to balance enforcement of private rights with public health objectives and priorities.

8.8. Further Reading

A useful guide to the TRIPS Agreement and its negotiating history is provided by UNCTAD-ICTSD in *Resource Book on TRIPS and Development* (Cambridge: Cambridge University Press, 2005). Keith Maskus, *Intellectual Property Rights in the Global Economy* (Washington, DC: Petersen Institute for International Economics, 2000) is a highly recommended book-length survey and analysis of the economic implications of the TRIPS Agreement. A 2002 report by the Commission on Intellectual Property Rights, a high-level group chaired by John Barton, provides an in-depth analysis and a set of policy recommendations to make the prevailing IPR regime more supportive of the needs of developing countries, see *Integrating Intellectual Property Rights and Development Policy*, London, September (2002) (http://www.iprcommission.org/papers/pdfs/final_report/CIPRcoverintrofinal.pdf). The trade policy and broader economic dimensions of the debate on TRIPS and essential medicines is discussed by Kamal Saggi in 'Trade-Related Policy Coherence and Access to Essential Medicines,' *Journal of World Trade*, 42 (2008): 69–39.

Ambassador B. K. Zutshi, India's chief negotiator during the deal-making stages of the Uruguay Round, gives an insiders' view of the TRIPS negotiations from a developing country perspective in 'Bringing TRIPS into the Multilateral Trading System', in J. Bhagwati and M. Hirsch (eds), *The Uruguay Round and Beyond: Essays in Honour of Arthur Dunkel* (Ann Arbor: University of Michigan Press, 1998). Jayashree Watal, *Intellectual Property Rights in the World Trade Organization: The Way Forward for Developing Countries* (New Delhi: Oxford University Press, 2000) provides a comprehensive legal analysis of the TRIPS Agreement, focusing in particular on the options and implications for developing countries.

An excellent resource for IPR-related disputes and policy developments is the Consumer Project on Technology (at www.cptech.org). Other Internet sources that provide information on recent developments concerning TRIPS include the WTO homepage (at www.wto.org); the World Intellectual Property Organisation (at www.wipo.org); the joint International Centre for Trade and Sustainable Development (ICTSD) and UNCTAD site on IPRs (at www.iprsonline.org); and the Consumer Project on Technology (at www.cptech.org/ip).