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Research Handbook in International Economic Law

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11. Intellectual property rights in world trade

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Technology has always played a significant role in economic development and the shifting fortunes of nations. Yet when the GATT was established in 1947, very limited attention was paid to 'intellectual property'. This is largely explained by the evolution of an international system for the regulation of intellectual property (IP) under the auspices of what today is known as the World Intellectual Property Organization (WIPO). As a subject of international regulation, intellectual property had not been overlooked. In fact, it was perhaps the first element of world trade subject to truly multilateral discipline with the Paris Convention for the Protection of Industrial Property of 1883 and the Berne Convention for the Protection of Literary and Artistic Work of 1886.

IP is regulated at the multilateral, regional, bilateral, national and sub-national levels. This chapter focuses on the multilateral regulatory system largely concentrated at the WTO and WIPO, but also refers to regulation at other levels of governance.

The forms of intellectual property

Intellectual property is a defined set of the intangible products of human creative activity.[1] Unlike real property and personal property which is often protected by means of physical security devices (such as fences and other enclosures), intellectual property is mainly protected by sets of enforceable legal rights granted to 'owners' or 'holders'.[2] These legal rights are intended to solve the economic problem described by Kenneth Arrow as the 'incomplete appropriability of knowledge'.[3] Because intellectual property is intangible and typically easy to copy and transport, it is difficult for business enterprises to capture the full value of investments in it (i.e., competitors can easily appropriate it.). Intellectual property rights ('IPRs') are an effort to solve this inappropriability problem.

[1] For a detailed technical discussion of intellectual property rights, see Frederick Abbott et al. (1999).

[2] Some intellectual property rights holders attempt to protect their interests through security devices, such as data encryption or software anticopy protections. See discussion of encryption technologies in Barlow (1994).

[3] Arrow (1962).

Intellectual property is usually referred to by the form of 'right' (or IPR) granted to the holder. So, for example, a 'patent' is a set of legal rights granted to an inventor. It is not the invention itself. Historically, the patent and trademark were referred to as 'industrial property rights' while the copyright and related rights were referred to as 'authors' and artists' rights'. However, with the advent of the protection of computer software by copyright, the line between industrial property rights and authors' and artists' rights blurred and this distinction is no longer particularly relevant.

Patent

The 'patent' is a set of rights granted to the inventor of a product or process which is 'new' (or 'novel'), involves an 'inventive step' (or is 'nonobvious') and is 'capable of industrial application' (or 'useful').[4] The inventor must disclose the invention in the patent application in a way that enables others to make the invention without undue experimentation. The minimum term of a patent under the TRIPS Agreement is 20 years from the filing of the application. The holder of a patent may prevent others from making, using, offering for sale, selling or importing the invention during the patent term. As with other IPRs, the rights of the patent holder are qualified by certain important exceptions. The patent is typically referred to as a 'hard' form of intellectual property because it excludes another person from using the invention without the consent of the patent holder even if the other person independently found the same invention.

The patent is intended to perform three functions: (1) to stimulate inventive activity; (2) to encourage investment in the products of inventive activity, and (3) to disseminate technical information to the public.[5] The extent to which the patent effectively performs these functions has been the subject of long debate. The principal alternative to using patents to stimulate inventive activity is government subsidy. Economists generally believe that patents are a more efficient policy instrument than government subsidies for promoting investment in innovation, while allowing that in certain circumstances subsidies can be more effective.[6] There is recent concern that an over-proliferation of

[4] The criteria of patentability are referred to by different words in European and American law. European law refers to new, involving an inventive step and capable of industrial application, while American law refers to novel, nonobvious and useful.

[5] These functions are elaborated in Fritz Machlup (1958), *An Economic Review of the Patent System*, Subcomm. on Patents, Trademarks and Copyrights, of the Committee on the Judiciary, 85th Congress, 2d Sess. (excerpts reprinted in Abbott et al. (1999), at 224–46).

[6] See Nordhaus (1969).

patents may impede inventive activity, at least in certain fields, as a 'patent thicket' grows.[7]

Patents have a cost to society in terms of allowing higher than competitive prices to be charged to consumers, and this cost must be weighed against their positive invention-encouraging effects. In some areas, the social cost of allowing market exclusivity may be quite high. By way of illustration, allowing the inventor of a new cancer drug to prevent others from making it may significantly increase its price and reduce patient access to it. Policy-makers have justified the social cost as necessary to provide an incentive and reward for the innovator. However, the patent term is limited. After some years, generic producers are allowed to copy the drug and enter the market providing enhanced access to patients. The social benefits and costs of patenting inventions in different fields of technology differ. High-definition television and cancer treatment serve different social functions, and limiting consumer access to these products has different social effects.

Trademark

The 'trademark' is a sign or symbol that distinguishes the goods or services of one enterprise from another in commerce. Trademarks may consist of virtually any form of sign, including letters and words, designs, colors, shapes, sounds and scents.[8] A trademark allows its holder to prevent others from using an identical or confusingly similar sign to identify its goods or services in commerce where such use would result in a likelihood of confusion. Trademark rights may last as long as the right holder continues to use the mark in commerce. In civil law jurisdictions, trademark rights are typically based on registration. In common-law jurisdictions, trademark rights may be based either on registration or on use in commerce (the latter referred to as 'common law' trademarks). In some jurisdictions, trademark rights may extend beyond the prevention of consumer confusion to encompass the prevention of 'dilution' of the trademark holder's interests, i.e., third parties may be prevented from 'tarnishing' or 'blurring' the trademark.

It is generally believed that trademarks serve an efficiency-enhancing function by providing consumers with an easy way to identify products with preferred qualities or characteristics.[9] Consumers come to identify certain 'brands' which they prefer, and make purchasing decisions based on brand-identification (as a substitute for more costly and time-consuming case-by-

7 See US Federal Trade Commission (2003), at 6–7.

8 Some jurisdictions impose limitations on the use of single colors as trademarks.

9 See discussion by the US Supreme Court of economic policies underlying trademark protection in *Qualitex v. Jacobson*, 514 US 159 (1995).

case product analysis and testing). Trademarks also provide a vehicle into which business enterprises can invest advertising dollars, stimulating brand identification and 'goodwill'.[10] Economists are divided as to whether it is useful to encourage investments in goodwill since there is not necessarily a correlation between the usefulness and quality of products and the amount of advertising invested in them. This can lead to market distortions (in which consumers make purchases based on artificially stimulated demand).

Copyright

'Copyright' is granted to authors and artists to protect expressive works against unauthorized reproduction or distribution by third parties. Expressive works are broadly defined, and include such things as books, films, music recordings and computer software. There is, in fact, no express limit on what material might be considered to embody protectable artistic expression. However, copyright does not extend to functional works or ideas.[11] This principle is often referred to as the 'idea-expression dichotomy', with the 'idea' excluded from copyright protection. Under the TRIPS Agreement the minimum term of copyright protection is the life of the author plus 50 years. However, in a number of places, including the United States and European Union, the duration of copyright has been extended to the life of the author plus 70 years. Copyright also extends to the rights of performers in the fixation of their unfixed performances, and to rights of producers of sound recordings and broadcasters. These latter rights traditionally were protected as 'neighboring rights' in European law, but as a consequence of more recent treaty developments are now considered the subject of copyright. Copyright also protects the 'moral' rights of authors and artists, the extent of protection varying among jurisdictions. Moral rights extend at least to the right of the author to be identified with the work, and not to suffer from the mutilation or distortion of the work with which he or she is identified. Copyright is considered a 'soft' form of IPR because it does not preclude independent creation by third parties.

Copyright is intended to benefit the public by encouraging authors and artists to create and disseminate their works.[12] As with other forms of IP, it is not easy to assess the economic effects of copyright protection. It is difficult to measure how much creative expression is gained (or lost) as a result of copyright, and what the economic value of that expression is. While movie

10 See McCarthy (2005), at §§2.17–2.30.

11 See generally *Feist Publications v. Rural Telephone Service*, 499 US 340 (1991).

12 Id.

and music producing companies routinely offer data regarding losses suffered as a result of inadequate enforcement of copyright protection,[13] the figures typically do not reveal the extent to which the claimed losses – which usually refer to lost opportunity costs – should be offset by the economic and social benefit to consumers of unauthorized copies, or of the economic gains/benefits to 'pirates'.[14] In the well-known Napster court battle between music producers and an online file-sharing service, economists had considerable difficulty estimating what the effect of nonenforcement of copyright protection was on music producers because of difficulties assessing the extent to which losses from uncompensated file-sharing were offset by gains from increased artist exposure and consequent CD sales.[15]

Design protection

Designs are covered by various forms of IPR, including design patent, copyright, trademark and trade dress, and *sui generis* registration systems. The protection of non-utilitarian designs has long been a problematic area for intellectual property law. The traditional 'utility patent' is granted with respect to a useful or functional invention. It is not suited to nonfunctional aesthetic design. In a number of jurisdictions, this led to the creation of a separate 'design patent' specifically granted to nonfunctional product elements. However, design patenting has a number of drawbacks, including that securing protection is time-consuming and costly. Copyright protection covers expressive works and in principle is suitable for design protection, but many designs include potentially functional elements, resulting in uncertainty at the enforcement stage. Trademark and trade dress also protect design. The design or shape of a product or its packaging may be distinctive and associated with a particular enterprise. However, as with copyright, trademark and trade dress offer protection only for nonfunctional design, and this aspect also creates enforcement uncertainty. To overcome problems with design protection by traditional forms of IP, jurisdictions such as the European Union have established design registration systems with somewhat more flexible standards than those associated with the traditional IPRs.

[13] See, for example, presentations by C.K. Chow, Eric Smith and James M. Zimmerman at Congressional-Executive Commission on China, Roundtable on 'Intellectual Property Protection as Economic Policy: Will China Ever Enforce its IP Laws?', May 16, 2005, available at http://www.cecc.gov/pages/roundtables/051605/index.php?PHPSESSID=4646c4dfd4ea4de24988b5b9d47a3d02.

[14] Of course, music and film producers are not concerned with 'global economic welfare effects'. They are concerned with how gains are allocated, i.e., their profitability.

[15] *A&M Records v. Napster*, 114 F. Supp. 2d 896 (ND Cal. 2000), subsequent history in *A&M Records v. Napster*, 239 F.3d 1004(9th Cir. 2001).

One of the industries most concerned with design protection is the textile or clothing industry. In this sector consumer preferences change very rapidly and an expensive time-consuming process for securing protection would not be particularly helpful to the industry. The TRIPS Agreement acknowledges this and obligates Members not to impede the grant of protection by costly, examination or publication requirements. The major economic issues associated with design protection arise when industries blur the line between form and function. For example, the most controversial issue in European design protection is the treatment of automobile spare parts, including body panels and motor parts. In its 2001 Design Regulation, the EC excluded engine components from design protection and put off for future negotiation a decision on whether automobile body parts were covered.[16]

Geographical indication

Geographical indications (or GIs) are identifiers that associate a product with a place based on the quality or characteristics of the product or goodwill associated with the place.[17] The classic illustrative GI is 'Champagne', i.e. the name of a region in France known for producing quality sparkling wines by a specific method. GIs are protected in a variety of ways in different national jurisdictions. The United States protects them by collective and certification trademarks, as well as by a special labeling system for wines and spirits administered by the Treasury Department. The European Union protects them by special registration systems, which typically include elaborate monitoring of production methods. Many Latin American countries protect 'appellations of origin' separately from trademarks. In addition, geographical indications are also protected by common and civil law unfair competition regimes.

GIs are controversial. The EU has been pressing at the WTO to increase the level of GI protection for agricultural products other than wines and spirits (which already enjoy high protection), but is resisted by the United States, among others. The EU is a high-cost producer of specialized agricultural products and is seeking higher prices for those products based on GI protection. The United States is a low-cost producer of bulk agricultural products and is concerned about potential market access restrictions from stronger GI protection. Whether other countries support one or the other 'camp' in this GIs debate largely depends on whether they are efficient large-scale agricultural producers, on one hand, or are producers of specialized niche products, on the other.

[16] Council Regulation (EC) No. 6/2002 of 12 December 2001 on Community designs, at recitals 12–13.

[17] A geographical indication is distinguished from a 'mark of origin' which merely identifies the place where a good is produced. The latter is not intended to denote characteristics.

Protection of layout design of integrated circuits

Integrated circuits (or semiconductors) are produced on the basis of three-dimensional maps or 'mask works' that are used to direct sophisticated equipment that etches circuits on semiconductor materials. In the 1980s, it was unclear whether such mask works could be protected by copyright (since they perform a function), and patent protection is often unsuitable to incremental innovations in IC design. *Sui generis* (or unique) systems of IC lay out protection were developed. Such systems can be given effect either through registration or automatic protection. There has been little enforcement activity based on *sui generis* IC layout-design protection, but it is the subject of TRIPS Agreement rules.

Protection of undisclosed information

Undisclosed information is generally protectable if it is commercially valuable, undisclosed and the business claiming rights takes reasonable steps to protect it. Protection of undisclosed information is generally (but not exclusively) synonymous with 'trade secret' protection. Such protection is provided in a variety of ways, including by specific statute or by unfair competition law. Trade secret protection generally lasts as long as the relevant information remains secret. The TRIPS Agreement specifically requires protection of undisclosed data with respect to new chemical entities in pharmaceutical and agricultural chemical products that is submitted for government regulatory purposes, requiring protection against 'unfair commercial use'.

Trade secret protection enables businesses to develop and maintain production processes, customer lists, recipes and other valuable information that provide advantages over competitors.[18] Allowing businesses to protect such information encourages competition and is generally thought to be healthy from an economic standpoint. Trade secret protection is controversial principally when it is abused, such as when businesses demand payment for information which is in the public domain as a condition to providing necessary products or services. The scope of protection of data submitted for regulatory purposes in the pharmaceutical and agricultural sector is highly controversial because the extent of protection helps to determine the speed at which copies (or 'generic' versions of 'originator' products) can be granted regulatory approval and brought to market.

[18] See discussion of economic policies underlying trade secret protection in *Kewanee Oil v. Bicron*, 416 US 470 (1974).

Multilateral regulation of IP

The early multilateral regulatory system

As noted in the introduction, some of the earliest efforts toward the multilateral regulation of economic activity were directed at intellectual property. The Paris Convention was concluded in 1883 and the Berne Convention was concluded in 1886. The Paris Convention established rules with respect to patents, trademarks and unfair competition. During negotiation of the Paris Convention, proposals were made to create harmonized international patent law. However, these efforts were unsuccessful owing, among other things, to wide variations in the way patents were regulated in different countries. The Berne Convention addressed copyright.

The Paris Convention establishes three basic principles. These are national treatment, right of priority and independence of patents. 'National treatment' is a principle well-known to trade lawyers. In the patent and trademark context, it means that foreign patent and trademark applicants must be treated equivalently with national applicants, and foreign holders of patent or trademark rights within the national territory should not be discriminated against on the basis of nationality. 'Right of priority' allows patent and trademark applicants a period in which they can file abroad without fear of pre-emption. A patent applicant in any Paris Convention country has a period of one year following its first filing to file within all other Paris Convention countries. During this 'priority period', acts which might otherwise defeat patentability (such as the publication of new 'art', or the third-party filing of an application for the same invention) will not have adverse effect. For trademarks the priority period is six months. The principle of 'independence of patents' means that acts taken by authorities with respect to a patent or trademark in one Paris Convention country will not affect the status of equivalent patents or trademarks in other Paris Convention countries. So, for example, if a court in one Paris country determines that a patent is invalid and orders it canceled, this does not affect the validity of patents on the same invention in other Paris countries. This rule reflects the fact that governments are distrustful of the possible motives of other governments in acting against their inventors.

By the late 1970s, from the standpoint of industrialized country patent holders, the Paris Convention was most notable for what it does not do. The Paris Convention does not define a patent or what criteria are used for granting it. It does not prescribe subject matter coverage, it does not set a minimum (or maximum) term of a patent, it does not define the rights of patent holders, and it was perceived as having a weak dispute settlement mechanism (which provides for recourse to the International Court of Justice). In addition, the Paris Convention includes liberal rules on compulsory licensing of patents.

The Berne Convention is a more complete legal instrument. It very broadly

defines the subject matter scope of copyright protection, it sets a minimum term of copyright (generally, the life of the author plus 50 years) and it prescribes rights that are accorded to copyright holders. In addition, it provides that copyright is established automatically on the creation of an expressive work, and precludes countries from making registration or notice a condition to copyright protection.

From the standpoint of the expressive industries, the major drawbacks of the Berne Convention are that it does not cover so-called 'neighboring rights' such as performances (which are addressed by other international agreements) and it employs the same arguably weak enforcement mechanism (the ICJ) as the Paris Convention.

Perceived weaknesses in the Paris and Berne Conventions, combined with the increasing importance of the intellectual property component of goods and services, generated demands for substantial changes to the international intellectual property system.

From WIPO to the GATT and WTO

By the late 1970s, industrialists in the United States had grown concerned with what they considered an inadequate attention to the protection of their intellectual property assets, particularly in developing and newly industrializing countries.[19] These concerns were spread across various industry sectors. Makers of 'brand name' goods were concerned over trademark counterfeiting. Recording companies and film studios were increasingly anxious about copyright piracy. Pharmaceutical and agricultural chemical producers were dissatisfied with the protection given to their innovations.

The concern of industry coincided with a movement among developing countries in favor of a 'New International Economic Order' (NIEO). That movement was centered in the Group of 77 and in multilateral bodies such as the United Nations Conference on Trade and Development (UNCTAD), and emphasized the imbalance in economic welfare between developed and developing countries. It advocated control by developing countries over their own resources, and demanded transfer of technology from North to South to remedy imbalances in development. The NIEO sought at WIPO to relax protection of IP, such as by providing more flexible rules for the compulsory licensing of patents.

In the mid-1980s WIPO was affected by a fundamental clash of interests and values. In negotiations for revision to the Paris Convention, the United

[19] On the background of the TRIPS Agreement and the transition from WIPO to the GATT and WTO, see generally, Abbott (1989), and Abbott (1997a, 1997b). On the political dimension, *see* Sell (2003).

States and other developed countries, including those of the European Community and Japan, demanded stronger protection of intellectual property rights (IPRs). Developing countries demanded more flexible rules. The negotiations failed, and as a consequence the United States, EC and Japan shifted focus to the GATT. Developing countries depended on GATT rules for exports to developed country markets for, among others, their agriculture and textile products. Developed countries had much greater leverage at the GATT as compared to WIPO. Thus was born the GATT Uruguay Round negotiations on the subject of 'Trade-Related Aspects of Intellectual Property Rights' or 'TRIPS'.

The TRIPS negotiations were among the most controversial aspects of the Uruguay Round. Developing countries, led by Argentina, Brazil and India, believed that agreeing to higher standards of IPRs protection at the GATT would have negative consequences, at least in the short term, by increasing their 'rent payments' to the developed countries for technology and expression. They were not persuaded that such protection would provide them with 'dynamic' innovation benefits that would offset increased rent outflows. Developing countries with an interest in adopting higher standards of IP protection could, of course, choose to do this outside the GATT.

The United States used a 'carrot and stick' approach to accomplishing its objectives on TRIPS. On the carrot side, it offered to reduce textile quotas and to help obtain concessions from the EC on agricultural export subsidies, each of which was of considerable interest to developing countries. On the stick side, it used its domestic Special Section 301 authority to threaten and impose trade sanctions on countries that failed to meet US standards of IPRs protection, making clear that it would not be satisfied to continue with the status quo at the GATT. Developing countries reluctantly agreed to the Agreement on Trade-Related Aspects of Intellectual Property Rights or TRIPS Agreement as one of the three pillars of the Uruguay Round (along with the GATT 1994 and the General Agreement on Trade in Services).

The entry into force of the TRIPS Agreement on January 1, 1995 as part of the new WTO created a situation in which two multilateral institutions share responsibility for regulation of the international IPRs system.[20] While the TRIPS Agreement, as discussed below, incorporates the provisions of various WIPO-administered agreements, there is no well-defined hierarchy or relationship between the rules and authority of the WTO and WIPO. A major distinction between the two, however, is that the TRIPS Agreement incorporates the WTO dispute settlement system, allowing for trade-based enforcement of its rules. Several of the WIPO Conventions permit recourse to the

[20] See Abbott (2000a).

International Court of Justice (ICJ), but no case has been brought before the ICJ on the basis of such a convention.

The TRIPS Agreement

The TRIPS Agreement consists of a preamble and seven (7) parts.[21] The first part defines the relationship between the TRIPS Agreement and national law, and between the TRIPS Agreement and certain WIPO Conventions. It includes the core national and most favored nation (MFN) treatment provisions. The second part incorporates the substantive rules applicable to different forms of IP. The third part sets out enforcement obligations of WTO Members. The fourth part addresses the acquisition and maintenance of protection. The fifth part concerns dispute settlement, the sixth part transitional arrangements, and the seventh part institutional matters.

Principles

The national treatment provision of the TRIPS Agreement obligates each Member to treat nationals of other Members on at least as favorable a basis as its own nationals with respect to the protection of IP.[22] National treatment is a common feature of international IP agreements, including WIPO Conventions, predating the TRIPS Agreement. The most favored nation treatment (MFN) provision obligates each Member to extend the same IP privileges and immunities granted to nationals of one Member to nationals of all other Members.[23] Prior to the TRIPS Agreement, MFN was not included in international IP agreements largely because it did not appear likely that a country would grant to any foreigners IP privileges more extensive than it granted to its own nationals. Thus, national treatment would be an adequate standard for all treaty partners. However, the United States in the early 1990s negotiated some agreements which appeared to give rights to US nationals that were not enjoyed by the nationals of its treaty partners, and other countries began to see MFN as necessary in the multilateral context. The Appellate Body has identified national treatment and MFN as fundamental principles of the TRIPS Agreement.[24]

The TRIPS Agreement left each Member to decide on its own policy with respect to the exhaustion of rights.[25] The point at which IPRs are 'exhausted'

21 For a complete technical analysis of the TRIPS Agreement on an article by article basis, including its negotiating history, see UNCTAD/ICTSD (2005), available at hppt://www.iprsonline.org.

22 Article 3, TRIPS Agreement.

23 Article 4, *id.*

24 See United States – Section 211 Omnibus Appropriations Act of 1998, WT/DS176 ('US – Havana Club').

25 Article 6, TRIPS Agreement.

determines when the holders of rights cease to control the movement of goods or services in commerce.[26] From an international trade standpoint, this is typically referred to as the 'parallel imports' issue because the rule of exhaustion adopted by each country determines whether goods first placed on the market under a 'parallel' IPR outside the country may be imported notwithstanding the presence of an IPR within the country.

There are several alternative approaches to exhaustion that countries may adopt, including national, regional and international exhaustion. And, different exhaustion rules may be adopted with respect to different IPRs by the same country.[27] When a country adopts a rule of international exhaustion, the rights of the IPR holder are exhausted when the good or service is first sold or placed on the market anywhere in the world. Assume that South Africa adopts a rule of international exhaustion of patent rights. If a product is first sold in India where there is a local patent, it may be imported into South Africa where the patent holder also controls a parallel patent. The patent holder for South Africa may not block the importation because its rights were exhausted when the product was first placed on the market in India.

Under a regional exhaustion approach, the holder's rights are exhausted when the good or service is placed on the market within the region. So, for example, the European Union has adopted an intra-union exhaustion doctrine. It provides that goods first placed on the market anywhere in the EU under an IPR may be imported into any other EU country. The importation may not be blocked by an economically linked holder of a parallel IPR in any other EU country. However, this rule does not extend to goods first placed on the market outside the EU. So, while an IPR-protected product placed on the market in France may be parallel imported into Germany, an IPR-protected product placed on the market in India may not be parallel imported into Germany or any other EU country.

Under a national exhaustion approach, exhaustion takes place only when goods or services are placed on the market within the territory of the subject country. A country may thus adopt a rule that when products are placed on the market within that country, the rights of IPRs holders are exhausted. Resales within the country may not be prevented. But holders of parallel IPRs may block the importation of products first placed on the market outside the country.

The rule of exhaustion has received quite a bit of attention in the case of

26 See Abbott (1998).

27 This is, for example, the case with respect to the United States which has different exhaustion rules for patents and trademarks, with the rule on copyright yet to be fully defined by the Supreme Court.

pharmaceutical products. Should a consumer in the United States be able to purchase and import a drug first sold by the patent holder in Canada or Europe at a lower price than is available in the United States? Consumers argue they should be entitled to seek the best price available for their medicines, wherever those medicines are placed on the market. Presumably pharmaceutical companies are making a profit wherever they are selling their products. Pharmaceutical companies, on the other side, argue that they are subject to different regulatory conditions in different countries and they should not be bound to prices that may be artificially established by regulatory authorities in any particular country.

The parallel imports debate has another dimension with respect to so-called 'differential' or 'equity' pricing strategies.[28] Some argue that pharmaceutical companies should be able to sell their products to poorer developing countries at low prices while charging higher prices in developed countries, and further argue that rules allowing parallel importation will prevent them from using such strategies.[29] They contend that arbitragers will buy drugs sold cheaply in developing countries and export them to wealthier markets. Others argue that exhaustion rules do not prevent companies from using differential pricing because national governments can control whether differentially priced products are exported and imported. They suggest that the pharmaceutical companies are using this argument as a way to prevent parallel importation which the companies oppose because it interferes with their optimal pricing strategies.[30]

The Doha Declaration on the TRIPS Agreement and Public Health, discussed later on, confirmed the right of WTO Members to decide on their own policies with respect to exhaustion.[31]

The TRIPS Agreement also includes principles confirming the importance of encouraging the transfer of technology to promote development,[32] and recognizing the right of Members to adopt measures consistent with the Agreement to protect public health and nutrition, as well as to control anti-competitive practices.[33]

WTO Members are required to give effect to the TRIPS Agreement in

28 See discussion and references in Abbott (2005a).

29 See, for example, Danzon and Towse(2005), at 438–52.

30 See Abbott (2005a).

31 Ministerial Conference, Declaration on the TRIPS Agreement and Public Health, adopted November 14, 2001, WT/MIN(01)/DEC/2, November 20, 2001, para. 5(d).

32 Article 7, TRIPS Agreement. For a discussion of TRIPS Agreement rules and the transfer of technology, see Correa (2005).

33 Article 8, *id.*

national law, but the agreement leaves to each Member the precise means for doing so.[34]

The substantive rules

The TRIPS Agreement identifies certain intellectual property subject matter as being subject to its rules.[35] The boundary lines of this identification are shaded because the Agreement incorporates provisions of WIPO Conventions that refer to subject matter not expressly addressed in the TRIPS Agreement (for example, trade names). Also, in some areas discretion on the scope of subject matter is left to Members.[36] Taking this shading into account, the TRIPS Agreement still does not apply to all subject matter that might come within the concept of IP as broadly defined, but rather it applies to subject matter that is addressed by the Agreement.

The broad categories of IP addressed by the Agreement are copyright, trademark, geographical indication, industrial design, patent, layout design of integrated circuit and protection of undisclosed information.

Copyright

For copyright, the TRIPS Agreement largely relies on the substantive rules of the Berne Convention which are incorporated by reference.[37] The Berne Convention includes a broad and flexible scope of copyright subject matter coverage. The term of protection prescribed by the Berne Convention at the time of adoption of the TRIPS Agreement was consistent with that of most developed countries.[38] The TRIPS Agreement adds rules clarifying that computer software and compilations of data (based on the creative activity

34 There is no explicit statement as to whether the agreement is intended to have 'self-executing' or 'direct effect' in national law. Since the substantive rules are comparatively precise, there is no strong reason why a Member could not choose to give it direct effect, though it appears that most countries have elected to implement TRIPS Agreement requirements through the adoption of amendments to IPRs legislation.

In Article 1.1, the TRIPS Agreement recognizes that each Member has the flexibility to choose the method of implementation within its own legal system and practice, signaling a certain level of flexibility.

35 Article 1.2, TRIPS Agreement.

36 The effect of the cross-reference to the Paris Convention in the coverage of trade names was the subject of an Appellate Body decision, US – Havana Club, discussed *infra*. The AB noted that obligations with respect to the scope of patent protection are the subject of some discretion on the part of Members.

37 Article 9.1, TRIPS Agreement.

38 The Berne Convention generally provides a term of the life of the author plus 50 years. Since the TRIPS Agreement was adopted, a number of countries including the United States and European Union have extended the term of copyright to life of the author plus 70 years.

involved in their assembly) are copyrightable subject matter.[39] The TRIPS Agreement also extends copyright to certain rights of performers in their unfixed performances,[40] and to certain rights of producers of phonograms and of broadcast organizations. The Agreement sets out a general provision on 'limitations and exceptions' to copyright, which is largely coextensive with a corresponding provision in the Berne Convention.[41] By incorporating relevant provisions of the Berne Convention, the TRIPS Agreement includes other exception provisions, for example, with respect to fair use.[42]

Trademark

The Paris Convention includes rules governing trademarks, but it does not define what a trademark is. The TRIPS Agreement provides a broad definition of trademark subject matter.[43] The TRIPS Agreement also makes service marks subject to an equivalent level of protection with trademarks on goods.[44] Trademark protection extends as long as the trademark holder continues to use the mark, subject to applicable requirements with respect to renewal of registration.[45] A minimum trademark renewal term of seven years is established.[46] Trademark holders are accorded the right to prevent third parties from using marks in a way that would result in a likelihood of confusion,[47] a standard familiar to common law and civil lawyers. The TRIPS Agreement extends rights with regard to so-called 'well known' marks, clarifying that the well-known character of a mark is determined by reference to the 'relevant sector of the public', and that rights in well-known marks extend to dissimilar goods or services where a connection with the trademark holder would be expected.[48] The Agreement limits conditions that can be attached to the use of marks.[49] The rules also include exceptions for fair use of marks.[50]

39 Article 10, TRIPS Agreement.

40 Prior to the TRIPS Agreement, performers in the United States did not have the right to prevent the recording of their performances.

41 Article 13, TRIPS Agreement, Article 9(2), Berne Convention.

42 See also Articles 10 and 10*bis*, Berne Convention.

43 Article 15.1, TRIPS Agreement.

44 *Id.*

45 The United States and the Commonwealth countries generally allow for common law rights in trademarks so that registration is not always required. For most civil law countries, trademarks are based solely on registration. The TRIPS Agreement does not affect this distinction.

46 Article 18, TRIPS Agreement.

47 Article 16.1, *id.*

48 Article 16.2–3, *id.*

49 Article 20, *id.*

50 Article 17, *id.*

There was relatively little controversy about incorporation of trademark protection in the TRIPS Agreement.[51] At the time of its adoption, trademark registration was common throughout the world. Under the TRIPS Agreement trademarks are essentially of indefinite duration; the owner does not lose protection for as long as it continues using its trademark on its goods or services.

Geographical indication

As noted earlier, a geographical indication is an identifier that associates a product with a place based on the quality or characteristics of the product or associated goodwill.[52] The TRIPS Agreement obligates Members to protect GIs based on rules derived from WIPO Conventions,[53] but provides relatively limited guidance as to how protection is to be afforded, leaving much of the work for future negotiations (which as of late 2006 is ongoing). However, the TRIPS Agreement provides additional specificity on the subject of wines and spirits, including a provision calling for negotiations to establish a register of geographical indications for wines for countries participating in the system.[54]

Industrial design

The TRIPS Agreement obligates Members to provide 10 years of protection to industrial designs, but does not prescribe a specific way to accomplish this.[55] The methods for protecting industrial design have traditionally included copyright, trademark and trade dress, design patent and *sui generis* design registration systems. The Agreement obligates Members to ensure that procedures and costs for the protection of textile designs do not unreasonably interfere with the opportunities to obtain protection.[56] Textile designs get special mention because of the large number of designs that producers seek to protect and the often short life cycle of such designs.[57]

51 Trademarks help consumers make purchasing decisions based on their accumulated knowledge about products and producers, and provide the vehicle by which companies promote their goods. There is a limited social cost to allowing a company to reserve a particular brand name for its own use, and a benefit to consumers from being able to associate products with producers.

52 Article 22.1, *id.*

53 Article 22.2, *id.*

54 Article 23, *id.*

55 Article 25, *id.*

56 Article 25.2, *id.*

57 A clothing producer may put a large number of new designs into production each year and without a firm basis for predicting the success of any particular design. Clothing fashions change rapidly, and if procedures for securing protection are time-consuming the result may not be useful.

Patent

The most significant changes to the international IP regulatory system brought about by the TRIPS Agreement were in the field of patents. The Paris Convention provides rules regarding the mechanisms by which patents are granted, and prescribes national treatment. It does not, however, define the subject matter scope of patent protection, the criteria of patentability or the term of patent protection. It includes a limited set of rules applicable to the compulsory licensing of patents.

The TRIPS Agreement provides that patents should be available for products and processes in all fields of technology on the basis of the criteria of novelty, inventive step and capability of industrial application.[58] It also provides for sufficiency of disclosure.[59] Taken together, these criteria reflect the basic rules of developed country patent systems. The Agreement provides that patents rights shall be available and enjoyed without discrimination based on place of invention, field of technology, and whether products are imported or locally produced.[60] The TRIPS Agreement prescribes a minimum 20-year term of protection counted from the filing of the patent application.[61]

The TRIPS Agreement allows for certain exclusions from patentability, such as for the protection of public order and for diagnostic or therapeutic procedures.[62] It permits Members to refuse patenting of animals and plants, but requires that some form of plant variety protection be provided.[63] This may be through patent or a *sui generis* form of protection. Also, the exclusion for animals and plants does not extend to non-biological and microbiological processes.

The TRIPS Agreement expands upon the compulsory licensing rules found in the Paris Convention, prescribing substantive and procedural conditions for the granting of such licenses.[64] However, it does not limit the grounds upon which compulsory licenses may be granted, and it provides for a waiver of procedural prerequisites in cases of national emergency, extreme urgency, or for public non-commercial use. In addition to the provision on compulsory licensing, the TRIPS Agreement incorporates a general provision concerning exceptions to patent rights.[65] This allows a Member to adopt limited exceptions that do not unreasonably conflict with the normal exploitation of the patent or the legitimate interests of patent holders, taking into account the legitimate interests of third parties. This general exception provision is the subject of an important panel decision to be discussed later.[66]

The requirement that countries subject inventions in all fields of technology to patent protection required a major change to the patent laws of many countries. Developing countries were granted a 10-year transition period in which to provide patent protection for subject matter areas not previously covered.[67] In respect of pharmaceutical and agricultural chemical product patents, special 'mailbox' rules required developing Members to accept applications filed during the transition period and preserve them for review when protection became available. If and when a patent was eventually granted the term would be limited based on the original filing date of the mailbox application.[68] This rather complex system was the subject of the first AB decision concerning TRIPS, and is discussed *infra*.[69] Because the 10-year transition period expired on January 1, 2005, the complex subject of mailbox applications will become a matter largely of historical interest once the complex processing situation in India is completed.[70]

Layout design of integrated circuit

The Treaty on Intellectual Property in Respect of Integrated Circuits (IPIC) was negotiated and signed under the auspices of WIPO, but has not entered into force.[71] The TRIPS Agreement incorporates most of the substantive rules of the IPIC Treaty, but modifies them to extend the term of protection and addresses concerns that had been raised regarding provisions of the treaty dealing with third-party purchasers with notice.[72] TRIPS Agreement provisions require that protection for 'original' mask works be provided for a

58 Article 27, TRIPS Agreement.
59 Article 29, *id.*
60 Article 27, *id.*
61 Article 33, *id.*
62 Article 27.2–3(a), *id.*
63 Article 27.3(b), *id.*
64 Article 31, *id.*
65 Article 30, *id.*

66 *Canada – Patent Protection of Pharmaceutical Products*, WT/DS114, 17 March 2000 ('Canada – Generic Pharmaceuticals').
67 The change would have a particularly significant effect in countries which did not provide patent protection for pharmaceutical products since bringing such products under patent protection would affect existing generic producers and almost certainly increase the price of medicines. Article 64.4, TRIPS Agreement.
68 Article 70.8, TRIPS Agreement.
69 India – Patent Protection for Pharmaceutical and Agricultural Chemical Products, WT/DS50, 5 September 1997 ('India – Mailbox').
70 India began to process a large number of mailbox applications as of January 1, 2005, and the extent to which this process generates legal controversy remains to be seen.
71 This is largely based on objections of the United States and Japan regarding the term of protection and provisions dealing with third-party users with notice.
72 Article 37, TRIPS Agreement.

minimum of 10 years following registration or first commercial exploitation anywhere in the world.[73] Members need not adopt registration systems.[74]

Protection of undisclosed information

The TRIPS Agreement requires Members to protect confidential commercial information, generally referred to in common law countries as 'trade secrets'. The Agreement accomplishes this by incorporating a provision of the Paris Convention addressing unfair competition and by broadly defining the protectable subject matter.[75] Information will be protected if it is not generally known in its precise configuration by those in the relevant sector, if it has commercial value because it is secret, and if the holder has taken reasonable steps to keep it secret. Members are to provide protection against such information being obtained 'contrary to honest commercial practices'. Trade secret protection is capable of lasting indefinitely, provided that the information remains confidential.

In addition to the general provisions concerning trade secrets, the TRIPS Agreement includes specific rules addressing undisclosed test or other data submitted to regulatory authorities as a condition for obtaining approval for pharmaceutical or agricultural chemical products using 'new chemical entities'.[76] Protection is to be provided against 'unfair commercial use', and the data are to be protected against disclosure except as necessary to protect the public. This is one of the most controversial provisions of the TRIPS Agreement. The United States asserts that it requires Members to provide fixed periods of 'market exclusivity' for innovator products, while many other Members dispute this, pointing to the flexible requirement that protection be provided against 'unfair commercial use' of data.

Competition

There is a very close relationship between laws regulating IP and laws regulating competition.[77] Although IPRs differ markedly in their characteristics, their general effect is to provide a basis for excluding third parties from marketing products under particular conditions. Competition (or antitrust) laws are intended to assure fair access to markets. On a static basis, it may appear that IPRs and competition law are fundamentally in conflict. However, IPRs may promote competition by fostering innovation and creative work,

73 Article 38, *id.*
74 Article 38.2, *id.*
75 Article 39.1–2, *id.*
76 Article 39.3, TRIPS Agreement.
77 See generally, Public Policy and Global Technological Integration, *supra* note 19 (2004).

thereby providing new products and services that challenge existing market participants. In a dynamic sense IPRs may be pro-competitive. Nonetheless, because IPRs provide a legal basis to exclude third parties from the market, it is necessary to be vigilant that such rights not be abused, such as by the imposition of excessively anticompetitive conditions on licensees.

The TRIPS Agreement includes several provisions that recognize the right of Members to police anticompetitive abuse of IPRs. These include a general provision recognizing the right of Members to adopt measures to control abuses of IPRs[78] and a more specific provision addressing restrictive conditions in licensing agreements,[79] as well as encouraging intergovernmental cooperation. In addition, rules on compulsory licensing specially attend to measures taken to address anticompetitive practices.[80] Also, a Member's exhaustion doctrine effectively addresses conditions of competition, and the rule allowing Members to adopt their own policies with respect to exhaustion is inherently a pro-competitive provision.

Enforcement obligations

A significant part of the TRIPS Agreement is devoted to the measures Members are expected to make available for the enforcement of IPRs.[81] It is important to note, however, that the TRIPS Agreement generally establishes a regime under which private IPRs holders are responsible for taking steps to enforce their rights. With limited exception, Members are not obligated to 'police' the private interests of IPRs holders.[82]

The TRIPS Agreement requires Members to establish effective procedures for the enforcement of IPRs, including provision for remedies to prevent further infringement.[83] The procedures must be fair and equitable. When decisions are taken by administrators, they should be subject to review by judicial authority.

Members are obligated to provide IPRs holders with access to civil judicial procedures to enforce their rights.[84] Parties should have adequate opportunity to present evidence.[85]

78 Article 8.2, TRIPS Agreement.
79 Article 40, *id.*
80 See, *inter alia*, Article 31(k), *id.*
81 Part III, *id.*
82 Article 61, TRIPS Agreement, requires Members to provide for criminal procedures and penalties for trademark counterfeiting and copyright piracy on a commercial scale, and this may be viewed as a policing obligation.
83 Article 41, *id.*
84 Article 42, *id.*
85 Articles 42–3, *id.*

Damages and injunctions should be available.[86] Judges should have the authority to order the destruction of infringing goods.[87] Abuse of legal process should be subject to remedial action.[88]

Procedures for provisional measures to prevent infringement and the destruction of evidence should be available.[89] When provisional measures are granted prior to hearing from an alleged infringer, the accused should be given an opportunity for a prompt review.

Members must provide procedures under which IPRs holders may provide notice to customs authorities of suspected shipments of infringing goods, and make available procedures for the suspension of entry into commerce.[90] Adequate security may be required to protect the importer.[91] The importer shall be notified, and a hearing on the suspension must be convened promptly.[92] The accuser may be required to indemnify the importer for wrongful detention of goods.[93]

Members are required to make available criminal procedures and penalties for willful trademark infringement and copyright piracy on a commercial scale.[94]

Acquisition and maintenance

The TRIPS Agreement includes a provision recognizing that Members may adopt procedures and formalities for the grant and maintenance of IPRs.[95] Members must, however, assure that procedures with respect to the grant of IPRs do not unreasonably curtail the period of protection. Final administrative determinations regarding the grant and maintenance of rights should be subject to judicial review.

Dispute settlement

Dispute settlement under the TRIPS Agreement is undertaken pursuant to the Dispute Settlement Understanding (DSU).[96] There is, however, one unique aspect to TRIPS dispute settlement that remains in effect in 2006. During the Uruguay Round, Members could not agree on whether so-called 'non-violation nullification or impairment' complaints should be permitted under the TRIPS Agreement.[97] A compromise was adopted which provided for a five-year moratorium on such non-violation complaints,[98] during which time Members were to negotiate on the 'scope and modalities' of such causes of action. Any agreement on scope and modalities, or on extension of the moratorium, would need to be adopted by consensus.[99] The five-year period passed with no action having been taken. At the Doha and subsequent Ministerials (Cancun and Hong Kong), Members agreed to extend the moratorium at least until the Ministerial Conference next following the Hong Kong Ministerial (which took place at the end of 2005).

Non-violation complaints might prove quite problematic under the TRIPS Agreement since there is considerable uncertainty as to what kind of 'market access' benefits a Member might have expected to obtain as a result of the protection of IP.[100]

TRIPS decisions under the DSU are discussed below.

Transitional arrangements

There are different types of transitional arrangements under the TRIPS Agreement.

Developed countries had one year to bring their IP systems into conformity with TRIPS standards.[101] Because developing and least developed Members (as well as Members in transition to market economy) would face adjustment difficulties in conforming to these standards, they were given longer transition periods. In general, developing countries (and Members in transition) had five years (until January 1, 2000) to conform to the TRIPS Agreement.[102] However, for patent subject matter areas which were not previously accorded protection, developing Members could take an additional five years (to January 1, 2005).[103] As noted earlier, if the period for providing pharmaceutical or agricultural chemical patent protection was extended, Members were required to put in place a 'mailbox' system, and provide 'exclusive marketing

86 Articles 44–5, *id.*
87 Article 46, *id.*
88 Article 48, *id.*
89 Article 50, *id.*
90 Article 51, *id.*
91 Article 53, *id.*
92 Article 54, *id.*
93 Article 56, *id.*
94 Article 61, *id.*
95 Article 62, *id.*
96 Article 64.1, *id.*

97 In a non-violation complaint, a Member alleges that while another Member has not acted inconsistently with an agreement, the other Member has acted in a way that deprives the complaining Member of benefits it expected to receive when it entered into the agreement. See Abbott (2000b).
98 Article 64.2, TRIPS Agreement.
99 Article 64.3, *id.*
100 See Abbott (2003).
101 Article 65.1, *id.*
102 Article 65.2, TRIPS Agreement. National and MFN treatment provisions took effect for all Members after one year. Article 65.1, *id.*
103 Article 65.4.

rights' for products meeting certain conditions.[104] In all cases, developing countries could not reduce levels of protection below TRIPS standards during the transition period.[105]

Least developed countries in general had until January 1, 2006 to apply TRIPS standards.[106] There was no rule against reducing levels of protection during the transition for least developed countries. Pursuant to the Doha Declaration on the TRIPS Agreement and Public Health, and implementing decisions, least developed countries have an additional 10-year period (until January 1, 2016) to provide pharmaceutical patent or data protection, and need not enforce patent and data rights that may already have been granted.[107] In December 2005 the general transition period for least developed countries was extended until July 1, 2013. However, other than in respect of pharmaceutical products, developing countries lost the flexibility to reduce levels of protection already in force.[108]

In addition to transition arrangements to take into account different levels of development, the TRIPS Agreement addressed subject matter that existed at the time the Agreement entered into force.[109] In general, if subject matter was capable of protection at the time the agreement became effective, it would benefit from TRIPS rules. There was no general requirement of retroactive protection.

Institutional matters

The WTO Agreement establishes the Council for Trade-Related Aspects of Intellectual Property Rights ('TRIPS Council') to oversee the implementation of the TRIPS Agreement.[110] The TRIPS Council has a number of specific responsibilities under the TRIPS Agreement, including reviewing the laws of Members,[111] periodically reviewing the operation of the TRIPS Agreement, and undertaking further negotiation or review in specific subject matter areas such as geographical indications and patents for living things. In addition, Members may propose additional areas of negotiation.

Pursuant to its internal rules of procedure, the TRIPS Council acts only by

104 Article 70.8, *id.*
105 Article 65.5, *id.*
106 Article 66.1, *id.*
107 Doha Declaration, para. 7.
108 This is a problem for least developed countries because most have strict IP laws put in place by colonial powers which do not reflect specific least developed country interests.
109 Article 70, TRIPS Agreement.
110 Article IV:5, WTO Agreement.
111 Article 71.1, TRIPS Agreement.

consensus.[112] If there is not consensus on a matter, it may be referred to the General Council which, at least in theory, may act under alternative WTO voting rules.

The TRIPS Council is also responsible for coordinating activities with WIPO.[113] A modest cooperation agreement has been concluded between the WTO and WIPO.[114]

TRIPS dispute settlement decisions

There have been a number of cases decided by WTO panels and the Appellate Body under the terms of the TRIPS Agreement. Other dispute settlement claims have been initiated and withdrawn. Below is a summary of the cases decided so far, and a discussion of one important claim that was withdrawn.[115]

India – Mailbox (US)

India – Patent Protection for Pharmaceutical and Agricultural Chemical Products, WT/DS50, 5 September 1997 (*'India – Mailbox'*) was the first WTO dispute under the TRIPS Agreement that resulted in a decision by a panel, and subsequently by the Appellate Body. The complaining party was the United States, which alleged that India had failed to adequately implement TRIPS Agreement requirements under Articles 70:8 and 70:9 to establish a so-called 'mailbox' to receive and preserve patent applications, and to adopt legislation authorizing the granting of exclusive marketing rights (EMRs).

The first part of the decision of the Appellate Body in this dispute concerned a difference over jurisprudence with the Panel. The Panel said that the United States and its patent holders had 'legitimate expectations' concerning the implementation by India of a mailbox system that would eliminate 'any reasonable doubts' concerning the future grant of patents. The Appellate Body said that the Panel had mistakenly applied the doctrine of non-violation nullification or impairment in formulating its approach to interpretation, and pointed out that non-violation complaints could not yet be brought under the TRIPS Agreement. The Appellate Body said that the proper means for interpreting the TRIPS Agreement was by application of the rules of the Vienna

112 Rules of Procedure for Meetings of the Council for TRIPS, IP/C/1, 28 September 1995, Rule 33.
113 Article 68, *id.*
114 The organizations, *inter alia*, agreed to the creation of a common register of IP laws, and this has been established at WIPO.
115 For a more complete discussion *see* Abbott (2004b) The discussion in this section of the chapter first appeared in Chapter 3.14, *TRIPS* – United Nations Conference on Trade and Development (UNCTAD) in *Course on Dispute Settlement in International Trade, Investment and Intellectual Property*, United Nations, 2003.

Convention on the Law of Treaties, which provides that treaties shall be interpreted based on their express terms and context, in light of their object and purpose. India was required to comply with the terms of the TRIPS Agreement, no more, no less. This meant that India would be required to provide a 'sound legal basis' for the treatment of mailbox applications.

The Appellate Body went on to examine India's claim that an administrative order allegedly given by the executive to the patent office was an adequate means to implement the mailbox requirement. India had not furnished the text of such an order to the Panel or Appellate Body. The Indian Patents Act required the patent office to reject applications that concerned subject matter for which patent protection could not be granted, including for pharmaceutical products. There was substantial evidence that under the Indian Constitution, the statutory Patents Act requirement to reject a patent application on subject matter grounds could not be modified by an executive administrative order. The Appellate Body agreed with the Panel that India had in fact failed to provide a sound legal basis for receiving and preserving mailbox applications.

Another aspect of the case involved India's alleged failure to adopt legislation authorizing the grant of EMRs. India argued that since no party had yet to qualify for the grant of EMRs, it had no need for legislative authority which could be provided as the circumstances warranted. The Appellate Body disagreed on the basis of the express text of the TRIPS Agreement which it held to require the adoption of legislation authorizing the grant of EMRs from the entry into force of the agreement.

The Appellate Body also rejected a Panel determination under Article 63 of the TRIPS Agreement that India had failed to comply with transparency obligations. The Appellate Body's rejection was based solely on grounds that the Panel had permitted the United States to add a cause of action to its complaint outside the Panel's terms of reference.

Canada – Generic Pharmaceuticals

Canada – Patent Protection of Pharmaceutical Products, WT/DS114, 17 March 2000 ('*Canada –Generic Pharmaceuticals*') involved a complaint brought by the European Communities (EC) against Canada alleging that provisions of Canadian patent law that allowed the stockpiling of products prior to the expiration of a patent term, and that authorized the use of patented inventions for the purposes of preparing and pursuing regulatory submissions prior to the expiration of a patent term, violated TRIPS obligations. The focus of the EC's complaint was the generic pharmaceutical sector. The EC claimed that the relevant provisions of Canada's Patent Act, when read in connection with its drug regulatory rules, allowed generic producers to obtain approval for and stockpile patented medicines contrary to TRIPS patent rules.

Canada conceded that the relevant provision of its Patent Act contravened

the rights of patent holders under Article 28.1 of the TRIPS Agreement. It invoked Article 30, asserting that it was providing limited exceptions to the rights of patent holders within the scope of that provision.

The Panel devoted a considerable portion of its decision to interpreting the meaning of the three elements of Article 30; that is, 'limited exception', not unreasonably interfering with the normal exploitation of the patent, and not unreasonably prejudicing the interests of the patent holder, taking into account the legitimate interests of third parties. In the Panel's view, a 'limited exception' refers to a narrow derogation, with reference to the range of rights provided to the patent holder. The element of 'normal exploitation' is used to address the way that patents are ordinarily used. The test of the patent holder's interests is used to consider the potential economic impact on the patent holder. The legitimate interests of third parties are not limited to legal interests in the patent relation, but include public social interests.

The Panel determined that Canada's stockpiling exception was not sufficiently 'limited' because it potentially allowed an unlimited quantity of patented products to be made during the patent term. It therefore did not qualify as a limited exception under Article 30. Having made this determination, the Panel did not address the other two elements that must be satisfied to support an Article 30 exception.

Canada's regulatory review exception allows third parties to use patented inventions during the term of the patent to develop submissions for approval, such as in the case of marketing approval for a generic pharmaceutical product. Canada does not extend the term of patents to take into account the period of time during which an invention is subject to regulatory review.

Regarding the first criterion under Article 30, that an exception must be limited, the Panel determined that Canada's regulatory review exception was limited because it addressed only a small part of the patent right, and was reasonably closely circumscribed.

Regarding the second criterion, that there is not unreasonable interference with normal patent exploitation, the Panel found it was not generally accepted that patent rights must be exploited without being subject to limited exceptions, such as use by third parties for regulatory review purposes. It was not an unreasonable interference with the normal exploitation of patents to subject them to this type of exception.

Regarding the third criterion, that there not be unreasonable prejudice to the patent holder (taking into account third-party interests), the Panel considered the EC's argument that Canada's regulatory review exception should have been combined with a 'patent term extension' to take into account the period during which the patent holder awaited marketing approval for its drug. In the EC's view, the failure to provide an extension meant that the patent holder suffered economically because its patent term was effectively reduced by the

period during which it awaited marketing approval, while the generic producer was enabled to begin marketing promptly upon the expiration of the patent. The Panel rejected the EC contention, finding that governments took account of the interests of the patent holder in adopting their regulatory review procedures, and that there was no requirement that the patent holder effectively be compensated because it had to subject its product to regulatory review.

The Panel finally considered whether Canada's regulatory review exception was inconsistent with Article 27.1 of the TRIPS Agreement in the sense of discriminating with respect to field of technology. The Panel began by holding that Article 30 exceptions are subject to Article 27.1, even though there is no language in Article 30 suggesting that exceptions that may be granted are restricted to a certain kind or class. However, it pointed out that Article 27.1 refers to 'discrimination' regarding field of technology, which is a pejorative term. The fact that Members may not 'discriminate' regarding a field of technology does not imply that they may not 'differentiate' among fields of technology for legitimate purposes. Having made these determinations, the Panel found that Canada's patent legislation neither differentiated nor discriminated since it was, by its terms and application, neutral as to field of technology.

US – Copyright Exemption

United States – Section 110(5) of the US Copyright Act, WT/DS160, 15 June 2000 ('*US – Copyright Exemption*') involved a claim by the EC against the United States alleging that exceptions in the US Copyright Act that permitted commercial establishments to provide radio and television entertainment to customers without payment of remuneration to copyright holders was TRIPS-inconsistent. The EC's claims were based on Articles 11*bis* and 11 of the Berne Convention that establish rights in favor of authors and artists with respect to the broadcast and communication to the public of their works. The US defended its exemptions on the basis of Article 13 of the TRIPS Agreement, that largely incorporates the exception provision found in Article 9(2) of the Berne Convention.

The US copyright exemptions basically covered two situations. The first ('homestyle exemption') allowed broadcasts to be received and transmitted to the public by a single apparatus of a kind ordinarily used in private homes, and was not directed to a specific category of establishment. The second ('business exemption') allowed general commercial establishments of a limited size, and bars and restaurants also of a limited (though larger) size, to receive and broadcast to the public through a specified range of equipment.

The Panel found that the US business exemption did not fall within the exception for 'certain special cases' within the meaning of Article 13 of the TRIPS Agreement. The range of establishments was too large, and the commercial significance to copyright holders was too great for this to be

considered a minor exemption. Although it might have stopped here, the Panel went on to complete its analysis of the other exception factors in Article 13 of the TRIPS Agreement so as to provide a factually complete record for the Appellate Body. The Panel found that copyright holders had a normal expectation of compensation for broadcast to the public of their works, and that commercial establishments of a substantial size would reasonably be expected to bear the burden of furnishing compensation to them. Since the business exemption covered a broad range of US commercial establishments, the lack of compensation unreasonably prejudiced the legitimate interests of the copyright holders.

The Panel found that the 'homestyle exemption' was in fact of limited scope, because among other things it had been construed narrowly by US courts. In respect to the normal exploitation of copyrighted works, the Panel found that there was a minimal market for single private receiver broadcasts, in particular since most small shop owners would not be willing to pay for a copyright license. On similar grounds, the Panel found that the legitimate interests of copyright holders were not unreasonably prejudiced.

Canada – Patent Term

Canada – Term of Patent Protection, WT/DS170, 18 September 2000 ('*Canada – Patent Term*') involved a complaint by the United States against Canada for an alleged failure to apply the minimum 20-year patent term requirement of Article 33 of the TRIPS Agreement to patents that were granted under pre-TRIPS Agreement patent legislation. This decision involved the interpretation of Articles 70.1 and 70.2 of the TRIPS Agreement that deal with application of the agreement to subject matter that existed prior to its entry into force.

Canada argued that it was not required to extend the term of patents that had been granted under an act that applied to patents granted up until 1989 (and remained in force when Article 33 became applicable), because Article 70.1 excluded application of the TRIPS Agreement to 'acts' which occurred before the date of application. In Canada's view, the grant of a patent was an 'act' that occurred before Article 33 became applicable. Canada argued that Article 70.2, which establishes obligations regarding 'subject matter existing at the date of application . . . and which is protected in that Member on the said date', referred to patents granted prior to application of the agreement, but did not require Canada specifically to undertake the act of extending the patent term, which was excluded under Article 70.1.

The decision of the Panel and Appellate Body in this case focused on the plain meaning of Articles 70.1 and 70.2. Neither the Panel nor the Appellate Body found Canada's attempt to distinguish the act of setting out a patent term (as within Article 70.1), and the general 'existing' nature of the patented

invention under Article 70.2, persuasive. The Appellate Body found that Article 70.2 required the application of Article 33 to the term of existing patents based on the express language of the TRIPS Agreement.

US – Havana Club

United States – Section 211 Omnibus Appropriations Act of 1998, WT/DS176/AB/R, 2 January 2002 (*'US – Havana Club'*), WT/DS176, involved a claim by the EC against the United States alleging TRIPS Agreement inconsistency of US legislation denying holders of trademarks confiscated by the government of Cuba without compensation the right to enforce those marks in US courts, and denying permission to register those marks at the US Patent and Trademark Office. The case involved a trademark ('Havana Club' for rum) that the government of Cuba took from Cuban national owners following the revolution, and that became the subject of a Cuban-French joint venture some 40 years later. Federal courts in the United States had upheld the validity of the US legislation and its application to the Cuban-French joint venture prior to the EC's initiation of the dispute at the WTO. The EC argued that the US legislation was inconsistent with rules concerning trademark registration of the Paris Convention, interfered with the basic rights of trademark holders under the TRIPS Agreement, and was inconsistent with TRIPS Agreement national and most favoured nation treatment rules.

The Appellate Body decided (confirming the Panel's view) that the obligation in the Paris Convention Article 6*quinquies telle quelle* (or 'as is') rule is addressed to accepting trademarks for registration in the same form, and not to eliminating Member discretion to apply rules concerning other rights in marks. It found that Articles 15 and 16 of the TRIPS Agreement do not prevent each Member from making its own determination regarding the ownership of marks within the boundaries established by the Paris Convention. It decided that Article 42 regarding procedural rights does not obligate a Member to permit adjudication of each substantive claim regarding trademark rights a party might assert, if that party is fairly determined *ab initio* not to be the holder of an interest in the subject mark. In sum, the Appellate Body confirmed the right of the United States to refuse registration and enforcement of trademarks it determines to have been confiscated in violation of strong public policy of the forum state.

The Appellate Body analyzed US law relating to Cuba's alleged confiscation of trademarks in regard to national and most favored nation treatment obligations. It observed that as a matter of WTO law, these obligations are fundamental. It rejected the Panel's determination that, although certain minor discriminatory aspects of the US legislation could be identified, those aspects were unlikely to have a practical effect, and so are not WTO-inconsistent. The

Appellate Body, in a somewhat strained reliance on an earlier GATT panel report (US – Section 337),[116] found that even discriminatory aspects unlikely to have effect in practice were nonetheless inconsistent with the US national treatment and MFN obligations.

The Appellate Body further held, contrary to the Panel, that trade names are within the subject matter scope of the TRIPS Agreement.

Although the Appellate Body identified what it considered to be a minor procedural defect in the mechanism adopted by the US Congress to effectuate its decision regarding the confiscated trademark, the Appellate Body affirmed in its entirety the authority of the Congress and Executive Branch to deny validity to a Cuban-French claim of trademark ownership.

EC – Geographical Indications

In *European Communities – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs* (*'EC – GIs'*), the United States (WT/DS174/R, 15 March 2005) and Australia (WT/DS290/R, 15 March 2005) each brought claims alleging that the EC's system of protecting geographical indications discriminated against foreign applicants for protection. The EC's regulations required as a condition for granting protection that the home country of a foreign applicant maintain a system of GIs protection equivalent to that of the EC – a so-called 'material reciprocity' requirement. The EC argued its regulations were qualified by reference to international obligations and that this assured WTO consistency. The panel rejected this claim based on its interpretation of the text of the regulations and the way they had been applied by the EC. The EC's material reciprocity requirement was found to derogate from national treatment requirements under Article 3 of the TRIPS Agreement and Article III of the GATT 1994. The panel also found that the EC's requirement that foreign governments make certain certifications on behalf of private applicants for GIs protection, which was not required from EC member states for EC nationals, was inconsistent with the national treatment standard.

The EC regulations permit GIs to be registered notwithstanding prior

116 Panel Report, *United States – Section 337 of the Tariff Act of 1930* (*'US – Section 337'*), adopted 7 November 1989, BISD 36S/345. The Appellate Body's reliance is strained because the Panel in the *US – Section 337* case identified a number of differences between rules applicable to patent proceedings involving domestically produced and imported goods, and found only a limited number inconsistent with US national treatment obligations. Those found to constitute discrimination (such as the incapacity of an import-related patent holder to assert counterclaims in a 337 proceeding) were matters that in intellectual property rights enforcement had significant consequences.

conflicting trademark registrations. The US and Australia argued that this was inconsistent with the EC's obligation to allow the registration and effective use of trademarks. The panel agreed that there was an inconsistency, but allowed the EC to maintain its system pursuant to the limited exception provision of Article 17 of the TRIPS Agreement. However, the panel indicated that the limited exception would not extend to linguistic versions of GIs that were not specifically registered.

US Claims regarding Brazil's compulsory licensing legislation

Although a dispute between the United States and Brazil regarding compulsory licensing was settled prior to the convening of a panel, because it raised important issues which may be relevant to future dispute settlement it may usefully be considered. On May 30, 2000, the United States requested consultations with Brazil under the WTO Dispute Settlement Understanding, stating:

> [The United States] request[s] consultations with the Government of Brazil ... concerning those provisions of Brazil's 1996 industrial property law (Law No. 9,279 of 14 May 1996; effective May 1997) and other related measures, which establish a 'local working' requirement for the enjoyability of exclusive patent rights that can only be satisfied by the local production – and not the importation – of the patented subject matter. Specifically, Brazil's 'local working' requirement stipulates that a patent shall be subject to compulsory licensing if the subject matter of the patent is not 'worked' in the territory of Brazil. Brazil then explicitly defines 'failure to be worked' as 'failure to manufacture or incomplete manufacture of the product', or 'failure to make full use of the patented process'. The United States considers that such a requirement is inconsistent with Brazil's obligations under Articles 27 and 28 of the *TRIPS Agreement*, and Article III of the GATT 1994.

The request for consultations was followed by a US request for establishment of a panel. The United States withdrew its complaint in this matter prior to the submission of written pleadings by either party. However, the request for consultations illustrates that provisions authorizing compulsory licensing for 'non-work' may be subject to a future challenge under Article 27 of the TRIPS Agreement.

The Paris Convention authorizes the grant of compulsory licenses for failure to work a patent. A major issue in a case such as that brought by the United States against Brazil is whether Article 27:1 of the TRIPS Agreement was intended to prohibit WTO Members from adopting and implementing local working requirements, and effectively to supersede the Paris Convention rule. The negotiating history of the TRIPS Agreement indicates that Members differed strongly on the issue of local working. Several delegations favored a direct prohibition of local working requirements, but the TRIPS Agreement did not incorporate a direct prohibition. Instead, it says that patent rights shall

be enjoyable without 'discrimination' as to whether goods are locally produced or imported. Under the jurisprudence of the *Canada-Generic Pharmaceuticals* case, this leaves room for local working requirements adopted for bona fide (i.e., non-discriminatory) purposes. A WTO Member might well argue that requiring production of certain defense-related inventions within the national territory is essential to national security, and therefore justifies a local working requirement. There are no doubt other justifiable grounds for requiring local working of a patent.

The importance of local working was demonstrated in 2005 congressional testimony by US Secretary of Health and Human Services Leavitt regarding US preparation for a potential avian flu pandemic. He said the United States believes that in a pandemic situation, foreign suppliers would divert products to their own markets, and that it was essential that the United States have its own manufacturing facilities for avian flu treatments.

Current and future issues

The role of WIPO

WIPO also continues to play a major role in regulating IP in world trade. First, WIPO administers treaties pursuant to which persons may secure registration of patents and trademarks in many countries, including the Patent Cooperation Treaty (PCT) and Madrid Agreement and Protocol. Administration of the PCT is highly technical work and employs a large staff. Second, WIPO continues to serve as a forum for negotiations on IPRs. Shortly following entry into force of the TRIPS Agreement, the WIPO Copyright Treaty and WIPO Performances and Phonograms Treaty (WPPT) were concluded at WIPO, and have entered into force. Among other things, negotiations on substantive patent law harmonization continue at WIPO, although the pace of these negotiations is slow due to continuing differences in national perceptions concerning the appropriate standards of protection. WIPO is cooperating with the governing body of the Convention on Biological Diversity in the development of rules on the relationship between IPRs and genetic resources, as well as traditional knowledge. Third, WIPO is increasingly assuming a role as forum for alternative dispute resolution with respect to IPRs, including those that protect domain names on the Internet.[117]

The most controversial of the ongoing WIPO negotiations concerns

[117] The WIPO Arbitration and Mediation Center serves as a dispute settlement service provider under the ICANN Uniform Domain Name Dispute Resolution Policy and routinely appoints panels to resolve disputes between persons claiming rights in trademarks and domain name registrants. Information about the Center can be found at http://www.wipo.int.

substantive patent law harmonization. Recall that the earliest efforts to negotiate the Paris Convention included proposals to create harmonized international patent law. Why is this subject matter so controversial? First, there is a substantial disparity in the capacity of countries to develop new technologies and commercialize them. The vast preponderance of patents is owned by enterprises in the industrialized countries. Developing countries are, on the whole, substantial 'net payers' for technology. While it may seem like a good idea from the standpoint of someone in the United States or Germany to have harmonized worldwide patent standards which would be based on the rules established in the highly industrialized countries, which rules would pave the way for a system in which multinational companies ultimately could apply for a single patent and obtain worldwide monopolies for their new products, this idea is looked at differently from the standpoint of people in countries who mainly pay higher prices for patented products, that is, the net payers.[118] Under the TRIPS Agreement, countries currently have substantial discretion in the way they define the criteria of patentability. This gives them the ability to control how easy or difficult it is to obtain patents. A country which is a net payer for technology may wish to make it more difficult to obtain patents, for example, by imposing a strict standard for inventive step. Also, there is concern among some developing countries that issues of importance to them, such as the protection of biodiverse resources, will not be given enough attention in these negotiations. Finally, but not exhaustively, even among the most highly developed countries like the United States and the EU there remain some significant differences in the way that the patent systems function and on which there is yet to be agreement on harmonization. For all these reasons, the substantive patent law harmonization negotiations at WIPO are contentious. However, the pressures from the industrialized countries to conclude such negotiations are growing ever stronger.

One of the most important policy debates likely to take place over the next several years concerns whether the world community will move toward adoption of an 'international patent' that will be effective for all (or most) countries.[119] Because of the disparate interests of countries at different levels of development, and because the idea of granting effective 'global monopolies' is so important, this idea has so far made limited headway. However, major industrial companies are likely to keep pressing for this as a way to reduce patenting costs and administrative problems.

[118] In fact, current negotiations for substantive patent law harmonization do not envision a 'single patent', rather uniform rules that must be applied by all countries.

[119] See Barton (2005), 617; and reports of ongoing work on WIPO Patent Agenda at http://www.wipo.int.

Other multilateral organizations and NGOs

While the TRIPS Agreement was negotiated with minimal public attention, the period since its adoption has seen a strong public focus on the role IPRs play in society. A substantial number of multilateral organizations, including the Food and Agricultural Organization (FAO), United Nations Conference on Trade and Development (UNCTAD), World Bank and World Health Organization (WHO), among others, have taken a much more active interest in IPRs-related matters in recent years.

From the standpoint of other multilateral organizations the control over IPRs issues exercised by the WTO raises concern. Do the FAO and WHO have the authority to regulate patents and trademarks in the areas of food products and public health, respectively? How does that authority relate to the authority of the WTO and the rules of the TRIPS Agreement? This is sometimes referred to as the problem of 'coherence'. At the moment, there is limited practical attention being given to this problem.

In addition to the governmental side, civil society through non-governmental organizations (NGOs), including Médecins Sans Frontieres (Doctors without Borders), Oxfam, and others recognize that IPRs may directly affect their capacity to pursue their missions and have become powerful advocates on IPRs issues that affect their work, including work in combating hunger, disease and economic inequity. Should only national governments have a voice at the WTO and other multilateral organizations because those governments are representative of their people? Or, is national representation at the WTO and other multilateral fora skewed in favor of industrial interests so that NGO representation is necessary to provide a counterweight? This is a contentious issue. In recent years NGOs have made it more difficult to conclude trade and IPRs negotiations on terms sought by industry, and industry has sought ways to limit the influence of NGOs, including by shifting negotiations to less transparent forums.

Policy issues

The medicines debate The TRIPS Agreement entered the public spotlight in a major way in the context of a debate concerning the role of patents on medicines.[120] Sharp controversy arose when the major pharmaceutical research companies, backed by the United States and European Union, on the basis of alleged inconsistencies with the TRIPS Agreement challenged legislation that had been adopted in South Africa to improve access to medicines. The TRIPS Agreement did not support or justify the pharmaceutical industry claims.

[120] Compare Abbott (2002) and Sykes (2002).

Industry was ultimately forced to withdraw its claims under intense public pressure reflecting the seriousness of the HIV-AIDS pandemic in Africa. As a result, however, WTO Ministers at the urging of developing countries and NGOs adopted the Doha Declaration on the TRIPS Agreement and Public Health in November 2001, which, among other things, confirmed the right of Members to take advantage of the flexibilities in the TRIPS Agreement.

Paragraph 6 of the Doha Declaration addressed the problem of effective use of compulsory licensing by countries with insufficient manufacturing capacity in the pharmaceutical sector.[121] It instructed the TRIPS Council to make a recommendation on the subject. After nearly two years of negotiation, the TRIPS Council recommended and the General Council adopted the August 30, 2003, Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, which provides a waiver of certain TRIPS obligations. More specifically, it waives the restriction otherwise imposed by Article 31(f), which limits production under compulsory license to predominant supply of a Member's domestic market, and also limits remuneration to the exporting country. On December 6, 2005, WTO Members adopted a Protocol Amending the TRIPS Agreement that will transform the August 30, 2003 Decision into an amendment of the TRIPS Agreement when it is approved by a sufficient number of Members. The Decision and waiver will continue in effect until the amendment is approved by all WTO Members.

The Decision and Amendment authorizes WTO Members to grant compulsory licenses for export to countries with insufficient manufacturing capacity for particular pharmaceutical products. It establishes procedures and conditions for using the system.[122] The Decision and Amendment are important elements of developing country TRIPS flexibility. In the post-January 1, 2005 environment, few new pharmaceutical products are likely to be available for import in generic versions from traditional suppliers such as India and China.[123] In order to obtain supplies, developing countries without manufacturing capacity may need to request countries with capacity to produce under compulsory license for them.

Paragraph 7 of the Doha Declaration extended until January 1, 2016, the obligation on 'least developed' WTO Members to provide pharmaceutical product patent and data protection, and perhaps more importantly provided that until that date least developed countries could elect not to enforce existing patents and data protection obligations. This decision had very important

121 See Abbott (2005c).
122 Abbott and Puymbroeck (2005).
123 This is not a foregone conclusion because India and China may choose to issue government use or compulsory licenses to supply their domestic markets, leaving substantial quantities available for export without use of the Decision and Amendment.

consequences for least developed countries. They could import or produce medicines patented within their territories without concern about infringement, and could register treatments without concern about data protection rules, provided only that the government decides to take advantage of WTO-recognized flexibilities. Least developed countries could avoid the procedures and obligations involved in the granting of government use or compulsory licenses, including the obligation to provide adequate remuneration in the circumstances of the case.

Pharmaceutical research and development is necessary for the introduction of new medicines. Patents provide one mechanism to encourage the funding of R&D, and the research-based pharmaceutical industry (Pharma) points to a risk that the weakening of patent protection ultimately will harm global consumers who will have fewer new treatments available.[124]

The problem of funding pharmaceutical R&D is a very complex one. In the United States, a great deal of public money (in each of 2005 and 2006, approximately $28 billion), administered by the National Institutes of Health, is directed to basic pharmaceutical research. A substantial portion of pharmaceutical R&D is accounted for by government subsidy. Only a small portion of global R&D funds is generated by sales in developing countries. The disease burdens in many of these countries, including HIV-AIDS, malaria, and tuberculosis, but also heart disease, diabetes, intestinal and respiratory disease, overwhelms the capacity of the health sector to provide treatment. Whether it is more important to increase patent rents from these countries, or alternatively to allow medicines to be made available at low prices, is a question that policymakers struggle with. The medicines debate will continue.

Protection of biodiverse resources

While the medicines debate has received the most public attention, there are other important policy issues being addressed in the TRIPS Council. These include the relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD), and whether the patent rules of the TRIPS Agreement should be amended, for example, to require disclosure in patent applications of the source and origin of genetic resources.[125]

The CBD recognizes that states own the genetic resources located within their territories, and requires that persons seeking to bioprospect for and exploit those resources have the 'prior informed consent' of the host country, as well as arrange for the equitable sharing of benefits from exploitation. The

124 For support in the academic literature, see DiMasi et al. (2003).
125 See contributions by Dutfield, Taubman, Cottier and Pannizon and Coombe, all in Maskus and Reichman (2005), at 495–614.

majority of genetic resource stocks are located in so-called 'Megadiverse' countries, and all but one of those is a developing country (the United States is the industrialized Megadiverse country). A number of developing countries have argued in the TRIPS Council and at WIPO that patent applications should include information regarding where genetic resources come from in order to allow them to effectively police their rights under the CBD. Patent applicants may otherwise be able to describe biotechnological inventions without providing information that will let the patent examiner know that information regarding the invention may be available from foreign sources, and without notice to the country which supplied the genetic resources that would allow it to determine whether there was prior informed consent. The United States so far is the country most strongly opposing the effort to require disclosure, arguing that the source and origin of genetic resources is not relevant to patentability and should not be part of the patent application process.

The regulation of IP at the regional and bilateral level

IP is regulated by regional organizations such as the European Union. The EU regional arrangement in many ways seeks to replicate a federal regulatory system, and from the standpoint of trade regulation is largely unique. Given the enlargement of the EU to 25 member states and its importance as a market for goods and services, the details of its IP regulatory system are important to those involved in international business.

There are many regional organizations, including the Andean Community, ASEAN (East Asia), APEC (Asia-Pacific), CARICOM (Caribbean), NAFTA (North America), MERCOSUR/I (South America Southern Cone and Venezuela) and SACU (Southern Africa). Each of these organizations has adopted some form of IP rules.

In recent years, the United States in particular has used regional and bilateral free trade negotiations as a way to obtain concessions from other countries on IPRs matters.[126] In the context of regional and bilateral free trade agreement negotiations, the United States has obtained commitments on standards of patent, copyright and trademark protection substantially higher than those found in the TRIPS Agreement or other multilateral agreements, and has also obtained major commitments for the protection of pharmaceutical products. Developing countries accepting these commitments are effectively agreeing to increase rent payments on medicines to the United States, and there is considerable debate about whether this serves the social welfare interests of these developing countries.

[126] See discussion and analysis of the phenomenon in Abbott (2005c), 348–58 and Abbott (2005b), 88–98, Drahos (2002); Fink and Reichenmiller (2005); World Bank (2005), chapter 5, at 98-B110.

Continuing tensions

Just as countries have different capacities and comparative advantages in terms of the production of goods and services, so they have different capacities for generating IP and making use of it.[127] A country with a well-developed educational system and research institutions, whether public or private, will have advantages over countries where these resources are lacking. Smaller countries like Switzerland and Singapore may compete with the United States in generating new technologies.[128] The countries with a high capacity for innovation may have a stronger interest in IP protection than countries more likely to be importers of innovation. Some regions, like Europe, with a long history of specialized agricultural production may have stronger interest in protecting geographical indications (like Champagne or Parma ham) than countries whose agricultural producing regions are less well identified with products. Therefore, just as countries differ in respect to their interests in offering and accepting concessions on tariffs and quotas in trade negotiations, they also differ in respect to their interests in offering and accepting concessions in IP. A country that is going to be a 'net payer' for technology, expression or identifiers will likely have a weaker interest in offering higher standards of IP protection.

The TRIPS Agreement effectively mandated universal standards of IP protection. These rules are applicable to countries at widely different stages of economic development, with different political, cultural and educational systems.[129] The balance reflected in the TRIPS Agreement was composed over time in various industrialized countries.[130] Developing countries must accommodate to these rules. In many cases, the infrastructure to do this is lacking. Some developing countries made policy choices that differed substantially from those of the US, EU and Japan. Those choices have now been unwound. The TRIPS Agreement took developmental and policy differences into account by including transition arrangements, but transition periods have

[127] An excellent review of the economic literature concerning the role of IPRs in economic development is Fink and Maskus eds (2005).

[128] If a small country lacks the factors necessary to move new technology into commercial scale production, it may elect to license out innovation to foreign producers.

[129] On differential interests in IPRs, see Maskus (2000), and Abbott (1998a).

[130] In the United States, the Constitution addresses IP. Congress plays an active role in regulating IP. US IP law is adjusted on a more or less regular basis to accommodate changes in technologies and perceptions about the proper balance between the rights that should be accorded to innovators and the access that should be permitted consumers. In areas of high social concern, such as pharmaceuticals, the US Congress has adopted highly complex mechanisms for balancing the interests of innovating companies, generic producers and consumers.

now largely expired. Negotiations on TRIPS subject matter at the WTO and in other fora continue to be a source of controversy. Because of the important and disparate interests at stake, this should not be surprising.

Conclusion

Intellectual property rights perform a variety of functions. They promote innovation and creative expression, and they protect investment. The promotion of innovation and protection of investment are important objectives for the global economy. New products and methods for producing them improve the quality of life and enhance productivity. It is important, however, to bear in mind that IPRs protection also imposes social and economic costs. It restricts the use of knowledge, even if for a limited time. The benefits of IPRs protection are not equitably shared among the richer and poorer nations. Just as national legislators must seek to strike a balance between the interests of various domestic stakeholders in IPRs protection, so must those responsible for negotiations at the multilateral level seek to strike an appropriate balance among industry and consumers, and among the wealthy and the poor. The people of the world are closely linked by new technologies and we share an interest in a stable and prosperous international environment.

References

Books

Abbott, Frederick M. and David Gerber (eds) (1997), *Public Policy and Global Technological Integration*, London, The Hague, Boston: Kluwer Law International.

Abbott, Frederick, Thomas Cottier and Francis Gurry, (1999), *The International Intellectual Property System: Commentary and Materials*, The Hague, The Netherlands: Kluwer Law International.

Fink, Carsten and Keith Masclus (eds), (2005), *Intellectual Property and Development, Lessons from Recent Economic Research*, Washingston, DC: The World Bank.

Maskus, Keith, (2000), *Intellectual Property Rights in the Global Economy*, Washington, DC: Institute for International Economics.

Maskus, Keith and Jerome H. Reichman (eds), (2005), *International Public Goods and Transfer of Technology*, Cambridge, UK: Cambridge University Press.

McCarthy, Thomas J. (2005) [1996], *McCarthy Trademarks and Unfair Competition*, 4th edn, July, Deerfield, IL: Clark Boardman Callaghan.

Nordhaus, William D. (1969), *Invention, Growth and Welfare*, Cambridge, MA: MIT Press.

Sell, Susan, (2003), *Private Power, Public Law, The Globalization of Intellectual Property Rights*, Cambridge Studies in International Relations (88), Cambridge, UK: Cambridge University Press.

Resource Book on TRIPS and Development (2005), UNCTAD/ICTSD, Cambridge, UK: Cambridge University Press.

Articles

Abbott, Frederick, M. (1989), 'Protecting First World Assets in the Third World: Intellectual Property Negotiations in the GATT Multilateral Framework', *Vanderbitt Journal of Transnational Law*, 22, 689.

Abbott, Frederick, M. (1997a), 'The WTO Trips Agreement and Global Economic Development' in *Public Policy and Global Technological Integration*, 39, The Hague: Kluwer Law International.

Abbott, Frederick M. (1997b), 'The WTO Trips Agreement and Global Economic Development', *Chicago-Kent Law Review*, 72, 385.

Abbott, Frederick M. (1998a), 'The Enduring Enigma of TRIPS: A Challenge for the World Economic System', *Journal of International Economic Law*, 1, 497.

Abbott, Frederick M. (1998b), 'First Report (Final) to the International Trade Law Committee of the International Law Association on the Subject of Parallel Importation (June 1997)', *Journal of International Economic Law*, 1, 607.

Abbott, Frederick M. (2000a), 'Distributed Governance at the WTO-WIPO: An Evolving Model for Open-Architecture Integrated Governance', *Journal of International Economic Law*, 3, 63.

Abbott, Frederick M. (2000b), 'TRIPS in Seattle: The Not-So-Surprising Failure and the Future of the TRIPS Agenda', *Berkeley Journal of Interational Law*, 18, 165.

Abbott, Frederick M. (2002), 'The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO', *Journal of International Economic Law*, 5, 469.

Abbott, Frederick M. (2003), 'Non-Violation Nullification or Impairment Actions under the TRIPS Agreement and the Fifth Ministerial Conference: A Warning and Reminder', QUNO Occasional Paper No. 11, July.

Abbott, Frederick M. (2004a), 'Are the Competition Rules in the WTO TRIPS Agreement Adequate?' *Journal of International Economic Law*, 7, 685.

Abbott, Frederick M. (2004b), 'WTO Dispute Settlement Practice Relating to the Agreement on Trade-Related Aspects of Intellectual Property Rights', in F. Ortino and E.-U. Petersmann (eds), *The WTO Dispute Settlement System 1995–2003*, at 421.

Abbott, Frederick M. (2004b), 'Managing the Hydra: The Herculean Task of Ensuring Access to Essential Medicines', in Maskus and Reichman (2005).

Abbott, Frederick M. (2005b), 'Toward a New Era of Objective Assessment in the Field of TRIPS and Variable Geometry for the Preservation of Multilateralism', *Journal of International Economic Law*, 8, 77.

Abbott, Frederick M. (2005c), 'The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health', *American Journal of International Law*, 99, 317.

Abbott, Frederick M. and R. Van Puymbroeck (2005c), 'Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision', World Bank Working Paper No. 61.

Arrow, Kenneth J. (1962), 'Economic Welfare and the Allocation of Resources for Invention', Richard R. Nelson (ed), in The Rate And Direction Of Inventive Activity: Economic And Social Factors, 609.

Barlow, John Perry (1994), 'The Economy of Ideas: A Framework for Patents and Copyrights in the Digital Age. (Everything you know about intellectual property is wrong.)', *Wired*, March, 2.

Barton, John H. (2005), 'Issues Posed by World Patent System', in Maskus and Reichman (2005).

Coombe, Rosemary J. (2005), 'Protecting Cultural Industries to Promote Cultural Diversity: Dilemmas for International Policymaking Posed by the Recognition of Traditional Knowledge', in Maskus and Reichman (2005).

Correa, Carlos (2005), 'Can the TRIPS Agreement Foster Technology Transferred to Developing Countries?', in Mascus and Reichman (2005).

Cottier, Thomas and Marion Pannizon (2005), 'Legal Perspectives on Traditional Knowledge: The Case for Intellectual Property Protection', in Masjus and Reichman (2005).

Danzon, Patricia M. and Adrian Towse (2005), 'Theory and Implementation of Differential Pricing for Pharmaceuticals', in Maskus and Reichman (2005).

DiMasi, J.A., R.W. Hansen and H.G. Grabowski (2003), 'The Price of Innovation: New Estimates of Drug Development Costs', *Journal of Health Economics*, 22, 151.

Drahos, Peter (2002), 'Developing Countries and International Intellectual Property Standards-Setting', *Journal of World Intellectual Property*, 5, 765.

Dutfield, Graham (2005), 'Legal and Economic Aspects of Traditional Knowledg', in Maskus and Reichman (2005).

Fink, Carsten and Patrick Reichenmiller (2005), 'Tightening TRIPS: The Intellectual Property Provisions of Recent US Free Trade Agreements', World Bank Trade Note No. 20.

Sykes, Alan O. (2002), 'Public Health and International Law: TRIPS, Pharmaceuticals, Developing Countries, and the Doha Solution', *Chicago Journal of International Law*, 3, 47.
Taubman, Anthony (2005), 'Saving the Village: Conserving Jurisprudential Diversity in the International Protection of Traditional Knowledge', in Maskus and Reichman (2005).

Reports

Fritz Machlup (1958), 'An Economic Review of the Patent System', Subcommittee on Patents, Trademarks and Copyrights, of the Committee on the Judiciary, 85th Congress, 2d Session.
US Federal Trade Commission (2005), *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, October.
World Bank (2005), *Global Economic Prospects 2005*, chapter 5.

Cases

A&M Records v. Napster, 114 F. Supp. 2d 896 (ND Cal. 2000), subsequent history in *A&M Records v. Napster*, 239 F.3d 1004 (9th Cir. 2001)
Feist Publications v. Rural Telephone Service, 499 US 340 (1991)
Kewanee Oil v. Bicron, 416 US 470 (1974)
Qualitex v. Jacobson, 514 US 159 (1995)

WTO DSU

Canada – Patent Protection of Pharmaceutical Products, WT/DS114, 17 March 2000 ('Canada – Generic Pharmaceuticals')
Canada – Term of Patent Protection, WT/DS170, 18 September 2000 ('Canada – Patent Term')
European Communities – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs ('EC – GIs'), the United States (WT/DS174/R, 15 March 2005) and Australia (WT/DS290/R, 15 March 2005)
India – Patent Protection for Pharmaceutical and Agricultural Chemical Products, WT/DS50, 5 September 1997 ('India – Mailbox')
United States – Section 110(5) of the US Copyright Act, WT/DS160, 15 June 2000 ('US – Copyright Exemption')
United States – Section 211 Omnibus Appropriations Act of 1998, WT/DS176 ('US – Havana Club')
United States – Section 337 of the Tariff Act of 1930 ('US – Section 337'), adopted 7 November 1989, BISD 36S/345

12. Power and cooperation in international environmental law

*Richard H. Steinberg**

This chapter examines international environmental regulation from economic, political, and legal perspectives. Section 1 introduces the economics and politics of international environmental regulation. International agreements on environmental issues are often seen as symmetric contracts among states, solving cooperation problems among states with similar interests, or facilitating side-payments from states that favor environmental regulation to states that would not otherwise support regulation. In contrast, some realist political scientists suggest that when international environmental interests vary across states, international environmental agreements often result from coercion of weaker states by more powerful ones.

With this framework in mind, the bulk of this chapter examines the negotiation and substance of the world's most important international environmental agreements.[1] Section 2 examines the main agreements related to international environmental protection of the oceans, including those concluded to protect fisheries and those intended to reduce land-based marine pollution. Section 3 examines the main agreements relating to global air pollution and climate change – the Montreal Protocol to the Vienna Convention for the Protection of the Ozone Layer (Montreal Protocol)[2] and the Kyoto Protocol to the United Nations Framework Convention on Climate Change (Kyoto Protocol).[3] Section 4 explores the main trade and the environment issues and agreements, including the Basel Convention on the Transboundary Movement of Hazardous Wastes (Basel Convention)[4] and the Convention on

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1 As this suggests, this chapter focuses on understanding commitments to (i.e., not compliance with) international environmental agreements.

2 Montreal Protocol on Substances that Deplete the Ozone Layer, 16 September 1987, 26 ILM 1541.

3 Kyoto Protocol to the FCCC, FCCC Conference of the Parties, 37 ILM 22 (1998).

4 Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, 22 March 1989, 28 ILM 649 (1989).