

Intellectual Property, International Protection

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A. Intellectual Property in General

- 1 Intellectual property is regulated at the multilateral, regional, bilateral, national, and sub-national levels. Intellectual property 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 ('Paris Convention') and the Berne Convention for the Protection of Literary and Artistic Work of 1886 ('Berne Convention').

B. Forms of Intellectual Property

- 2 Intellectual property is a defined set of the intangible products of human creative activity. Unlike real property and personal property which are 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’. These legal rights are intended to solve the economic problem described by Kenneth Arrow as the ‘incomplete appropriability of knowledge’. As 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, ie competitors can easily appropriate it. Intellectual property rights (‘IPRs’) are an effort to solve this problem.
- 3 Intellectual property is usually referred to by the form of ‘right’ 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’ (see also → *Industrial Property, International Protection*). 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.

1. Patent

- 4 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 ‘non-obvious’), and is capable of industrial application (or ‘useful’). 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 → *Agreement on Trade-Related Aspects of Intellectual Property Rights (1994)* (‘TRIPS Agreement’) of the → *World Trade Organization (WTO)* (described in paras 50–54 below) 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.
- 5 The patent is intended to perform three functions: (a) to stimulate inventive activity; (b) to encourage investment in the products of inventive activity; and (c) to disseminate technical information to the public. The extent to which the patent effectively performs these functions has been the subject of long debate. The principal alternatives to using patents to stimulate inventive activity are government subsidies and prizes. 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. Prizes may be quite useful in the context of promoting innovative solutions to defined technical problems, but are less relevant to the ‘open-ended’ promotion of innovation. There is recent concern that an over-proliferation of patents may impede inventive activity, at least in certain fields, as a ‘patent thicket’ grows.
- 6 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, the prospect of patent protection may promote invention of a new anti-cancer medicine by encouraging investment in pharmaceutical research and development. At the same time, the granted patent may allow one supplier to control the market, significantly increasing the price of the new treatment and reducing patient access to it. The patent term is limited, so that generic producers eventually may copy the medicine and enter the market. But, there remain serious questions about the impact on patients and public health during the term of the patent. 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.

2. Trademark

- 7 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, colours, shapes, sounds, and scents. A trademark allows its holder to prevent others from using an identical or confusingly similar sign to identify its goods or services in commerce. 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, ie, third parties may be prevented from 'tarnishing' or 'blurring' the trademark.

- 8 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. 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 product testing. Trademarks also provide a vehicle into which business enterprises can invest advertising dollars, stimulating brand identification and 'goodwill'. 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.

3. Copyright

- 9 '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. 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 'neighbouring 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.
- 10 Copyright is intended to benefit the public by encouraging authors and artists to create and disseminate their works. As with other forms of intellectual property, it is difficult 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 film and music producing companies routinely offer data regarding losses suffered as a result of inadequate enforcement of copyright protection, 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'. 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 non-enforcement 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, attendance at performances, and/or consequent CD sales.

4. Design Protection

- 11 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 non-functional aesthetic design. In a number of jurisdictions, this led to the creation of a separate design patent specifically granted to non-functional product elements. However, design patenting has a number of drawbacks, including the fact 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. As an identifying symbol, the design or shape of a product may serve a trademark function. 'Trade dress' refers to the packaging of a product that may be distinctive and associated with a particular enterprise. However, as with copyright, trademark and trade dress offer protection only for non-functional design, and this aspect also creates enforcement uncertainty. To overcome problems with design protection by traditional forms of intellectual property, jurisdictions such as the European Union have established design registration systems with somewhat more flexible standards than those associated with the traditional IPRs.
- 12 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 WTO 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 Council Regulation (EC) 6/2002 of 12 December 2001 on Community Designs ([2002] OJ L3/1), the EC excluded engine components from design protection and put off for future negotiation a decision on whether automobile body parts were covered.

5. Geographical Indication

- 13 Geographical indications ('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. The classic illustrative GI is 'Champagne', ie 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 labelling 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.
- 14 The EU has been pressing the WTO to increase the level of GI protection for agricultural products other than wines and spirits—which already enjoy strong protection—but this has been resisted by the United States, among others. The EU is a comparatively high cost producer of specialized agricultural products and is seeking higher prices for those products based on GI protection. The United States is a comparatively 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 rely on efficient large-scale agricultural production, on one hand, or are seeking to succeed in the global marketplace as producers of specialized products on the other.

6. Protection of Layout-Design of Integrated Circuits

- 15 Integrated circuits ('IC')—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 layout 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.

7. Protection of Undisclosed Information

- 16 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 specialized 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'.
- 17 Trade secret protection enables businesses to develop and maintain production processes, customer lists, recipes, and other valuable information that provide advantages over competitors. 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, though recognizing that training materials may incorporate information in the public domain, yet be of independent value based on their organization. The scope of protection of data submitted for regulatory purposes in the pharmaceutical and agricultural sector is highly controversial because the extent of such protection helps to determine the speed at which copies—or 'generic' versions of 'originator' products—can be granted regulatory approval and brought to market.

C. Multilateral Regulation of Intellectual Property

1. The Early Multilateral Regulatory System

- 18 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 was addressed to copyright.
- 19 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 (→ *National Treatment, Principle*). 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 country will not affect the status of equivalent patents or trademarks in other Paris Convention countries. So, for example, if a court in one country determines that a patent is invalid and orders it cancelled, this does not affect the validity of patents on the same invention in other Paris Convention countries. This rule reflects the fact that governments are distrustful of the possible motives of other governments in acting against their inventors.
- 20 The Paris Convention does not prescribe a rule of 'territoriality' with respect to the geographical scope of patent protection, but there is a strong tradition among Paris Convention parties to apply such protection for and within their national territory. Countries typically do not attempt to grant their patent holders the right to exclude competitors from the market on foreign territory. Such a right would be exceedingly difficult to enforce given that it would intrude upon foreign jurisdictional prerogatives. However, there is a modest trend in some legal systems to take activities occurring abroad into account when determining whether a local patent has been infringed. This is because modern technology has created more possibility for infringement to involve actions taken in more than one country, with a direct and substantial impact on a country where a patent is in force.
- 21 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 (ICJ)*. In addition, the Paris Convention includes liberal rules on compulsory licensing of patents.
- 22 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.
- 23 From the standpoint of the expressive industries, the major drawbacks of the Berne Convention are that it does not cover so-called 'neighbouring 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.
- 24 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.

2. From the World Intellectual Property Organization to the General Agreement on Tariffs and Trade and World Trade Organization

- 25 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. 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.
- 26 The concern of industry coincided with a movement among → *developing countries* in favour of a → *New International Economic Order (NIEO)*. That movement was centred in the → *Group of 77 (G77)* 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 (→ *Natural Resources, Permanent Sovereignty over*), and demanded transfer of technology from North to South to remedy imbalances in development. The NIEO sought at → *World Intellectual Property Organization (WIPO)* to relax protection of intellectual property, such as by providing more flexible rules for the compulsory licensing of patents.
- 27 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 States and other developed countries, including those of the European Community ('EC') and Japan, demanded stronger protection of intellectual property rights. Developing countries demanded more flexible rules. The negotiations failed, and as a consequence the United States, EC, and Japan shifted focus to the → *General Agreement on Tariffs and Trade (1947 and 1994)* ('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 ('TRIPS').
- 28 The TRIPS negotiations were among the most controversial aspects of the GATT Uruguay Round (1986–93). 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 intellectual property protection could, of course, choose to do this outside the GATT.
- 29 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 authority—granted by the 1974 Trade Act's Special Section 301—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 TRIPS Agreement as one of the three pillars of the World Trade Organization system; along with the GATT and the → *General Agreement on Trade in Services (1994)* ('GATS').
- 30 The entry into force of the TRIPS Agreement on 1 January 1995 as part of the new WTO created a situation in which two multilateral institutions share responsibility for regulation of the international IPRs system. While the TRIPS Agreement incorporates the provisions of various WIPO-administered agreements (as discussed in para. 31 below), there is no well-defined hierarchy or relationship between the rules and authority of the WTO and WIPO. There is the very general Agreement between the World Intellectual Property Organization and the World Trade Organization on their cooperation, but it does not purport to define the responsibilities of the organizations on substantive matters. A major distinction between the two, however, is that the TRIPS Agreement incorporates the WTO dispute settlement system (→ *World Trade Organization, Dispute Settlement*), allowing for trade-based enforcement of its rules (→ *World Trade Organization, Enforcement System*). Several of the Conventions administered by WIPO ('WIPO Conventions') permit recourse to the ICJ, but no case has been brought before the ICJ on the basis of such a convention.

3. The Agreement on Trade-Related Aspects of Intellectual Property Rights

- 31 The TRIPS Agreement consists of a preamble and seven parts. The first part defines the relationship between the TRIPS Agreement and national law (see also → *International Law and Domestic [Municipal] Law*), and between the TRIPS Agreement and certain WIPO Conventions. It includes the core national and most-favoured-nation treatment ('MFN') provisions. The second part incorporates the substantive rules applicable to different forms of intellectual property. 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.

(a) Principles

- 32 The national treatment provision of the TRIPS Agreement obligates each Member to treat nationals of other Members on at least as favourable as its own nationals with respect to the protection of intellectual property. National treatment is a common feature of international intellectual property agreements, including WIPO Conventions, predating the TRIPS Agreement. The most-favoured-nation treatment provision obligates each Member to extend the same intellectual property privileges and immunities granted to nationals of one Member to nationals of all other Members. Prior to the TRIPS Agreement, MFN was not included in international intellectual property agreements largely because it did not appear likely that a country would grant to any foreigners intellectual property 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 WTO Appellate Body has identified national treatment and MFN as fundamental principles of the TRIPS Agreement (see also → *World Trade, Principles*).
- 33 The TRIPS Agreement left each Member to decide on its own policy with respect to the exhaustion of rights. The point at which IPRs are 'exhausted' determines when the holders of rights cease to control the movement of goods or services in commerce. 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.
- 34 There are several alternative approaches to exhaustion that countries may adopt, including national, regional, and international exhaustion. In addition, different exhaustion rules may be adopted with respect to different IPRs by the same country. 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.
- 35 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.
- 36 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.
- 37 The rule of exhaustion has received quite a bit of attention in the case of 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.
- 38 The parallel imports debate has another dimension with respect to so-called 'differential' or 'equity' pricing strategies. 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. 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.

- 39 The Doha Declaration on the TRIPS Agreement and Public Health ('Doha Declaration'; discussed in paras 75–76 below) confirmed the right of WTO Members to decide on their own policies with respect to exhaustion.
- 40 The TRIPS Agreement also includes principles confirming the importance of encouraging the transfer of technology to promote development, and recognizing the right of Members to adopt measures consistent with the TRIPS Agreement to protect public health and nutrition, as well as to control anticompetitive practices.
- 41 WTO Members are required to give effect to the TRIPS Agreement in national law, but the agreement leaves to each Member the precise means for doing so.

(b) The Substantive Rules

- 42 The TRIPS Agreement identifies certain intellectual property subject matter as being subject to its rules. 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: a 'trade name' identifies a business, as distinguished from a 'trademark' that identifies a good or service. Also, in some areas discretion on the scope of subject matter is left to Members. Taking this shading into account, the TRIPS Agreement still does not apply to all subject matter that might come within the concept of intellectual property as broadly defined, but rather it applies to subject matter that is addressed by the TRIPS Agreement.
- 43 The broad categories of intellectual property addressed by the TRIPS Agreement are copyright, trademark, geographical indication, industrial design, patent, layout-design of integrated circuits, and protection of undisclosed information.

(i) Copyright

- 44 For copyright, the TRIPS Agreement largely relies on the substantive rules of the Berne Convention which are incorporated by reference. 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. The TRIPS Agreement adds rules clarifying that computer software and compilations of data—based on the creative activity involved in their assembly—are copyrightable subject matter. The TRIPS Agreement also extends copyright to certain rights of performers in their unfixed performances, and to certain rights of producers of phonograms and of broadcast organizations. The TRIPS Agreement sets out a general provision on limitations and exceptions to copyright, which is largely coextensive with a corresponding provision in the Berne Convention. By incorporating relevant provisions of the Berne Convention, the TRIPS Agreement includes other exception provisions, for example, with respect to fair use. Under the concept of fair use, persons other than the copyright holder are allowed to use copyrighted material without permission for certain purposes, such as academic criticism.

(ii) Trademark

- 45 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. The TRIPS Agreement also makes service marks subject to an equivalent level of protection with trademarks on goods. While a trademark identifies and distinguishes a tangible product, a service mark identifies and distinguishes a service, such as a travel agency or banking service. The term 'trademark' may be used to refer broadly to both trademark and service mark.
- 46 Trademark protection extends as long as the trademark holder continues to use the mark, subject to applicable requirements with respect to renewal of registration. A minimum trademark renewal term of seven years is established. Trademark holders are accorded the right to prevent third parties from using marks in a way that would result in a likelihood of confusion, 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. The TRIPS Agreement limits conditions that can be attached to the use of marks. The rules also include exceptions for fair use of marks. In the trademark context, fair use includes matters such as use in comparative advertising.

- 47 There was relatively little controversy about incorporation of trademark protection in the TRIPS Agreement. 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.

(iii) Geographical Indication

- 48 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. The TRIPS Agreement obligates Members to protect GIs based on rules derived from WIPO Conventions, 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 2009, are ongoing. A specific form of protection for wines and spirits precludes third parties from using protected geographical designations even if they take steps to avoid consumer confusion, such as by adding the term '-like' to their usage. The TRIPS Agreement includes a provision calling for negotiations to establish a register of geographical indications for wines for countries participating in the system.

(iv) Industrial Design

- 49 The TRIPS Agreement obligates Members to provide 10 years of protection to industrial designs, but does not prescribe a specific way to accomplish this. The methods for protecting industrial design have traditionally included copyright, trademark, and trade dress, design patent, and *sui generis* design registration systems. The TRIPS 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. 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.

(v) Patent

- 50 The most significant changes to the international intellectual property 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.
- 51 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. It also provides for sufficiency of disclosure. 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. The TRIPS Agreement prescribes a minimum 20 year term of protection counted from the filing of the patent application.
- 52 The TRIPS Agreement allows for certain exclusions from patentability, such as for the protection of public order and for diagnostic or therapeutic procedures. It permits Members to refuse patenting of animals and plants, but requires that some form of plant variety protection be provided. 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.
- 53 The TRIPS Agreement expands upon the compulsory licensing rules found in the Paris Convention, prescribing substantive and procedural conditions for the grant of such licenses. 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 (→ *Emergency, State of*), 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. 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 WTO panel decision.
- 54 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. In respect to 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. This rather complex system was the subject of the first WTO Appellate Body decision concerning TRIPS (WTO *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products* [16 January 1998] WT/DS50/AB/R). As the 10 year transition period expired on 1 January 2005, the complex subject of mailbox applications will become a matter largely of historical interest once the complex patent application processing situation in India is completed.

(vi) Layout-Design of Integrated Circuits

- 55 The Treaty on Intellectual Property in Respect of Integrated Circuits ('IPIC Treaty') was negotiated and signed under the auspices of WIPO, but has not entered into force. 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. TRIPS Agreement provisions require that protection for 'original' mask works be provided for a minimum of 10 years following registration or first commercial exploitation anywhere in the world. Members need not adopt registration systems.

(vii) Protection of Undisclosed Information

- 56 The TRIPS Agreement requires Members to protect confidential commercial information, generally referred to in common law countries as 'trade secrets'. The TRIPS Agreement accomplishes this by incorporating a provision of the Paris Convention addressing unfair competition and by broadly defining the protectable subject matter. 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.
- 57 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'. Protection is to be provided against unfair commercial use, and the data is 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 and European Union assert 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.

(c) Competition

- 58 There is a very close relationship between laws regulating intellectual property and laws regulating competition. 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 (→ *Antitrust or Competition Law, International*). 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, 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.
- 59 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 and a more specific provision addressing restrictive conditions in licensing agreements, as well as encouraging intergovernmental cooperation. In addition, rules on compulsory licensing specially attend to measures taken to address anticompetitive practices. 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.

(d) Enforcement Obligations

- 60 A significant part of the TRIPS Agreement is devoted to the measures Members are expected to make available for the enforcement of IPRs. 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.

- 61 The TRIPS Agreement requires Members to establish effective procedures for the enforcement of IPRs, including provision for → *remedies* to prevent further infringement. The procedures must be fair and equitable (→ *Fair and Equitable Treatment*). When decisions are taken by administrators, they should be subject to review by judicial authority.
- 62 Members are obligated to provide IPRs holders with access to civil judicial procedures to enforce their rights. Parties should have adequate opportunity to present evidence (see also → *International Courts and Tribunals, Evidence*).
- 63 Damages and injunctions should be available. Judges should have the authority to order the destruction of infringing goods. Abuse of legal process should be subject to remedial action.
- 64 Procedures for provisional measures to prevent infringement and the destruction of evidence should be available (→ *Interim [Provisional] Measures of Protection*). When provisional measures are granted prior to hearing from an alleged infringer, the accused should be given an opportunity for a prompt review.
- 65 Members must provide procedures under which IPRs holders may provide notice to customs authorities of suspected shipments of counterfeit trademark and copyright pirated goods, and make available procedures for the suspension of their entry into commerce. Adequate security may be required to protect the importer. The importer shall be notified, and a hearing on the suspension must be convened promptly. The accuser may be required to indemnify the importer for wrongful detention of goods.
- 66 Members are required to make available criminal procedures and penalties for wilful trademark infringement and copyright piracy on a commercial scale.

(e) Acquisition and Maintenance

- 67 The TRIPS Agreement includes a provision recognizing that Members may adopt procedures and formalities for the grant and maintenance of IPRs. 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.

(f) Dispute Settlement

- 68 Dispute settlement under the TRIPS Agreement is undertaken pursuant to the Dispute Settlement Understanding. 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. A compromise was adopted which provided for a five year → *moratorium* on such non-violation complaints, 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*. The five year period passed with no action having been taken. At the subsequent Ministerial meetings of the → *Doha Round* in Cancun (2003), Hong Kong (2005), and Geneva (2009), Members agreed to extend the moratorium at least until the next Ministerial meeting following the Geneva meeting.
- 69 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 intellectual property.

(g) Transitional Arrangements

- 70 There are different types of transitional arrangements under the TRIPS Agreement. Most of the transition time frames have expired. However, least developed countries in general had until 1 January 2006 to apply TRIPS standards. 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 were granted an additional 10 year period—until 1 January 2016—to provide pharmaceutical patent or data protection, and need not enforce patent and data rights that may already have been granted. In December 2005 the general transition period for least developed countries was extended until 1 July 2013. However, other than in respect of pharmaceutical products, → *developing countries* lost the flexibility to reduce levels of protection already in force.

(h) Institutional Matters

- 71 The WTO Agreement establishes the Council for Trade-Related Aspects of Intellectual Property Rights ('TRIPS Council') to oversee the implementation of the TRIPS Agreement. The TRIPS Council has a number of specific responsibilities under the TRIPS Agreement, including reviewing the laws of Members, 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*.
- 72 Pursuant to its internal rules of procedure, the TRIPS Council acts only by consensus. 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.
- 73 The TRIPS Council is also responsible for coordinating activities with WIPO. A modest cooperation agreement has been concluded between the WTO and WIPO (Agreement between the World Intellectual Property Organization and the World Trade Organization).

(i) TRIPS Dispute Settlement Decisions

- 74 There have been a number of cases decided by WTO Panels and the Appellate Body under the terms of the TRIPS Agreement: (a) *WTO India—Patent Protection for Pharmaceutical and Agricultural Chemical Products* (1997), (b) *WTO Canada—Patent Protection of Pharmaceutical Products* (2000), (c) *WTO United States—Section 110(5) of the US Copyright Act* (2000), (d) *WTO Canada—Term of Patent Protection* (2000), (e) *WTO United States—Section 211 Omnibus Appropriations Act of 1998* (2002), (f) *WTO European Communities—Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs, Complaint by the United States* (2005), (g) *WTO European Communities—Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs—Complaint by Australia* (2005), and (h) *WTO China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights* (2009). Other dispute settlement claims have been initiated and withdrawn.

(j) The Medicines Debate

- 75 The TRIPS Agreement entered the public spotlight in a major way in the context of a debate concerning the role of patents on medicines. 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. The 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 → *Non-Governmental Organizations* ('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.
- 76 Para. 6 Doha Declaration addressed the problem of effective use of compulsory licensing by countries with insufficient manufacturing capacity in the pharmaceutical sector. 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 Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health ('2003 Waiver Decision'), which provides a waiver of certain TRIPS obligations. More specifically, it waives the restriction otherwise imposed by Art. 31(f) TRIPS Agreement, which limits production under compulsory license to supplying a Member's domestic market, and also limits remuneration to the exporting country. On 6 December 2005, WTO Members adopted the Decision on the Amendment of the TRIPS Agreement ('2005 Amendment') that will transform the 2003 Waiver Decision into an amendment of the TRIPS Agreement when it is approved by a sufficient number of Members. The 2003 Waiver Decision will continue in effect until the 2005 Amendment is approved by all WTO Members. As of 19 September 2009, the 2005 Amendment had been accepted by 52 Members, including Brazil, China, the European Union, India, and the United States.

77 The 2003 Waiver Decision and the 2005 Amendment authorize 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. The 2003 Waiver Decision and the 2005 Amendment are important elements of developing country TRIPS flexibility.

4. The Role of the World Intellectual Property Organization

78 WIPO also continues to play a major role in this area. First, WIPO administers treaties pursuant to which persons may secure registration of patents and trademarks in many countries, including the Patent Co-operation Treaty ('PCT'), the Madrid Agreement concerning the International Registration of Marks ([done 14 July 1967, entered into force 19 September 1970] 828 UNTS 390), and the Protocol relating to the Madrid Agreement concerning the International Registration of Marks ([done 27 June 1989, entered into force 1 December 1995] [2000] vol II CTIA 1260). Administration of the PCT is highly technical work and employs a large staff. Secondly, WIPO continues to serve as a forum for negotiations on IPRs. Shortly following the entry into force of the TRIPS Agreement, the WIPO Copyright Treaty ([adopted 20 December 1996; entered into force 6 March 2002] [1997] 36 ILM 65; 'WCT') and the WIPO Performances and Phonograms Treaty ([done 20 December 1996, entered into force 20 May 2002] [1997] 36 ILM 76; '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. Thirdly, 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*.

79 The fourth session of the Provisional Committee on Proposals Related to a WIPO Development Agenda ('PCDA') met on 11–15 June 2007. At that meeting, the PCDA approved a list of 45 proposals in a number of areas, including capacity building, → *technical assistance*, norm-setting, and → *technology transfer*, in addition to proposing the establishment of a permanent Committee on Development and Intellectual Property at WIPO. In October 2007, the proposal for the Committee was adopted by the WIPO General Assembly. The Committee on Development and Intellectual Property held its first meeting in Geneva on 3–7 March 2008. This Committee has broad mandate to study and make recommendations with respect to improving the intellectual property framework in order to better promote the development and use of technology, especially by developing countries.

80 A controversial ongoing WIPO negotiation concerns substantive patent law harmonization through a Draft Substantive Patent Law Treaty ('DSPLT'). Negotiations on the DSPLT have proceeded slowly because of differences in perspective as to the range of subject matter to be included, particularly as between developed and developing countries, and because of differences on substantive rules—such as the grace period for non-anticipating disclosure—which continue to divide developed countries. There is no reason to expect these negotiations to make rapid progress in the near future, absent some significant shift in the position of key States.

81 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. Due to 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.

5. Other Multilateral Organizations and Non-Governmental Organizations

82 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 Agriculture Organization of the United Nations (FAO)*, the → *United Nations Conference on Trade and Development (UNCTAD)*, World Bank, and the → *World Health Organization (WHO)*, among others, have taken a much more active interest in IPRs-related matters in recent years.

83 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. An Inter-Governmental Working Group on Health, Innovation and Intellectual Property ('IGWG') worked for two years on a draft Global Strategy and Plan of Action intended to improve the way innovation is generated and the way results are made available to those in need. Following the second session of IGWG at the end of April 2008, the World Health Assembly adopted the Global Strategy and Plan

of Action on Public Health, Innovation and Intellectual Property, setting in motion further elaboration of mechanisms to implement it.

- 84 In addition to the governmental side, → *civil society* through non-governmental organizations, including Médecins Sans Frontières (Doctors without Borders), Oxfam International, 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. In recent years NGOs have played an important role in IPRs negotiations at all levels of governance.

6. Protection of Biodiverse Resources

- 85 There are other important IPRs policy issues being addressed at the multilateral level. These include the relationship between the TRIPS Agreement and the Convention on Biological Diversity, 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.

7. The Regulation of Intellectual Property at the Regional and Bilateral Level

- 86 Intellectual property is regulated by regional organizations such as the European Union (see eg → *European Patent System*). 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 27 Member States and its importance as a market for goods and services, the details of its intellectual property regulatory system are important to those involved in international business.
- 87 There are many regional organizations, including the → *Andean Community of Nations (CAN)*, the → *Association of Southeast Asian Nations (ASEAN)*, the → *Asia-Pacific Economic Cooperation (APEC)*, the → *Caribbean Community (CARICOM)*, the → *North American Free Trade Agreement (1992) ('NAFTA')*, the → *MERCOSUR* for the South America Southern Cone, and the Southern African Customs Union (→ *Regional Co-operation and Organization: African States; 'SACU'*). Each of these organizations has adopted some form of intellectual property rules.
- 88 In recent years, the United States and European Union have used regional and bilateral trade negotiations as a way to secure concessions from other countries on IPRs matters.

D. Conclusion

- 89 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.

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