INTERNATIONAL AND REGIONAL TRADE LAW:
THE LAW OF THE WORLD TRADE ORGANIZATION

J.H.H. Weiler
NYU School of Law

Sungjoon Cho
Chicago-Kent College of Law

Isabel Feichtner
Goethe University, Frankfurt

Julian Arato
Brooklyn Law School

Unit XI: Trade-Related Aspects of Intellectual Property Rights (TRIPS)

The Law of World Trade Organization
Unit XI: The Trade-Related Aspects of Intellectual Property Rights (TRIPS)

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I. Overview

TRIPS : A MORE DETAILED OVERVIEW OF THE TRIPS AGREEMENT
Overview: the TRIPS Agreement

The TRIPS Agreement, which came into effect on 1 January 1995, is to date the most comprehensive multilateral agreement on intellectual property.

https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm

The areas of intellectual property that it covers are: copyright and related rights (i.e. the rights of performers, producers of sound recordings and broadcasting organizations); trademarks including service marks;geographical indications including appellations of origin; industrial designs;patents including the protection of new varieties of plants; the layout-designs of integrated circuits; and undisclosed information including trade secrets and test data.

The three main features of the Agreement are:

- **Standards**. In respect of each of the main areas of intellectual property covered by the TRIPS Agreement, the Agreement sets out the minimum standards of protection to be provided by each Member. Each of the main elements of protection is defined, namely the subject-matter to be protected, the rights to be conferred and permissible exceptions to those rights, and the minimum duration of protection. The Agreement sets these standards by requiring, first, that the substantive obligations of the main conventions of the WIPO, the Paris Convention for the Protection of Industrial Property (Paris Convention) and the Berne Convention for the Protection of Literary and Artistic Works (Berne Convention) in their most recent versions, must be complied with. With the exception of the provisions of the Berne Convention on moral rights, all the main substantive provisions of these conventions are incorporated by reference and thus become obligations under the TRIPS Agreement between TRIPS Member countries. The relevant provisions are to be found in Articles 2.1 and 9.1 of the TRIPS Agreement, which relate, respectively, to the Paris Convention and to the Berne Convention. Secondly, the TRIPS Agreement adds a substantial number of additional obligations on matters where the pre-existing conventions are silent or were seen as being inadequate. The TRIPS Agreement is thus sometimes referred to as a Berne and Paris-plus agreement.

- **Enforcement**. The second main set of provisions deals with domestic procedures and remedies for the enforcement of intellectual property rights. The Agreement lays down certain general principles applicable to all IPR enforcement procedures. In addition, it contains provisions on civil and administrative procedures and remedies, provisional measures, special requirements related to border measures and criminal procedures, which specify, in a certain amount of

detail, the procedures and remedies that must be available so that right holders can effectively enforce their rights.

- **Dispute settlement**. The Agreement makes disputes between WTO Members about the respect of the TRIPS obligations subject to the WTO's dispute settlement procedures.

In addition the Agreement provides for certain basic principles, such as national and most-favoured-nation treatment, and some general rules to ensure that procedural difficulties in acquiring or maintaining IPRs do not nullify the substantive benefits that should flow from the Agreement. The obligations under the Agreement will apply equally to all Member countries, but developing countries will have a longer period to phase them in. Special transition arrangements operate in the situation where a developing country does not presently provide product patent protection in the area of pharmaceuticals.

The TRIPS Agreement is a minimum standards agreement, which allows Members to provide more extensive protection of intellectual property if they so wish. Members are left free to determine the appropriate method of implementing the provisions of the Agreement within their own legal system and practice.

Certain general provisions

As in the main pre-existing intellectual property conventions, the basic obligation on each Member country is to accord the treatment in regard to the protection of intellectual property provided for under the Agreement to the persons of other Members. Article 1.3 defines who these persons are. These persons are referred to as “nationals” but include persons, natural or legal, who have a close attachment to other Members without necessarily being nationals. The criteria for determining which persons must thus benefit from the treatment provided for under the Agreement are those laid down for this purpose in the main pre-existing intellectual property conventions of WIPO, applied of course with respect to all WTO Members whether or not they are party to those conventions. These conventions are the Paris Convention, the Berne Convention, International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations (Rome Convention), and the Treaty on Intellectual Property in Respect of Integrated Circuits (IPIC Treaty).

Articles 3, 4 and 5 include the fundamental rules on national and most-favoured-nation treatment of foreign nationals, which are common to all categories of intellectual property covered by the Agreement. These obligations cover not only the substantive standards of protection but also matters affecting the availability, acquisition, scope, maintenance and enforcement of intellectual property rights as well as those matters affecting the use of intellectual property rights specifically addressed in the Agreement. While the national treatment clause forbids discrimination between a Member's own

nationals and the nationals of other Members, the most-favoured-nation treatment clause forbids discrimination between the nationals of other Members. In respect of the national treatment obligation, the exceptions allowed under the pre-existing intellectual property conventions of WIPO are also allowed under TRIPS. Where these exceptions allow material reciprocity, a consequential exception to MFN treatment is also permitted (e.g. comparison of terms for copyright protection in excess of the minimum term required by the TRIPS Agreement as provided under Article 7(8) of the Berne Convention as incorporated into the TRIPS Agreement). Certain other limited exceptions to the MFN obligation are also provided for.

The general goals of the TRIPS Agreement are contained in the Preamble of the Agreement, which reproduces the basic Uruguay Round negotiating objectives established in the TRIPS area by the 1986 Punta del Este Declaration and the 1988/89 Mid-Term Review. These objectives include the reduction of distortions and impediments to international trade, promotion of effective and adequate protection of intellectual property rights, and ensuring that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade. These objectives should be read in conjunction with Article 7, entitled “Objectives”, according to which the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations. Article 8, entitled “Principles”, recognizes the rights of Members to adopt measures for public health and other public interest reasons and to prevent the abuse of intellectual property rights, provided that such measures are consistent with the provisions of the TRIPS Agreement.

Substantive standards of protection

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During the Uruguay Round negotiations, it was recognized that the Berne Convention already, for the most part, provided adequate basic standards of copyright protection. Thus it was agreed that the point of departure should be the existing level of protection under the latest Act, the Paris Act of 1971, of that Convention. The point of departure is expressed in Article 9.1 under which Members are obliged to comply with the substantive provisions of the Paris Act of 1971 of the Berne Convention, i.e. Articles 1 through 21 of the Berne Convention (1971) and the Appendix thereto. However, Members do not have rights or obligations under the TRIPS Agreement in respect of the rights conferred under Article 6*bis* of that Convention, i.e. the moral rights (the right to claim authorship and to object to any derogatory action in relation to a work, which would be prejudicial to the author's honour or reputation), or of the rights derived therefrom. The provisions of the Berne Convention referred to deal with questions such as subject-matter to be protected, minimum term of protection, and rights to be

conferred and permissible limitations to those rights. The Appendix allows developing countries, under certain conditions, to make some limitations to the right of translation and the right of reproduction.

In addition to requiring compliance with the basic standards of the Berne Convention, the TRIPS Agreement clarifies and adds certain specific points.

Article 9.2 confirms that copyright protection shall extend to expressions and not to ideas, procedures, methods of operation or mathematical concepts as such.

Article 10.1 provides that computer programs, whether in source or object code, shall be protected as literary works under the Berne Convention (1971). This provision confirms that computer programs must be protected under copyright and that those provisions of the Berne Convention that apply to literary works shall be applied also to them. It confirms further, that the form in which a program is, whether in source or object code, does not affect the protection. The obligation to protect computer programs as literary works means e.g. that only those limitations that are applicable to literary works may be applied to computer programs. It also confirms that the general term of protection of 50 years applies to computer programs. Possible shorter terms applicable to photographic works and works of applied art may not be applied.

Article 10.2 clarifies that databases and other compilations of data or other material shall be protected as such under copyright even where the databases include data that as such are not protected under copyright. Databases are eligible for copyright protection provided that they by reason of the selection or arrangement of their contents constitute intellectual creations. The provision also confirms that databases have to be protected regardless of which form they are in, whether machine readable or other form. Furthermore, the provision clarifies that such protection shall not extend to the data or material itself, and that it shall be without prejudice to any copyright subsisting in the data or material itself.

Article 11 provides that authors shall have in respect of at least computer programs and, in certain circumstances, of cinematographic works the right to authorize or to prohibit the commercial rental to the public of originals or copies of their copyright works. With respect to cinematographic works, the exclusive rental right is subject to the so-called impairment test: a Member is excepted from the obligation unless such rental has led to widespread copying of such works which is materially impairing the exclusive right of reproduction conferred in that Member on authors and their successors in title. In respect of computer programs, the obligation does not apply to rentals where the program itself is not the essential object of the rental.

According to the general rule contained in Article 7(1) of the Berne Convention as incorporated into the TRIPS Agreement, the term of protection shall be the life of the author and 50 years after his death. Paragraphs 2 through 4 of that Article specifically allow shorter terms in certain cases. These provisions are supplemented by Article 12 of the TRIPS Agreement, which provides that whenever the term of protection of a work,

other than a photographic work or a work of applied art, is calculated on a basis other than the life of a natural person, such term shall be no less than 50 years from the end of the calendar year of authorized publication, or, failing such authorized publication within 50 years from the making of the work, 50 years from the end of the calendar year of making.

Article 13 requires Members to confine limitations or exceptions to exclusive rights to certain special cases which do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the right holder. This is a horizontal provision that applies to all limitations and exceptions permitted under the provisions of the Berne Convention and the Appendix thereto as incorporated into the TRIPS Agreement. The application of these limitations is permitted also under the TRIPS Agreement, but the provision makes it clear that they must be applied in a manner that does not prejudice the legitimate interests of the right holder.

Related rights

The provisions on protection of performers, producers of phonograms and broadcasting organizations are included in Article 14. According to Article 14.1, performers shall have the possibility of preventing the unauthorized fixation of their performance on a phonogram (e.g. the recording of a live musical performance). The fixation right covers only aural, not audiovisual fixations. Performers must also be in position to prevent the reproduction of such fixations. They shall also have the possibility of preventing the unauthorized broadcasting by wireless means and the communication to the public of their live performance.

In accordance with Article 14.2, Members have to grant producers of phonograms an exclusive reproduction right. In addition to this, they have to grant, in accordance with Article 14.4, an exclusive rental right at least to producers of phonograms. The provisions on rental rights apply also to any other right holders in phonograms as determined in national law. This right has the same scope as the rental right in respect of computer programs. Therefore it is not subject to the impairment test as in respect of cinematographic works. However, it is limited by a so-called grand-fathering clause, according to which a Member, which on 15 April 1994, i.e. the date of the signature of the Marrakesh Agreement, had in force a system of equitable remuneration of right holders in respect of the rental of phonograms, may maintain such system provided that the commercial rental of phonograms is not giving rise to the material impairment of the exclusive rights of reproduction of right holders.

Broadcasting organizations shall have, in accordance with Article 14.3, the right to prohibit the unauthorized fixation, the reproduction of fixations, and the rebroadcasting by wireless means of broadcasts, as well as the communication to the public of their television broadcasts. However, it is not necessary to grant such rights to broadcasting organizations, if owners of copyright in the subject-matter of broadcasts are provided with the possibility of preventing these acts, subject to the provisions of the Berne Convention.

The term of protection is at least 50 years for performers and producers of phonograms, and 20 years for broadcasting organizations (Article 14.5).

Article 14.6 provides that any Member may, in relation to the protection of performers, producers of phonograms and broadcasting organizations, provide for conditions, limitations, exceptions and reservations to the extent permitted by the Rome Convention.

Trademarks

The basic rule contained in Article 15 is that any sign, or any combination of signs, capable of distinguishing the goods and services of one undertaking from those of other undertakings, must be eligible for registration as a trademark, provided that it is visually perceptible. Such signs, in particular words including personal names, letters, numerals, figurative elements and combinations of colours as well as any combination of such signs, must be eligible for registration as trademarks.

Where signs are not inherently capable of distinguishing the relevant goods or services, Member countries are allowed to require, as an additional condition for eligibility for registration as a trademark, that distinctiveness has been acquired through use. Members are free to determine whether to allow the registration of signs that are not visually perceptible (e.g. sound or smell marks).

Members may make registrability depend on use. However, actual use of a trademark shall not be permitted as a condition for filing an application for registration, and at least three years must have passed after that filing date before failure to realize an intent to use is allowed as the ground for refusing the application (Article 14.3).

The Agreement requires service marks to be protected in the same way as marks distinguishing goods (see e.g. Articles 15.1, 16.2 and 62.3).

The owner of a registered trademark must be granted the exclusive right to prevent all third parties not having the owner's consent from using in the course of trade identical or similar signs for goods or services which are identical or similar to those in respect of which the trademark is registered where such use would result in a likelihood of confusion. In case of the use of an identical sign for identical goods or services, a likelihood of confusion must be presumed (Article 16.1).

The TRIPS Agreement contains certain provisions on well-known marks, which supplement the protection required by Article 6*bis* of the Paris Convention, as incorporated by reference into the TRIPS Agreement, which obliges Members to refuse or to cancel the registration, and to prohibit the use of a mark conflicting with a mark which is well known. First, the provisions of that Article must be applied also to services. Second, it is required that knowledge in the relevant sector of the public acquired not only as a result of the use of the mark but also by other means, including as a result of its promotion, be taken into account. Furthermore, the protection of registered well-known marks must extend to goods or services which are not similar to those in respect

of which the trademark has been registered, provided that its use would indicate a connection between those goods or services and the owner of the registered trademark, and the interests of the owner are likely to be damaged by such use (Articles 16.2 and 3).

Members may provide limited exceptions to the rights conferred by a trademark, such as fair use of descriptive terms, provided that such exceptions take account of the legitimate interests of the owner of the trademark and of third parties (Article 17).

Initial registration, and each renewal of registration, of a trademark shall be for a term of no less than seven years. The registration of a trademark shall be renewable indefinitely (Article 18).

Cancellation of a mark on the grounds of non-use cannot take place before three years of uninterrupted non-use has elapsed unless valid reasons based on the existence of obstacles to such use are shown by the trademark owner. Circumstances arising independently of the will of the owner of the trademark, such as import restrictions or other government restrictions, shall be recognized as valid reasons of non-use. Use of a trademark by another person, when subject to the control of its owner, must be recognized as use of the trademark for the purpose of maintaining the registration (Article 19).

It is further required that use of the trademark in the course of trade shall not be unjustifiably encumbered by special requirements, such as use with another trademark, use in a special form, or use in a manner detrimental to its capability to distinguish the goods or services (Article 20).

Geographical indications

Geographical indications are defined, for the purposes of the Agreement, as indications which identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin (Article 22.1). Thus, this definition specifies that the quality, reputation or other characteristics of a good can each be a sufficient basis for eligibility as a geographical indication, where they are essentially attributable to the geographical origin of the good.

In respect of all geographical indications, interested parties must have legal means to prevent use of indications which mislead the public as to the geographical origin of the good, and use which constitutes an act of unfair competition within the meaning of Article 10*bis* of the Paris Convention (Article 22.2).

The registration of a trademark which uses a geographical indication in a way that misleads the public as to the true place of origin must be refused or invalidated *ex officio* if the legislation so permits or at the request of an interested party (Article 22.3).

Article 23 provides that interested parties must have the legal means to prevent the use of a geographical indication identifying wines for wines not originating in the place indicated by the geographical indication. This applies even where the public is not being misled, there is no unfair competition and the true origin of the good is indicated or the geographical indication is accompanied be expressions such as “kind”, “type”, “style”, “imitation” or the like. Similar protection must be given to geographical indications identifying spirits when used on spirits. Protection against registration of a trademark must be provided accordingly.

Article 24 contains a number of exceptions to the protection of geographical indications. These exceptions are of particular relevance in respect of the additional protection for geographical indications for wines and spirits. For example, Members are not obliged to bring a geographical indication under protection, where it has become a generic term for describing the product in question (paragraph 6). Measures to implement these provisions shall not prejudice prior trademark rights that have been acquired in good faith (paragraph 5). Under certain circumstances, continued use of a geographical indication for wines or spirits may be allowed on a scale and nature as before (paragraph 4). Members availing themselves of the use of these exceptions must be willing to enter into negotiations about their continued application to individual geographical indications (paragraph 1). The exceptions cannot be used to diminish the protection of geographical indications that existed prior to the entry into force of the TRIPS Agreement (paragraph 3). The TRIPS Council shall keep under review the application of the provisions on the protection of geographical indications (paragraph 2).

Industrial designs

Article 25.1 of the TRIPS Agreement obliges Members to provide for the protection of independently created industrial designs that are new or original. Members may provide that designs are not new or original if they do not significantly differ from known designs or combinations of known design features. Members may provide that such protection shall not extend to designs dictated essentially by technical or functional considerations.

Article 25.2 contains a special provision aimed at taking into account the short life cycle and sheer number of new designs in the textile sector: requirements for securing protection of such designs, in particular in regard to any cost, examination or publication, must not unreasonably impair the opportunity to seek and obtain such protection. Members are free to meet this obligation through industrial design law or through copyright law.

Article 26.1 requires Members to grant the owner of a protected industrial design the right to prevent third parties not having the owner's consent from making, selling or importing articles bearing or embodying a design which is a copy, or substantially a copy, of the protected design, when such acts are undertaken for commercial purposes.

Article 26.2 allows Members to provide limited exceptions to the protection of industrial designs, provided that such exceptions do not unreasonably conflict with the normal

exploitation of protected industrial designs and do not unreasonably prejudice the legitimate interests of the owner of the protected design, taking account of the legitimate interests of third parties.

The duration of protection available shall amount to at least 10 years (Article 26.3). The wording “amount to” allows the term to be divided into, for example, two periods of five years.

Patents

The TRIPS Agreement requires Member countries to make patents available for any inventions, whether products or processes, in all fields of technology without discrimination, subject to the normal tests of novelty, inventiveness and industrial applicability. It is also required that patents be available and patent rights enjoyable without discrimination as to the place of invention and whether products are imported or locally produced (Article 27.1).

There are three permissible exceptions to the basic rule on patentability. One is for inventions contrary to *ordre public* or morality; this explicitly includes inventions dangerous to human, animal or plant life or health or seriously prejudicial to the environment. The use of this exception is subject to the condition that the commercial exploitation of the invention must also be prevented and this prevention must be necessary for the protection of *ordre public* or morality (Article 27.2).

The second exception is that Members may exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals (Article 27.3(a)).

The third is that Members may exclude plants and animals other than micro-organisms and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, any country excluding plant varieties from patent protection must provide an effective *sui generis* system of protection. Moreover, the whole provision is subject to review four years after entry into force of the Agreement (Article 27.3(b)).

The exclusive rights that must be conferred by a product patent are the ones of making, using, offering for sale, selling, and importing for these purposes. Process patent protection must give rights not only over use of the process but also over products obtained directly by the process. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts (Article 28).

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties (Article 30).

The term of protection available shall not end before the expiration of a period of 20 years counted from the filing date (Article 33).

Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application (Article 29.1).

If the subject-matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process, where certain conditions indicating a likelihood that the protected process was used are met (Article 34).

Compulsory licensing and government use without the authorization of the right holder are allowed, but are made subject to conditions aimed at protecting the legitimate interests of the right holder. The conditions are mainly contained in Article 31. These include the obligation, as a general rule, to grant such licences only if an unsuccessful attempt has been made to acquire a voluntary licence on reasonable terms and conditions within a reasonable period of time; the requirement to pay adequate remuneration in the circumstances of each case, taking into account the economic value of the licence; and a requirement that decisions be subject to judicial or other independent review by a distinct higher authority. Certain of these conditions are relaxed where compulsory licences are employed to remedy practices that have been established as anticompetitive by a legal process. These conditions should be read together with the related provisions of Article 27.1, which require that patent rights shall be enjoyable without discrimination as to the field of technology, and whether products are imported or locally produced.

Layout-designs of integrated circuits

Article 35 of the TRIPS Agreement requires Member countries to protect the layout-designs of integrated circuits in accordance with the provisions of the IPIC Treaty (the Treaty on Intellectual Property in Respect of Integrated Circuits), negotiated under the auspices of WIPO in 1989. These provisions deal with, *inter alia*, the definitions of “integrated circuit” and “layout-design (topography)”, requirements for protection, exclusive rights, and limitations, as well as exploitation, registration and disclosure. An “integrated circuit” means a product, in its final form or an intermediate form, in which the elements, at least one of which is an active element, and some or all of the interconnections are integrally formed in and/or on a piece of material and which is intended to perform an electronic function. A “layout-design (topography)” is defined as the three-dimensional disposition, however expressed, of the elements, at least one of which is an active element, and of some or all of the interconnections of an integrated circuit, or such a three-dimensional disposition prepared for an integrated circuit intended for manufacture. The obligation to protect layout-designs applies to such

layout-designs that are original in the sense that they are the result of their creators' own intellectual effort and are not commonplace among creators of layout-designs and manufacturers of integrated circuits at the time of their creation. The exclusive rights include the right of reproduction and the right of importation, sale and other distribution for commercial purposes. Certain limitations to these rights are provided for.

In addition to requiring Member countries to protect the layout-designs of integrated circuits in accordance with the provisions of the IPIC Treaty, the TRIPS Agreement clarifies and/or builds on four points. These points relate to the term of protection (ten years instead of eight, Article 38), the applicability of the protection to articles containing infringing integrated circuits (last sub clause of Article 36) and the treatment of innocent infringers (Article 37.1). The conditions in Article 31 of the TRIPS Agreement apply *mutatis mutandis* to compulsory or non-voluntary licensing of a layout-design or to its use by or for the government without the authorization of the right holder, instead of the provisions of the IPIC Treaty on compulsory licensing (Article 37.2).

Protection of undisclosed information

The TRIPS Agreement requires undisclosed information -- trade secrets or know-how -- to benefit from protection. According to Article 39.2, the protection must apply to information that is secret, that has commercial value because it is secret and that has been subject to reasonable steps to keep it secret. The Agreement does not require undisclosed information to be treated as a form of property, but it does require that a person lawfully in control of such information must have the possibility of preventing it from being disclosed to, acquired by, or used by others without his or her consent in a manner contrary to honest commercial practices. “Manner contrary to honest commercial practices” includes breach of contract, breach of confidence and inducement to breach, as well as the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition.

The Agreement also contains provisions on undisclosed test data and other data whose submission is required by governments as a condition of approving the marketing of pharmaceutical or agricultural chemical products which use new chemical entities. In such a situation the Member government concerned must protect the data against unfair commercial use. In addition, Members must protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

Control of anti-competitive practices in contractual licences

Article 40 of the TRIPS Agreement recognizes that some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology (paragraph 1). Member countries may adopt, consistently with the other provisions of the Agreement, appropriate measures to prevent or control practices in the licensing of

intellectual property rights which are abusive and anti-competitive (paragraph 2). The Agreement provides for a mechanism whereby a country seeking to take action against such practices involving the companies of another Member country can enter into consultations with that other Member and exchange publicly available non-confidential information of relevance to the matter in question and of other information available to that Member, subject to domestic law and to the conclusion of mutually satisfactory agreements concerning the safeguarding of its confidentiality by the requesting Member (paragraph 3). Similarly, a country whose companies are subject to such action in another Member can enter into consultations with that Member (paragraph 4).

II. Geographical Indications

TRIPS: GEOGRAPHICAL INDICATIONS
Background and the current situation

https://www.wto.org/english/tratop_e/trips_e/gi_background_e.htm#general

A product's quality, reputation or other characteristics can be determined by where it comes from. Geographical indications are place names (in some countries also words associated with a place) used to identify products that come from these places and have these characteristics (for example, "Champagne", "Tequila" or "Roquefort").

Two issues are debated in the TRIPS Council under the Doha mandate: creating a multilateral register for wines and spirits; and extending the higher (Article 23) level of protection beyond wines and spirits.

Geographical indications in general back to top

A product's quality, reputation or other characteristics can be determined by where it comes from. Geographical indications are place names (in some countries also words associated with a place) used to identify products that come from these places and have these characteristics (for example, "Champagne", "Tequila" or "Roquefort"). Protection required under the TRIPS Agreement is defined in two articles.

All products are covered by **Article 22**, which defines a **standard level of protection**. This says geographical indications have to be protected in order to avoid misleading the public and to prevent unfair competition.

Article 23 provides a **higher or enhanced level of protection** for geographical indications for wines and spirits: subject to a number of exceptions, they have to be protected even if misuse would not cause the public to be misled.

Exceptions (**Article 24**). In some cases, geographical indications do not have to be protected or the protection can be limited. Among the exceptions that the agreement allows are: when a name has become the common (or "generic") term (for example, "cheddar" now refers to a particular type of cheese not necessarily made in Cheddar, in the UK), and when a term has already been registered as a trademark.

Information that members have supplied during a fact-finding exercise shows that countries employ a wide variety of legal means to protect geographical indications: ranging from specific geographical indications laws to trademark law, consumer protection law, and common law. The TRIPS Agreement and current TRIPS work in the WTO takes account of that diversity.

Two issues are debated under the Doha mandate, both related in different ways to the higher (Article 23) level of protection: creating a **multilateral register for wines and spirits**; and **extending the higher (Article 23) level of protection** beyond wines and spirits. Both are as contentious as any other subject on the Doha agenda.

Although the two issues are discussed separately, some delegations see a relation between them. In July 2008, a group of WTO members called for a "procedural decision" to negotiate three intellectual property issues in parallel: these two geographical indications issues, and a proposal to require patent applicants to disclose the origin of genetic resources or traditional knowledge used in their inventions (see document TN/C/W/52 of 19 July 2008). But members remain divided over this idea, opponents arguing particularly that the only mandate is to negotiate the multilateral register.

Multilateral register for wines and spirits back to top

This negotiation, which takes place in dedicated "special sessions" of the TRIPS Council, is about creating a multilateral system for notifying and registering geographical indications for wines and spirits. These are given a level of protection that is higher than for other geographical indications. The multilateral register is discussed separately from the question of "extension" — extending the higher level of protection to other products — although some countries consider the two to be related. The work began in 1997 under Article 23.4 of the TRIPS Agreement and now also comes under the Doha Agenda (the Doha Declaration's paragraph 18).

Background

On 21 April 2011, the then chairperson Darlington Mwape of Zambia circulated a five-page report to the Trade Negotiations Committee as did chairs of all the Doha Round negotiating groups. He attachedthe current draft "composite text", developed in 2011, the first single text to contain the range of members' views since talks began in 1997 — text options are marked by square brackets.

He concluded his report: "All delegations have made a genuine effort to find common language while defending their interests. (…) I do believe that working on treaty language formulations regarding the structure, operation and implications of the Register has — for the first time — helped all delegations to have a clearer view of each other's positions, proposals and wordings. While I am aware that there still is a long way to go, I do believe that the Draft Composite Text (…) provides a good basis on which to continue negotiations towards a multilateral system of notification and registration for geographical indications for wines and spirits."

Since circulation of the 2011 report, WTO members have not been able to move forward in the TRIPS Special Session and remain divided over the scope and the substance of the multilateral register to be negotiated. The chair of the TRIPS Special Session until April 2014, Alfredo Suescum of Paraguay, concluded in his report

(TN/IP/22) of 1 April 2014 that "under current circumstances, Members are not ready to take forward substantive work on the GI Register as a priority. Finding a solution to Members' very different concerns with respect to the negotiating mandate and linkages to other WTO work continues to appear central to permitting substantive work in the TRIPS Special Session to resume".

Recent developments

On 23 February 2015, the TRIPS Special session held an informal information session in which the Secretariat provided a detailed factual overview of past work in the TRIPS Special Session, tracing the negotiations of a register for wine and spirit GIs from 1997 to 2011.

The chair of the Special Session of the TRIPS Council, Dacio Castillo of Honduras, circulated his report (TN/IP/23) to the Trade Negotiations Committee on 3 December 2015.

The Doha mandate

The Doha Declaration's deadline for completing the negotiations was the Fifth Ministerial Conference in Cancún in 2003. Since this was not achieved, the negotiations are now taking place within the overall timetable for the round.

Since then …

Three sets of proposals have been submitted over the years, representing the two main lines of argument in the negotiations and some proposed compromises. The latest are (documents downloadable from Documents Online http://docsonline.wto.org on the WTO website):

- The **EU's** detailed proposal (TN/IP/W/11) circulated in June 2005 calls for the TRIPS Agreement to be amended (by adding an annex to Article 23.4).

  The paper proposes that when a geographical indication is registered, this would establish a "rebuttable presumption" that the term is to be protected in other WTO members — except in a country that has lodged a reservation within a specified period (for example, 18 months). A reservation would have to be on permitted grounds. These include when a term has become generic or when it does not fit the definition of a geographical indication. If it does not make a reservation, a country would not be able to refuse protection on these grounds

after the term has been registered.

- A "**joint proposal**", document TN/IP/W/10/Rev.4, was first submitted in 2005 and revised several times. Its sponsors are: Argentina, Australia, Canada, Chile, Costa Rica, Dominican Republic, Ecuador, El Salvador, Guatemala, Honduras, Israel, Japan, Republic of Korea, Mexico, New Zealand, Nicaragua, Paraguay, Chinese Taipei, South Africa, the US.

  This group does not want to amend the TRIPS Agreement. Instead, it proposes a decision by the TRIPS Council to set up a voluntary system where notified geographical indications would be registered in a database. Those governments choosing to participate in the system would have to consult the database when taking decisions on protection in their own countries. Non-participating members would be "encouraged" but "not obliged" to consult the database.

- **Hong Kong, China** has proposed a compromise (document TN/IP/W/8). Here, a registered term would enjoy a more limited "presumption" than under the EU proposal, and only in those countries choosing to participate in the system.

These three proposals have been laid out side by side so that they can be compared easily, in a Secretariat paper (document TN/IP/W/12 of 14 September 2005 with additions in May 2007). An earlier compilation is in various versions of the 2003 document TN/IP/W/7. All of these are available on Documents Online http://docsonline.wto.org.

At the heart of the debate are a number of key questions. When a geographical indication is registered in the system, what legal effect, if any, would that need to have within member countries, if the register is to serve the purpose of "facilitating protection" (the phrase used in Article 23.4)? And to what extent, if at all, should the effect apply to countries choosing not to participate in the system. There is also the question of the administrative and financial costs for individual governments and whether they would outweigh the possible benefits.

Opinions are strongly held on both sides of the debate, with some highly detailed arguments presented by each side.

As an idea of the issues under negotiation, the main headings of the latest Secretariat compilation (TN/IP/W/12)are:

- Preamble
- Legal form
- Participation

- Notification (mandatory elements, optional elements, format and other aspects)
- Registration ("formality examination", reservations, content of registrations, form of register)
- Consequences of registration (in participating members, in non-participating members, in least-developed country members)
- Duration and renewal of registrations
- Modifications and withdrawals of notifications and registrations
- Fees and costs

In July 2008, a group of WTO members called for a "procedural decision" to negotiate three intellectual property issues in parallel: these two geographical indications issues, and a proposal to require patent applicants to disclose the origin of genetic resources or traditional knowledge used in their inventions (see document TN/C/W/52 of 19 July 2008). But members remain divided over this idea, opponents arguing particularly that the only mandate is to negotiate the multilateral register.

Extending the "higher level of protection" beyond wines and spirits back to top

Geographical indications for **all** products are currently covered by Article 22 of the TRIPS Agreement. The issue here is whether to expand the **higher** level of protection (Article 23) — currently given to wines and spirits — to other products. (The difference is explained above.) A number of countries want to negotiate extending this higher level of protection to other products. Some others oppose the move, and the debate has included the question of whether the Doha Declaration provides a mandate for negotiations.

Some countries have said that progress in this aspect of geographical indications would make it easier for them to agree to a significant deal in agriculture. Others reject the view that the Doha Declaration makes this part of the balance of the negotiations. At the same time, the European Union has also proposed negotiating the protection of specific names of specific agricultural products as part of the agriculture negotiations.

Latest: On 21 April 2011, Director-General Pascal Lamy circulated a 6-page **report** on his consultations on two issues mandated by the 2005 Hong Kong Ministerial Conference: extending to other products the higher level of protection for geographical indications beyond wines and spirits ("GI extension"); and proposals dealing with the relationship between the WTO's intellectual property (TRIPS) agreement and the UN Convention on Biological Diversity, including what is sometimes called biopiracy. On both issues delegations differ in interpreting the 2001 mandate — whether these are

negotiations — as well as the substance. Mr Lamy has chaired the consultations as director-general, not chairperson of the Trade Negotiations Committee.

He concluded that members' views continue to diverge on both issues but that discussions underscore the benefits of understanding more fully how countries' own intellectual property systems work — the scope of protection for geographical indications in practice in various countries, and the "practical and operational context" of the existing patent mechanisms for disclosing the origins of genetic material and any associated traditional knowledge used in inventions.

(Shortly before, on 19 April 2011, a group of members submitted a draft amendment to the TRIPS Agreement on this topic: document **TN/C/W/60**.)

The Doha mandate

The Doha Declaration notes in its paragraph 18 that the TRIPS Council will handle work on extension under the declaration's paragraph 12 (which deals with implementation issues). Paragraph 12 says "negotiations on outstanding implementation issues shall be an integral part" of the Doha work programme, and that implementation issues "shall be addressed as a matter of priority by the relevant WTO bodies, which shall report to the Trade Negotiations Committee [TNC] … by the end of 2002 for appropriate action." Delegations interpret Paragraph 12 differently. Many developing and European countries argue that the so-called outstanding implementation issues are already part of the negotiation and its package of results (the "single undertaking"). Others argue that these issues can only become negotiating subjects if the Trade Negotiations Committee decides to include them in the talks — and so far it has not done so.

Since then …

This difference of opinion over the mandates means that the discussions have had to be organized carefully. At first they continued in the TRIPS Council. More recently, they have been the subject of informal consultations chaired by the WTO director-general or by one of his deputies.

Members remain deeply divided, with no agreement in sight, although they are ready to continue discussing the issue.

Those advocating extension include Bulgaria, the EU, Guinea, India, Jamaica, Kenya, Madagascar, Mauritius, Morocco, Pakistan, Romania, Sri Lanka, Switzerland, Thailand, Tunisia and Turkey. They see the higher level of protection as a way to improve marketing their products by differentiating them more effectively from their competitors'; and they object to other countries "usurping" their terms. The latest proposal from the

EU is document TN/IP/W/11, circulated in June 2005. This calls for the TRIPS Agreement to be amended so that all products would be eligible for the higher level of protection in Article 23, and the exceptions in Article 24 (see above), together with the multilateral registration system currently being negotiated for wines and spirits (see above).

Those opposing extension include Argentina, Australia, Canada, Chile, Colombia, the Dominican Republic, Ecuador, El Salvador, Guatemala, Honduras, New Zealand, Panama, Paraguay, the Philippines, Chinese Taipei and the United States. They argue that the existing (Article 22) level of protection is adequate. They caution that providing enhanced protection would be a burden and would disrupt existing legitimate marketing practices. They also reject the "usurping" accusation particularly when migrants have taken the methods of making the products and the names with them to their new homes and have been using them in good faith.

The Secretariat has compiled the issues raised and the views expressed in this debate, in document WT/GC/W/546 and TN/C/W/25. In June 2008, Director-General Pascal Lamy issued a report on consultations conducted on his behalf by his deputy, Rufus Yerxa, in document TN/C/W/50, which also includes consultations under the heading of the TRIPS Agreement and the Convention on Biological Diversity (CBD).

In July 2008, a group of WTO members called for a "procedural decision" to negotiate three intellectual property issues in parallel: these two geographical indications issues, and a proposal to require patent applicants to disclose the origin of genetic resources or traditional knowledge used in their inventions (see document TN/C/W/52 of 19 July 2008). But members remain divided over this idea, opponents arguing particularly that the only mandate is to negotiate the multilateral register.

III. TRIPS and Public Health

https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm00_e.htm

TRIPS and Pharmaceutical Patents: Facts Sheets

Philosophy: TRIPS attempts to strike a balance

The WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) attempts to strike a balance between the long term social objective of providing incentives for future inventions and creation, and the short term objective of allowing people to use existing inventions and creations. The agreement covers a wide range of subjects, from copyright and trademarks, to integrated circuit designs and trade secrets. Patents for pharmaceuticals and other products are only part of the agreement.

The balance works in three ways:

- Invention and creativity in themselves should provide social and technological benefits. Intellectual property protection encourages inventors and creators because they can expect to earn some future benefits from their creativity. This encourages new inventions, such as new drugs, whose development costs can sometimes be extremely high, so private rights also bring social benefits.

- The way intellectual property is protected can also serve social goals. For example, patented inventions have to be disclosed, allowing others to study the invention even while its patent is being protected. This helps technological progress and technology dissemination and transfer. After a period, the protection expires, which means that the invention becomes

The TRIPS Agreement

Article 27
Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application[(5)]. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:
(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Article 29
Conditions on Patent Applicants

1. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.

2. Members may require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants.

available for others to use. All of this avoids “re-inventing the wheel”.

The TRIPS Agreement

Article 7
Objectives

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Article 8
Principles

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

- The TRIPS Agreement provides flexibility for governments to fine tune the protection granted in order to meet social goals. For patents, it allows governments to make exceptions to patent holders’ rights such as in national emergencies, anti-competitive practices, or if the right-holder does not supply the invention, provided certain conditions are fulfilled. For pharmaceutical patents, the flexibility has been clarified and enhanced by the 2001 Doha Declaration on TRIPS and Public Health. The enhancement was put into practice in 2003 with a decision enabling countries that cannot make medicines themselves, to import pharmaceuticals made under compulsory licence. In 2005, members agreed to make this decision a permanent amendment to the TRIPS Agreement, which will take effect when two thirds of members accept it.

What is the basic patent right?

Patents provide the patent owner with the legal means to prevent others from making, using, or selling the new invention for a limited period of time, subject to a number of exceptions.

A patent is not a permit to put a product on the market

A patent only gives an inventor the right to prevent others from using the patented invention. It says nothing about whether the product is safe for consumers and whether it can be supplied. Patented pharmaceuticals still have to go through rigorous testing and approval before they can be put on the market.

Under TRIPS, what are member governments' obligations on pharmaceutical patents?

IN GENERAL (see also "exceptions")

Patenting: WTO members have to provide patent protection for any invention, whether a **product** (such as a medicine) or a **process** (such as a method of producing the chemical ingredients for a medicine), while allowing certain exceptions. *Article 27.1*. Patent protection has to last at least 20 years from the date the patent application was filed. *Article 33*

Non-discrimination: Members cannot discriminate between **different fields of technology** in their patent regimes. Nor can they discriminate between the **place of invention** and whether products are **imported or locally produced**. *Article 27.1*

Three criteria: To qualify for a patent, an invention has to be new ("novelty"), it must be an "inventive step" (i.e. it must not be obvious) and it must have "industrial applicability" (it must be useful). *Article 27.1*

Disclosure: Details of the invention have to be described in the application and therefore have to be made public. Member governments have to require the patent applicant to disclose details of the invention and they may also require the applicant to reveal the best method for carrying it out. *Article 29.1*

ELIGIBILITY FOR PATENTING

Governments can refuse to grant patents for three reasons that may relate to public health:

- inventions whose commercial exploitation needs to be prevented to protect human,

The TRIPS Agreement

Article 30
Exceptions to Rights Conferred

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

animal or plant life or health — *Article 27.2*
- diagnostic, therapeutic and surgical methods for treating humans or animals — *Article 27.3a*
- certain plant and animal inventions — *Article 27.3b*.

Under the TRIPS Agreement, governments can make limited exceptions to patent rights, provided certain conditions are met. For example, the exceptions must not "unreasonably" conflict with the "normal" exploitation of the patent. *Article 30*.

RESEARCH EXCEPTION AND "BOLAR" PROVISION

Many countries use this provision to advance science and technology. They allow researchers to use a patented invention for research, in order to understand the invention more fully.

In addition, some countries allow manufacturers of generic drugs to use the patented invention to obtain marketing approval — for example from public health authorities — without the patent owner's permission and before the patent protection expires. The generic producers can then market their versions as soon as the patent expires. This provision is sometimes called the "regulatory exception" or "Bolar" provision. *Article 30*

This has been upheld as conforming with the TRIPS Agreement in a WTO dispute ruling. In its report adopted on 7 April 2000, a WTO dispute settlement panel said Canadian law conforms with the TRIPS Agreement in allowing manufacturers to do this. (The case was titled "Canada — Patent Protection for Pharmaceutical Products")

ANTI-COMPETITIVE PRACTICES, ETC

The TRIPS Agreement says governments can also act to prevent patent owners and other holders of intellectual property rights from abusing intellectual property rights, "unreasonably" restraining trade, or hampering the international transfer of technology. *Articles 8 and 40*

The TRIPS Agreement

Article 8
Principles

[…]

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

SECTION 8: CONTROL OF ANTI-COMPETITIVE PRACTICES IN CONTRACTUAL LICENCES

Article 40

1. Members agree that some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology.

2. Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. As provided above, a Member may adopt, consistently with the other provisions of this Agreement, appropriate measures to prevent or control such practices, which may include for example exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member.

[…]

COMPULSORY LICENSING

Compulsory licensing is when a government allows someone else to produce the patented product or process without the consent of the patent owner. In current public discussion, this is usually associated with pharmaceuticals, but it could also apply to patents in any field.

The agreement allows compulsory licensing as part of the agreement's overall attempt to strike a balance between promoting access to existing drugs and promoting research and development into new drugs. But the term "compulsory licensing" does not appear in the TRIPS Agreement. Instead, the phrase "**other use without authorization of the right holder**" appears in the title of **Article 31**. Compulsory licensing is only part of this since "other use" includes use by governments for their own purposes.

Compulsory licensing and government use of a patent without the authorization of its owner can only be done under a number of conditions aimed at protecting the legitimate interests of the patent holder.

For example: Normally, the person or company applying for a licence must have first attempted, unsuccessfully, to obtain a voluntary licence from the right holder on reasonable commercial terms — *Article 31b*. If a compulsory licence is issued, adequate remuneration must still be paid to the patent holder — *Article 31h*.

However, for "national emergencies", "other circumstances of extreme urgency" or "public non-commercial use" (or "government use") or anti-competitive practices, there is no need to try for a voluntary licence — *Article 31b*.

Compulsory licensing must meet certain additional requirements. In particular, it cannot be given exclusively to licensees (e.g. the patent-holder can continue to produce), and usually it must be granted mainly to supply the domestic market.

The TRIPS Agreement

Article 31
Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

[…]

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

[…]

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

[…]

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

[…]

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

[…]

WHAT ARE THE GROUNDS FOR USING COMPULSORY LICENSING?

The TRIPS Agreement

Article 6
Exhaustion

For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

The TRIPS Agreement does not specifically list the reasons that might be used to justify compulsory licensing. In Article 31, it does mention national emergencies, other circumstances of extreme urgency and anti-competitive practices — but only as grounds when some of the normal requirements for compulsory licensing do not apply, such as the need to try for a voluntary licence first. *Doha declaration 5(b) and (c)*

PARALLEL IMPORTS, GREY IMPORTS AND 'EXHAUSTION' OF RIGHTS

Parallel or grey-market imports are not imports of counterfeit products or illegal copies. These are products marketed by the patent owner (or trademark- or copyright-owner, etc) or with the patent owner's permission in one country and imported into another country without the approval of the patent owner.

For example, suppose company A has a drug patented in the Republic of Belladonna and the Kingdom of Calamine, which it sells at a lower price in Calamine. If a second company buys the drug in Calamine and imports it into Belladonna at a price that is lower than company A's price, that would be a parallel or grey import.

The legal principle here is "exhaustion", the idea that once company A has sold a batch of its product (in this case, in Calamine), its patent rights are exhausted on that batch and it no longer has any rights over what happens to that batch.

The TRIPS Agreement simply says that none of its provisions, except those dealing with non-discrimination ("national treatment" and "most-favoured-nation treatment"), can be used to address the issue of exhaustion of intellectual property rights in a WTO dispute. In other words, even if a country allows parallel imports in a way that another country might think violates the TRIPS Agreement, this cannot be raised as a dispute in the WTO unless fundamental principles of non-discrimination are involved. The Doha Declaration clarifies that this means that members can choose how to deal with exhaustion in a way that best fits their domestic policy objectives. *Article 6 and Doha declaration 5(d)*

The Doha declaration

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

[…]

(b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

(c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

(d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

[…]

THE DOHA DECLARATION ON TRIPS AND PUBLIC HEALTH

Some governments were unsure of how these TRIPS flexibilities would be interpreted, and how far their right to use them would be respected. The African Group (all the African members of the WTO) were among the members pushing for clarification.

A large part of this was settled at the Doha Ministerial Conference in November 2001. In the main Doha Ministerial Declaration of 14 November 2001, WTO member governments stressed that it is important to implement and interpret the TRIPS Agreement in a way that supports public health — by promoting both access to existing medicines and the creation of new medicines.

They therefore adopted a separate declaration on TRIPS and Public Health. They agreed that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. They underscored countries' ability to use the flexibilities that are built into the TRIPS Agreement, including compulsory licensing and parallel importing. And they agreed to extend exemptions on pharmaceutical patent protection for least-developed countries until 2016.

On one remaining question, they assigned further work to the TRIPS Council — to sort out how to provide extra flexibility, so that countries unable to produce pharmaceuticals domestically can obtain supplies of copies of patented drugs from other countries. (This is sometimes called the "Paragraph 6" issue, because it comes under that paragraph in the separate Doha declaration on TRIPS and public health.)

IMPORTING UNDER COMPULSORY LICENSING ('PAR.6')

Article 31(f) of the TRIPS Agreement says products made under compulsory licensing must be "predominantly for the supply of the domestic market". This applies to countries that can manufacture drugs — it limits the amount they can export when the drug is made under compulsory licence. And it has an impact on countries unable to make medicines and therefore wanting to import generics. They would find it difficult to find countries that can supply them with drugs made under compulsory licensing.

The legal problem for exporting countries was resolved on 30 August 2003 when WTO members agreed on legal changes to make it easier for countries to import cheaper generics made under compulsory licensing if they are unable to manufacture the medicines themselves. When members agreed on the decision, the General Council chairperson also read out a statement setting out members' shared understandings on how the decision would be interpreted and implemented. This was designed to assure governments that the decision will not be abused.

The decision actually contains **three** waivers:

- Exporting countries' obligations under Article 31(f) are waived — any member country can export generic pharmaceutical products made under compulsory licences to meet the needs of importing countries.

- Importing countries' obligations on remuneration to the patent holder under compulsory licensing are waived to avoid double payment. Remuneration is only required on the export side.

- Exporting constraints are waived for developing and least-developed countries so that they can export within a regional trade agreement, when at least half of the members were categorized as least-developed countries at the time of the decision. That way, developing countries can make use of economies of scale.

Carefully negotiated conditions apply to pharmaceutical products imported under the system. These conditions aim to ensure that beneficiary countries can import the generics without undermining patent systems, particularly in rich countries. They include measures to prevent the medicines from being diverted to the wrong markets. And they require governments using the system to keep all other members informed, although WTO approval is not required. At the same time phrases such as "reasonable measures within their means" and "proportionate to their administrative capacities" are included to prevent the conditions becoming burdensome and impractical for the importing countries.

All WTO member countries are eligible to import under this decision. But 23 developed countries have announced voluntarily that they will not use the system to import: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and the US.

After they joined the EU in 2004, another 10 countries have been added to the list: Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic and Slovenia.

And 11 more said they would only use the system to import in national emergencies or other circumstances of extreme urgency: Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey, United Arab Emirates.

After that, several potential exporting countries changed their laws and regulations in order to implement the waivers and to allow production exclusively for export under compulsory licence. At the time of writing (September 2006) Norway, Canada, India and the EU have formally informed the TRIPS Council that they have done so.

The 2003 waivers are interim; the ultimate goal is to amend the TRIPS Agreement itself, and a decision to do this was reached in December 2005, accompanied again by a chairperson's statement. The amendment — a direct translation of the waivers — enters into force when two thirds of members accept it.

What does 'generic' mean?

Dictionaries tend to define a "generic" as a product — particularly a drug — that does not have a trademark. For example, "paracetamol" is a chemical ingredient that is found in many brandname painkillers and is often sold as a (generic) medicine in its own right, without a brandname. This is "generic from a trademark point of view".

Sometimes "generic" is also used to mean copies of patented drugs or drugs whose patents have expired — "generic from a patent point of view". This is not necessarily different since patented drugs are almost always sold under a brandname or trademark. When copies of patent drugs are made by other manufactures, they are either sold under the name of the chemical ingredient (making them clearly generic), or under another brandname (which means they are still generics from the point of view of patents).

Whether a drug is generic is one question. Whether it infringes intellectual property rights and is pirated or counterfeit is a separate question. Generic copies are legal from the patent point of view when they are made after the patent has expired or under voluntary or compulsory licence — but pirated and counterfeit products are by definition illegal.

Developing countries' transition periods

GENERAL

Developing countries and economies in transition from central planning did not have to apply most provisions of the TRIPS Agreement until 1 January 2000. The provisions they did have to apply deal with non-discrimination. *Article 65.2 and 65.3*

Least-developed countries were given until 1 January 2006. *Article 66.1.* On 30 November 2005, members agreed to extend the deadline to 1 July 2013, or to the date a country is no longer "least-developed", if that is earlier.

The TRIPS Agreement

Article 65
Transitional Arrangements

1. Subject to the provisions of paragraphs 2, 3 and 4, no Member shall be obliged to apply the provisions of this Agreement before the expiry of a general period of one year following the date of entry into force of the WTO Agreement.

2. A developing country Member is entitled to delay for a further period of four years the date of application, as defined in paragraph 1, of the provisions of this Agreement other than Articles 3, 4 and 5.

3. Any other Member which is in the process of transformation from a centrally-planned into a market, free-enterprise economy and which is undertaking structural reform of its intellectual property system and facing special problems in the preparation and implementation of intellectual property laws and regulations, may also benefit from a period of delay as foreseen in paragraph 2.

4. To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years.

5. A Member availing itself of a transitional period under paragraphs 1, 2, 3 or 4 shall ensure that any changes in its laws, regulations and practice made during that period do not result in a lesser degree of consistency with the provisions of this Agreement.

Article 66
Least-Developed Country Members

1. In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period.

[…]

For pharmaceutical patents this is extended to 2016 under the Doha Declaration on TRIPS and Public Health.

Most **new members** who joined after the WTO was created in 1995 have agreed to apply the TRIPS Agreement as soon as they joined. *Determined by each new member's terms of accession*

PHARMACEUTICALS AND AGRICULTURAL CHEMICALS

Some developing countries delayed patent protection for pharmaceutical products (and agricultural chemicals) until 1 January 2005.

This was allowed under provisions that say a developing country that did not provide product patent protection in a particular area of technology when the TRIPS Agreement came into force (on 1 January 1995), has up to 10 years to introduce the protection. *Article 65.4*

However, for pharmaceuticals and agricultural chemicals, countries eligible to use this provision (i.e. countries that did not provide protection on 1 January 1995) had two obligations.

They had to allow inventors to file patent applications from 1 January 1995, even though the decision on whether or not to grant any patent itself need not be taken until the end of this period — *Article 70.8*. This is sometimes called the "**mailbox**" provision (a metaphorical "mailbox" is created to receive and store the applications). The date of filing is significant, which is why the mailbox provisions were set up. It is used for assessing whether the application meets the criteria for patenting, including novelty ("newness").

And if the government allowed the relevant pharmaceutical or agricultural chemical product to be marketed during the transition period, it had to — subject to certain conditions — provide the patent applicant an **exclusive marketing right** for the product for five years, or until a decision on a product patent was taken, whichever was shorter. *Article 70.9*

Which countries used the extra transition period under Article 65.4, wholly or partially? The answer is not entirely straightforward. Thirteen WTO members — Argentina, Brazil, Cuba, Egypt, India, Kuwait, Morocco, Pakistan, Paraguay, Tunisia, Turkey, United Arab Emirates and Uruguay — notified "mailbox" systems to the TRIPS Council, indicating that at the time they did not grant patent protection to pharmaceutical products. It is possible that a few other members should have notified the WTO but did not do so.

The TRIPS Agreement

Article 70
Protection of Existing Subject Matter

[…]

8. Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member shall:
(a) notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed;
(b) apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application; and
(c) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with Article 33 of this Agreement, for those of these applications that meet the criteria for protection referred to in subparagraph (b).

9. Where a product is the subject of a patent application in a Member in accordance with paragraph 8(a), exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member.

For more information

The WTO website's gateway to TRIPS:
http://www.wto.org/english/tratop_e/trips_e/trips_e.htm
TRIPS, pharmaceuticals and public health:
http://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm
The Doha Declaration on TRIPS and Public Health:
http://www.wto.org/english/tratop_e/trips_e/healthdeclexpln_e.htm
The 30 August 2003 decision on importing and exporting under compulsory licence:
http://www.wto.org/english/news_e/pres03_e/pr350_e.htm

IV. Dispute Settlement

DISPUTE SETTLEMENT: DISPUTE DS362
China — Measures Affecting the Protection and Enforcement of Intellectual Property Rights

https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds362_e.htm

Current status

Implementation notified by respondent on **19 March 2010**

Key facts

Short title:	China — Intellectual Property Rights
Complainant:	United States
Respondent:	China
Third Parties:	Argentina; Australia; Brazil; Canada; European Communities; India; Japan; Korea, Republic of; Mexico; Chinese Taipei; Thailand; Turkey
Agreements cited: (as cited in request for consultations)	Intellectual Property (TRIPS): Art. 3.1, 9.1, 14, 41.1, 46, 59, 61
Request for Consultationsreceived:	10 April 2007
Panel Reportcirculated:	26 January 2009

Summary of the dispute to date

The summary below was up-to-date at 26 May 2010
See also: One-page summary of key findings of this dispute

Consultations

Complaint by the United States.

On 10 April 2007, the United States requested consultations with China concerning certain measures pertaining to the protection and enforcement of intellectual property rights in China.

The four matters on which the United States requests consultations are:

- the thresholds that must be met in order for certain acts of trademark counterfeiting and copyright piracy to be subject to criminal procedures and penalties;

- goods that infringe intellectual property rights that are confiscated by Chinese customs authorities, in particular the disposal of such goods following removal of their infringing features;

- the scope of coverage of criminal procedures and penalties for unauthorized reproduction or unauthorized distribution of copyrighted works; and

- the denial of copyright and related rights protection and enforcement to creative works of authorship, sound recordings and performances that have not been authorized for publication or distribution within China.

The United States claims that in relation to the four above-mentioned matters possible inconsistencies with the TRIPS Agreement arise as follows:

- The lack of criminal procedures and penalties for commercial scale counterfeiting and piracy in China as a result of the thresholds appears to be inconsistent with China's obligations under Articles 41.1 and 61 of the TRIPS Agreement.

- The requirement that infringing goods be released into the channels of commerce under the circumstances set forth in the measures at issue appears to be inconsistent with China's obligations under Articles 46 and 59 of the TRIPS Agreement.

- Authors of works whose publication or distribution has not been authorized (and whose publication or distribution is therefore prohibited) appear not to enjoy the minimum standards of protection specially granted by the Berne Convention in respect of those works (and may never enjoy such protection if the work is not authorized, or is not authorized for distribution or publication in the form as submitted for review). In addition, the rights of authors of works whose publication or distribution is required to undergo pre-publication or pre-distribution review appear to be subject to the formality of successful conclusion of such review. The foregoing appears to be inconsistent with China's obligations under Article 9.1 of the TRIPS Agreement. In addition, to the extent that the Copyright Law also denies protection of so-called related rights to performers and producers of sound recordings during the period of any pre-publication or pre-distribution, the Copyright Law appears to be inconsistent with China's obligations under Article 14 of the TRIPS Agreement. Furthermore, to the extent that different pre-distribution and pre-authorization review processes for Chinese nationals' works, performances (or their fixations) and sound recordings than for foreign nationals' works, performances (or their fixations) and sound recordings result in earlier or otherwise more favourable protection or enforcement of copyright or related rights for Chinese authors' works, Chinese performers' performances (or their fixations) and Chinese producers' sound recordings, the measures at issue appear to be inconsistent with China's obligations under Article 3.1 of the TRIPS Agreement. Additionally, to the extent that Article 4 of the Copyright Law causes foreign authors of works whose publication or distribution has not been authorized not to enjoy the rights granted to Chinese authors, the measures at issue appear to be inconsistent with China's obligations under Article 9.1 of the TRIPS Agreement (with respect at least to China's obligations to comply with Articles 5(1) and 5(2) of the Berne Convention). In addition, to the extent that Article 4 of China's Copyright Law makes it impossible for rights holders to enforce their copyrights or related rights with respect to works, performances or sound recordings that have not been authorized for publication or distribution, China appears to act inconsistently with China's obligations under Article 41.1 of the TRIPS

Agreement.

- To the extent that wilful copyright piracy on a commercial scale that consists of unauthorized reproduction — but not unauthorized distribution — of copyrighted works, and vice versa, may not be subject to criminal procedures and penalties under the law of China, this would appear to be inconsistent with China's obligations under Articles 41.1 and 61 of the TRIPS Agreement.

On 20 April 2007, Japan requested to join the consultations. On 25 April 2007, Canada and the European Communities requested to join the consultations. On 26 April 2007, Mexico requested to join the consultations. Subsequently, China informed the DSB that it had accepted the requests of Canada, the European Communities, Japan and Mexico to join the consultations.

On 13 August 2007, the United States requested the establishment of a panel. At its meeting on 31 August 2007, the DSB deferred the establishment of a panel.

Panel and Appellate Body proceedings

At its meeting on 25 September 2007, the DSB established a panel. Argentina, the European Communities, Japan, Mexico and Chinese Taipei reserved their third-party rights. Subsequently, Australia, Brazil, Canada, India, Korea, Thailand and Turkey reserved their third-party rights. On 3 December 2007, the United States requested the Director-General to compose the panel. On 13 December 2007, the Director-General composed the panel. On 16 July 2008, the Chairman of the panel informed the DSB that due to the complexity of issues presented in this case, the panel would not be able to complete its work within six months from the date of the panel's composition. The panel expected to issue its final report to the parties by November 2008.

On 26 January 2009, the panel report was circulated to Members. The panel concluded that the Copyright Law, specifically the first sentence of Article 4, is inconsistent with China's obligations under Article 5(1) of the Berne Convention (1971), as incorporated by Article 9.1 of the TRIPS Agreement; and Article 41.1 of the TRIPS Agreement.

With respect to the Customs measures, the panel determined that Article 59 of the TRIPS Agreement is not applicable to these measures insofar as they apply to goods destined for exportation and that the United States has not established that these measures are inconsistent with Article 59 of the TRIPS Agreement, as it incorporates the principles set out in the first sentence of Article 46 of the TRIPS Agreement. The panel also determined that the Customs measures are inconsistent with Article 59 of the TRIPS Agreement, as it incorporates the principle set out in the fourth sentence of Article 46 of the TRIPS Agreement and that the United States has not established that the criminal thresholds are inconsistent with China's obligations under the first sentence of Article 61 of the TRIPS Agreement.

The panel exercised judicial economy with respect to the claim under Article 5(2) of the Berne Convention (1971), as incorporated by Article 9.1 of the TRIPS Agreement, the claims under Article 61 of the TRIPS Agreement (with respect to the Copyright Law) and the claims under Article 41.1 of the TRIPS Agreement and under the second sentence of Article 61 of the TRIPS Agreement (with respect to the criminal thresholds).

The panel concluded that, to the extent that the Copyright Law and the Customs measures as such are inconsistent with the TRIPS Agreement, they nullify or impair benefits accruing to the United States under that Agreement, and recommended that China bring the Copyright Law and the Customs measures into conformity with its obligations under the TRIPS Agreement.

At its meeting on 20 March 2009, the DSB adopted the panel report.

Implementation of adopted reports

On 15 April 2009, China informed the DSB that it intended to implement the DSB recommendations and rulings and that it would need a reasonable period of time to do so. On 29 June 2009, China and the United States informed the DSB that they had agreed that the reasonable period of time for China to implement the DSB recommendations and rulings shall be 12 months from the adoption of the report. Accordingly, the reasonable period of time expired on 20 March 2010. On 19 March 2010, China reported that on 26 February 2010, the Standing Committee of the 11thNational People's Congress had approved the amendments of the Chinese Copyright Law and that on 17 March 2010, the State Council had adopted the decision to revise the Regulations for Customs Protection of Intellectual Property Rights. Thus, it had completed all necessary domestic legislative procedures for implementing the DSB recommendations and rulings. The United States said that it was not yet in a position to share China's claim that it had implemented the DSB recommendations and rulings.

On 8 April 2010, China and the United States notified the DSB of Agreed Procedures under Articles 21 and 22 of the DSU.