17: Patents: Subject Matter and Patentability Requirements

> Article 27.1 Patentable Subject Matter
>
> 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.* Subject to paragraph 4 and 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.
>
> [Footnote]*: For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.

1. Introduction: overview, terminology, definition and scope

1.1 Overview of TRIPS provisions on patents

TRIPS (Part II, Section 5) contains standards relating to patents and covers both substantive standards as well as specific issues of enforcement that are generally applicable to patents. The following provisions are noteworthy:[512]

(a) Members may not exclude any field of technology from patentability, and they may not discriminate as to fields of technology, the place of invention and whether products are imported or locally produced (Article 27);

(b) Members may exclude from patentability: inventions contrary to *ordre public* or morality; certain methods for human or animal treatment; and plants and animals, with some qualifications. Members may also provide for limited exceptions to the exclusive rights conferred by a patent, provided certain requirements are met (Articles 27, 30);

(c) The domestic patent laws must provide a minimum term of twenty years of protection from the filing date. Such protection must depend on the same

[512] See UNCTAD, *The TRIPS Agreement and Developing Countries*, Geneva, 1996, paras 111–114 [hereinafter UNCTAD, 1996].

conditions of eligibility though the definition of the specific standards of patentability is left to national laws (Article 33 and 27);

(d) The patentee's bundle of exclusive rights must include the right to prevent the importation of the patented products (Article 28), subject to the applicable rules of exhaustion (Article 6);

(e) Compulsory licences remain available and can be granted under the existing law of the Member country, subject to the conditions set forth in the Agreement (Article 31).

These provisions build on standards previously established by the Paris Convention,[513] such as the rights of priority, which even WTO Members who do not adhere to this Convention must now respect. Single countries may deviate from these universal patent law standards only to the extent that they make use of transitional periods, which vary with the beneficiary's status as either a developing country, an economy in transition or a least-developed country (LDC).[514] For example, developing countries could postpone implementing most of the required standards for a period of five years (Article 65). LDCs under Article 66.1 obtained a reprieve for eleven years, while a proof of hardship may qualify them for further delays and other concessions.[515] Under the Doha Declaration on the TRIPS Agreement and Public Health, this original transition period has been extended for LDCs until 2016, *inter alia* with respect to the granting of patents on pharmaceutical products.

The provisions on enforcement (Part III of the Agreement) are generally applicable to patent rights, although Member countries need not apply the special requirements of border control measures to patents. Such measures are obligatory for trademarks and copyrights. In addition, the Agreement (Articles 70.8 and 70.9) describes the procedures to be followed in case a Member country applies the transitional periods provided for under Article 65 of the Agreement to pharmaceutical products and agro-chemicals. This provision allows developing countries to delay the recognition of pharmaceutical patents for up to ten years from the date of entry into force of TRIPS. The transitional periods are automatically applicable, i.e., there is no need for prior notification or declaration by concerned Member countries. However, Members that apply the extended period of 10 years for pharmaceutical or agrochemicals are bound to accept the filing of new applications for pharmaceutical product patents during that period, and they are further bound eventually to grant exclusive marketing rights (EMRs) for a limited period (Article 70.9).[516]

This and the subsequent chapters of this book (numbers 18-26) deal in detail with the following patent issues: subject matter and patentability requirements; non-discrimination; *ordre public* and morality; therapeutic, surgical and diagnostic methods; biotechnological inventions: genetic resources, plant variety

[513] Paris Convention for the Protection of Industrial Property, Stockholm Act of 14 July 1967.

[514] For details on the transitional arrangements, see Chapter 33.

[515] See also WTO Agreement, Article XI(2), requiring LDCs only ... "to undertake commitments and concessions to the extent consistent with the individual development, financial and trade needs or their administrative and institutional capabilities".

[516] For details, see Chapter 36.

protection, traditional knowledge; rights and exceptions; disclosure of information; non-voluntary uses; and, process patents: burden of proof.

1.2 Terminology, definition and scope

Article 27.1 contains the overriding requirement that patents shall be available for all types of product and process inventions, subject to the principle of non-discrimination (with regard to the place of invention, the field of technology and whether products are imported or locally produced), and to certain facultative exceptions discussed below.

A patent confers an exclusive right granted by a state to an inventor for a certain period of time[517] in return for disclosure of his or her invention in a document known as the patent specification. The description of the invention in the specification must be sufficient that others skilled in the technological field ("skilled in the art") are able to read the specification and perform the invention for themselves after the patent expires. The extent of the exclusive rights is defined in the part of the patent application known as the claims. Only third parties carrying out activities that fall within the claims will commit infringement of the patent. The way in which the claims are construed varies from jurisdiction to jurisdiction. In some a fairly literal approach is adopted, and functional equivalents not claimed in the specification will not infringe the patent. Others treat functional equivalents that would be obvious to third parties skilled in the art as falling within the claims.

Under the Paris Convention for the Protection of Industrial Property, states were free to exclude areas from patentability, as well as to provide special rules for certain types of inventions. In addition, they had freedom to define the requirements for patentability. TRIPS has changed this situation. Article 27.1 includes a general obligation of patentability addressing in this manner one of the major concerns raised by the pharmaceutical industry with respect to prevailing regimes prior to TRIPS. In addition, all discrimination between sectors (as well as on the basis of the place of invention) has been banned. As discussed below,[518] Article 27.1, *in fine*, also provided a basis for limiting the power of States to differentiate the treatment conferred to products locally produced and imported. Though not explicitly mentioned in this provision, the main aim of the proponents of such a non-discrimination clause was to restrain the use of compulsory licences for lack of local exploitation. Being the result of a compromise, this aspect of Article 27.1 has been the subject of considerable controversy.[519]

2. History of the provision

2.1 Situation pre-TRIPS

At the start of the Uruguay Round, about 50 countries did not grant protection to pharmaceutical products at all, and some excluded pharmaceutical processes from protection as well. Many also excluded food and other products from patentability.[520]

[517] At least twenty years from the date of filing, Article 33 TRIPS – see Chapter 22 below.

[518] See Chapter 25.

[519] See Chapter 25.

[520] See UNCTAD, 1996.

The main international instrument dealing with patents before the entry into force of TRIPS was the Paris Convention. Unlike Article 27.1, though, the Convention allowed exclusions from patentability and did not establish any patentability criteria;[521] it was up to the Paris Union countries to determine these in their domestic laws.

2.2 Negotiating history

The drafting of Article 27.1 was in part based on Article 10 of the draft WIPO Patent Law Treaty of 1991. This required that patents be available for inventions in all fields of technology, subject to fulfilling the usual requirements for patentability: (1) novelty; (2) industrial applicability; and, (3) display of an inventive step. Article 27.1 establishes therefore a general principle of patentability. The same principle was codified at the time of the negotiations in Article 52(1) of the European Patent Convention[522] and in many national patent laws.

2.2.1 The Anell Draft

"SECTION 5: PATENTS

1. Patentable Subject Matter

1.1 Patents shall be [available] [granted] for [any inventions, whether products or processes, in all fields of technology,] [all products and processes] which are new, which are unobvious or involve an inventive step and which are useful or industrially applicable.

1.2 Patents shall be available according to the first-to-file principle.

1.3 Requirements such as filing of an adequate disclosure in a patent application and payment of reasonable fees shall not be considered inconsistent with the obligation to provide patent protection.

(See also point 3.1 below)[523]

1.4 The following [shall] [may] be excluded from patentability:

[. . .]

1.4.2 Scientific theories, mathematical methods, discoveries and materials or substances [already existing] [in the same form found] in nature.

[. . .]

1.4.5 [Production, application and use of] nuclear and fissionable material, [and substances manufactured through nuclear transformation].

1.5B PARTIES may exclude from patentability certain kinds of products, or processes for the manufacture of those products on grounds of public interest, national security, public health or nutrition.

[. . .]"[524]

[521] I.e. the criteria of novelty, inventive step and industrial applicability as laid down in Article 27.1 of the TRIPS Agreement.

[522] This Article reads as follows: "European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step".

[523] Point 3.1 of the Anell Draft concerned the disclosure obligation. See Chapter 24.

[524] See Chairman's report to the Group of Negotiation on Goods, document MTN.GNG/NG11/W/76, of 23 July 1990.

The patentability of both products and processes for inventions in all fields of technology was an unresolved issue in the Anell Draft, but opposition in this respect was dropped by the time the Brussels Draft was tabled. Paragraphs 1.4.2, 1.4.5, and 1.5B above do not appear in the final form of TRIPS. Paragraph 1.4.2 was an express recognition that for the purpose of patentability, discoveries have to be distinguished from inventions. Even though this distinction is not expressly made in the current Article 27.1, Members do have broad discretion to exclude natural substances from patentability.[525] The bracketed reference in paragraph 1.4.2 to materials or substances "in the same form found" in nature reflects some Members' practice to allow for the patentability of biological material once this has been isolated from its natural environment.[526] The reference in paragraph 1.4.5 to nuclear and fissionable material was later taken out of the patent context and inserted into the general TRIPS provision on security exceptions under Article 73.[527] Finally, the public interest clause in paragraph 1.5B above was not included as such in the final version of TRIPS. National security interests are referred to under Article 73. Public health and nutrition as well as the public interest in more general terms are included under Article 8.1 as objectives that Members may promote and protect in the formulation of domestic IPR legislation. But this provision does not authorize Members to deviate from the substantive obligations under TRIPS, as is made clear by its final phrase ("provided that such measures are consistent with the provisions of this Agreement").[528]

2.2.2 The Brussels Draft

> "1. Subject to the provisions of paragraphs 2 and 3 below, 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. [note]. [Patents shall be available without discrimination as to where the inventions were made.]
>
> [. . .]
>
> [note]"[529] (essentially identical to the current version of TRIPS)

At the time of the Brussels Draft, the non-discrimination requirement with respect to the availability of patents, as contained in the current Article 27.1, second sentence, was still controversial. The provision took its final form under the 1991 Dunkel Draft.[530]

[525] See Section 3 of this chapter.

[526] See Section 3 of this chapter, with respect to the patentability of isolated micro-organisms under the European Patent Convention and under U.S. patent law.

[527] For more details, see Chapter 39.

[528] For more details on Article 8, see Chapter 6.

[529] See Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Revision, Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, MTN.TNC/W/35/Rev. 1, 3 Dec. 1990.

[530] See Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, MTN.TNC/W/FA, 20 December 1991.

3. Possible interpretations

3.1 Availability in all fields of technology

> 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 . . .

The introductory phrase "subject to the provisions of paragraphs 2 and 3" – which provide for non-mandatory exceptions to patentability – indicates that, where established by national laws, such exceptions override the general rules contained in paragraph 1 of Article 27.

This Article explicitly obliges making patents available for both product and processes,[531] and prohibits distinctions relating to the field of technology to which the invention belongs. Thus the exclusions from patentability of pharmaceutical products that were once common in national patent laws[532] will not be permissible after full implementation of TRIPS.

An important interpretative question is whether this Article obliges Members to protect use*s* as such, for instance, new uses of known products, in addition to products and processes. Comparative law on this issue varies considerably. In the USA, the patenting of use inventions, where admitted, depends on whether the purpose of the use is novel and non-obvious. Method inventions may be judged independently of the purpose. Even if intended for a novel purpose, the key consideration in determining the patentability of a method invention is whether it could be anticipated by other methods.[533] In the United States, patents on uses are confined to a particular "method-of-use", which does not encompass protection of the product as such.[534] In Europe, the patentability of a known product for a new specific purpose is allowed under Article 54(5) of the European Patent Convention. Thus, the identification of the *first* medical indication of a known product may permit patenting of the product.[535] In cases where an application

[531] Process patents can confer rights not only over the use of the process in question, but also over products obtained directly by the process, see Article 28.1(b), TRIPS Agreement. However, in the latter case problems arise where the product is either a known substance or a discovery (as to the meaning of "discovery" see below, under Section 3.2.1 of the present chapter (on novelty) and under Section 7 of the present chapter). Product-by-process claims of this sort give rise to especial problems in relation to biotechnology. This is discussed in Chapter 21.

[532] Other examples of exclusions were, for instance, in the case of India, chemical processes, methods of agriculture and horticulture (including herbicides and pesticides), alloys and new uses for known products or processes. Argentina was a typical example of another approach which, while excluding pharmaceuticals from patentability, permitted process patents, except in relation to pharmaceutical products producible through a single procedure (because this was thought to be an indirect form of product patent). Such exclusions are not permissible under Article 27.1.

[533] See, e.g., Bernd Hansen and Fritjoff Hirsch, *Protecting inventions in chemistry. Commentary on chemical case law under the European Patent Convention and the German Patent Law*, WILEY-VCH, Weinheim 1997, p. 120 [hereinafter Hansen and Hirsch].

[534] See, e.g., Robert P. Merges, *Patent law and policy. Cases and materials*, Contemporary Legal Educational Series, Boston 1992, p. 489 [hereinafter Merges].

[535] The Technical Board of Appeal of the European Patent Office has ruled that such claims should be deemed as covering all therapeutic uses of the product as in the case of claims on a

refers to the *second* medical indication of a known pharmaceutical product, however, an obstacle to patentability arises. Patent applications over the therapeutic use of a known product essentially are instructions to the physician about how to employ a certain substance to treat a particular disease. Such a new use, hence, is equivalent to a *method of therapeutic treatment*, which is deemed non-patentable under European law.

In order to overcome such barrier, however, since 1984 the European Patent Office admitted, under a legal fiction, claims on the second medical indication of a known pharmaceutical product when framed under the so-called "Swiss formula".[536] The difference between this legal fiction and Article 54(5) of the European Patent Convention as discussed above is the following: Article 54(5) allows the patenting of a (known) *product* for a new specific purpose. The "Swiss formula", on the other hand, concerns the patenting of the *use* of the product, thus a method, and not a product. However, the "Swiss formula" suffers from "the logical objection that it lacks novelty, since it claims the use of the compound for preparation of a medicament, and normally the medicament itself will be the same as that already used for the first pharmaceutical indication".[537]

Under TRIPS, WTO Members are free to decide whether to allow the patentability of the uses of known products, including for therapeutic use,[538] and are certainly free to adopt the "Swiss formula" approach. The Agreement only obliges them to grant patents for products and processes (Article 27.1). Many patent laws recently adopted in developing countries make no specific reference to the availability of patents for uses, leaving unclear whether the protection for processes covers uses or methods of use.

Any application for a patent must satisfy the basic criteria of novelty, inventive step and industrial applicability. Accordingly, Article 27.1 makes it clear that patents are to be granted for inventions. TRIPS, however, does not define what an "invention" is; it only specifies the requirements that an invention should meet in order to be patentable (Article 27.1). This leaves Members considerable freedom to determine what should be deemed an invention and, if they so desire, to exclude from patentability any substance which exists in nature as being a mere discovery and not an invention. As pointed out before, the Anell Draft of Article 27[539] was explicit on the point that discoveries of things already existing in nature are, in principle, unpatentable. Article 8 of the draft Patent Law Treaty mentioned above was also explicit on this, as is the European Patent Convention.

pharmaceutical composition. Infringement of such claims would only take place when the product is commercialized for direct therapeutic use, and not in bulk (Philip Grubb, *Patents for chemicals, pharmaceuticals and biotechnology. Fundamentals of global law, practice and strategy*, Clarendon Press, Oxford 1999, p. 218 [hereinafter Grubb]).

[536] "Use of X for the manufacture of a medicine to treat Y".

[537] See, e.g., Grubb, p. 221.

[538] Because patents protect inventions but not discoveries, the discovery of a new purpose for a product cannot render a known product patentable *as such* under general principles of patent law. This remains the case unless in connection with the new purpose the product is forced to be present in an amended new form (Hansen and Hirsch, p. 104).

[539] See above, Section 2.2 of this chapter.

There are various other examples of specific exclusions that were present in earlier drafts of TRIPS, but which are not in the current text. For example, there is now no provision in TRIPS equivalent to Article 52.2 of the European Patent Convention which provides –

> "The following in particular shall not be regarded as inventions within the meaning of paragraph 1:
>
> (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers ..."

However, this does not exempt patent applications covering such subject matter from the requirement of satisfying the basic criteria of novelty, inventive step and industrial applicability. In the case of computer programs, the reality is that the industry has advanced to the point where most "new" programs are largely assemblages of existing programs.[540] Obviously, an attempt to patent existing programs would fail because of lack of novelty. On the other hand, a new assemblage might pass the test of novelty,[541] but it could well fail the requirement of inventive step if such an assemblage would be obvious to a skilled programmer.

3.2 Patentability Criteria

> . . . provided that they are new, involve an inventive step and are capable of industrial application . . . [542]

This provision sets up the criteria of patentability, without however harmonizing the way in which they have to be implemented. Thus, Members have considerable leeway in applying those three criteria (novelty, inventive step and industrial applicability). As long as they respect the basic definitions of those criteria as set out below, they may implement them according to what is most appropriate for their specific level of development. For instance, the criterion of "industrial applicability" may be interpreted in a narrow or wide way. Members may require that

[540] These are, in principle, protected by copyright as required by the TRIPS Agreement Article 10. As far as information technology is concerned, the difference between patents and copyrights is the following: while the latter protects original computer programs as an *expression of thought* against unauthorized copying, patent protection covers the *underlying ideas*, procedures and methods of operation (cf. also Article 9.2 TRIPS). The minimum term of protection under the Berne Convention (Article 7(1)) is the life of the author plus 50 years after his death. This means that most programs are technically still in copyright. However, copyright only protects the expression of ideas, and in any case the authorship and the ownership of many basic programs is now unknown. An assembly of such programs, independently arrived at by a skilled programmer to solve a particular problem, would not infringe copyright unless the proprietors of those basic programs were to surface. In this event, which in practice seldom occurs, the offer of a reasonable royalty should suffice.

[541] The equivalent in mechanical terms would be a novel assemblage of known integers, such as the well-known "Workmate" portable workbench.

[542] A footnote to this Article states 'For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively'.

the invention result in a true industrial product; or they may settle for a wider approach, requiring only a certain degree of utility of the invention in the widest sense, i.e. without insisting on the creation of a product usable by industry.[543] In fact, there is a general opinion that OECD offices have been somewhat lax in granting some types of patents including pharmaceutical patents, and this may not be in the interest of developing countries.[544] Those relying on examination under the Patent Cooperation Treaty may experience a similar problem.

3.2.1 "Novelty"

This requirement generally means that the information must not have been available to the public prior to the original application date (the priority date).[545] Since the inventor is granted a patent for disclosing something new, it follows that if the invention has already been disclosed in literature available to the public, the applicant (the "inventor") can disclose nothing new in return for the grant, and is either not entitled to be granted a patent, or if one has been granted, is liable to have it revoked. The disclosure may have taken place within the jurisdiction or elsewhere in the world. It also follows from the nature of invention that the discovery of things already existing in nature, e.g., a new plant or mineral, is not an invention.

Prior *secret* use destroyed patentability and afforded grounds for revocation under some patent systems, for example those based on the old UK law.[546] UK law, however, had to be changed to comply with the European Patent Convention. A prior secret use is not part of the state of the art, and it is the state of the art at the time the application is filed (the "priority date") that is relevant for the purposes of satisfying the novelty requirement under Article 27.1.

3.2.2 "Inventive step"

The invention must not merely be something new; it must represent a development over prior art.[547] While under patent law in Europe and in many other countries

[543] Cf. infra, under Section 3.2.3 of this chapter (Industrial applicability).

[544] See, e.g., Carlos Correa, *Trends in drug patenting. Case studies*, Corregidor, Buenos Aires, 2001 [hereinafter Correa 2001b].

[545] European Patent Office case law has it that the theoretical possibility of having access to information renders it available to the public (case T 444/88), whatever the means by which the invention was made accessible, and – in the case of prior public use – irrespective of whether there were particular reasons for analysing the product (cases G 1/92,). The United States requires complete disclosure in a *single* publication to destroy novelty, despite the fact that a skilled person may have been able to derive the invention without effort from a combination of publications. In addition, under U.S. law oral disclosure of an invention *outside* the United States does not destroy novelty. This relative concept of novelty has allowed the patenting in the USA of knowledge and materials used by indigenous communities abroad. See, e.g., Carlos Correa, *Traditional knowledge and intellectual property. Issues and options surrounding the protection of traditional knowledge*, QUNO, Geneva, 2001 [hereinafter Correa, 2001a].

[546] The Patents Act 1949 s. 32(1)(l) provided for revocation of a patent on the ground that the invention claimed was secretly used in the United Kingdom before the priority date.

[547] In European Patent Office (EPO) jurisprudence, the relevance of which is discussed below, "inventive step" is distinguished from technical progress. Therefore technical progress comparisons with marketed products as alleged support for this requirement being satisfied are not

this is generally described as an "inventive step", in the United States the requirement is defined as "non-obviousness". Footnote 5 to Article 27.1 specifically permits a Member to consider that "inventive step" is synonymous with "non-obvious".

The inventive step is often evaluated by considering the "unexpected" or "surprising" effect of the claimed invention. U.S. courts, however, currently reject this approach and stress that patentable inventions may result either from painstaking research, slow trial and error, or serendipity.[548] The low standard of inventiveness applied in some countries, including in the United States, has led to the grant of a large number of patents on minor or trivial developments, often aggressively used to artificially extend the duration of protection and to block legitimate competition.[549]

Given the market disruption and costs that patents granted on low or non-inventive developments may cause, developing countries may opt for high standards of inventiveness. Thus, the World Bank has suggested that developing countries "could set high standards for the inventive step, thereby preventing routine discoveries from being patented."[550]

TRIPS, as mentioned, leaves significant freedom for Members to determine the degree of strictness to be applied for judging the inventive step. Though applying a low threshold may facilitate the patenting of incremental developments, which predominate in domestic industry in developing countries, this would be done at the cost of unduly restraining competition and increasing litigation costs in key areas such as pharmaceuticals where extensive patenting of minor developments has become normal practice.[551] In order to promote and reward minor innovations related forms of IP could be adopted, such as utility models.[552]

Both the European Patent Office (EPO) and the national courts in the member countries of the European Patent Convention have in the past expressed the view that computer-implemented inventions contributing to the state of the art in a way not obvious to a person of normal skill in the field concerned is more than just a computer program "as such" and may consequently be patented.[553] However,

sufficient. There must be demonstrated the presence of an inventive step with regard to the closest state of the art – see cases T 181/82; T 164/83 (also cases T 317/88 and T 385/94).

[548] See, e.g., Jay Dratler, *Intellectual property law, commercial, creative, and industrial property*, Law Journal Press 1999, §2.03[3].

[549] See, e.g., John Barton, *Reforming the patent system*, Science, vol. 287, 17 March 2000, p. 1933–1934 [hereinafter Barton].

[550] World Bank (2001), Global Economic Prospects and the Developing Countries, p. 143.

[551] See, e.g., Carlos Correa, *Trends in Drug Patenting.* Case Studies, Corregidor, Buenos Aires, 2001.

[552] Utility models protect the *functional* aspect of models and designs, generally in the mechanical field. Though novelty and inventiveness are required, the criteria for conferring protection are generally less strict than for patents. The term of protection also is shorter. Utility models are concerned with the way in which a particular configuration of an article works, unlike *industrial designs*, which are only concerned with its ornamental aspect.

[553] Cf. the document of the European Commission *Patents: Commission proposes rules for inventions using software*, available at <http://europa.eu.int/comm/internal_market/en/indprop/comp/02-277.htm>.

Members retain the right not to protect computer programs that produce no "technical effect" beyond the operation of the computer where they reside.

3.2.3 "Industrial applicability"

The invention must be capable of being used in any kind of industry (including agriculture). Industry in this sense is any physical activity of a technical character.[554]

Members considerably differ in their treatment of industrial applicability. Under U.S. law, the concept applied is "utility".[555] Hence, certain developments that do not lead to an industrial product may be patented in the USA: an invention only needs to be operable and capable of satisfying some function of benefit to humanity (i.e. be useful).[556] This concept is broader than the industrial applicability required in Europe and other countries. The U.S. rule permits the patentability of purely experimental inventions that cannot be made or used in an industry, or that do not produce a so-called technical effect,[557] as illustrated by the large number of patents granted in the United States on methods of doing business, and by the patenting of research tools, such as expression sequence tags (ESTs) and single nucleotide polymorphisms (SNPs).[558]

Surgical techniques and diagnostic procedures could arguably fail this requirement, but can in any event be specifically excluded from patentability under Article 27.3 (a) as discussed below.

4. WTO jurisprudence

On 30 April 1996, the USA requested consultations with Pakistan under the Dispute Settlement Understanding (DSU) for an alleged violation of, *inter alia*, Article 27 of TRIPS.[559] However, on 25 September 1997, the two parties to the dispute informed the Dispute Settlement Body (DSB) that they had found a common solution. Thus, a panel was never established.

[554] The technical character of an invention is a basic requirement of patentability (see Article 27.1 TRIPS: "... patents shall be available ... in all fields of *technology*, ..." (emphasis added)). According to the European Patent Office's Guidelines on Patentability, any physical activity of a technical character is an activity which belongs to the useful or practical arts as distinct from the aesthetic or fine arts – Guideline C-IV, 4.1. The Guidelines are available at <http://www.European-patent-office.org>.

[555] Footnote 5 to Article 27.1 specifically permits a Member to consider that "capable of industrial application" is synonymous with "useful".

[556] See, e.g., Donald S. Chisum and Michael A. Jacobs, *Understanding Intellectual Property Law*, Legal Text series, Matthew Bender, New York 1992, pp. 2–50 [hereinafter Chisum and Jacobs].

[557] It should be noted that "technical effect" has no official definition. The doctrine has its origins in German patent law (see Graham Dutfield, *Intellectual Property Rights and the Life Science Industries: A Twentieth Century History,* Ashgate, Aldershot 2003, p. 81).

[558] The guidelines for examining utility were changed in the USA in 2001, possibly leading to the exclusion from patentability of some of these matters. See USPTO Utility Examination Guidelines Federal Register Vol 66 No 4 January 5, 2001.

[559] WTO document WT/DS36.

5. Relationship with other international instruments

5.1 WTO Agreements

No specific relationships have been identified.

5.2 Other international instruments

The Paris Convention requires the protection of patents, but does not establish rules on the patentability requirements.

As noted above, Article 10.1 requires computer software to be protected as a literary work under the Berne Convention.[560]

6. New developments

6.1 National laws

Most developing countries that have amended their patent laws to implement TRIPS have adopted (often in conformity with previous domestic law and practice) *universal* novelty, inventive step and industrial applicability as requirements for protection. Given the considerable room available for the interpretation and application of these requirements, national practices may differ significantly and also evolve over time.

6.2 International instruments

In 2001 the Director General of WIPO announced a new initiative, approved by the WIPO Assembly, called the "WIPO Patent Agenda" for worldwide discussions aiming at preparing a strategic blue print that would underlie the future development of the international patent system.[561] One of the components of the Agenda is the development and harmonization of substantive patent law with the goal of adopting a new Substantive Patent Law Treaty. This Treaty, if adopted, could include rules on the patentability requirements discussed above and, thus, eliminate or limit the freedom that currently countries have to define and implement such requirements.[562] In this context, the Commission on Intellectual Property Rights [hereinafter IPR Commission] cautioned in its report:

> "Developing countries should identify a strategy for dealing with the risk that WIPO harmonisation will lead to standards that do not take account of their interests. This could be done by seeking a global standard reflecting the recommendations of this report; it could be done by seeking continued flexibility in the WIPO standards; it could be done by rejection of the WIPO process if it appears that the outcome will not be in the interests of developing countries."[563]

[560] The basic provision of that Convention relating to literary works is Article 2.

[561] See WIPO, *Agenda for development of the international patent system*, document A/36/14.

[562] See WIPO documents SCP/7/3 and SCP/7/4 of March 6, 2002.

[563] *Integrating Intellectual Property Rights and Development Policy*, Report of the Commission on Intellectual Property Rights, London, September 2002, p. 132. The Report can be consulted at: <http://www.iprcommission.org/graphic/documents/final_report.htm>.

6.3 Regional and bilateral contexts

6.3.1 Regional

In 2000, the European Commission proposed the creation of a Community patent to give inventors the possibility of acquiring one single patent legally valid throughout the EU.[564] Currently, patents in European countries are granted either by the national patent offices as a national right or by the European Patent Office (EPO) as a "European Patent". The latter is, however, not the same as the proposed Community patent: it is not a uniform, single right, but a bundle of national patents. Thus, even though there is just one application procedure, matters of substantive law are still regulated by the member states of the European Patent Convention (EPC), which may require the patent to be translated into their national language. In addition, the national courts remain competent to apply national patent laws, which may vary considerably across the EPC member states.

In addition to the proposal on the Community Patent, the Commission has issued a proposal for an EC Directive on the protection by patents of computer-implemented inventions.[565] This proposal distinguishes between two types of inventions. On the one hand, those involving the use of a computer program and thereby contributing to the state of the art in the technical field concerned would be eligible for patent protection. On the other hand, computer programs as such or business methods employing existing technological ideas would not be eligible as patents. However, they continue to benefit from copyright protection to be provided according to Article 10.1.[566]

The Commission's proposal still needs to be adopted by both the EU Council and the EU Parliament.[567]

7. Comments, including economic and social implications

7.1 General observations on TRIPS patent provisions, including Article 27.1

Of all the measures contained in TRIPS, the patent provisions may be the most significant in terms of economic implications for developing countries. This follows from the growing importance of patents in major industrial sectors, particularly in R&D-intensive sectors, from the number and breadth of the patent provisions that are covered and from the differences in the scope and extent of protection

[564] The draft Council Regulation on a Community Patent is available in a EU Council document of 8 March 2004, at <http://register.consilium.eu.int/pdf/en/04/st07/st07119.en04.pdf>.

[565] Cf. COM (2002) 92 final of 20 February 2002, available at: <http://europa.eu.int/comm/internal_market/en/indprop/comp/com02-92en.pdf>.

[566] For details, see Chapter 8.

[567] There are some remaining controversies between theses two EU bodies. In particular, the Parliament favours wide exceptions to patentability for computer-implemented inventions, covering the use of patented technology for interoperability and data handling. See <http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/04/659&format=HTML&aged=0&language=EN&guiLanguage=en>.

that will now have to be afforded by both developed and developing countries, as compared with prior law.

The major impact of the Agreement will be felt in cases where patent protection needs to be extended (after the transitional period) to new subject-matter areas, such as pharmaceuticals, agrochemicals, beverages and food, in order to implement Article 27.1 of the Agreement. Important economic effects may also arise from the obligation to extend the term of protection (20 years from application).

Many studies have been conducted on the general implications of introducing or reinforcing intellectual property protection in developing countries.[568] Particular concerns have been expressed with regard to the availability and pricing of medicines after product patents are introduced in compliance with TRIPS. The introduction of patents will normally lead to prices higher than those that would have prevailed in the absence of protection, but the quantum of the price differential will vary significantly with a number of factors, such as: (i) the length of the transitional period applied by a particular member country; (ii) the date of granting and the scope of the exclusive marketing rights (EMRs) eventually conferred; (iii) the conditions under which patents are granted and, particularly, the availability of compulsory licences, and the way in which competition law is applied; and (iv) the share of the market attributable to patented products, their price elasticity, the substitutability of products, differences between the market structure pre-TRIPS and post-TRIPS, the eventual existence of price controls, the significance of local production of pharmaceuticals, the size and technological capabilities of local firms, among other factors.

The extended period of patent protection and the strengthened exclusive rights will limit the scope for early legitimate imitation by local firms. As a result, when a given invention finally enters the public domain, the technology may already have been superseded by other protected technologies. However, local inventors will also obtain a longer period in which to recover their investments, although the aggregate amount of such investments will normally fall well below that in developed countries.

Given the lack of reliable empirical data, predictions about the likely economic effects of the patent provisions tend to vary with the general outlook of the investigators. On balance, it seems fair to say that, at least from the medium- and long-term perspective, the economic effects of the patent provisions depend largely on the levels of development of countries and sectors concerned, the speed, nature and cost of innovation, as well as on the measures developing countries may take in adopting the new framework. The introduction of patents will entail sacrifices in static efficiency[569] while benefits for most developing countries in terms of dynamic efficiency[570] are uncertain, particularly to the extent that research

[568] Cf. Part One of UNCTAD, 1996.

[569] *Static efficiency* is achieved when there is an optimum utilization of existing resources at the lowest possible cost. See UNCTAD, 1996.

[570] *Dynamic efficiency* is the optimal introduction of new products or products of superior quality, more efficient production processes and organization, and (eventually) lower prices over time. While patents may sacrifice static efficiency, to the extent that they stimulate innovation, they may in the long term improve dynamic efficiency. See UNCTAD, 1996.

and development of drugs for diseases prevalent in developing countries (such as malaria) continues to be neglected.

The producers able and willing to supply the world market with low-price pharmaceutical products which were under patent in developed countries have principally been situated in Brazil, China and India. Producers in these (and any other) countries are able to continue to manufacture a range of generic products while still complying with TRIPS because pharmaceuticals were not patentable under their local laws until recently. Brazil's Patent Law was amended in 1996 with effect from March 15, 1997. China became the 143rd Member of the WTO on 11 December 2001, 30 days after it had notified the Director-General that it had completed domestic ratification of its accession package. India, as a founding Member of the WTO, has been a Member of TRIPS since 1 January 1995, but has taken advantage of a transition period allowing it to delay introduction of pharmaceutical product patent protection until January 1, 2005.

At present some Members are pressing developing and least-developed countries to accelerate their adoption of patent protection for pharmaceutical products. This is not advisable. A survey of the more important economics literature on pharmaceutical protection in developing countries concluded that:

> "The preponderance of conclusions is pessimistic about the net effects of drug patents on the economic welfare of developing countries (or, more accurately, of net importers of patented drugs)."[571]

Although arguments can be made that the introduction of patents can be beneficial in stimulating innovation and attracting inward investment, there is little or no empirical evidence to confirm that this is likely to apply in the case of developing and least-developed countries:

> "It is remarkable how little is known about the potential effects of changing global policy regimes in this fundamental manner, despite the fact that the pharmaceutical sector is the most extensively studied of all IP-sector industries."[572]

Most inventions in the pharmaceutical field today are made by research teams, which require the availability of a pool of reasonably well-educated researchers. Some quite poor countries do have good educational systems, and in such cases, pharmaceutical companies may channel research (or production) facilities into those countries because of the lower labour costs. The Republic of Ireland benefited from this factor a generation ago. However, the link between the location of research and development facilities and the existence of patent protection is by no means clear-cut. India, for example, developed a significant capacity for the production of raw materials for the pharmaceutical industry, without patent protection. It was also able to attract much inward investment for software development at a time when the protection of software under Indian law was problematic. India, however, had at the relevant time a well-developed law of contract, and this can for certain purposes substitute for intellectual property law.

[571] Keith Maskus, *Intellectual Property Rights in the Global Economy*, IIE 2000, p. 160 [hereinafter Maskus].

[572] Maskus, p. 160.

On January 1, 2005, or January 1, 2016 (subject to any further extension), whichever is applicable, the "mailbox" applications that were submitted during the transition period will be operationalized (see Chapter 36), and patent protection will become available for such of those applications as satisfy the normal criteria of patentability set out above. Accordingly, those developing countries at present exporting off-patent pharmaceutical products will lose that capacity with regard to mailbox applications and medicines invented after the operative date in the relevant country. After the expiry of the relevant transitional period, and subject to the doctrine of exhaustion of rights,[573] the importers of such off-patent products will similarly have to cease such importation. The extent to which compulsory licensing under Article 31 might be used in this new situation is discussed below.[574]

Article 27.1 does not create the obligation to grant patents for computer programs. The refusal by the European Commission to consider computer programs as such to be patentable is motivated by the concern that otherwise the distinction between patent rights on the one side and copyrights on the other might be blurred.[575] For developing countries, this approach has an important implication: if a computer program as a whole were patentable, the practice of reverse engineering,[576] which is legal under copyright protection, could be prevented by the patent holder.[577]

Finally, it is relevant to consider here the concerns expressed by developing countries in connection with the general patentability requirement of TRIPS in relation to biological materials and traditional knowledge. Several cases of "biopiracy" or misappropriation have been identified in the past, and fears have been raised with regard to the implications of Article 27.1 in that regard. There are a number of responses to these fears. In the first place, discoveries of things already existing in nature are, in principle, unpatentable. Article 8 of the draft Patent Law Treaty mentioned above, was explicit on this, as is the European Patent Convention. So also was the Anell Draft of Article 27.[578] Article 27.1 makes it clear that patents are to be granted for inventions, and a discovery of something already existing in nature is not an invention. Unfortunately, in practice, because the applicant is not obliged to disclose the origin of the substance over which the patent is sought, the granting office will often be ignorant of whether the substance is a

[573] See Chapter 5.

[574] See Chapter 25.

[575] As observed above, patents cover only those *specific components* of a software application that are based on some inventive step, whereas copyrights protect the *entire* program against unauthorized copying.

[576] I.e. the dismantling of a finished product into its various components in order to examine how it was originally put together.

[577] The practice of reverse engineering of computer programs is targeted at the underlying *idea*, but not the *expression* of that idea. Consequently, reverse engineering leaves copyright untouched, but would possibly affect patents, if those were available. See also the EC Commission's document *Patents: Commission proposes rules for inventions using software*, available at: <http://europa.eu.int/comm/internal_market/en/indprop/comp/02-277.htm>.

[578] The draft in relevant part (paragraph 1.4.2) read: "Scientific theories, mathematical methods, discoveries and materials or substances [already existing] [in the same form found] in nature." See above, Section 2.2 of this chapter.

discovery. In such a case a patent could well be granted. Although such a patent would be liable to be revoked, there are obviously costs involved in obtaining expert advice and in applying for revocation, especially through national courts. Such costs may be beyond the means of those affected. There seems to be no reason, however, under TRIPS why a national patent office – which is normally given powers to regulate its own procedures – should not of its own initiative follow a complaint, carry out an investigation, and revoke a patent it has granted.[579] Such powers would, of course, have to be exercised judicially and in accordance with the requirements of TRIPS. But the conferring of judicial powers on a patent office is not inconsistent with TRIPS[580] and may offer a more attractive, quicker and cheaper solution than compelling complainants to have recourse to the courts.

[579] In the case of *R v. Comptroller-General of Patents, Designs and Trade Marks, ex parte Ash & Lacy Building Products,* 1 February 2002, Laddie J held that the Comptroller of the UK Patent Office had power to continue revocation proceedings, even though she could not compel the patentee to participate in them. In this respect UK practice differs from that of the European Patent Office.

[580] The procedure of the European Patent Office permits oppositions after grant. The UK Patent Office has quite extensive judicial powers conferred on it, including the possibility of trying alleged infringements. Re-examination can also be conducted by the U.S. Patent and Trademark Office.

18: Patents: Non-Discrimination

> Article 27.1 Patentable Subject Matter
>
> . . . 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.

1. Introduction: terminology, definition and scope

The requirement that patent rights shall be available and enjoyable without discrimination as to the field of technology follows from the general rule of patentability contained in the first sentence of Article 27.1.[581] This second sentence, however, adds an important element: while patents need to be recognized in all fields of technology (subject only to permissible exceptions as discussed in Chapters 19–21 below), the law cannot discriminate in its treatment of different fields, both in terms of availability of rights and of capacity to enjoy them. For instance, patents may not last differently depending on the field of technology involved, nor can they be subject to more stringent conditions (e.g., with regard to the acquisition of rights) in certain fields than in others. This rule may be deemed to include both positive (i.e., superior rights) and negative (i.e., inferior rights) discrimination. This rule, however, is not absolute, as discussed below (Section 3).

A provision which sought to limit the grant and enjoyment of patent rights to inventions made within a particular Member would clearly be contrary to this provision. It would also be contrary to this provision to have a requirement under which evidence of inventive acts were restricted to the territory of a particular country, and foreign applicants were not permitted to prove a date of invention which antedated their filing date in that particular country.[582]

It should be noted that there is no comparable non-discrimination clause in other sections of TRIPS, and that the obligation under Article 27.1 is limited only to discrimination based on the three elements indicated in the provision, that

[581] See Chapter 17.

[582] See discussion in Sections 2.1 and 6 below.

is, place of the invention, field of technology, and local production/importation. Discrimination based on other factors is not banned.[583]

2. History of the provision

2.1 Situation pre-TRIPS

Neither the Paris Convention nor national laws contained a provision comparable to Article 27.1. Hence, discrimination now banned was permissible, such as establishing different terms of patent protection according to the field of technology, as provided for under some domestic patent law.[584]

The principle that patents shall be available, and patent rights enjoyable without discrimination as to the place of invention had generally been accepted under the European Patent Convention. However, in some countries, differential treatment was granted to patents depending on the country of invention. That was the case, for instance, under the Canadian regulation on compulsory licences introduced in 1988 and in force until Bill C-91 was passed in February 1993.[585] The United States – the single country to maintain a "first-to-invent" rule concerning entitlement to a patent[586] – imposed a discriminatory burden on foreign inventors under §104 of the U.S. Patents Act. Evidence of inventive acts was restricted to the territory of the USA. Consequently, evidence by foreign applicants that the date of invention antedated their U.S. filing date was inadmissible if it were based solely on knowledge, use or other activity in a country other than the USA. This territorial limitation was later extended to Canada and Mexico under the North American Free Trade Area Treaty, and subsequently to WTO Member countries.

Similarly, national laws could treat patents differently depending on the local or imported origin of the product. Thus, Section 337 of the U.S. Tariff Act accorded to imported products challenged as infringing U.S. patents treatment less favourable than the treatment accorded to similarly challenged products of U.S. origin. This Section was found inconsistent with the GATT in *United States – Section 337 of the Tariff Act of 1930*.[587]

It has been a common feature in patent laws (of developed and developing countries) to provide for compulsory licences in cases of "non-working" (in conformity with Article 5.A (4) of the Paris Convention), and to interpret that working was only satisfied by local production (not by importation). Some commentators

[583] As to the difference between the general rules of non-discrimination contained in Articles 3 (national treatment) and 4 (most-favoured-nation treatment) and the patent-specific non-discrimination rule in Article 27.1, see Section 5 of this chapter, below.

[584] On the term of patent protection, Article 33, see Chapter 22.

[585] For details, see UNCTAD-ICTSD, Jerome H. Reichman and Catherine Hasenzahl (2002), *Non-Voluntary Licensing of Patented Inventions : The Canadian Experience*. Intellectual Property Rights & Sustainable Development Series, November 2002 [hereinafter Reichman, Hasenzahl, The Canadian Experience], available at <http://www.iprsonline.org/unctadictsd/docs/reichman_hasenzahl_Canada.pdf>.

[586] The rule applied in the USA is said to be in conformity with Article 1(8) of the U.S. Constitution which provides that Congress has power 'to promote the progress of science and useful arts, by securing for limited times to . . . inventors the exclusive right to their . . . discoveries.' It is also thought by many to be fair, because the patent is granted to the first inventor, and not to the first to apply.

[587] See L/6439-365-345 (1989 GATT TPD LEXIS 2).

have interpreted Article 27.1 as a ban to such differentiation but, as discussed in Chapter 25 below, such interpretation is controversial.

2.2 Negotiating history

2.2.1 The Anell Draft

The Anell Draft contained no provision comparable with the current non-discrimination clause in Article 27.1.

2.2.2 The Brussels Draft

> "Patents shall be available without discrimination as to where the inventions were made."

Thus, the Brussels Draft did include a non-discrimination clause with respect to patented inventions. However, this clause covered only part of the final provision under Article 27.1. The draft referred only to non-discrimination as to the place of invention, but did not expressly prohibit discrimination as to the field of technology and as to the place where the protected product is produced. The latter has to be distinguished from the place of invention, which may not be the same as the place of production.

3. Possible interpretations

Under Article 27.1 Members are obliged to make available patents, that is to ensure the right to obtain a patent, irrespective of the place of invention, the field of technology, or whether products are imported or locally produced. Availability does not mean, however, that a patent needs to be granted in all circumstances, since this will depend on the applicant's ability to meet the patentability requirements and other conditions (such as appropriate disclosure).

An important element for the interpretation of this provision is the concept of "patent rights". While defining in Article 28 the patentee's rights as exclusive, the Agreement makes clear that patents confer a *negative* right, that is, the legal faculty to prevent others from doing certain acts relating to the invention, and not a *positive* right with regard to his/her own products or processes. Thus, the fact that a patent has been granted on a medicine does not give the patent owner the right to sell it, unless health regulations have been complied with, but he can, immediately after the patent grant, prevent others from using the invention.[588]

To "discriminate" means "be, set up, or act on the basis of, a difference . . . make a distinction, especially unjustly on grounds of race or colour or sex".[589]

In the *EC-Canada* case,[590] the panel made a distinction between "discrimination" and "differentiation". It clarified that the conduct prohibited by Article 27.1 is "discrimination" as to the field of technology; that "discrimination" is not the same as "differentiation"; and, that WTO Members can adopt different rules for

[588] See also Chapter 22.

[589] The Concise Oxford Dictionary, p. 274.

[590] *Canada – Patent Protection for Pharmaceutical Products* [*EC – Canada*], WT/DS 114/R.

particular product areas, provided that the differences are adopted for *bona fide* purposes (see Section 4 below).

Finally, Article 27.1 prohibits discrimination based on whether the invention is locally produced or imported.[591]

4. WTO jurisprudence

4.1 EC – Canada

On 19 December 1997, the European Communities and their Member states requested consultations with Canada under the DSU for the latter's alleged violation of, *inter alia*, Article 27.1. The EC contended, *inter alia*, that under Canadian law, patent rights were not enjoyable without discrimination as to the field of technology within the meaning of Article 27.1, second sentence. The panel, however, did not find a violation of Article 27.1, since the challenged provision of the Canadian law (Section 55.2(1)) was not limited to pharmaceutical products, but was applicable to every product that was subject to marketing approval requirements.[592] Though the panel based part of its findings on Article 27.1, it refused to provide a general definition of what "discrimination" meant. It argued that

> "In considering how to address these conflicting claims of discrimination, the Panel recalled that various claims of discrimination, de jure and de facto, have been the subject of legal rulings under GATT or the WTO.[593] These rulings have addressed the question whether measures were in conflict with various GATT or WTO provisions prohibiting variously defined forms of discrimination. As the Appellate Body has repeatedly made clear, each of these rulings has necessarily been based on the precise legal text in issue, so that it is not possible to treat them as applications of a general concept of discrimination. Given the very broad range of issues that might be involved in defining the word "discrimination" in Article 27.1 of the TRIPS Agreement, the Panel decided that it would be better to defer attempting to define that term at the outset, but instead to determine which issues were raised by the record before the Panel, and to define the concept of discrimination to the extent necessary to resolve those issues".[594]

The panel also considered the applicability of the non-discrimination clause to the exceptions regulated in Article 30 of TRIPS. It held that

> "Article 27.1 prohibits discrimination as to enjoyment of "patent rights" without qualifying that term. Article 30 exceptions are explicitly described as "exceptions to the exclusive rights conferred by a patent" and contain no indication that any

[591] For the possible implications of this provision on the issuance of compulsory licenses, see Chapter 25.

[592] *Canada – Patent Protection for Pharmaceutical Products* [*EC – Canada*], WT/DS 114/R, at para. 7.99.

[593] See, e.g., *Japan – Taxes on Alcoholic Beverages*, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R (adopted 1 November 1996); *European Communities – Regime for the Importation, Sale and Distribution of Bananas*, WT/DS27/AB/R (adopted 17 November 1997); *EC Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, WT/DS48/AB/R (adopted 15 February 1998); *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/R (adopted 6 November 1998).

[594] See *EC – Canada*, para. 7.98.

exemption from non-discrimination rules is intended. A discriminatory exception that takes away enjoyment of a patent right is discrimination as much as is discrimination in the basic rights themselves. The acknowledged fact that the Article 31 exception for compulsory licences and government use is understood to be subject to the non-discrimination rule of Article 27.1, without the need for any textual provision so providing, further strengthens the case for treating the non-discrimination rules as applicable to Article 30" (para. 7.91).

The panel added that limiting an exception to a particular field of technology does not make it acceptable under the condition of "limited exception" imposed by Article 30. The panel argued that

"...it is not true that being able to discriminate against particular patents will make it possible to meet Article 30's requirement that the exception be "limited". An Article 30 exception cannot be made "limited" by limiting it to one field of technology, because the effects of each exception must be found to be "limited" when measured against each affected patent. Beyond that, it is not true that Article 27 requires all Article 30 exceptions to be applied to all products. Article 27 prohibits only discrimination as to the place of invention, the field of technology, and whether products are imported or produced locally. Article 27 does not prohibit bona fide exceptions to deal with problems that may exist only in certain product areas. Moreover, to the extent the prohibition of discrimination does limit the ability to target certain products in dealing with certain of the important national policies referred to in Articles 7 and 8.1, that fact may well constitute a deliberate limitation rather than a frustration of purpose. It is quite plausible, as the EC argued, that the TRIPS Agreement would want to require governments to apply exceptions in a non-discriminatory manner, in order to ensure that governments do not succumb to domestic pressures to limit exceptions to areas where right holders tend to be foreign producers." (para. 7.92)

4.2 United States – Brazil

In January 2001, the United States launched a challenge against Brazilian legislation that authorizes the granting of compulsory licences and parallel imports in instances when patents are not locally worked.[595] The dispute, however, ended several months later, when the U.S. complaint was withdrawn.[596] In a separate case Brazil asked the United States for consultations with regard to provisions of U.S. law limiting the right to use or sell any federally owned invention only to a licensee that agrees that any products embodying the invention or produced through the use of the invention will be manufactured substantially in the United States.[597]

[595] See *Brazil – Measures Affecting Patent Protection* [*United States – Brazil*], Request for the Establishment of a Panel by the United States, January 9, 2001, WT/DS199/3. On February 1, 2001, the DSB established a panel, however, no panel members were appointed. Cuba, the Dominican Republic, Honduras, India and Japan reserved third party rights. See also Chapter 25 (Section 4 on WTO jurisprudence).

[596] Without prejudice to their respective positions, the United States and Brazil have agreed to enter into bilateral discussions before Brazil makes use of Article 68 against a U.S. patent holder. *Brazil – Measures Affecting Patent Protection,* Notification of Mutually Agreed Solution WT/DS199/4, G/L/454, IP/D/23/Add.1, July 19, 2001. See also Joint U.S.-Brazil Statement, June 25, 2001.

[597] See WT/DS224/1, February 7, 2001. This case was not pursued.

5. Relationship with other international instruments

As mentioned above, the Paris Convention expressly authorizes, on certain conditions, compulsory licensing for the failure to work patents locally. TRIPS does not contain such a clear and express authorization. The Agreement, as opposed to the Paris Convention, applies the principle of non-discrimination on a higher, more uniform level. While both agreements contain the national treatment principle,[598] the Paris Convention does not oblige Member countries to prohibit, in their domestic legislation, the discrimination of patents as to the place of invention, the field of technology or whether products are imported or locally produced. As long as these sorts of discrimination are applied to both nationals and foreigners, the general principle of national treatment is respected. Here, TRIPS goes one step further: not only must Members ensure equal treatment of nationals and foreigners, but on top of that, they have to comply with certain minimum standards, prohibiting, in general, the above discriminations.

In this context, it should be noted that where two countries are parties to the Paris Convention, but only one is a WTO Member, TRIPS does not create any obligations.[599] It only applies (and thus, as the later treaty, supersedes the Paris Convention), where both (or all) countries are WTO Members.[600]

6. New developments

The non-discrimination clause provides for a principle that is not stated, as such, in national laws, but that should be respected while establishing the rights and obligations of patent owners. The adoption of such a clause forced Canada to eliminate differential treatment for inventions made in the country with regard to compulsory licences. It also underpinned the amendment to the above-mentioned Section 104 of the U.S. Patent law, which was revised in order to extend the right to establish priority with respect to an invention not only in NAFTA countries, but in any WTO Member.[601]

However, the main impact of the non-discrimination clause has probably been in the area of compulsory licensing. Though debatable, the interpretation of the last sentence of Article 27.1 in the sense that working of a patent can be satisfied by importation for the purposes of compulsory licences, is likely to have led many countries to consider importation as equivalent to local production for the purposes of working an invention. An important exception is Article 68 of the

[598] See Article 3 of the TRIPS Agreement, Articles 2 and 3, Paris Convention.

[599] See Article 30.4(b), Vienna Convention.

[600] See Article 30.4(a) in conjunction with Article 30.3, Vienna Convention. For more details on the interplay between the Paris Convention and the TRIPS Agreement in that case, see Chapter 3.

[601] The U.S. Patents Act currently provides the following –
§104 Inventions made abroad
(a) In General
(1) Proceedings
In proceedings in the Patent and Trademark Office, in the courts, and before any other competent authority, an applicant for a patent, or a patentee, may not establish a date of invention by reference to the knowledge or use thereof, or other activity with respect thereto, in a foreign country other than a NAFTA country or a WTO member country, except as provided in §§119 and 365 of this title.

Brazilian patent law, as amended in 1996 which, as noted above, was challenged by the USA. Also, the Indonesian patent law, as revised in 2001, provides that the patent holder is obliged to make the patented products or use the patented process in Indonesia. He can be exempted from this obligation if the making of the product or the use of the process is only suitable to be implemented on a regional scale (Article 17).

7. Comments, including economic and social implications

The non-discrimination rule contained in Article 27.1 is intended to protect rightholders against arbitrary policies that undermine their rights, when such policies are adopted on grounds of the field of technology, the place of invention or the origin (locally manufactured or imported) of the products.

The need to differentiate the rights according to the types of inventions concerned has been extensively debated. Many have wondered why patent rights of equal effect and duration should be granted to inventors who have made different contributions, some of them significant and others less so.[602] Debates have largely focused on the duration of patent rights, since the rate of obsolescence of technology and the periods necessary to recover R&D investments significantly vary across sectors.[603]

In fact, patent laws in many countries currently allow for a differentiation based on the field of technology, as illustrated by the extension of protection conferred to pharmaceutical patents in the USA and Europe in order to compensate for the period required to obtain the marketing approval of a new drug.

In the light of the panel's distinction in the *EC-Canada* case between discrimination and differentiation,[604] questions arise as to the extent to which national patent laws may differentiate in the treatment of patent rights and obligations on justified, *bona fide*, grounds. The Doha Declaration on the TRIPS Agreement and Public Health gives an indication in this direction. The fact that public health and, in particular pharmaceuticals (paragraphs 6 and 7), has been singled out as an issue requiring special attention in the implementation of TRIPS, suggests that public health-related patents may deserve to be treated differently from other patents. Also, French patent law, not challenged so far by any WTO Member, differentiates in the treatment of pharmaceutical products for the purposes of granting compulsory licences.[605]

[602] See, e.g., Lester Thurow, *Needed: A New System of Intellectual Property Rights*, Harvard Business Review, September – October: 1997.

[603] See Chapter 22 below.

[604] See Section 3 above.

[605] The French patent law provides that: "Where the interest of public health demand, patents granted for medicines or for processes for obtaining medicines, for products necessary in obtaining such medicines or for processes for manufacturing such products may be subject to *ex officio* licences in accordance with Article L. 613-17 in the event of such medicines being made available to the public in insufficient quantity or quality or at (abnormally high prices) by order of the Minister responsible for industrial property at the request of the Minister responsible for health." (Law No. 92-597 of 1 July, 1992, Article L. 613-16).

19: Patents: Ordre Public and Morality

> **Article 27.2 Patentable Subject Matter**
>
> 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.

1. Introduction: terminology, definition and scope

States have the right to protect the public interest, and patent law is not an exception to this general principle. Based on a long established tradition in patent law (particularly in the European context), TRIPS allows (but not mandates)[606] two possible exceptions to patentability, based on *ordre public* and morality. The implementation of these exceptions, which need to be provided for under national law in order to be effective, means that a WTO Member may, in certain cases, refuse to grant a patent when it deems it necessary to protect higher public interests.[607]

The term "*ordre public*", derived from French law, is not an easy term to translate into English, and therefore the original French term is used in TRIPS. It expresses concerns about matters threatening the social structures which tie a society together, i.e., matters that threaten the structure of civil society as such.

"Morality" is "the degree of conformity to moral principles (especially good)".[608] The concept of morality is relative to the values prevailing in a society. Such values are not the same in different cultures and countries, and change over time. Some important decisions relating to patentability may depend upon the judgement about morality. It would be inadmissible that patent offices grant patents to any kind of invention, without any consideration of morality.[609]

[606] See the text of Article 27.2: "Members *may* exclude from patentability. . . " (emphasis added).

[607] Note that while Article 27.2 allows not to grant a patent, Article 30 relates to exceptions to exclusive rights, that is, it is operative only when a patent has been granted. See Chapter 23 below.

[608] The Concise Oxford Dictionary, p. 637.

[609] See, e.g., Alberto Bercovitz, *Panel Discussion on Biotechnology*, in Kraih Hill and Laraine Morse (Eds.), *Emergent Technologies and Intellectual Property. Multimedia, Biotechnology & Others Issues*, ATRIP, CASRIP Publications Series No. 2, Seattle 1996, p. 53.

Article 27.2 clarifies, unlike equivalent precedents in national laws, that protection of *ordre public* or morality includes the protection of "human, animal or plant life or health or to avoid serious prejudice to the environment", thereby explicitly allowing for exceptions to patentability when any of these interests may be negatively affected by patent grants. The concept of "health" may be deemed to encompass not only medical care, but also the satisfaction of basic requirements such as adequate food, safe water, shelter, clothing, warmth and safety.[610] The "environment" refers to the "surrounding objects, region, or conditions, especially circumstances of life of person or society".[611]

Finally, it should be noted, as examined in more detail below, that WTO Members can provide for the exceptions referred to but they are subject under Article 27.2 to one important condition: non-patentability may only be established if the commercial exploitation of the invention needs to be prevented to protect the interests referred to above. This excludes the possibility of applying such exceptions when, for instance, it would be in the interest of public health to promote the diffusion of an invention (e.g., a medicinal product), since a Member cannot refuse a patent on *ordre public* or morality grounds and, at the same time, permit the commercialisation of the invention.

2. History of the provision

2.1 Situation pre-TRIPS

Ordre public and morality considerations had been taken into account in many jurisdictions before the adoption of TRIPS. In the USA, for instance, traditionally the concept of inventions contrary to *ordre public*, as applied by the courts, referred to an invention that was "frivolous or injurious to the well-being, good policy, or sound morals of a society".[612]

European laws[613] and many other civil law jurisdictions had provided for explicit exceptions on terms comparable to Article 27.2. That was the case, in particular, of Article 53(a) of the European Patent Convention, whose wording probably inspired the drafters of TRIPS. After the adoption of Article 4*quater* in the Paris Convention,[614] many national laws were reformed so as to acknowledge that a

[610] See, e.g., Robert Beaglehole and Ruth Bonita, *Public Health at the Crossroads. Achievements and prospects*, Cambridge University Press, Melbourne 1999, p. 45; Fraser Mustard, *Health, health care and social cohesion*, in Daniel Drache and Terry Sullivan (editors), Health Reform. Public Success. Private Failure, Routledge, London and New York 1999.

[611] The Concise Oxford Dictionary, p. 323.

[612] See *Lowell v. Lewis*, 15 (a. 1018 No. 8568) (C.D. Mass. 1817), quoted in Chisum and Jacobs, p. 2.5. In the United States, "the trend is to restrict this subjective public policy approach to utility" (*Idem*).

[613] See, e.g. Rainer Moufang, *The Concept of "Ordre Public" and Morality in Patent Law*, in Geertrui Van Overwalle (Ed.), Patent Law, Ethics and Biotechnology, Katholieke Universiteit Brussel, Bruxelles 1998, No.13, p. 69 [hereinafter Moufang].

[614] Article 4*quater* reads as follows: "The grant of a patent shall not be refused and a patent shall not be invalidated on the ground that the sale of the patented product or of a product obtained by means of a patented process is subject to restrictions or limitations resulting from the domestic law." This provision is thus equivalent to the last part of Article 27.2 TRIPS. However, there is no comparable reference to *ordre public* or morality.

possible conflict with simple statutory law could not be regarded as a sufficient reason for rejecting a patent application.

2.2 Negotiating History

2.1 The Anell Draft

"1.4 The following [shall] [may] be excluded from patentability:

1.4.1 Inventions, [the publication or use of which would be], contrary to public order, [law,] [generally accepted standards of] morality, [public health,] [or the basic principle of human dignity] [or human values]."

[. . .]

2.2 The Brussels Draft

"2. PARTIES may exclude from patentability inventions, the prevention within their territory of the publication or any exploitation of which is necessary; to protect public morality or order, including to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement; or to protect human, animal or plant life or health."

The final text is closer to that of Article 53 of the European Patent Convention. However, the latter refers to conflicts that may follow not only from the exploitation but also from the "publication" of the invention, an alternative that in the view of some authorities would be irreconcilable with Article 27.2 of TRIPS.[615]

Article 27.2 makes it clear that an exclusion from patentability cannot be grounded merely on the fact that the existing law of a Member prohibits exploitation. The present wording is a change from the Brussels Draft that read "including to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement". In other words, an exclusion from patentability must be justified within the terms of Article 27.2 itself.

3. Possible interpretations

> Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect . . .

Article 27.2 is concerned with the exclusion of particular inventions, not categories of inventions which are dealt with in Article 27.3 (discussed in Chapter 21 below). It is clear from the wording of the provision that the risk must come from the commercial exploitation of the invention, not from the invention as such. It would also seem, given the wording of Article 27.2, that the likely impact must be within the territory concerned, not that of another Member.

An exception based on this Article can be applied only when it is necessary to prevent the "commercial exploitation" of the invention. Therefore, the condition

[615] See, e.g., Moufang, p. 72.

for the application of the exception would not be met if there is a need to prevent non-commercial uses of the invention (e.g., for scientific research).

It has been debated whether the exception can only be applied when there is an actual prohibition on the commercialization of the invention, or when there is need to prevent it (even if still not done by the government concerned). According to one opinion, an effective ban should exist in order to make the exception viable.[616] It has been held, however, that TRIPS "does not require an actual ban of the commercialization as a condition for exclusions; only the necessity of such a ban is required. In order to justify an exclusion under Article 27 (2) TRIPS, a Member state would therefore have to demonstrate that it is necessary to prevent – by whatever means – the commercial exploitation of the invention. Yet, the Member would not have to prove that under its national laws the commercialization of the invention was or is actually prohibited".[617]

. . . is necessary to protect ordre public or morality, . . .

Article 27.2 introduces a "necessity test" to assess whether protection of an overriding social interest is justified. Though TRIPS constitutes the *lex specialis* for dealing with patent issues in the WTO framework, the GATT/WTO jurisprudence on Article XX of GATT is likely to play a role in the interpretation of said Article.[618]

Article XX (a) and (b) of GATT have a similar structure to Article 27.2, and it is clear that, for the purposes of these provisions exclusions must be objectively justified.[619] These provisions permit Members to make exceptions to the basic GATT free trade principle on the ground (a) that it is *necessary* to protect public morals, and (b) that it is *necessary* to protect human, animal or plant life [emphasis added]. Thus, under GATT, quarantine, sanitary and similar regulations must not constitute arbitrary or unjustifiable discrimination or a disguised restriction on trade. A measure is justified only if no reasonable alternative is available to a Member which is not inconsistent, or at least less inconsistent, with GATT.[620]

[616] Adrian Otten, *Viewpoint of the WTO*, (M. Swaminathan, Ed.), in Agrobiodiversity and Farmers' Rights Proceedings of a Technical Consultation on an Implementation Framework for Farmers' Rights, M.S. Swaminathan Research Foundation, Madras 1996.

[617] Dan Leskien and Michael Flitner, *Intellectual Property Rights and Plant Genetic Resources: Options for a Sui Generis System*, Issues in Genetic Resources No. 6, IPGRI, Rome 1997, p. 15.

[618] In the *India- Patent Protection for Pharmaceutical and Agricultural Chemical Products* case (WT/DS50) the panel held that the TRIPS Agreement has a "relatively self-contained, *sui generis* status within the WTO." However, it also held that the Agreement is "an integral part of the WTO system, which itself builds upon the experience of over nearly half a century under the GATT 1947" (para. 7.19).

[619] See *GATT Analytical Index*, Vol. I, p. 518 *et seq*.

[620] See 1990 Panel Report on *Thailand 'Thailand - Restrictions on Importation of and Internal Taxes on Cigarettes'* BISD 37S/200, adopted November 7, 1990. A contracting party cannot justify a measure inconsistent with GATT provisions as 'necessary' in terms of Article XX(b) if an alternative measure it could reasonably be expected to employ not inconsistent with GATT is available to it. Thus a Thai government restriction on the importation of cigarettes could not be justified in terms of the desirable objective of stopping people smoking, given that alternatives such as anti-smoking campaigns are available, and have been shown to be effective in a number of countries around the world. Similarly, a United States measure prohibiting the importation of tuna under

Ordre public encompasses, according to European law, the protection of public security and the physical integrity of individuals as part of society.[621] This concept includes also the protection of the environment, but is deemed to be narrower than 'public order', which appeared in some drafts of the Agreement. Though European law may be an important source for the interpretation of that concept, there is no generally accepted notion of "*ordre public*" and no reason for other WTO Members to follow the European approach. Members have a considerable flexibility to define which situations are covered, depending upon their own conception of the protection of public values.

Ordre public should be contrasted with the exclusion from patentability on morality grounds. Morality seems to depend, for the purposes of this Article, on the particular culture of a country or region.[622] While it is possible to give a meaning to "morality" which is not culturally dependent, it would seem likely that the provision was drafted from a more relativist viewpoint and could include, for instance, religious concerns in a particular Member. According to Ladas, morality

> "... reflects customs and habits anchored in the spirit of a particular community. There is no clearly objective standard of feeling, instincts, or attitudes toward a certain conduct. Therefore, specific prescriptions involving uniform evaluation of certain acts are extremely difficult."[623]

The jurisprudence of the European Patent Office (EPO) has distinguished between *ordre public* and morality (Decision T.356/93). Under the Guidelines for Examination of the EPO, "ordre public" is linked to security reasons, such as riot or public disorder, and inventions that may lead to criminal or other generally offensive behaviour (Part C, chapter IV, 3.1). This concept also encompasses the protection of the environment.[624] Under the morality clause, the Office has to establish whether

the Marine Mammal Protection Act to save dolphin life and health (they often get caught in the nets used to catch tuna) was held not to be fully consistent with the GATT obligations, because other means of protecting dolphins were available—see *United States – Restrictions on Imports of Tuna* BISD 29S/155. On the other hand, the Appellate Body held that a French prohibition of manufacture, processing, sale, import and marketing of asbestos and asbestos containing products was "necessary" to protect human life in terms of GATT Article XX(b) (See *European Communities – Measures Affecting Asbestos or Products Containing Asbestos* [*EC – Asbestos*], WT/DS135/AB/R of 12 March 2001). In particular, the Appellate Body denied the availability of alternative and equally effective measures such as "controlled use" of asbestos as advocated by Canada (see *EC – Asbestos*, para. 174. For a detailed analysis of this jurisprudence, see Jan Neumann, Elisabeth Türk, *Necessity Revisited – Proportionality in World Trade Organization Law After Korea – Beef, EC – Asbestos and EC – Sardines*, Journal of World Trade 2003, vol. 37, No. 1, pp. 199 – 233.). See also Carlos Correa, *Implementing National Public Health Policies in the Framework of the WTO Agreements*, 34 Journal of World Trade 2000, vol. 34, No. 5, 2, p. 92-96.

[621] "Ordre public" is a legal expression with a long tradition in the area of international private law, where it serves as a last resort when the application of foreign law leads to a result which would be wholly unacceptable for the national legal order. See, e.g., Moufang, p. 71.

[622] Gervais, p. 149.

[623] Stephen P. Ladas, *Patents, Trademarks, and Related Rights. National and International Protection*, Harvard University Press 1975, pp. 1685–1686.

[624] In case T 356/93 the Board of Appeal of the European Patent Office observed "It is generally accepted that the concept of 'ordre public' covers the protection of public security and the physical integrity of individuals as part of society. This concept encompasses also the protection of the environment. Accordingly, under Article 53(a) EPC, inventions the exploitation of which is likely

an invention would be so abhorrent for the public that its patenting would be inconceivable. Morality includes the totality of the accepted norms which are deeply rooted in a particular culture.

The analysis of the application of Article 53.b) of the EPC is made case-by-case. The EPO has employed two methods for that purpose: the balancing of interests at stake[625] and the opinion of the vast majority of the public.[626] In all the cases where these methods were applied, the EPO affirmed the patentability of the inventions under examination.

> . . . including to protect human, animal or plant life or health or to avoid serious prejudice to the environment,. . .

Article 27.2 includes *examples* of permissible exceptions to patentability, for the protection of human, animal or plant life or health, and avoiding serious prejudice to the environment within the relevant Member.

As mentioned, some decisions by the EPO show that the effects of an invention on the environment may constitute a valid ground for denying patentability. However, the EPO refused to assume a *regulatory role* on the introduction of genetic engineering inventions. In dealing with this issue, one of the opposition decisions argued that

> "A patent does not give a positive right to its proprietor to use the invention but rather only confers the right to exclude others from using the invention for a limited period of time. If the legislator is of the opinion that certain technical knowledge should be used under limited conditions only it is up to him to enact appropriate legislation."[627]

As noted by Moufang, patent examiners "are not specifically trained in ethics or in risk assessment. Since patents do not give a positive right to use the protected inventions, other bodies have to shoulder the responsibility for the decisions of society whether certain technology can and should be put into practice."[628]

to breach public peace or social order (for example, through acts of terrorism) or to seriously prejudice the environment are to be excluded from patentability as being contrary to 'ordre public"'.

[625] The balancing of interests takes into consideration the advantages and disadvantages of an invention, including the possible environmental risks due to the eventual dissemination of genes in nature (Decision T.19/90). In the area of plant technology, the Board of Appeals of the EPO has argued that plant genetic engineering is not a technical domain that, as such, may be deemed contrary to morality or public order. In decision T 356/93 (Plant Genetic Systems), it reasoned that it needed to be established in each individual case whether a particular invention relates to an improper use or has destructive effects on plant biotechnology. The Board held that "inventions the exploitation of which is likely to breach public peace or social order (for example, through acts of terrorism) or to seriously prejudice the environment are to be excluded from patentability as being contrary to ordre public".

[626] The opinion of the majority of the public was considered by the Opposition Division of the EPO in a decision of 8.12.94 in the case of "Relaxin". The patent related to a DNA fragment codifying for a human protein. The Office examined whether the invention would appear immoral for the vast majority of the public.

[627] Decision T0019/90, in the "oncomouse" case.

[628] Moufang, p. 72.

> . . . provided that such exclusion is not made merely because the exploitation is prohibited by their law.

The last sentence of Article 27.2 establishes that the sole fact that the exploitation is prohibited by law is not sufficient reason to exclude patentability. This is in line with Article 4*quater* of the Paris Convention, which contains a rule equivalent, though not identical, to the provision contained in the last part of Article 27.2: it stipulates that the grant of a patent shall not be refused (or the registration of a patent not be invalidated) for the sole reason that the sale of the patented product is restricted or limited under domestic law. Thus, mere marketing restrictions as such cannot justify exclusions from patentability. There has to be a specific link between the commercial exploitation of the patent and the respective Member's *ordre public* or morality: Article 27.2 requires that this commercial exploitation would represent a particular danger to either *ordre public* or morality.

4. WTO jurisprudence

There is no specific WTO jurisprudence on this provision. It might be of interest, however, noting the discussion about the concept of "exploitation" in the *EC - Canada* case. Canada took the position that "exploitation" of the patent "involves the extraction of commercial value from the patent by "working" the patent, either by selling the product in a market from which competitors are excluded, or by licensing others to do so, or by selling the patent rights outright. The European Communities also defined "exploitation" by referring to the same three ways of "working" a patent" (para. 7.51). Since the parties differed primarily on their interpretation of the term "normal", the panel defined "normal exploitation" as

> "The normal practice of exploitation by patent owners, as with owners of any other intellectual property right, is to exclude all forms of competition that could detract significantly from the economic returns anticipated from a patent's grant of market exclusivity. The specific forms of patent exploitation are not static, of course, for to be effective exploitation must adapt to changing forms of competition due to technological development and the evolution of marketing practices" (para. 7.55).

5. Relationship with other international instruments

5.1 WTO Agreements

Article XX, letters (a) and (b) of the GATT 1994 authorizes WTO Members to deviate from GATT obligations through measures necessary to protect public morals; as well as human, animal or plant life or health, subject to further requirements.[629]

[629] This provision reads: "Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:

(*a*) necessary to protect public morals;

(*b*) necessary to protect human, animal or plant life or health;"

5.2 Other international instruments

6. New developments

6.1 National laws

The approach expressed in Article 27.2 was retained in post-TRIPS developments in Europe,[630] and can be found in many other national laws. Moreover, some recent legislative changes in patent law have defined specific exceptions based on ethical considerations in relation to inventions consisting of parts of the human body or techniques applied to human beings. Thus, as a result of a comprehensive legislative initiative in the field of bioethics, the French domestic patent law, as amended in July 1994, provides that the human body, its elements and products as well as knowledge relating to the overall structure of a human gene or elements thereof may not, as such, form the subject matter of a patent. The Australian Patents Act stipulates that "human beings, and the biological processes for their generation, are not patentable inventions". The European Directive on Biological Inventions, similarly, provides that the human body and its elements in their natural state shall not be considered patentable inventions. However, patents over human genes or cell lines have been granted as a matter of routine by the EPO, whose Opposition Division has not found any reasons why the patenting of human genes should be intrinsically unethical.[631]

6.2 International instruments

6.3 Regional and bilateral context

A number of regional and bilateral free trade agreements such as CAFTA, USA-Jordan, USA-Singapore, and USA-Australia contain exceptions to patentability similar to Article 27.2, TRIPS. On the other hand, the USA-Chile FTA does not expressly provide for such exception.[632]

6.4 Proposals for review

There have been no proposals for review of this Article.

7. Comments, including economic and social implications

A patent is simply a grant of exclusive rights. It does not of itself authorise the exploitation of the patented invention, and this can be regulated in separate

[630] The 1998 European Directive on Biotechnological Inventions contains a provision (Article 9) similar to Article 53 of the European Patent Convention. See, e.g., Vandergheynst, Dominique, *La notion d'ordre public et des bonnes mœurs dans la proposition de directive européenne relative à la protection juridique des inventions biotechnologiques*, in Geertrui Van Overwalle (Ed.), Patent Law, Ethics and Biotechnology, Katholieke Universiteit Brussel, Bruxelles 1998, No. 13, pp. 82–92; Deryck Beyleveld; Roger Brownsword and Margaret Llewelyn, *The morality clauses of the Directive on the Legal Protection of Biotechnological Inventions: conflict, compromise and the patent community*, in Richard Goldberg and Julian Lonbay (Eds.), Pharmaceutical Medicine. Biotechnology, and European Law, Cambridge University Press 2000.

[631] Moufang, pp. 75–76.

[632] For details, see Roffe, 2004, who in this context discusses a TRIPS non-derogation clause contained in the U.S.-Chile FTA.

legislation provided this is consistent with Article 27.2 (that is, for example, that it is necessary to protect human, animal or plant life or health or to avoid serious prejudice to the environment). In the case of pharmaceutical inventions, for example, separate marketing approval is usually required before the invention can be prescribed by doctors for their patients. This marketing approval can sometimes take several years after the grant of the patent. A classic example of an invention contrary to *ordre public* would be a novel kind of letter bomb. It would clearly be permissible to exclude such devices from patentability under Article 27.2. The non-disclosure of the mechanism of the device in a patent specification is a necessary first step in such prevention.

One important point to be considered is the extent to which the role of a patent office in judging and eventually denying a patent on the basis of moral or public order grounds may be sufficient to prevent the harmful effects from taking place. Given the limited competence of a patent office, non-patentability would only ensure that an invention is not the subject of property rights, but by no means would this be sufficient to prevent the use of the invention by any interested person, since it would remain in the public domain.

20: Patents: Therapeutic, Surgical and Diagnostic Methods

> Article 27.3 (a) Patentable Subject Matter
>
> Members may also exclude from patentability:
> diagnostic, therapeutic and surgical methods for the treatment of humans or animals; . . .

1. Introduction: terminology, definition and scope

While TRIPS in Article 27.1 only requires the protection of processes and products,[633] some national laws have extended patentability to inventions consisting of methods of using certain products or performing certain steps.

Article 27.3(a) applies specifically to *methods* for the treatment of humans or animals. It makes clear that in this area, for the purpose of patentability, the (patentable) products or processes need to be differentiated from the methods of the treatment. In other words, *the way inventions are used* in order to heal humans or animals may be excluded from patentability. The reasons for this exception are various and depend on each country's perspective. While European countries advance ethical or moral considerations for this provision's equivalent in Article 52(4) of the European Patent Convention,[634] developing countries have stressed, *inter alia*, the need for local availability of treatment methods.[635]

Therapeutic, surgical and diagnostic methods produce effects on the human (or animal) body, and not an industrial effect. Therefore, they may be deemed not patentable because of non-compliance with the industrial applicability requirement provided for in most patent laws, even in the absence of a specific exception. However, in the United States[636] and other countries, such as Australia and New Zealand, patent law allows for the patenting of medical methods if they satisfy the definition of process and the other conditions of eligibility.[637]

[633] See Chapter 17.

[634] Set out below, Section 3 of this chapter (Possible interpretations).

[635] Gervais, p. 150.

[636] In the USA, "utility" and not industrial applicability is required, thereby allowing for a broader scope of patentability.

[637] A bill enacted in 1996 (amending U.S. patent law, 35 USC 287.c) determined, nevertheless, that the use of patented surgical procedures is protected from infringement suits. See, e.g., Grubb, p. 220.

2. History of the provision

2.1 Situation pre-TRIPS

Therapeutic, surgical and diagnostic methods were excluded from patent protection under European law, as well as the laws of many other countries before the adoption of TRIPS. Under Article 52(4) of the European Patent Convention, for instance, the exclusion of methods of treatment follows from the requirement of industrial applicability. This is spelled out in Article 52(4) which provides that

> "Methods of treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods."

2.2 Negotiating History

Both the Anell Draft and the Brussels Draft included a provision similar to Article 27.3 (a).

2.2.1 The Anell Draft

"1.4 The following [shall] [may] be excluded from patentability:

[. . .]

1.4.3 Methods of [medical] treatment for humans [or animals]."

2.2.2 The Brussels Draft

"3. PARTIES may also exclude from patentability:

(a) [Diagnostic, therapeutic and] surgical methods for the treatment of humans and animals;"

3. Possible interpretations

Members may also exclude from patentability: . . .

TRIPS allows Members to provide for an exclusion to patentability in the cases referred to, but does not oblige them to do so. The exclusions are facultative, or could be limited to some of the methods mentioned in Article 27.3 (a).

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; . . .

The exception applies to methods of treatment; that is, to procedures designed to treat humans or animals. This possible exception does not encompass the means utilized to perform the treatment. Accordingly, while for example a novel form of surgical procedure cannot be patented, a novel form of apparatus invented to

enable that procedure to be carried out is, in principle, patentable. It can be argued that pharmaceutical products constitute a therapeutic treatment for humans and animals, and therefore might be excluded from patentability. However, it would be difficult to sustain this argument in light of the negotiating history of TRIPS, which addressed at some length issues surrounding pharmaceutical patents, as well as provisions such as the Article 70.8 "mailbox" rule that expressly cover pharmaceutical patents.

4. WTO jurisprudence

There has been no specific dispute on issues covered by this provision.

5. Relationship with other international instruments

5.1 WTO Agreements

5.2 Other international instruments

As noted above, there is an equivalent of this provision in Article 52(4) of the European Patent Convention. The exclusion is consistent with the object of the Paris Convention Article 1(1) which states that the countries to which it applies constitute a Union for the protection of "industrial property". Article 1(3) provides that "industrial property" shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to agricultural and extractive industries and to all manufacture or natural products such as wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers and flour.[638] Broad as this definition is, it clearly does not cover methods of therapeutic treatment, surgery or diagnosis.

6. New developments

6.1 National laws

6.2 International instruments

6.3 Regional and bilateral contexts

6.4 Proposals for review

The exclusion under Article 27.3(a) is connected to the generally accepted concept of patentable subject matter, and is unlikely to be modified without a major change in international views on this matter. Nevertheless, the view has been expressed from time to time that it might be appropriate to permit the patenting of a new surgical procedure since that would ensure its disclosure and dissemination.[639]

[638] This list should not be read as requiring the things listed to be patentable *as such*. As noted above, patents are granted for *inventions*, and the discovery of a new plant or mineral existing in nature would not be an invention. Consequently, the above listed natural products would only be patentable if they were *modified* in a way that satisfied the patentability criteria of novelty, inventive step and industrial applicability.

[639] Jeremy Phillips and Alison Firth, *Introduction to Intellectual Property*, 4th ed., Butterworths, Witltshire 2000, p. 59, citing Cuthbert *Patent Law Reform in New Zealand: Should Methods*

However, it is very unlikely that this view will find wide acceptance in the medical profession, and without such acceptance, the exclusion is likely to remain.

7. Comments, including economic and social implications

The exclusion authorized by Article 27.3(a) is fairly narrow, and has few implications for the way in which funding for medical research is directed. For example, new devices such as scanners and fibre optic cameras to enable surgery to be carried out without the invasive techniques that were formerly necessary, are in principle patentable. On the other hand, techniques such as keyhole surgery made possible by such devices may be excluded from patentability. Similarly, pharmaceutical products and apparatus that now render surgery unnecessary, where it was necessary previously, are patentable.

Even in countries where the patentability of such methods is allowed, patents granted are relatively rare. One possible reason for this is that enforcing such patents is very problematic. The patent owner would need to monitor the activities by a more or less large number of doctors and surgeons, who generally provide their services subject to strict privacy rules. Enforcement may be more feasible when new and complex methods are applied by a small number of easily identifiable professionals. This may be the case of gene therapies, at least until they become safer and more widely diffused.

The exclusion of therapeutic methods may have significant implications in the pharmaceutical sector, in relation to the patentability of the new use of a known pharmaceutical product.[640] In effect, there is no real difference between patent claims relating to the use of a substance and those relating to a therapeutic method: in both cases a new medical activity is claimed, i.e., a new way of using one or more known products.[641] The patenting of a new therapeutic effect of a known pharmaceutical product, therefore, is contrary to the ban on patents for therapeutic methods, where applied. Some countries have overcome this problem by admitting the patentability of a new use of an existing drug under the so called "Swiss claims", under which a method claim is drafted as a claim for the use of a product to manufacture a medicine.[642] There is no obligation under TRIPS, however, to adopt this approach.

of Medical Treatment be Patentable? Patent World, May 1997; Kell, *Expanding the Frontiers of Patentability: Methods of Medical Treatment of the Human Body*, EIPR 1995, p. 202.

[640] This is an issue of increasing economic importance, in part due to the decline in the discovery of new molecules with significant therapeutic value.

[641] Bengt Domeij, *Pharmaceutical Patents in Europe*, Kluwer Law International / Norstedts Juridik, Stockholm 2000, p. 178.

[642] See Chapter 17, Section 3.

21: Patents: Biotechnological Inventions: Genetic Resources, Plant Variety Protection, Traditional Knowledge

> Article 27.3(b) Patentable Subject Matter
>
> Members may also exclude from patentability:
>
> 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.

1. Introduction: terminology, definition and scope

Article 27.3(b) addresses one of the most controversial issues covered by TRIPS. The often called "biotechnology clause" describes subject matter that Members *may* exclude from patentability while, at the same time, specifically obliges Members to protect microorganisms and certain biotechnological processes.

The drafting of this clause – the single one in the whole TRIPS Agreement subject to an early review[643] – reflected, on the one hand, the strong interests of some developed countries in ensuring protection of biotechnological innovations and, on the other, the important differences existing among such countries with regard to the scope of protection, as well as the concerns of many developing countries about the patentability of life forms.

Since the adoption of the Agreement, the differences in the treatment of biotechnological inventions among developed countries have been reduced,[644] but not eliminated.[645] Many developing countries have indicated, in the process of review of Article 27.3(b) and in preparations for the Third WTO Ministerial Conference (December 1999), their discomfort with the implications of this provision, particularly in view of several cases of protection, in developed countries, of biological

[643] Which should have taken place in 1999.

[644] Particularly with the approval of the EU Directive on Biotechnological Inventions (No. 96/9/EC of March 11, 1996).

[645] Thus, plant varieties and animal races are not patentable in Europe, while they are eligible for protection in the USA.

resources or traditional knowledge (such as quinoa, ayahuasca and curative uses of turmeric)[646] originating in developing countries. In the opinion of these countries, there is need to reconcile Article 27.3(b) with the relevant provisions of the Convention on Biological Diversity, particularly on prior informed consent and benefit sharing.

Article 27.3(b) leaves considerable flexibility for Members to adopt different approaches to the patentability of inventions relating to plants and animals, but unambiguously requires the protection of micro-organisms.[647] In addition, this Article obliges Members to provide protection for "plant varieties". The distinction between a "plant", that is, a living organism that belongs to the plant kingdom, and a "plant variety"[648] must be borne in mind for the interpretation of this clause. For example, when a pest-resistant gene is introduced by means of genetic engineering in a certain number of cotton plants[649], one or more "transgenic" plants are obtained. The patentability of these plants may or may not be admitted under national law. These plants, however, do not necessarily constitute a "plant variety", unless whenever cultivated, the resulting plants retain certain predetermined characteristics and can be propagated unchanged.

In case a Member chooses to protect living organisms through patents,[650] only such organisms having undergone a certain technical modification are not

[646] See Correa, 2001 and UNCTAD-ICTSD, Policy Discussion Paper (2003).

[647] A "micro-organism" is "an organism not visible to naked eye" (*The Concise Oxford Dictionary*, Oxford University Press, Seventh Ed., 1982). Note, however, that in the Council for TRIPS, there is no agreement on a common definition of what constitutes a micro-organism (see Communication from the European Communities and their Member States to the Council for TRIPS of 17 October 2002, IP/C/W/383, page 1).

[648] According to the UPOV Convention (as revised in 1991) a "plant variety" is "a plant grouping within a single botanical taxon of the lowest rank, which grouping, irrespective of whether the conditions for the grant of a breeder's right are fully met, can be defined by the expression of the characteristics resulting from a given genotype or combination of genotypes, distinguished from any other plant grouping by the expression of at least one of the said characteristics and considered as a unit with regard to its suitability for being propagated unchanged". One essential element in this definition is that a plant "variety" is a *grouping* of plants which retain their distinguishing characters when reproduced from seeds or by asexual means (for example, cuttings). See National Research Council, Committee on Managing Global Genetic Resources: *Agricultural Imperatives, Managing Global Genetic Resources. Agricultural Crop Issues and Policies*, National Academy Press, Washington, D.C. 1993, p. 412. Expressed in less technical terms, a plant variety is the technical modification of a naturally existing plant. The result of this modification is a transformed plant which retains certain characteristics when reproduced from seeds or by asexual means (the latter meaning reproduction not from seeds but through methods such as cutting, division, layering, etc.).

[649] While inserting genes is the task of *biotechnologists*, developing a variety is the responsibility of *breeders*. "Plant breeding" is the science-based activity that aims to improve the quality and yield of plant varieties yield, see W. Hale and J. Margham, *The Harper Collins Dictionary: Biology*, Harper Perennial, New York 1991, p. 430 [hereinafter Hale and Margham]. Two ways of breeding have to be distinguished. "Conventional " breeding" (as opposed to genetic engineering) utilizes selection, crossing and other methods in order to obtain the expression of the desired traits in a group of plants. Genetic engineering is the general term referring to all techniques used to isolate particular genetic material (i.e. DNA) from one organism and introduce it into another organism, thus resulting in the latter being "transgenic". See Geoff Tansey, *Food Security, Biotechnology and Intellectual Property. Unpacking some issues around TRIPS*. A Discussion Paper, Quaker United Nations Office, Geneva 2002, p. 6, quoting Peter Lund.

[650] Note that under Article 27.3(b), only micro-organisms, microbiological and non-biological processes have to be protected through patent law. For plant varieties, Members may establish *sui*

pre-existent in nature and may thus be considered as new. Since the determination of the precise meaning of novelty (like the other patentability criteria) is left to the WTO Members' discretion, the degree of technical intervention required to satisfy the novelty criterion varies widely among domestic patent laws.[651]

While Article 27.3(b) is flexible about the form of protection of plant varieties, it forced the introduction of IPR protection in an area in which most developing countries had none before the adoption of the Agreement. This obligation has raised concerns in some of those countries about the impact of IPR protection on farming practices (particularly the re-use and exchange of seed by farmers), genetic diversity, and food security.

2. History of the provision

2.1 Situation pre-TRIPS

After the decision by the U.S. Supreme Court in *Diamond v. Chakrabarty* (1980),[652] which accepted for the first time a patent on a living organism *per se*,[653] the patentability of such matter expanded in industrialized countries to include cells and sub-cellular parts, including genes, as well as multicellular organisms. An accepted principle since the 1980s in those countries was that the fact that an invention consisted of, was based on or employed living matter, was not a sufficient reason to exclude patent protection, including for biological materials pre-existing in nature (provided that the latter were claimed in an isolated or purified form). Despite this trend, considerable differences remain in those countries with regard to the scope of patentability of biotechnology-related inventions. Divergences were even more profound with respect to developing countries.[654]

In the field of plant varieties, few countries (most of them developed countries) had adopted at the time of the negotiation of TRIPS specific regulations on breeders' rights and had adhered to the Convention for the Protection of New Varieties of Plants ("the UPOV Convention") of December 2, 1961, which was subsequently revised in 1972, 1978 and 1991.[655] In addition, the 1978 Act of the UPOV Convention did not permit the provision of both breeders' rights and patent protection for the same genera or species (Article 2).[656]

generis systems that do not rely on the same criteria for protection as patents (i.e. novelty, inventive step and industrial applicability). For details, see Sections 3 and 5 of this chapter.

[651] For more details, see Section 3 of this chapter.

[652] 447 U.S. 303 (1980).

[653] The patent, filed in 1972, related to a genetically modified microorganism. It asserted 36 claims related to the invention of "a bacterium from the genus Pseudomonas containing therein at least two stable energy-generating plasmids, each of these plasmids providing a separate hydrocarbon degradative pathway".

[654] See World Intellectual Property Organization, Memorandum on Exclusion from Patent Protection, Doc. No. HL/CE/IV/INF/1, reprinted in 27 Industrial Property, 192 (1988).

[655] UPOV is a French acronym for what is referred to in English as the International Union for the Protection of New Varieties of Plants. WIPO and UPOV are closely associated. The UPOV Convention is a shorthand for the treaty administered by that organization.

[656] This limitation was lifted by the 1991 revision of the Convention (see below, Section 5.2 of this chapter).

2.2 Negotiating history

The initial negotiating proposals by the United States, Japan, the Nordic countries and Switzerland aimed at broad patent coverage for plants and living organisms.[657] In contrast, most developing countries (joined by the European Community countries in relation to plant varieties and animal races) rejected such an approach.

2.2.1 The Anell Draft

The Anell Draft text under negotiation in July 1990 (W/76) showed how substantial the divergences among the parties were. A heavily bracketed text alluded to the possible exclusion from patentability of

> "1.4.4 [Any] plant or animal [including micro-organisms] [varieties] or [essentially biological] processes for the production of plants or animals; [this does not apply to microbiological processes or the products thereof]. [As regards biotechnological inventions, further limitations should be allowed under national law]."

2.2.2 The Brussels Draft

By December 1990, the parties had not agreed on the issue of patent protection for plants and animals, and the differences were still outstanding. The Brussels Draft text provided, in bracketed language, that parties could exclude from patentability:

> "[b) A. Animal varieties [and other animal inventions] and essentially biological processes for the production of animals, other than microbiological processes or the products thereof. PARTIES shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. This provision shall be reviewed [. . .] years after the entry into force of this Agreement.]
>
> [b) B. Plants and animals, including microorganisms, and parts thereof and processes for their production. As regards biotechnological inventions, further limitations should be allowed under national law.]"

Paragraph A essentially reflected the views of developed countries, and paragraph B of developing countries. As a simple comparison with the adopted Article 27.3(b) shows, the developed countries' approach finally prevailed to a large extent.

3. Possible interpretations

3.1 Plants and animals

Members may also exclude from patentability . . . plants and animals

Article 27.3(b) allows for the exclusion from patentability of "plants and animals" in general. In the absence of any distinction, and in the light also of the second

[657] See Terence Stewart (Ed.), *The GATT Uruguay Round. A negotiating History* (1986–1992), Kluwer Law and Taxation Publishers 1993, p. 2294.

sentence of the same Article that introduces an exception for one particular classification (plant varieties), the scope of the exception under Article 27.3(b) is to be interpreted in broad terms. Consequently, Members may exclude plants as such (including transgenic plants),[658] plant varieties (including hybrids), as well as plant cells, seeds and other plant materials. They may also exclude animals (including transgenic) and animal races.

Members may opt to exclude from patentability only certain categories of plant and animal inventions. Thus, in European countries the prohibition to patent a plant "variety" does not prevent the patenting of plants as such. Similarly, the granting of a patent by the European Patent Office on the "Harvard oncomouse" (a mouse genetically modified to facilitate the testing of anti-cancer drugs) was also based on the judgment that it was not a "race" but a specifically altered "animal".[659]

3.2 Micro-organisms

. . . other than micro-organisms . . .

A "micro-organism" is an organism that is not normally perceptible by the eye. The scientific concept of "micro-organism" refers to "a Member of one of the following classes: bacteria, fungi, algae, protozoa or viruses."[660]

An important question is whether microorganisms as found in nature should be patented under this provision. It is generally accepted that "to be patentable, a micro-organism cannot be as it exists in nature".[661] However, in some jurisdictions it is sufficient to isolate a microorganism and identify a use therefore to obtain a patent.

Thus, in countries that are parties to the European Patent Convention a patent may be granted when a substance found in nature can be characterized by its structure, by its process of isolation or by other criteria, if it is new in the sense that it was not previously available to the public. The European Directive on Biotechnological Inventions clarifies that "biological material which is isolated from its natural environment or processed by means of a technical process may be the subject of an invention even if it already occurred in nature" (Article 3.2).

In the United States, an isolated or purified form of a natural product is patentable. The concept of "new" under the novelty requirement does not mean "not preexisting" but "novel" in a prior art sense, so that the unknown but natural

[658] Note that the transgenic character alone is not sufficient for the plant to be considered a plant variety. On top of the transgenic modification, the transformed plant would have to be stable in its characteristics, i.e. retain them after reproduction. See above, under Section 1.

[659] Article 27.2 of the TRIPS Agreement allows Members not to grant patents on inventions which are contrary to *ordre public* or morality. See Chapter 19. An exception of this kind, provided for under European law, has been invoked (albeit unsuccessfully) before the European Patent Office in relation to patent applications related to transgenic plants and animals. See Frédéric Pollaud-Dulian, *La Brevetabilité des inventions. Etude comparative de jurisprudence*, France-OEB, Le Droit des Affaires, No. 16, Paris 1997.

[660] See J. Coombs, *Macmillan Dictionary of Biotechnology*, Macmillan, London and Basinstoke 1986, p. 198.

[661] U.S. Communication to the Council of TRIPS, IP/C/W/209, 3 October 2000.

existence of a product does not preclude the product from the category of statutory subject matter. Similarly, in Japan the Enforcement Standards for Substance Patents stipulated that patents can be granted on chemical substances artificially isolated from natural materials, when the presence of the substance could not be detected without prior isolation with the aid of physical or chemical methods.

Members may also opt for a narrower scope of patentability, confining it to microorganisms that have been genetically modified.[662] TRIPS, in effect, does not define what an "invention" is; it only specifies the requirements that an invention should meet in order to be patentable (Article 27.1).[663]

Another important practical issue relates to the patenting of cells, genes and other sub-cellular components. In many jurisdictions, the patenting of these materials has become common practice.[664] Though these materials are not visible to the naked eye, they do not constitute "microorganisms" and, therefore, are not subject to the obligation established in Article 27.3 (b).

3.3 Processes

> Members may also exclude from patentability . . . essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.

Another possible exclusion from patentability relates to essentially biological processes for the production of plants or animals. Processes for the therapeutic treatment or utilization of plants and animals are not covered by the exception.[665]

The notion of "essentially biological process" has been defined by the European Patent Office on the basis of the degree of "technical intervention"; if the latter plays an important role in the determination of or control over the results, the process may be patentable.[666] Under this notion, conventional breeding methods are generally not patentable. In contrast, methods based on modern biotechnology (e.g., tissue culture,[667] insertion of genes in a plant) where the technical intervention is significant, would be patentable.

[662] See, e.g., Article 10.XI of the Brazilian Industrial Property Code (Law No. 9.279, 14 May 1996), which excludes from patentability "biological materials found in nature", even if isolated, including the "genome or germplasm" of any living being.

[663] See Chapter 17.

[664] For instance, genetic materials may be patented in many countries if claimed in a non-naturally occurring form, that is, as an isolated or purified molecule. In the United States, the doctrine of *Re Deuel* (1995) has paved the way for the patenting of DNA even when encoding known proteins, on the grounds that – due to the degeneracy of the genetic code – their structure could not have been predicted. In Europe, however, gene sequences which code for a known protein are generally now regarded as *prima facie* obvious, although such was not the case in the earliest days of molecular biology.

[665] Diagnostic, therapeutic and surgical methods for the treatment of animals may be exempted from patentability under Article 27.3 (a) of the TRIPS Agreement.

[666] Guidelines for Examination of the EPO, No. X-232.2.

[667] This is a technique in which individual cells grow and divide in a bath of sterile, nutritive fluid, used *inter alia*, in plant breeding (Hale and Margham, p. 528).

The exclusion of "essentially biological processes" does not extend to "non-biological" processes for the production of plants or animals. It does not extend either to microbiological processes which are generally patentable. It is not so simple to determine when a process is "microbiological". In principle, this concept would include any process that uses or modifies microorganisms. There are, however, processes that only include one or more steps that are "microbiological." In accordance with the European Directive on Biotechnological Inventions, such processes should be deemed as "microbiological" if at least one essential step is microbiological (Article 2.2).

3.4 Plant varieties

> 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.

TRIPS obliges Members to protect plant varieties by means of patents, an effective *sui generis* regime or a combination of both. While the granting of patents is regulated under considerably detailed standards, the only requirement with respect to a *sui generis* system is that it must confer an "effective" protection. Countries can, thus, determine the scope and contents of the rights to be granted.

The flexibility permitted by Article 27.3(b) in relation to the form of protection for plant varieties has been the reflection, to a large extent, of the lack of consensus on the matter among the industrialized countries during the TRIPS negotiations. While in the USA, Australia and Japan a plant variety may be patented as such, this is not the case in Europe, as mentioned above. The reference to a "*sui generis* system" may be deemed to suggest the breeder's rights regime, as established in the UPOV Convention. However, the possibility is open to combine the patent system with the breeders' rights regime, or to develop other *"sui-generis"* forms of protection.

Industrial property protection for plant varieties is not new. In the 1920s and 1930s several countries introduced legislation that gradually evolved into a *sui generis* system of protection ("breeders' rights") distinct from the patent system. Based on requirements of distinctness, novelty, uniformity and stability, breeders' rights have typically been permitted to control the commercialization of propagating materials (like seeds), without interfering, however, either with the use of saved seeds by farmers on their own land ("farmers' privilege") or with the development of new varieties by a third party taking as a starting point a protected variety ("breeders' exemption"). Such *sui generis* regime obtained recognition at the international level in the 1960s with the adoption of the UPOV Convention. The Convention introduced minimum standards for the recognition of breeders' rights and, as mentioned, it initially prohibited the provision of patent and *sui generis* protection for plant varieties.[668]

[668] The limitation contained in Article 2 of the 1978 Act was not applicable to countries that provided double protection before the expiry of the period for signature of the 1978 Act (Article 37). This allowed the United States to maintain both patents and breeders' rights for plant varieties.

Breeders' rights protect plant varieties, which are new, distinct, uniform and stable. They grant the faculty to exclude non-authorized persons from using and multiplying propagating materials of protected varieties. Several features differentiate breeders' rights from patents. The former apply to a specific variety (which must physically exist), while patents may refer to genes, cells, plants, seeds or (where allowed) the varieties as such. Another important difference is that the breeder's rights system generally allows farmers to re-use in their own exploitations the seeds they have obtained, a possibility that patents generally exclude.[669] In addition, under breeders' rights protected varieties may be used for further breeding without the authorization of the title-holder ("breeders' exemption"). This may not be possible, depending on national legislation, under patent law.

3.5 Review

> The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

TRIPS entered into force on 1 January 1995. Though the review should have taken place in 1999 there has been no agreement at the Council for TRIPS on the meaning of "review". Developed countries have held that a "review of implementation" is what is called for,[670] while for developing countries a "review" should open the possibility of revising the provision itself.[671]

The review of Article 27.3(b) was also one of the TRIPS issues dealt with at the Ministerial Meeting at Doha in 2001. In this respect, the Doha Declaration included the following mandate for the Council for TRIPS:[672]

> "19. We instruct the Council for TRIPS, in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this Declaration, to examine, *inter alia*, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by Members pursuant to Article 71.1. In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension."

[669] Since living organisms are self-replicating, the sale of a patented organism is at the same time the sale of the means by which the organism can be replicated. Patent rights are deemed in this case to extend to the descendants of the protected organism.

[670] See, e.g., U.S. communication IP/C/W/209; Australia communication IP/C/W/310 ("the coverage of this agenda item is relatively narrow, that is, the item is concerned with a review of the effectiveness of the operation of an optional exclusion to patentability . . . ").

[671] This view is based on the literal text of the provision, as compared to Article 71.1 where the negotiating parties used the expression "review the implementation". According to *The Concise Oxford Dictionary* (Oxford University Press, Seventh edition, 1982, reprinted in 1989), "review" is "revision" which in turn means "to read or look over or reexamine or reconsider and correct, improve, or amend . . . law, constitution, etc."

[672] See paragraph 19 of the Ministerial Declaration, WT/MIN(01)/DEC/1 of 20 November 2001.

Implementing this mandate, the Council for TRIPS has been discussing, *inter alia*, the following agenda items:

(a) the review of the provisions of Article 27.3(b);

(b) the relationship between TRIPS and the Convention on Biological Diversity (CBD);

(c) the protection of traditional knowledge (TK) and folklore.[673]

The Council has addressed these items together, due to their interrelated character. Despite consultations held by the Chair, Members have so far not been able to remove their substantive differences over these issues. A number of proposals made under the three items above will be analyzed in the following paragraphs.

3.5.1 Review of Article 27.3(b)

With respect to the review of Article 27.3(b), some developing country Members, as mentioned above, interpret "review" as opening up the possibility of *amending* Article 27.3(b). In particular, the African Group in a June 2003 submission to the Council[674] proposed an amendment of Article 27.3(b):

> "The African Group maintains its reservations about patenting any life forms as explained on previous occasions by the Group and several other delegations. In this regard, the Group proposes that Article 27.3(b) be revised to prohibit patents on plants, animals, micro-organisms, essentially biological processes for the production of plants or animals, and non-biological and microbiological processes for the production of plants or animals. For plant varieties to be protected under the TRIPS Agreement, the protection must clearly, and not just implicitly or by way of exception, strike a good balance with the interests of the community as a whole and protect farmers' rights and traditional knowledge, and ensure the preservation of biological diversity.
>
> In any case, the Council for TRIPS must ensure that the exceptions for ordre public or morality in paragraph 2 of Article 27 are not rendered meaningless by any provisions in its paragraph 3(b) through requiring Members to do what is otherwise contrary to ordre public and morality in their societies. The barest minimum in this regard, would be to clarify that paragraph 3(b) does not in any manner restrict the rights of Members to resort to the exceptions in paragraph 2.
>
> [. . .]
>
> As pointed out above, the African Group has consistently raised serious concerns about patents on life forms and research tools and on the basis of these concerns the Group has maintained that there should not be a possibility, within the framework of the TRIPS Agreement, of patents on micro-organisms as well as on non-biological and microbiological processes for the production of plants and animals.
>
> It is the view of the Group that the distinction drawn in Article 27.3(b) for micro-organisms, and for non-biological and microbiological processes for the

[673] See, e.g., WTO/AIR/2322 of 27 May 2004, WTO/AIR/2246 of 5 February 2004, and WTO/AIR 2104 of 20 May 2003.

[674] See Joint Communication from the African Group, IP/C/W/404 of 26 June 2003 [hereinafter African Group June 2003].

> production of plants or animals, is artificial and unwarranted, and should be removed from the TRIPS Agreement, so that the exception from patentability in paragraph 3(b) covers plants, animals, and micro-organisms, as well as essentially biological processes and the non-biological and microbiological processes for the production of plants or animals."

This proposal has been the basis of controversial debates within the Council in 2003 and 2004. Developed Members have rejected an amendment of Article 27.3(b) in the above sense, referring, *inter alia*, to their biotechnology industries.[675] The EC, for example, has proposed that those Members seeking to avoid the patenting of natural materials could make use of the TRIPS flexibilities, i.e. to define narrowly the patentability criteria. In this vein, genetic resources occurring in nature would not be patentable (failing to meet the novelty requirement).[676]

The aim of some developed countries, if a revision did take place, would be to eliminate the exception for plants and animals, and to establish that the UPOV Convention as revised in 1991 should be the *only* means of protection available for plant varieties, excluding other *sui generis* systems. Thus, according to the United States, the TRIPS Council should consider

> "whether it is desirable to modify the TRIPS Agreement by eliminating the exclusion from patentability of plants and animals and incorporating key provisions of the UPOV agreement regarding plant variety protection."[677]

For many developing countries, in contrast, it would be important to maintain the exception for plants and animals, as well as the flexibility to develop *sui generis* regimes on plant varieties which are suited to the seed supply systems of the countries concerned.

3.5.2 Relationship between TRIPS and CBD

Different views on the TRIPS-CBD relationship have been expressed at the Council for TRIPS in relation to the review of Article 27.3(b). While developed countries have found no inconsistencies between the two treaties,[678] several developing countries have indicated the need to reconcile them, possibly by means of a revision of TRIPS.[679]

[675] This point was raised by the EC in the March 2004 Meeting of the Council.

[676] The EC expressed this view during the March 2004 Meeting of the Council. See also the Communication from the European Communities and their Member States to the Council for TRIPS of 17 October 2002, IP/C/W/383 [hereinafter EC October 2002], in which the EC rejects an amendment of Article 27.3(b), stating that this provision provides sufficient flexibility to design patent protection according to a country's needs, interests or ethical standards.

[677] Communication from the United States of 19 November 1998, WT/GC/W/115, under item II.A. See also the Communication from the European Commission to the Council and the European Parliament, *The EU approach to the Millennium Round* 1999, p. 16. Note that in recent bilateral free trade agreements, there is a trend towards qualifying UPOV as the sole possible means of plant variety protection. See Section 6.3 of this chapter.

[678] See, e.g., U.S. communication IP/C/W/209; Australia communication IP/C/W/310.

[679] See, e.g., the African Group proposal to harmonize the TRIPS Agreement with the CBD in WT/GC/W/202, and the Indian proposal in WT/GC/W/225.

The main concern of many developing countries is that TRIPS does not require patent applicants whose inventions incorporate or use genetic material or associated knowledge to comply with certain obligations under the Convention for Biological Diversity (CBD). This convention makes access to genetic material subject to prior informed consent of and equitable benefit sharing with the Contracting Party providing the genetic resources.[680] Developing countries have repeatedly voiced concern about possible misappropriation of their genetic resources by developed country patent applicants.[681]

In order to address such concerns, developing countries have proposed in the Council for TRIPS to amend TRIPS in a way as to require an applicant for a patent relating to biological materials or traditional knowledge to provide, as a condition for obtaining the patent:

- disclosure of the source and country of origin of the biological resource and of the traditional knowledge used in the invention;
- evidence of prior informed consent through approval of authorities under the relevant national regime; and
- evidence of fair and equitable benefit sharing under the relevant national regime.[682]

The approach to enforce CBD obligations through the TRIPS patent system is opposed by a number of developed countries,[683] supporting the alternative idea of pursuing ongoing work in WIPO's Intergovernmental Committee on Intellectual

[680] See Article 15 CBD. For more details, see Section 5.2 of this chapter.

[681] See, e.g., African Group June 2003, p. 4.

[682] See Submission by Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, India, Peru, Thailand, Venezuela, IP/C/W/403 of 24 June 2003. These three issues were also included in a checklist submitted to the Council for TRIPS on 2 March 2004 by Brazil, Cuba, Ecuador, India, Peru, Thailand and Venezuela (see IP/C/W/420). The African Group has made a similar proposal, advocating the amendment of Article 29, TRIPS Agreement (conditions on patent applicants), to include an obligation to disclose the country of origin of any biological resources and traditional knowledge as well as to provide confirmation of compliance with domestic access regulations. See African Group June 2003, p. 6.

[683] At the March and June 2004 Council Meetings, the USA and Japan expressed particular opposition to this approach. Switzerland, on the other hand, acknowledged that these issues should be dealt with under the patent system and has proposed to amend the WIPO Patent Cooperation Treaty (PCT) to include, in appropriate cases, the declaration of origin of genetic material in patent applications as a voluntary requirement (IP/C/W/400; reiterated in IP/C/W/423). The proposal includes a concrete description of when disclosure would be relevant, as well as a penalty system for failure to comply in which case the patent would be rejected or withdrawn. Finally, the EC (see EC October 2002) has signalled its agreement to examine and discuss the possible introduction of a system that keeps track of all patent applications regarding genetic resources. At the same time, however, the EC has made clear (ibid.) that legal consequences of the non-respect of a disclosure obligation should lie outside the ambit of patent law. As opposed to the issue of disclosure of origin, the EC at the March 2004 Meeting of the Council for TRIPS expressed reluctance to engage in discussions on the item of prior informed consent. For an overview of the June 2003 and June 2004 Meetings of the Council for TRIPS, see ICTSD Bridges Trade BioRes, 13 June 2003, *CBD-TRIPS Discussion Picking Up Speed At the WTO* (<http://www.ictsd.org/biores/03-06-13/story1.htm>); and ICTSD, Bridges Weekly Trade News Digest, 23 June 2004, *Quiet TRIPS Council Focuses on Health, Biodiversity-Related Issues* (<http://www.ictsd.org/weekly/04-06-23/story3.htm>).

Property and Genetic Resources, Traditional Knowledge and Folklore (IGC).[684] Overall, the issue remains controversial.

3.5.3 The protection of traditional knowledge (TK) and folklore

Discussions in the Council for TRIPS have mainly focused on the question of the right forum for TK protection. Developing countries are almost unanimous in their firm support of the idea that TK protection should be negotiated in the WTO.[685] In these countries' view, any other forum, including WIPO, would not provide the appropriate means for the enforcement of rights.

On the other side, developed Members are opposed to treating TK in the WTO and insist that the matter be dealt with under WIPO auspices (in the IGC).[686] Some of the arguments relate to the expertise of WIPO as well as to the overloaded Doha agenda of the WTO that would not permit sufficient resources to take up a new issue such as TK.

Another controversial issue in this context is the term of protection of TK. While developing countries support the African Group's position[687] that there should be no limitation, like in the case of GIs, developed Members stress the necessity to preserve the public domain in this area.[688]

4. WTO jurisprudence

There is no WTO jurisprudence so far on this subject.[689]

5. Relationship with other international instruments

5.1 WTO Agreements

Other WTO Agreements do not have direct implications on the matters regulated under Article 27.3 (b).

[684] For an overview of the ongoing work in the IGC, see South Centre/CIEL IP Quarterly Update: First Quarter 2004. *Intellectual Property and Development: Overview of Developments in Multilateral, Plurilateral, and Bilateral Fora*, available at <http://www.ciel.org/Publications/IP_Update_Spring04.pdf>. See also South Centre/CIEL IP Quarterly Update: Second Quarter 2004. *Intellectual Property and Development: Overview of Developments in Multilateral, Plurilateral, and Bilateral Fora*, available at <http://www.ciel.org/Publications/IP_Update_Summer04.pdf>.

[685] See, e.g., the African Group June 2003.

[686] See, e.g., EC October 2002, p. 2: "The EC support further work towards the development of an international *sui generis* model for legal protection of TK in WIPO. At this stage, the TRIPS Council is not the right place to negotiate a protection regime for a complex new subject matter like TK or folklore. This is an issue where the WTO should ideally be able to build on the work done by the WIPO Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore. Depending on the outcome of the WIPO process, the TRIPS Council will have to determine whether this result warrants further work in the WTO."

[687] See the African Group June 2003, Annex Draft Decision on Traditional Knowledge, para. 4 (c).

[688] This point was raised by the EC at the March 2004 Meeting of the Council for TRIPS. The EC maintained that TK and GIs are different, the latter protecting only the name, while TK protects the knowledge incorporated in a product.

[689] The USA requested consultations under the DSU against Argentina in relation, *inter alia,* to the patentability of micro-organisms (WT/DS 196/1).

5.2 Other international instruments

5.2.1 UPOV

The International Convention for the Protection of New Varieties of Plants, administered by the Union for the Protection of New Varieties of Plants (UPOV), was established in Paris in 1961 and revised three times since then. UPOV sets forth standards, including national treatment, for the granting of "breeders' rights" as a *sui generis* form of protection for plant varieties. The last revision, which took place in 1991,[690] introduced significant reforms to the 1978 Act of the Convention.[691]

In order to be eligible for protection, a plant variety must meet the following requirements:

(i) Novelty. The variety must not – or, where the law of a state so provides, must not for more than one year – have been offered for sale or marketed with the consent of the breeder in the state where the applicant seeks protection, nor for more than four years (six years in the case of grapevines and trees, including rootstocks) in any other state. The 1991 Act makes the one-year period of grace compulsory and requires that "propagating or harvested material of the variety" must not have been "sold or otherwise disposed of to others" (Article 6 of the 1991 Act).

(ii) Distinctness. The variety must be clearly distinguishable by one or more important characteristics from any other variety whose existence is a matter of common knowledge (Article 7 of the 1991 Act).

(iii) Uniformity. Subject to the variation that may be expected from the particular features of its mode of propagation, the variety must be sufficiently uniform in its relevant characteristics (Article 8 of the 1991 Act).

(iv) Stability. Subject to the variation that may be expected from the particular features of its mode of propagation, the variety must be stable in its essential characteristics. This is the case if the latter remain unchanged after repeated propagation or, in the case of a particular cycle of propagation, at the end of each such cycle (Article 9 of the 1991 Act).

(v) Denomination. The variety must be given a denomination enabling it to be identified; the denomination must not be liable to mislead or to cause confusion as to the characteristics, value or identity of the new variety or the identity of the breeder (Article 5 (2) in conjunction with Article 20 (2) of the 1991 Act).

The Convention in Article 11 provides for the so-called right of priority. Any breeder (national or a resident of a Member state) may file a first application for

[690] Though new members to UPOV can only join the 1991 Act, many countries still remain obliged under the 1978 Act of the Convention.

[691] The main changes included the expansion of the coverage of protection to all plant genera and species; the extension of the breeder's exclusive rights, in certain cases, beyond reproductive material, to harvested material and products obtained through illegal use of propagating material; allowing members the option to accumulate breeders' rights and patent protection for plant varieties (a possibility excluded under the 1978 Act); and introduction of the concept of "essentially derived varieties" (For an explanation of this term, see below under this Section).

protection of a given plant variety in any of the Member states. If the breeder files an application for the same variety in any other Member state within 12 months from the filing of the first application, the breeder will enjoy a right of priority for this later application.

Protection is granted after the competent authority of the Member state in which protection is sought has ascertained that the plant variety for which protection is sought fulfils the above criteria. The examination of homogeneity and stability, as mentioned, must take into account the particularities of the mode of propagation of the variety.

According to Article 14(1)(a) of the Convention, as amended in 1991, there are seven acts of exploitation for which the breeder's authorization is required: (i) production or reproduction (multiplication); (ii) conditioning for the purpose of propagation; (iii) offering for sale; (iv) selling or other marketing; (v) exporting; (vi) importing; (vii) stocking for any of these purposes.

The above mentioned rights may be exercised in respect of the propagating material, and also in respect of the harvested material (including whole plants and parts of plants), provided that the latter has been obtained through the unauthorized use of propagating material, and that the breeder has had no reasonable opportunity to exercise his right in relation to the propagating material.

The breeder's right extends, in addition to the protected variety itself, to varieties which are not clearly distinguishable from the protected variety, which are "essentially derived" from the protected variety,[692] and those whose production requires the repeated use of the protected variety.

As in the case of UPOV 1978, according to UPOV 1991 the underlying genetic resource embodied in a protected plant variety is freely available to third parties for the purpose of breeding other varieties (breeders' exemption). This is crucial for the further improvement of existing varieties. However, Article 15(1)(iii) in conjunction with Article 14(5) of UPOV 1991 now makes clear that the breeders' exemption does not apply where the third party's breeding activities do not result in a genuinely new variety, but in one that is essentially derived from the initial, protected variety.[693] This is because the breeder's exclusive rights to the initial variety extend to those essentially derived varieties, as observed above.[694]

[692] See Article 14 (5)(a) of UPOV 1991. A variety which is essentially derived from a protected variety and which fulfils the criteria of novelty, distinctness, uniformity and stability, may be the subject of protection by a third party but cannot be exploited without the authorization of the breeder of the original variety. The concept of essential derivation applies to varieties which are predominantly derived from another variety and which, except for the differences that result from the act of derivation, conform to the initial variety in the expression of the essential characteristics that result from the genotype or a combination of genotypes of the initial variety (Article 14(5) of the UPOV Convention, 1991 Act).

[693] See also Biswajit Dhar, *Sui Generis Systems for Plant Variety Protection. Options under TRIPS*. A Discussion Paper, Quaker United Nations Office, Geneva 2002, p. 15 [hereinafter Dhar].

[694] In effect, this provision means that the breeder of breeders' right-protected variety A has the right to demand that the breeder of variety B secure his or her authorization to commercialise B if it was essentially derived from A. The main idea here is that breeders should not be able to acquire protection too easily for minor modifications of extant varieties or free-ride without doing any breeding of their own, problems that the increased application of biotechnology in this field appeared likely to exacerbate. Beyond resolving these particular issues, the provision was

It can thus be noted that the new concept of "essentially derived" varieties as introduced by UPOV 1991 enlarges the exclusive right of breeders, extending those rights from the initial variety to all varieties essentially derived therefrom (Article 14 (5)(a)(i)).

Under UPOV 1978, farmers were permitted to save seeds for re-use in their exploitations. UPOV 1991 made this exemption optional for Member countries, which may restrict the breeder's rights "in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting on their own holdings" (Article 15 (2)). This exemption, in addition, is to be applied "within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder". Thus, the Diplomatic Conference that adopted the 1991 revision indicated that Article 15 (2) should not be interpreted as extending the "privilege" to sectors of agricultural or horticultural production where it is not "a common practice".[695] Here again, UPOV 1991 provided for a considerable strengthening of the exclusive breeders' rights. While under UPOV 1978, farmers were authorized to re-use in any way protected material without the obligation to pay any royalty to commercial breeders,[696] Article 15 (2) of UPOV 1991 results in an important limitation of the farmers' privilege. Farmers are not allowed to sell protected seeds, but are limited to their re-use for propagating purposes on their own land.[697]

also intended to ensure that patent rights and breeders' rights operate in a harmonious fashion in jurisdictions where plants and their parts, seeds and genes are patentable and access to these could be blocked by patent holders. Such a practice would undermine one of the main justifications for breeders' rights protection, which is that breeders should be able to secure returns on their investments but without preventing competitors from being able freely to access breeding material. An example here might be useful. Let us consider the case of a breeders' right-protected variety called A and a patented genetic element owned by a separate company. The owner of a patent on this genetic element is free to use A to produce his or her variety B and, absent of the essential derivation provision, place B on the market with no obligations to the owner of A despite the fact that B differs from A only in the addition of the patented genetic element. However, the owner of A would need a license from the producer of B to use the patented genetic element in the breeding of further varieties. In such a situation, then, patents can have the effect of blocking the breeders' exemption that breeders' rights normally provide. It should be noted here that the breeders' right-issuing office will not itself determine whether a variety is essentially derived from an earlier one. This will be left to the courts. See Graham Dutfield, *Intellectual Property Rights, Biogenetic Resources and Traditional Knowledge*, Earthscan: London 2004, p. 35; R. Jördens, *Legal and technological developments leading to this symposium: UPOV's perspective*. Paper presented at WIPO-UPOV Symposium on the Co-existence of Patents and Plant Breeders' Rights in the Promotion of Biotechnological Developments. 25 October 2002, Geneva, p. 6. It is noteworthy that the EC Directive on the Legal Protection of Biotechnological Inventions seeks to make breeders' rights and patents operate more harmoniously by providing that where the acquisition or exploitation of a breeder's right is impossible without infringing a patent, or vice versa, a compulsory license may be applied for. If issued, the licensor party will be entitled to cross-license the licensee's patent or breeder's right.

695 It should be noted that the UPOV Convention contains minimum standards of protection and, hence, any member country may decide to provide higher protection than that resulting from the Convention rules.

696 See Dhar, p. 15.

697 In addition, the exercise of the farmers' privilege shall be "subject to the safeguarding of the legitimate interests of the breeder" (Article 15(2) UPOV 1991), which might be taken by some countries as an authorization to require the farmer to pay royalties to the breeder for the re-use of protected seeds.

The UPOV Convention also allows access to and the use of protected material without the consent of the title-holder in cases of public interest, against an equitable remuneration.

5.2.2 Convention on Biological Diversity

The Convention on Biological Diversity (CBD) of 1992 deals with the conservation and sustainable use of genetic resources. It recognizes the states' sovereign rights over the genetic resources residing in their jurisdictions (Article 3). The Convention requires each Contracting Party to implement several measures in order to ensure the *in-situ* and *ex-situ* conservation of genetic resources.

Article 15 of the CBD recognizes the authority of national governments to determine access to genetic resources, subject to national legislation.[698] Notwithstanding this recognition, each Contracting Party "shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention" (Article 15.2).

According to Article 15 para. 4 and 5 of the Convention, access, where granted, shall be on mutually agreed terms and subject to prior informed consent (PIC) of the Contracting Party providing genetic resources,[699] unless otherwise determined by that Party. In addition, the CBD stipulates that each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties. Most importantly, each Contracting Party is bound to take legislative, administrative or policy measures with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms (Article 1 para. 6 and 7).

Article 16 regulates the access to and transfer of technology, which are deemed "essential elements for the attainment of the objectives" of the Convention. Contracting Parties undertake to provide and/or facilitate access for and transfer to other Contracting Parties of "technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment" (Article 16.1). For the case of developing countries, access "shall be provided and/or facilitated under fair and most favourable terms, including on concessional and preferential terms

[698] Under the framework established by the 1983 International Undertaking on Plant Genetic Resources (IU, the predecessor of the 2001 International Treaty on Plant Genetic Resources for Food and Agriculture), plant genetic resources for food and agriculture (PGRFA) were deemed a "common heritage of mankind" and subject to a system of free exchange among the parties to the IU ("Plant genetic resources are a common heritage of mankind to be preserved, and to be freely available for use, for the benefit of present and future generations", IU Preamble).

[699] For the purpose of the Convention, the "genetic resources being provided by a Contracting Party" are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with the Convention (Article 15.3).

where mutually agreed, and, where necessary, in accordance with the financial mechanism established by Articles 20 and 21" (Article 16.2).

The Convention addresses the case where technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources are subject to intellectual property rights. In such a case, the access and transfer shall be provided on terms which recognize and are consistent with the "adequate and effective protection" of intellectual property rights (Article 16.2). However, the Contracting Parties shall cooperate "subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives" (Article 16.5).

Moreover, each Contracting Party undertakes to take legislative, administrative or policy measures, as appropriate, with regard to intellectual property, the handling of biotechnology and the distribution of its benefits, with the aim that

- Contracting Parties, in particular those that are developing countries, which supply genetic resources are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights, where necessary, through the provisions of Articles 20 and 21 and in accordance with international law and consistent with paragraphs 4 and 5 of Article 16 (Article 16.3).
- The private sector facilitates access to, joint development and transfer of technology referred to in Article 16.1 for the benefit of both governmental institutions and the private sector of developing countries and in this regard shall abide by the obligations included in paragraphs 2 and 3 of Article 16 (Article 16.4).
- An effective participation in biotechnological research activities is ensured to those Contracting Parties, especially developing countries, which provide the genetic resources for such research (Article 19.1).
- Priority access by Contracting Parties, especially developing countries, is promoted on a fair and equitable basis to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms (Article 19.2).

Finally, each Contracting Party shall, directly or by requiring any natural or legal person under its jurisdiction providing any living modified organism resulting from biotechnology, provide any available information about the use and safety regulations required by that Contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced (Article 19.4).

The relationship between the provisions of TRIPS and the CBD has given rise to different opinions,[700] ranging from perfect harmony to collision. The collision has been associated with the possible granting of IPRs, based on or consisting of genetic resources, without observing the prior informed consent and benefit sharing obligations established by the CBD. It has also been held that a possible

[700] See UNCTAD-ICTSD Policy Discussion Paper. For an overview of the current discussion at the Council for TRIPS, see Section 3 of this chapter, above.

conflict may arise in the context of the *implementation* of both instruments, but not necessarily as a result of normative contradictions.[701]

6. New developments

6.1 National laws

Considerable differences exist in national laws with regard to the patentability of biotechnological inventions. The facultative exceptions allowed by Article 27.3(b) have been incorporated into the national laws of many developed and developing countries.[702] Plant and animal varieties are not patentable in the majority of countries.[703] Based on the exceptions allowed by TRIPS, some developing countries have explicitly excluded the patentability of pre-existing biological materials, including genes, unless they are genetically altered. Patents may still be granted, in these cases, for the process used to obtain a biotechnology-based product.

For most developing countries, Article 27.3(b) called for a substantial change in national law, since the majority did not protect plant varieties at the time of negotiation and adoption of the Agreement. Many developing countries have joined or are in the process of joining UPOV, while others have explored the development of non-UPOV modes of protection,[704] including the recognition of "Farmers' Rights".[705] For instance, the Parliament of India passed, on 9 August 2001, a Plant Variety Protection and Farmers' Rights Act. The Act includes provisions for farmers' varieties to be registered, with the help of governmental or non-governmental organizations. The applicant for registration of a variety must disclose information regarding the use of genetic material conserved by any tribal or rural family. Any village or local community may claim compensation for the contribution made in the evolution of a variety. A Gene Fund is created, which should be the

[701] "Many policy-makers and members of civil society are concerned that the TRIPS Agreement promotes private commercial interests at the expense of other important public policy objectives, such as those contained in the CBD. Specifically they are concerned that the TRIPS Agreement is creating serious challenges to the successful implementation of the CBD, including in relation to . . . access and benefit sharing, protection of traditional knowledge, technology transfer, and the conservation and sustainable use of biological diversity", WWF/CIEL, *Biodiversity & Intellectual Property Rights: Reviewing Intellectual Property Rights in Light of the Objectives of the Convention on Biological Diversity*, Joint Discussion Paper, Gland–Geneva 2001, pp. 11–12.

[702] See, e.g., the replies to the questionnaire circulated by the WTO Secretariat, IP/C/W/122 and 126; OMPI/BIOT/WG/99/1, 28 October 1999. See also OECD, *Intellectual property practices in the field of biotechnology*, Working Party of the Trade Committee, TD/TC/WP(98)15/Final, Paris 1999 [hereinafter OECD].

[703] Only in five OECD countries plants *per se*, parts of plants *and* plant varieties are patentable. In only six of such countries patents may cover animals *per se*, animal organs *and* animal varieties (OECD, p. 5). Many patent laws adopted in developing countries have excluded the patentability of plants and animals or, more narrowly, of plant varieties and animal races.

[704] See, e.g., Organization of African States (OAU), *African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources*.

[705] See on this concept, Carlos Correa, *Options for the implementation of Farmers' Rights at the national level*, South Centre, Working Paper, Geneva 2000.

recipient of all revenues payable to the farming communities. The Act also contains a provision on "Farmers Rights" according to which

> "The farmer . . . shall be deemed to be entitled to save, use, sow, resow, exchange, share or sell his farm produce including seed of a variety protected under this Act in the same manner as he was entitled before the coming into force of this Act, provided that the farmer shall not be entitled to sell branded seed of a variety protected under this Act" (Section 39 (iv)).[706]

Peru has established a comprehensive legal system for the protection of traditional knowledge associated with biodiversity.[707] This law reflects the CBD requirements of prior informed consent and benefit sharing. It enables indigenous and local communities to assert their rights over collectively held knowledge. For this purpose, the law obliges interested parties to obtain the prior informed consent of those communities providing the biodiversity-related knowledge. In case of industrial or commercial use, interested parties are required to sign a contract with an organization representing the indigenous communities. According to Article 27 of the new law, such contracts (or licences) have to include, *inter alia*, the right of indigenous communities to claim a minimum compensation, i.e. 5 percent of gross sales of commercial products derived from collective knowledge.

6.2 International instruments

6.2.1 The ITPGRFA

In November 2001, the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) was agreed upon at the FAO Conference in Rome. It builds on the 1983 International Undertaking on Plant Genetic Resources for Food and Agriculture (IU) and entered into force on 29 June 2004, after ratification by 40 Parties. As opposed to the IU, the ITPGRFA contains legally-binding obligations with respect to access to and benefit-sharing of plant genetic resources in the particular area of food and agriculture. It harmonizes the earlier provisions of the IU with the CBD, recognizing both the Parties' sovereignty over their plant genetic resources and their dependence for food security on the exchange of those resources with other Parties. The ITPGRFA seeks to avoid high transaction costs resulting from bilateral exchanges of breeding material as required under the CBD (Article 15) by establishing a multilateral system to facilitate access and benefit-sharing of genetic resources.[708] This multilateral system of exchange operates by means of a standard Material Transfer Agreement to be adopted by the

[706] For the purpose of clause (iv) branded seed means any seed put in a package or any other container and labeled in a manner indicating that such seed is of a variety protected under this Act.

[707] Law No. 27811, in force since 10 August 2002. For more details, see M. Ruiz and I. Lapena, *New Peruvian Law Protects Indigenous Peoples' Collective Knowledge*, in: Bridges Between Trade and Sustainable Development, September 2002 (year 6, no. 6), p. 15, available at <http://www.ictsd.org/monthly/bridges/BRIDGES6-6.pdf>.

[708] See Tansey, p. 10.

ITPGRFA's Governing Body (Article 12.4). A general pool of the resources of those crops covered by the Treaty is established and made available for further research, breeding and education purposes.[709]

As far as the relationship between the ITPGRFA and TRIPS is concerned, it is in particular Article 12.3(d) of the ITPGRFA that has been subject to controversy.[710] There are several areas of possible conflict of those two agreements. Article 12.3(d) and (f), dealing with access to plant genetic resources for food and agriculture, provides that such access shall be provided, *inter alia*, according to the following conditions:

(d) Recipients shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts or components, *in the form received* from the Multilateral System; (emphasis added)

(f) Access to plant genetic resources for food and agriculture protected by intellectual and other property rights shall be consistent with relevant international agreements, and with relevant national laws;

Paragraph (f) makes clear that the ITPGRFA is not intended to circumvent the disciplines of TRIPS. It thus informs the interpretation of paragraph (d), which cannot be seen as an authorization of the Parties to violate the TRIPS patent provisions. According to its terms, paragraph (d) does not disallow the patenting of plant genetic resources in general, but only *in the form received* from the Multilateral System. This clearly excludes the patenting of seeds as acquired from a seed bank. On the other hand, it is not clear if the provision also excludes the patenting of such genetic material that has been modified or isolated from its natural environment. A more detailed analysis of this issue would however go beyond the scope of this book.

Finally, Article 13 of the ITPGRFA provides that benefits accruing from the facilitated access to the covered plant genetic resources shall be shared fairly and equitably (Article 13.1). Four benefit-sharing mechanisms are foreseen (Article 13.2): exchange of information; access to and transfer of technology; capacity building; and sharing of the benefits arising from commercialization.

Article 13.2(b)(i) of the Treaty subjects the access to and transfers of technology to the respect of applicable property rights and access laws. Subsection (d)(ii) of the same provision specifies that the standard Material Transfer Agreement (i.e. the Treaty's standardized means of providing facilitated access to the covered genetic resources) shall include a requirement obliging recipients of material accessed from the Multilateral System to pay to a specific financial resources body an equitable share of the benefits arising from the commercialization of products incorporating such material.[711]

[709] For further details on the ITPGRFA, see Tansey, p. 10, as well as the UNCTAD-ICTSD Policy Discussion Paper.

[710] See UNCTAD-ICTSD Policy Discussion Paper, p. 109.

[711] For more details on the benefit-sharing provisions of the ITPGRFA see Tansey, p. 11. On the ITPGRFA's approach to Farmers' Rights see UNCTAD-ICTSD Policy Discussion Paper, p. 109.

6.2.2 The Doha Declaration

As mentioned under Section 3 of this chapter, paragraph 19 of the 2001 Doha Ministerial Declaration provides the Council for TRIPS with a mandate to examine, under the review of Article 27.3(b), issues such as the relationship between TRIPS and the Convention on Biological Diversity and the protection of traditional knowledge and folklore.

6.2.3 The COP 7

At its seventh meeting in February 2004, the Conference of the Parties (COP) to the Convention on Biological Diversity (CBD) decided to mandate its Ad Hoc Open-ended Working Group on Access and Benefit-sharing to elaborate and negotiate an international regime on access to genetic resources and benefit-sharing with the aim of adopting instruments to effectively implement the provisions in Article 15 and Article 8(j) of the Convention[712] and the three objectives of the Convention (i.e. conservation of biodiversity; sustainable use of biodiversity; and fair and equitable benefit sharing).[713] In the same context, the COP also addressed the relationship between IPRs and genetic resources and associated traditional knowledge:

> "7. *Requests* the Ad hoc Open-ended Working Group on Access and Benefit-Sharing to identify issues related to the disclosure of origin of genetic resources and associated traditional knowledge in applications for intellectual property rights, including those raised by a proposed international certificate of origin/source/legal provenance, and transmit the results of this examination to the World Intellectual Property Organization and other relevant forums.
>
> 8. *Invites* the World Intellectual Property Organization to examine, and where appropriate address, taking into account the need to ensure that this work is supportive of and does not run counter to the objectives of the Convention on Biological Diversity, issues regarding the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications, including, *inter alia*:
>
> (a) Options for model provisions on proposed disclosure requirements;
>
> (b) Practical options for intellectual property rights application procedures with regard to the triggers of disclosure requirements;
>
> (c) Options for incentive measures for applicants;
>
> (d) Identification of the implications for the functioning of disclosure requirements in various World Intellectual Property Organization-administered treaties;
>
> (e) Intellectual property-related issues raised by proposed international certificate of origin/source/legal provenance; and regularly provide reports to the Convention on Biological Diversity on its work, in particular on actions or steps proposed to

[712] On Article 15, CBD, see above, Section 5.2. Article 8(j), CBD provides that each Contracting Party shall, as far as possible and appropriate, "Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices".

[713] See UNEP/CBD/COP/7/L.28 of 20 February 2004.

address the above issues, in order for the Convention on Biological Diversity to provide additional information to the World Intellectual Property Organization for its consideration in the spirit of mutual supportiveness;

9. *Invites* the United Nations Conference on Trade and Development and other relevant international organisations to examine the issues in, and related to, the matters specified in paragraphs 7 and 8 in a manner supportive of the objectives of the Convention on Biological Diversity and prepare a report for submission to the on-going process of the work of the Convention on Biological Diversity on access and benefit sharing."[714]

6.3 Regional and bilateral contexts

6.3.1 Regional and bilateral

The European Directive on Biotechnological Inventions (No. 96/9/EC of March 11, 1996) has set forth, as mentioned, specific standards for the patent protection of biotechnological inventions. The Directive may be considered as essentially declaratory of long standing law throughout much of Europe.[715]

In numerous bilateral and regional agreements the issue of patentability of biotechnological inventions and of the protection of plant varieties have been addressed. In many cases such agreements require the patentability of plants and animals, and the adherence (by the developing country partner) to the UPOV Convention. In fact, the most active negotiations on TRIPS-plus provisions in the area of biotechnology have been taking place on the regional and bilateral levels. An exhaustive analysis of these agreements would go beyond the scope of this Book. Recent examples include the Central American Free Trade Agreement,[716] NAFTA, the draft Free Trade Area of the Americas (FTAA), and the free trade agreements USA – Jordan, EU – Mexico and some Euro-Mediterranean Association Agreements.[717] These agreements declare UPOV to be the appropriate vehicle for the protection of plant breeders' rights, despite Members' freedom under Article 27.3(b) to implement a non-UPOV *sui generis* system of protection. The effect of such regional and bilateral agreements is illustrated by the quickly increasing number of new Members of UPOV.[718]

[714] See UNEP/CBD/COP/7/L.28, pages 10/11.

[715] See, e.g., Grubb, p. 213.

[716] The negotiations between the USA and El Salvador, Guatemala, Honduras, Nicaragua and Costa Rica were concluded in January 2004.

[717] See OECD, *The Relationship Between Regional Trade Agreements and the Multilateral Trading System: Intellectual Property Rights*, TD/TC/WP(2002)28/FINAL, 2002. In the case of the free trade agreement between the USA and Chile, the latter has committed to adhere to the 1991 Act of UPOV by 1 January, 2009. In addition, the Chile – USA FTA provides a "best effort" clause in order for each Party to undertake best efforts to develop and propose legislation to make available patent protection for plants under certain circumstances. For a detailed analysis of the USA – Chile FTA, see Roffe, 2004.

[718] After 1 January 1995, Belarus, Bolivia, Brazil, Bulgaria, Chile, China, Colombia, Croatia, Ecuador, Estonia, Kenya, Kyrgyzstan, Latvia, Lithuania, Mexico, Nicaragua, Panama, Paraguay, Portugal, the Republic of Korea, the Republic of Moldova, Romania, the Russian Federation, Singapore, Slovenia, Trinidad and Tobago, Tunisia, and Ukraine became Members of UPOV 1991 or 1978.

6.4 Proposals for review

As mentioned above, several proposals have been made in relation to the review of Article 27.3(b).[719]

7. Comments, including economic and social implications

Although biotechnology was known since fermentation was used to produce beer and make bread, the economic interest in biotechnology has increased extraordinarily since "modern" biotechnology emerged in the late 1970s as a result of the development of monoclonal antibody technology and the techniques of molecular biology and recombinant DNA.[720] Since the 1980s considerable progress has been made in the development of biotechnology-based pharmaceuticals (e.g., recombinant erithropoietin, growth hormone) as well as in the application of genetic engineering to animals and plants (e.g., transgenic varieties resistant to herbicides or insects).

While genetic engineering-based industries are largely concentrated in developed countries, developing countries possess most of the biodiversity available in the world. They are the source of genetic resources of great value for agriculture and industry (e.g., medicinal plants). Traditional farmers, in particular, have contributed in the past and continue to improve plant varieties and to preserve biodiversity. They provide gene pools crucial for major food crops and other plants. Developing countries have voiced their concerns, and in some cases have taken concrete action in relation to what they consider an illegitimate appropriation by foreign companies or researchers under the patent system.[721,722]

The recognition of IPRs, more specifically of patents, on plants has also raised significant concerns. Many, particularly in developing countries, fear that IPRs may prevent farmers from re-using saved seeds, thus limiting traditional practices that are essential for their survival. In addition, the patenting of certain traits (e.g., higher oil content, disease resistance, higher yield, etc.), genes or plant varieties may limit further research and breeding, including in crops essential for food security. Finally, according to one view, IPRs may contribute to further uniform and monoculture strategies that erode biodiversity, and to increased concentration in farming and in the seeds industry.[723] Small

[719] See Section 3 of this chapter.

[720] CEFI, *The Challenges of Biotechnology*, Madrid 1997, p. 218.

[721] Thus, the Council for Scientific and Industrial Research (CSIR) from India asked for a re-examination of the U.S. patent No. 5,401,5041 granted for the wound healing properties of *turmeric*. The U.S. Patent and Trademark Office (USPTO) revoked this patent after ascertaining that there was no novelty, the innovation having been used and reported on in India for centuries. India has also set up a project to document traditional medicinal knowledge in a digital form, and has proposed the inclusion of a special classification in the International Patent Classification (IPC) in order to enable the retrieval of information on traditional knowledge for patent examination.

[722] See in this regard the Communication from the USA to the Council of TRIPS, IP/C/W/209, 3 October 2000.

[723] In this context, it has been observed that the patenting of genetic material through one company may prevent other companies from further research depending on that genetic material. A frequent reaction in both developed and developing countries is an increasing number of mergers and

and medium farmers and breeders are likely to suffer the most devastating impact.[724]

In the opinion of the proponents of an expanded and reinforced, patent-based approach, however, protection is required to provide an incentive to innovate and the necessary reward for R&D high investments. In their view, the possible negative impact of IPR protection would be offset by benefits in terms of new and better plant varieties.

The possible development of *sui generis* regimes for plant varieties and for traditional knowledge[725] has also attracted considerable interest as means to do justice to traditional and indigenous communities, and to provide them with economic compensation for their contributions.[726]

Finally, attention shall be drawn to the recommendations adopted by the Commission on Intellectual Property Rights (IPR Commission) in its final report. As to plants and intellectual property protection, the Commission concluded:

> "Developing countries should generally not provide patent protection for plants and animals, as is allowed under Article 27.3(b) of TRIPS, because of the restrictions patents may place on use of seed by farmers and researchers. Rather they should consider different forms of *sui generis* systems for plant varieties.
>
> Those developing countries with limited technological capacity should restrict the application of patenting in agricultural biotechnology consistent with TRIPS, and they should adopt a restrictive definition of the term "micro-organism."
>
> Countries that have, or wish to develop, biotechnology-related industries may wish to provide certain types of patent protection in this area. If they do so, specific exceptions to the exclusive rights, for plant breeding and research, should be established. The extent to which patent rights extend to the progeny or multiplied product of the patented invention should also be examined and a clear exception provided for farmers to reuse seeds.
>
> The continuing review of Article 27.3(b) of TRIPS should also preserve the right of countries not to grant patents for plants and animals, including genes and genetically modified plants and animals, as well as to develop *sui generis* regimes for the protection of plant varieties that suit their agricultural systems. Such regimes should permit access to the protected varieties for further research and breeding, and provide at least for the right of farmers to save and plant-back seed, including the possibility of informal sale and exchange."[727]

acquisitions by multinational companies in order to control or benefit from other companies' patents. This again creates important entry barriers to innovative start-ups, thus raising serious concerns about the maintenance of effective competition in the agricultural industries' sector. See IPR Commission report, p. 65. The report is available at <http://www.iprcommission.org/graphic/documents/final_report.htm>. The page numbers refer to the pdf version of the full report as available on the internet and as a hard copy.

[724] For an analysis of the implications of patents on plants, see The Crucible Group, *People, plants and patents. The impact of intellectual property on trade, plant biodiversity, and rural society*, IDRC, Ottawa, 1994.

[725] See, e.g., the OAU *African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources*.

[726] For a review of the literature on this subject, see Graham Dutfield, *Literature survey on intellectual property rights and sustainable human development*, Geneva 2002.

[727] IPR Commission report, p. 66.

With regard to the issue of access to plant genetic resources and farmers' rights, the Commission recommended that:

> "Developed and developing countries should accelerate the process of ratification of the FAO International Treaty on Plant Genetic Resources for Food and Agriculture and should, in particular, implement the Treaty's provisions relating to:
>
> • Not granting IPR protection of any material transferred in the framework of the multilateral system, in the form received.
>
> • Implementation of Farmers' Rights at the national level, including (a) protection of traditional knowledge relevant to plant genetic resources for food and agriculture; (b) the right to equitably participate in sharing benefits arising from the utilisation of plant genetic resources for food and agriculture; (c) the right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture."[728]

The Commission also addressed the concern that overly broad patents might inhibit further research by recommending:

> "Developing countries providing patent protection for biotechnological inventions should assess whether they are effectively susceptible to industrial application, taking account of the USPTO guidelines as appropriate.
>
> Developing countries should adopt the best mode provision to ensure that the patent applicant does not withhold information that would be useful to third parties. If developing countries allow patents over genes as such, regulations or guidelines should provide that claims be limited to the uses effectively disclosed in the patent specification, so as to encourage further research and commercial application of any new uses of the gene."[729]

[728] Ibid, p. 69.

[729] Ibid, pp. 117/118.

22: Patents: Rights Conferred

Article 28 Rights Conferred

1. A patent shall confer on its owner the following exclusive rights:

(a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing* for these purposes that product;

(b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

[Footnote]*: "This right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6."[730]

Article 32 Revocation/Forfeiture

An opportunity for judicial review of any decision to revoke or forfeit a patent shall be available.

Article 33 Term of Protection

The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.*

[Footnote]*: "It is understood that those Members which do not have a system of original grant may provide that the term of protection shall be computed from the filing date in the system of original grant."

[730] Article 6 of TRIPS stipulates that "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."

1. Introduction: terminology, definition and scope

Patents are granted in relation to products and processes, dealt with in paragraphs 1 and 2, respectively, of Article 28. A product is a "thing or substance produced by natural process or manufacture."[731] A process is a "series of operations in manufacture, printing, photography, etc".[732]

Article 28 obliges Members to ensure that patent owners enjoy exclusive rights, and details the minimum content of such rights, which may be exercised with regard to acts performed *during* manufacturing as well as to acts performed *after* manufacturing. The exclusive[733] nature of the rights conferred is inherent to patent grants, though not to all forms of intellectual property.[734] It permits the title-holder, if successful in the exploitation of the invention, to obtain significant rents during the lifetime of the patent, thus fulfilling one of the basic purposes of patent grants.

While defining the patentee's rights as exclusive, the Agreement makes it clear that patents confer a negative right, that is, the legal faculty to prevent others from doing certain acts relating to the invention (*ius excluendi*), rather than a positive right with regard to his products or processes.[735] This distinction is important for the interpretation of Article 28, as well of other provisions in this Section.[736]

Much of the content of Article 28.1(a) reflected the status of prior legislation on the matter. Article 28.1(b), which provides for the extension of the protection conferred on a process patent to the product directly obtained by that process, introduced in contrast a standard applied in many developed countries but generally unknown in most developing countries.

Article 32 addresses an important issue in patent law: the revocation[737]or forfeiture[738] of a patent. However, this provision only establishes a procedural requirement (the availability of judicial review), and does not stipulate the grounds or other substantive conditions for such acts to take place, thereby leaving considerable leeway to Members to legislate on the matter. In particular, Article 32

[731] The Concise Oxford Dictionary, p. 821.

[732] The Concise Oxford Dictionary, p. 820.

[733] "Exclusive" means "shutting out, not admitting of", *The Concise Oxford Dictionary,* p. 336.

[734] See, e.g. Articles 22.2 (geographical indications) and 39.1 (undisclosed information) of the Agreement.

[735] Thus, the acquisition of a patent right on a product does not empower the patent owner to produce it if this were contrary, for instance, to environmental regulations, or to commercialize it, if prior marketing approval were required.

[736] For example, the enjoyment of "patent rights" in Article 27.1, if strictly interpreted, should be understood in relation to products made, used, sold, etc, by a third party, and not to the own patentee's products.

[737] "Revocation" is the result of an act of repealing, annulling, withdrawing, rescinding, or cancelling a right. See *The Concise Oxford Dictionary,* p. 893. In the present context, a patent can be revoked where grounds exist that would have justified a refusal to grant the patent in the first place.

[738] "Forfeiture" takes place when a right is lost as penalty of crime, neglect, etc. See *The Concise Oxford Dictionary,* p. 384. As opposed to the *revocation* of a patent, forfeiture does not address the situation where the patent should not have been granted from the beginning, but rather where the original grant was justified, and only afterwards the patentee behaved in a way that forfeited his right.

does not limit a Member's right to determine the *grounds* for revocation and forfeiture.

The duration of patent rights is established in Article 33, which mandates a minimum term of twenty years counted from the date of filing of the application. Since under the Paris Convention for the Protection of Industrial Property members were free to determine the duration of patents, considerable diversity existed on this matter at the time of the negotiation of TRIPS. Article 33 is likely to have a powerful harmonizing effect to the extent that, as suggested by recent legislative changes, most countries tend to adopt the 20 years term. The interpretation of this provision has been addressed in one case decided under the Dispute Settlement Understanding, as discussed below.

2. History of the provisions

2.1 Situation pre-TRIPS

Article 28.1(a) reflects standards followed in many countries before TRIPS. Though under different formulations, patent laws had generally covered acts of making, selling or otherwise disposing of the invention. Some laws also covered acts of keeping or stocking a patented product, as well as acts by a third party who assisted in the preparations for infringing acts ("contributory infringement").[739] In some cases, acts of using the invention were subject to the patentee's exclusive rights, including use without making or sale.[740] In contrast, prior to TRIPS the act of importation was not generally enumerated as an exclusive right of the patent owner, though in some jurisdictions such act was indirectly covered.[741]

The extension of protection to products directly obtained by the patented process, as provided for under Article 28.1(b), had not obtained broad acceptance before TRIPS. The Paris Convention alluded to the rights in respect of products obtained by a patented process in a foreign country, but deferred to national law the option to recognize exclusive rights in respect of the imported products (Article 5*quater*).

Such extension had been applied in some developed countries, often with considerable controversy.[742] In the case of the USA, the extension was only introduced by a legislative amendment in 1988.[743] The extension was not provided, however, in the laws of most developing countries, where process patents only covered, in

[739] See, e.g., W. Cornish, *Intellectual property: Patents, copyright, trade marks and allied rights*, second edition, Sweet & Maxwell, New York 1989, p. 167.

[740] For example, acts of purchasing and using a machine (see, e.g., Chisum and Jacobs, pp. 2–217).

[741] See, e.g., Lionel Bently and Brad Sherman, *Intellectual property law*, Oxford University Press, New York 2001, p. 490 [hereinafter Bently and Sherman].

[742] See, e.g., Hansen and Hirsch, pp. 356–359; Joseph Straus, *Reversal of the burden of proof, the principle of 'fair and equitable procedures' and preliminary injunctions under the TRIPS Agreement*, The Journal of World Intellectual Property 2000, vol. 3, No. 6, pp. 807–823 (809) [hereinafter Straus].

[743] Process Patent Amendments Act of 1988. Prior to this amendment, a patent owner could petition the U.S. International Trade Commission for an order prohibiting importation of a product under Tariff Act 337, only if "an industry in the United States, relating to the Article protected by the patent . . . concerned, exists or is in the process of being established", see, e.g., Chisum and Jacobs, pp. 2–220.

general, the right to exclude others from the domestic use of the process, but not to impede the importation of products manufactured abroad with the patented process. The inclusion of this obligation in TRIPS was the outcome of a long and difficult negotiation.[744]

Great diversity existed before TRIPS in relation to the duration of patent rights. Under the Paris Convention, members had full freedom to determine the term of protection. Different terms were provided for by national laws, sometimes calculated from grant, and in other cases from filing. Thus, many developed and developing countries had patent duration of 15 to 17 years counted from the date of grant. In some countries, protection was even shorter. For instance, in India, process patents for food, drug and medicines were granted for five years from the date or sealing or seven years from the date of filing, whichever was shorter.[745]

2.2 Negotiating history

2.2.1 Exclusive rights

2.2.1.1 The Anell Draft. The Anell Draft reflected considerable differences between parties with regard to the enumeration of exclusive rights:

"2. Rights Conferred

2.1A A patent shall confer on its owner at least the following exclusive rights:

(a) to prevent third parties not having his consent from the acts of: making, using, [putting on the market, offering] [or selling] [or importing] [or importing or stocking for these purposes] the product which is the subject matter of the patent.

(b) where the subject matter of a patent is a process, to prevent third parties not having his consent from the act of using the process, and from the acts of: using, [putting on the market, offering] [selling,] [or importing,] [or importing or stocking for these purposes,] at least the product obtained directly by that process.

2.1B Once a patent has been granted, the owner of the patent shall have the following rights:

(a) The right to prevent others from making, using or selling the patented product or using the patented process for commercial or industrial purposes.

(b) The right to assign, or transfer by succession, the patent and to conclude licence contracts.

(c) The right to a reasonable remuneration when the competent authorities of a PARTY to the present agreement use a patent for government purpose or provide for the granting of a licence of right or a compulsory licence. Such reasonable remuneration will be determined having regard to the economic situation of the PARTY, the nature of the invention, the cost involved in developing the patent and other relevant factors.

(See also point 5A.3.9 below)"

[744] See, Gervais, p. 154.

[745] Section 53(1) of the Patent Act, 1970.

2.2.1.2 The Brussels Draft. The Brussels Draft (3 December 1990) on exclusive patent rights was essentially identical to the current version of Article 28; however, the part now contained in Article 28 concerning the rights of a process patent holder in the products directly obtained by that process was bracketed, thus indicating the negotiators' disagreement on this issue:

"Article 28: Rights Conferred

1. A patent shall confer on its owner the following exclusive rights:

(a) to prevent third parties not having his consent from the acts of: making, using, offering for sale, selling, or importing [footnote] for these purposes the product which is the subject matter of the patent;

(b) where the subject matter of a patent is a process, to prevent third parties not having his consent from the act of using the process [, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process].

2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

[Footnote]: "This right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6."

2.2.2 Revocation/Forfeiture

2.2.2.1 The Anell Draft. The Anell Draft provided:

"6. Revocation/Forfeiture

6A.1 A patent [[may not be revoked or forfeited [merely] on grounds [of non-working] stipulated in 5A.2 above]] [may only be revoked on grounds that it fails to meet the requirements of 1.1 and 1.3 above].

6A.2 Judicial review shall be available in the case of forfeiture of a patent where applicable.

6B A patent may be revoked on grounds of public interest and where the conditions for the grant of compulsory licences are not fulfilled."

2.2.2.2 The Brussels Draft. The Brussels Draft was identical to the current version of Article 32 TRIPS.

2.2.3 Term of protection

2.2.3.1 The Anell Draft. The Anell Draft provided:

"4. Term of Protection

4A.1 The term of protection shall be [at least] [15 years from the date of filing of the application, except for inventions in the field of pharmaceuticals for which the term shall be 20 years] [20 years from the date of filing of the application] [or where other applications are invoked in the said application, 20 years from the

filing date of the earliest filed of the invoked applications which is not the priority date of the said application].[746]

4A.2 PARTIES are encouraged to extend the term of patent protection in appropriate cases, to compensate for delays regarding the exploitation of the patented invention caused by regulatory approval processes.

4B It shall be a matter for national legislation to determine the duration of protection."

2.2.3.2 The Brussels Draft

"[1A The term of protection available shall not end before the expiration of a period of 20 years counted from the filing date. [footnote]]

[1B It shall be a matter for national legislation to determine the term of protection.]

[Footnote]: It is understood that those Members which do not have a system of original grant may provide that the term of protection shall be computed from the filing date in the system of original grant."

It was the former proposal (minimum term of 20 years) that was finally adopted as Article 33 of TRIPS.

3. Possible interpretations

3.1 Article 28.1 (a)

> Rights Conferred
>
> 28.1. A patent shall confer on its owner the following exclusive rights:
>
> (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing [6] for these purposes that product;

Article 28.1, largely inspired by Article 19 of the WIPO draft Patent Law Treaty,[747] enumerates the exclusive rights in relation to a product in a manner substantially similar to pre-existing laws. It covers acts of:

(a) "Making", meaning constructing, framing, creating, from parts or other substances.[748] The exclusive rights may be exercised in relation to any acts resulting in the production of the product, including by manufacturing and other methods

[746] At the initial stages of the TRIPS negotiations, Japan proposed a term of 15 years from the date of grant, as available in its law; Australia and New Zealand 16 years from the date of filing a complete specification. The EC and USA proposed a higher standard of 20 years from the date of filing, which was finally adopted. Countries supporting a shorter term did not unite to propose any alternative and, hence, the issue was decided by default, see Jayashree Watal, *Intellectual property rights in the WTO and developing countries*, Kluwer Law International, The Hague/London/Boston 2001, p. 114.

[747] See, e.g., Gervais, p. 153.

[748] The Concise Oxford Dictionary, p. 611.

(e.g., extraction from a natural product) independently of the scale of production[749] and, most importantly, of the method of production used. This signifies that whatever the process used by a third party, an infringement would occur whenever the patented product is made, even if an independently developed and inventive process were used.[750] Similarly, it is immaterial for the purpose of establishing an infringement whether the product is made for domestic consumption or for export.[751]

In principle, the patent owner may prevent acts of "making", including where a product is made for non-commercial purposes. In order to avoid this effect, patent laws normally provide for exceptions in respect of acts done for private non-commercial purposes, and/or for scientific research and education.[752]

Few problems have arisen under national laws in determining what "making" means, except in the cases of repair or modification of a patented product, where infringement depends on the extent of repair or modification and on the circumstances of the particular case.[753]

(b) "Using", meaning utilization of the product by a third party. This concept may include a sales demonstration, but not merely possession or display,[754] acts of commercialization which do not entail a sale, such as renting or leasing, as well as the utilization of a product as part of a land vehicle, aircraft or vessel.[755] It may permit the right holder to act against the acquirer and user of an infringing product, and not only against the party who manufactured or sold it.

However, the exclusive right of the patent owner in respect of acts of "using" is subject to the principle of exhaustion of rights. According to this principle, as interpreted under most laws, the patent owner cannot control the use of the product after its first sale. National laws differ, however, with respect to the concept and geographical scope of the exhaustion principle. Exhaustion may be established at the national level (i.e., for acts taking place within the country only); at the regional level (e.g., for acts occurring in countries which are members of a common

[749] Many laws provide for an exception to the exclusive patentee's rights for the preparation for individual cases, in a pharmacy or by a medical doctor, of a medicine in accordance with a medical prescription.

[750] Unless a dependent patent and a compulsory licence – under the terms allowed by Article 31 (l) of the TRIPS Agreement – were obtained by the third party.

[751] In the USA, for instance, making an entire patented product for export infringes the patent (see. e.g. Chisum and Jacobs, pp. 2–219). The coverage of exports under the patentee's exclusive rights is one of the underlying problems in the discussion of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, and the reason why an exception based on Article 30 of the Agreement was originally suggested. See the "Doha Ministerial Declaration on the TRIPS Agreement and Public Health" [hereinafter "the Doha Declaration"], WT/MIN(01)/DEC/W/2, 14 November 2001. See also the EU submission to the Council for TRIPS, IP/C/W/339, 4 March 2002. For more details on paragraph 6 of the Doha Declaration, see Chapter 25.

[752] See Chapter 23.

[753] See, e.g., Bently and Sherman, pp. 488.

[754] See, e.g., Chisum and Jacobs, p. 2–217.

[755] See Article 5*ter* of the Paris Convention.

market); or with an international scope. Several countries have followed this latter approach in recent changes of legislation.[756]

(c) "Offering for sale", including acts aimed at the commercialization of a product, even where the latter has not yet occurred. This right may be deemed partially implicit in the right of selling, but this is not necessarily the case in some jurisdictions.[757]

(d) "Selling", covering transactions for the transfer, against a price, of a patented product. It represents one of the most common modes of infringement. Acts of selling without making are covered under this right, for instance, by a person who purchases and resells a patented product, or by a person who imports it.

(e) "Importing", covering the introduction of the patented product into the country where protection is conferred, even if done for non-commercial purposes or free of cost. The importation of a product has not been generally enumerated in national patent laws as part of the exclusive rights.[758] Footnote 6 subjects the application of this provision to the principle of exhaustion of rights, as established by national law.[759]

Article 28.1 does not refer to acts by a contributory infringer, nor to acts of keeping or stocking a patented product, which are specifically contemplated under some national laws.

3.2 Article 28.1(b)

> (b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, . . .

Article 28.1(b) describes the acts that can be prevented by the owner of a process patent. Process patents are generally deemed to include methods of "making" a product.[760] The patent owner may prevent the use of such method in the country of registration of the patent. If a product is obtainable by different processes, a

[756] See Chapter 5.

[757] For instance, in the USA, the patent law does not provide for penalties for the offer to sell a patented product. See, e.g., Richard Neff and Fran Smallson (1994), *NAFTA. Protecting and enforcing intellectual property rights in North America*, SHEPARD'S, Colorado, p. 86.

[758] In some jurisdictions it has been held that importation amounts to infringement of a patent only when a person deals with the patented invention in the course of trade or for the purposes of profit (Bently and Sherman, p. 490). In the USA, importing a patented product has not been deemed, alone, an infringement, but any subsequent sale or use of the product could infringe (see, e.g., Chisum and Jacobs, pp. 2–220).

[759] See Chapter 5.

[760] In the USA, processes also encompass "method-of-use" patents, which allow the protection of inventions consisting of the use of a product not suggested by the prior art, when the product is known and not patentable. Method-of-use patents do not entail protection of the product as such. See, e.g., Merges, p. 489. The TRIPS Agreement, however, does not oblige to follow this particular approach.

third party can legally make it, provided that it employs a different process,[761] and provided that the patentee does not also hold a patent on that product.[762]

> . . . and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

This provision also allows for the extension of the protection conferred on a process to the product "obtained directly by that process". This extension, coupled with the reversal of burden of proof,[763] implies a significant strengthening of patent rights on process inventions under TRIPS.

Without such extension, a process patent granted in country A could not be invoked in cases where the patented process has been utilized in country B and the resulting product is imported into country A. The extension of the protection to the product obtained directly by the patented process addresses this problem. It constitutes an exception to the general principle according to which the protection conferred for an invention is defined by the object of the invention.

Article 28.1(b) applies when a product has been *directly* obtained by the patented process, and not merely when it is *obtainable* by it.[764] The difference is important, since in the chemical sector the same product may, in many cases, be obtained through different processes. The extended protection only applies when it may be proven that the product was produced by the patented process.[765] In some cases, however, it may be difficult to determine whether a product has been directly obtained by a patented process, such as when the process involves different steps and only some of them are covered by the patent.[766] For the extended protection to arise there should be a direct relationship between the process and product, that is, there should be no material or important steps outside the scope of the patent claims that intervene between the process and the product in question.[767]

An important, and still open, question arises in relation to the application of this extension to cases in which the obtained products were specifically excluded

[761] If an infringement is invoked, courts would normally determine whether the alternative process can be deemed or not "equivalent" to the patented process. See, e.g, Harold Wegner, *Patent law in biotechnology, chemicals & pharmaceuticals*, Stockton, Chippenham 1994, p. 526 [hereinafter Wegner, 1994].

[762] In that case, the patentee may invoke his exclusive right to prevent others from *making the product*, see Article 28.1 (a). As explained above, this right prevents third parties from making the protected product through whichever process.

[763] See Chapter 26.

[764] The insertion of "at least" in the last sentence of Article 28.1(b) suggests that Members may, but are not obliged to, extend protection to products not directly obtained by the protected process.

[765] In case the conditions under Article 34 are met, the burden of proof is reversed; in that case the extended protection applies when the *alleged infringer* cannot prove that the product was made through a process different from the patented one. For details, see also Chapter 26.

[766] See, e.g., Hansen and Hirsch, p. 357.

[767] See, e.g., Bentley and Sherman, 2001, p. 493.

from patentability by the national law, such as in the case of plants and animals.[768] It may be argued that when a unique process is known, such extension would be tantamount to the protection of the product as such, thereby *de facto* overriding the prohibition to patent the product.

3.3 Article 28.2

> 28.2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

Intellectual property rights, like other property, can be assigned or transferred by succession. Article 28.2 makes it clear that patent owners have no restriction to assign their rights, be it on an onerous or on a cost-free basis. This Article seems to ban conditions (such as the transfer of the business or goodwill)[769] that would limit the ability to transfer the patent rights. However, measures such as requiring that the transfer be in writing and registered with the patent office would be admissible.

The "right . . . to conclude licensing contracts" seems to allude to the freedom to contract, that is, to the patent owner's discretion to enter into a licensing agreement. This provision would seem to exclude any measure that would impose on the patent owner an obligation to licence his invention. However, Article 31 explicitly allows Members to provide for compulsory licences, thereby authorizing Members to grant licences without or against the consent of the patent owner.[770]

Though patent owners enjoy, in principle, the right to *determine the terms and conditions* of the licences they grant, Article 28.2 does not prevent Members from subjecting such terms and conditions to commercial and other national laws, including competition laws. Nevertheless, Article 40 of TRIPS circumscribes the measures that states may adopt to regulate licensing practices and conditions.[771]

3.4 Revocation (Article 32)

> Article 32 Revocation/Forfeiture
>
> An opportunity for judicial review of any decision to revoke or forfeit a patent shall be available.

This Article provides that any decision to revoke of forfeit a patent, for any reason, must be subject to a judicial review. It does not establish the grounds for revocation or forfeiture, which can be determined by national laws. Under European law,[772] for instance, revocation may take place when it is determined that

[768] See Chapter 21.

[769] See, e.g., Articles 21 and 31 (e) of the TRIPS Agreement.

[770] See Chapter 25.

[771] See Chapter 29.

[772] See Articles 52–7 and 138C(1) of the European Patent Convention.

(a) the invention was not patentable, because it did not meet any of the patentability requirements;

(b) the patent was granted to a person who was not entitled to that patent;

(c) the specification of the patent did not disclose the invention clearly enough and completely enough for it to be performed by a person skilled in the art; or

(d) the subject matter in the patent extends beyond the subject matter in the application as filed.

As indicated, in the negotiations concerning the Anell Draft (see above), attempts were made to limit revocation to cases where a patent had failed to meet the criteria for grant but this position did not find sufficient support. Hence, Members may contemplate, for instance, revocation on grounds of public interest.[773]

The revocation may proceed with regard to the patent as a whole, or in respect of some of the claims. In countries where the law requires that one principal and one or more subordinated claims be submitted, the invalidation of the principal claim means the revocation of the whole patent. TRIPS leaves full freedom to Members to legislate upon these issues.

Similarly, there are no specific limitations in Article 32 with regard to the grounds and conditions for forfeiture. Most patent laws provide for the forfeiture of a patent when maintenance fees are not timely paid. Such fees are charged in order to finance patent offices' activities and, in some cases, also to pursue some policy objectives, such as inducing the early termination of patent rights (see below).

The Paris Convention mandates that a period of grace of not less than six months be "allowed for the payment of the fees prescribed for the maintenance of industrial property rights, subject, if the domestic legislation so provides, to the payment of a surcharge" (Article 5*bis* (1)). In any case, the countries of the Union shall have the right to provide for the restoration of patents which have lapsed by reason of non-payment of fees (Article 5*bis* (2)). Forfeiture may also be established as a sanction for abuses by the patent holder, such as in cases of non-working. However, Article 5A (3) of the Paris Convention stipulates that "forfeiture of the patent shall not be provided for except in cases where the grant of compulsory licences would not have been sufficient to prevent the said abuses. No proceedings for the forfeiture or revocation of a patent may be instituted before the expiration of two years from the grant of the first compulsory licence."

Article 32 requires the availability of a "judicial review". It seems to be premised on the assumption that revocation or forfeiture is determined by an administrative body, and that the subsequent intervention of a judicial authority is necessary to ensure a due process of law. Under many laws, however, revocation can only be declared by judicial authorities, and the judicial review may only proceed once a final decision is reached by the highest competent court. A question also arises as

[773] See, e.g., Gervais, p. 168. Some developing countries' laws (e.g., Andean Group, Costa Rica) allow for the revocation of patents granted in cases where the origin of the biological materials claimed is not disclosed. The consistency of this solution with the TRIPS Agreement is currently subject to considerable debate. See Chapter 24.

to whether "judicial"[774] in this context necessarily means the intervention of a judicial court, or whether the mandated review could be made by an administrative authority, provided that it follows the formal legal procedures of a court of law.

3.5 Term of protection

> Article 33 Term of Protection
>
> The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date. [Footnote 8].
>
> [Footnote 8]: It is understood that those Members which do not have a system of original grant may provide that the term of protection shall be computed from the filing date in the system of original grant.

This provision establishes a minimum standard, that is, protection must *at least* extend for twenty years from the filing date.[775] However, during the negotiations on this provision, some developed countries attempted to determine a longer term of protection for products the marketing of which is subject to regulatory approval as established, for instance, for pharmaceutical products in the USA, Europe and other countries. This approach was not accepted by the negotiating parties; no Member, hence, may be obliged to grant a term longer than twenty years from filing in any field of technology.[776]

The content of Article 33 was clarified in the *Canada – Term of patent protection* case. Based on the ordinary meaning of "available,"[777] the panel concluded that "patent right holders are entitled, as a matter of right, to a term of protection that does not end before twenty years from the date of filing"[778] and that the use of such a word "probably reflects the fact that patent right holders must pay fees from time to time to maintain the term of protection and that patent authorities are to make those terms 'available' to patent right holders who exercise their right to maintain the exclusive rights conferred by the patent" (para. 6.110).

The Appellate Body, in reviewing the panel's report, argued that

> "In our view, the words used in Article 33 present very little interpretative difficulty. The "filing date" is the date of filing of the patent application. The term of protection "shall not end" before twenty years counted from the date of filing of the patent application. The calculation of the period of "twenty years" is clear and specific. In simple terms, Article 33 defines the earliest date on which the term of

[774] "Judicial" is "of, done by, proper to, a court of law" (*The Concise Oxford Dictionary,* p. 543).

[775] The footnote to this Article applies in countries which give effect to patents granted in other jurisdictions, such as in the case of countries that rely on the patent law of their ex-metropolis.

[776] See Article 1.1 above which provides that "... Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement ...".

[777] The *Black's Law Dictionary* defines the word "available" as "having sufficient force or efficacy; effectual; valid" and the word "valid" in turn means "having legal strength or force, incapable of being rightfully overthrown or set aside".

[778] See WT/DS170/R, para. 6.103.

> protection of a patent may end. This earliest date is determined by a straightforward calculation: it results from taking the date of filing of the patent application and adding twenty years. As the filing date of the patent application and the twenty-year figure are both unambiguous, so too is the resultant earliest end date of the term of patent protection."[779]

In supporting the panel's interpretation, the Appellate Body added that "in Article 33 of TRIPS, the word 'available' means 'available, as a matter of right', that is to say, available as a matter of legal right and certainty."[780]

4. WTO jurisprudence

4.1 Exclusive rights

There have been no specific decisions on Article 28. In the *Canada-Patent protection of pharmaceutical products* case, however, the panel stressed that the exclusion of "all forms of competition" is the essence of patent rights. It held that

> "The normal practice of exploitation by patent owners, as with owners of any other intellectual property right, is to exclude all forms of competition that could detract significantly from the economic returns anticipated from a patent's grant of market exclusivity . . . Patent laws establish a carefully defined period of market exclusivity as an inducement to innovation, and the policy of those laws cannot be achieved unless patent owners are permitted to take effective advantage of that inducement once it has been defined."[781]

4.2 Term of protection

As mentioned, in the *Canada – Term of patent protection* case[782] the panel and the Appellate Body addressed the interpretation of Article 33. Canada had argued that Section 45 of its Patent Act, which established a 17-year terms from the date on which the patent was issued, did not prescribe a term of protection that would end before the expiration of the 20-year period from the date of filing. Canada argued that a term of protection of at least equal to (and frequently in excess of) a period of 20 years from the date of filing was "available" under Section 45 and that this Section was, therefore, consistent with Article 33 of TRIPS. It considered that 17 years of "effective" protection for the "exclusive privilege and property rights" conferred by the Patents Act were "equivalent or superior" to the term of "exclusive privilege and property rights" provided by Article 33. Canada made such assertion based on the fact that:

> "the time-period between the filing date and issuance of patent necessarily erodes the term of patent protection in cases where, as in Article 33, the protection period is measured as of the filing date. Since the time-period between the filing date and issuance of patent is on average five years in Canada, it was Canada's

[779] See WT/DS170/AB/R, 18 September 2000, para. 85.

[780] Ibid., para. 90.

[781] See WT/DS/114/R, para. 7.55.

[782] See WT/DS114/R (Report of the Panel) and WT/DS170/AB/R (Report of the Appellate Body).

> contention that a patent right holder will receive only 15 years of 'exclusive privilege and property rights' under a system that grants a 20-year protection term as of the filing date whereas Section 45 provides a successful patent applicant with 17 years of constant protection for the 'exclusive privilege and property rights'" (para. 6.90).

Both the panel and the Appellate Body rejected Canada's arguments. In examining what "available" in Article 33 meant in the context of this dispute, the AB stated that

> "The key question for consideration with respect to the "availability" argument is, therefore, whether Section 45 of Canada's Patent Act, together with Canada's related regulatory procedures and practices, make available, as a matter of legal right and certainty, a term of protection of twenty years from the filing date for each and every patent. The answer is clearly in the negative, even without disputing the assertions made by Canada with respect to the many statutory and other informal means available to an applicant to control the patent process. The fact that the patent term required under Article 33 can be a by-product of possible delays in the patent-granting process does not imply that this term is available, as a matter of legal right and certainty, to each and every Old Act patent applicant in Canada" (para. 91).
>
> "To demonstrate that the patent term in Article 33 is "available", it is not sufficient to point, as Canada does, to a combination of procedures that, when used in a particular sequence or in a particular way, may add up to twenty years. The opportunity to obtain a twenty-year patent term must not be "available" only to those who are somehow able to meander successfully through a maze of administrative procedures. The opportunity to obtain a twenty-year term must be a readily discernible and specific right, and it must be clearly seen as such by the patent applicant when a patent application is filed. The grant of the patent must be sufficient in itself to obtain the minimum term mandated by Article 33. The use of the word "available" in Article 33 does not undermine but, rather, underscores this obligation" (para. 92).

5. Relationship with other international instruments

5.1 WTO Agreements

5.2 Other international instruments

6. New developments

6.1 National laws

The enumeration of exclusive rights in Article 28 has been adopted, in some cases literally, by a number of developing countries that changed their patent laws in order to implement the Agreement.[783]

[783] See, e.g., Article 42 of the Brazilian Industrial Property Code (1996); Article 52 of the Andean Community "Common Regime on Industrial Property" (Decision 486, 2000); the Kenyan Industrial Property Act (2001) which explicitly incorporates, however, the right of "stocking" a protected product (Article 54(1)(a)(ii)).

Article 33 has had a significant impact in many developed and developing countries, which were bound to amend provisions relating to the duration of conferred rights. Thus, the USA, New Zealand, Portugal[784] and Canada were among the developed countries that changed their legislation in order to conform to the 20-year term mandated by TRIPS. Numerous developing countries that previously granted a shorter term of patent protection also modified their laws accordingly.

6.2 International instruments

6.3 Regional and bilateral contexts

6.3.1 Regional

Article 1709(5) of NAFTA enumerates the exclusive rights conferred on the patent owner. Unlike Article 28.1(a) of TRIPS, NAFTA neither enumerates the right to prevent others from offering for sale, nor the right to prevent the importation of a patented product. The NAFTA provision, however, empowers the owner of a process patent to prevent the importation of a product obtained directly by that process.

6.3.2 Bilateral

The USA-Jordan Agreement on the Establishment of a Free Trade Area (October 2000) provides for an extension of the patent term for pharmaceutical products:

> "With respect to pharmaceutical products that are subject to a patent ... each Party shall make available an extension of the patent term to compensate the patent owner for unreasonable curtailment of the patent term as a result of the marketing approval process" (Article 23 (a)).

6.4 Proposals for review

There are no proposals for review of Articles 28, 32 and 33.

7. Comments, including economic and social implications

Product patents confer broader rights than process patents. Thus, once a product is patented, third parties can be excluded from the market even in cases where they develop their own processes for obtaining the same product. This explains why some industries, such as the pharmaceutical industry, were so keen to include in TRIPS a general obligation to protect product inventions in all fields of technology, as provided for in Article 27.1. Protection of pharmaceutical process only had allowed the development in some countries of domestic industries that were able to produce and market copies of products patented elsewhere.

However, the protection given to process patents is potentially broad because all the different products that can be obtained with a single process fall within the remit of the patent and, additionally, protection may be deemed to include not

[784] The USA filed a WTO dispute against Portugal in 1996 for not extending the 20-year patent term to patents filed before 1 June 1995, the date of modification of the Portuguese patent law. Portugal amended this provision in 1996, and the case was dropped.

only the products that flow from the process, but also the products that are based upon such products, that is, their derivatives.[785]

Under Article 28.1(b) products manufactured abroad can be deemed infringing of a patented process in the country of importation. This extension of protection, which significantly strengthens process patents is based on economic considerations, since it is not always possible to obtain a patent for the product, or the patent thereon may have expired. However, there has to be a *direct* relationship between the process and the product. If patentees were able to regulate the use of products that only come into existence as a result of material steps that occur outside the claimed process, the ambit of the monopoly would unduly extend beyond the scope of the patented invention.[786]

Though in a post-TRIPS scenario, pharmaceutical product patents will be recognized in all WTO Members, the extension under Article 28.1(b) will still be relevant in relation to off-patent products, especially when only one process of production is economically efficient or technically viable. In fact, large pharmaceutical firms are active in the patenting of production processes in order to extend the protection beyond the expiry of the product patent, or to mitigate the lack of product patent protection in some countries.[787] The extension of process patent protection may be used by such firms to impede the formulation of pharmaceuticals by domestic firms based on imported active ingredients (if directly obtained by the patented process).

The timely revocation of wrongly granted patents protects the public domain from undue appropriation, thus facilitating the diffusion of knowledge and competition. Members may opt to broadly or narrowly define the grounds for such a revocation. Given the growing number of low quality patents granted in many jurisdictions, due to poor search of the prior art, the application of loose patentability standards, or defects in the specification or claims,[788] accessible and low cost procedures for revocation may avoid costly distortions in the operation of the patent system.[789]

Economists have extensively examined the efficiency implications of the patent system and the optimal patent life. Determining *a priori* the optimal patent life of any given invention is costly and in some cases may simply be impossible. If the patent lasts for a too long period, social costs may exceed the social benefits realized from patents. Such costs notably include a sacrifice in static efficiency[790]

[785] See, e.g., Bently and Sherman, p. 493.

[786] See, e.g., Bentley and Sherman, p. 494.

[787] See, e.g., Carlos Correa, *Reforming the Intellectual Property Rights System in Latin America*, The World Economy 2000, vol. 23, no.6.

[788] See, e.g., Barton, pp. 1933–1934.

[789] Pre-grant opposition mechanisms can also be considered for this purpose. See, e.g., Carlos Correa, *Integrating Public Health Concerns into Patent Legislation in Developing Countries*, South Centre 2000 [hereinafter Correa, 2000a].

[790] It is recalled (cf. supra) that *static efficiency* is achieved when there is an optimum utilization of existing resources at the lowest possible cost, whereas *dynamic efficiency* is the optimal introduction of new products or products of superior quality, more efficient production processes and organization, and (eventually) lower prices over time. While patents may sacrifice static efficiency, to the extent that they stimulate innovation, they may in the long term improve dynamic efficiency.

due to prices above marginal costs, and the costs incurred by competitors in trying to "invent around". While a long period of protection may be justifiable in the case of major inventions, for minor improvements, which nowadays constitute the bulk of patent grants, the optimal period of protection should be shorter and commensurate with the lower investment in skill, time, and resources made by the patentee.[791]

[791] The granting of utility models or "petty patents" for minor inventions may provide a way of approaching this issue (see U Suthersanen, *Incremental inventions in Europe: a legal and economic appraisal of second tier patents*. Journal of Business Law, July 2001, pp 319–343.). Another option is to establish a modest annual maintenance fee for the first several years of a patent's life which thereafter escalates at regular intervals until the patent period is exhausted. In Germany, for instance, the outcome of this approach has been that "fewer than 5% of German patents remain in force for their entire term, the average patent life being a little less than eight years. Thus, the renewal fee system reduces the social costs of patent monopolies. In addition, it has apparently had no adverse effect on inventive activity in Germany" (Robert Cooter and Thomas Ulen, *Law and Economics*, Harper Collins Publishers, USA 1988, p. 138. It should be noted that utility models are also available in Germany.

23: Patents: Exceptions to Rights Conferred

> **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 third parties.

1. Introduction: terminology, definition and scope

Patents confer an exclusive right, that is, the right to prevent others from using (in various forms) the invention, without the authorization of the patent holder. The market power conferred by patents, and the important benefits the patent owner may obtain, constitute one of the essential elements of patent grants. However, the conferred rights are not absolute. Under most patent laws, such rights may not be exercised with regard to certain acts by third parties. This means that under certain specified circumstances, there may be exceptions to the exclusive rights.[792]

The purpose of the exceptions as well as their scope may vary significantly among national laws, depending on the policy objectives pursued in each country. Such exceptions may apply in relation to non-commercial acts (e.g., private use, scientific research) or to commercial acts. In some cases, they aim at increasing static efficiency by speeding up competition (e.g., the early working exception) while in others the main concern is enhancing dynamic efficiency by avoiding barriers to future research (e.g., experimental exception).

Exceptions to patent rights operate automatically, in the sense that there is no need for a party to obtain a specific authorization from a governmental body or judicial court, as it is the case with compulsory licences, to perform the exempted act. As a result, the exceptions may be invoked as a defence in case of alleged infringement by any third party, at any time during the lifetime of the patent.

[792] These exceptions should not be confused with the exceptions to patentability, which exclude a given subject matter from protection and, therefore, lead to the non-granting of a patent (see Article 27, paras. 2 and 3, TRIPS). The exceptions considered here apply when a patent has been granted.

TRIPS does allow the establishment of exceptions to patent rights under specified conditions. Since no equivalent provision was found in the Paris Convention, the negotiating parties relied instead on the text of Article 9(2) of the Berne Convention.[793]

Because Article 30 does not enumerate the specific acts that may be exempted, the kind and scope of the permissible exceptions depend, as discussed below, on the interpretation of the three cumulative conditions set forth by Article 30. National lawmakers face the complex task of defining possible exceptions to patent rights in the light of such conditions. Comparative law and WTO case law may provide useful guidance in the design of this important aspect of patent laws.

2. History of the provision

2.1 Situation pre-TRIPS

Various exceptions to patent rights were provided by national laws at the time of the negotiation and adoption of TRIPS. They included, among others:

- use of the invention for teaching and research;[794]
- commercial experimentation on the invention to test or improve on it;[795]
- experiments made for the purposes of seeking regulatory approval for marketing of a product after the expiration of a patent;[796]
- preparation of medicines under individual prescriptions;
- use of the invention by a third party that had used it *bona fide* before the date of application of the patent ("prior use");
- importation of a patented product that has been lawfully marketed in a foreign country ("parallel imports").[797]

[793] Art. 9(2) of the Berne Convention reads as follows: "It shall be a matter for legislation in the countries of the Union to permit the reproduction of such works in certain special cases, provided that such reproduction does not conflict with a normal exploitation of the work and does not unreasonably prejudice the legitimate interests of the author."

[794] This exception has been admitted, for instance, in the USA, though in a limited manner, basically for scientific purposes (Wegner, 1994, p. 267).

[795] For instance, case law in Europe has accepted research done to find out more information about a product – provided that it is not made just to convince licensing authorities or customers about the virtues of an alternative product – and to obtain further information about the uses of a product and its possible side-effects and other consequences of its use. See W. Cornish, *Experimental Use of Patented Inventions in European Community States*, International Review of Industrial Property and Copyright Law 1998, vol. 29, No.7, p.736 [hereinafter Cornish, 1998].

[796] This is generally known as the "Bolar exception", which was introduced for the first time by the U.S. Drug Price Competition and Patent Term Restoration Act (1984) in order to permit testing of a drug for establishing the bio-equivalency of generic products before the expiration of the relevant patent. This exception is named "Bolar" after a case judged by U.S. courts in *Roche Products Inc. vs. Bolar Pharmaceutical Co.*(733 F. 2d. 858, Fed. Cir., cert. denied 469 US 856, 1984), in which the issue of the exception was dealt with. The court denied Bolar the right to begin the FDA approval process before the expiration of the patent.

[797] Parallel imports may be justified under the "exhaustion principle" as recognized in Article 6 of the TRIPS Agreement and under any national laws, provided that the domestic patent law does not follow a regime of national exhaustion. See Chapter 5.

While these exceptions limit the rights of the patent owner, the purpose and scope of the exempted acts varied considerably. TRIPS has not attempted to constrain the freedom of Members to determine the *grounds* of the possible exceptions, but has established the substantive *conditions* for their admissibility.

2.2 Negotiating history

The negotiation of this provision centred on the scope of the exceptions to be allowed, as well as the way in which it would be formulated. As indicated by the Anell Draft, some of the negotiating parties (notably the European Communities,[798] Brazil[799] and Canada[800]) were inclined to develop a non-exhaustive list of specific exceptions.[801]

2.2.1 The Anell Draft

"2.2 Exceptions to Rights Conferred

2.2 [Provided that legitimate interests of the proprietor of the patent and of third parties are taken into account,] limited exceptions to the exclusive rights conferred by a patent may be made for certain acts, such as:

2.2.1 Rights based on prior use.

2.2.2 Acts done privately and for non-commercial purposes.

2.2.3 Acts done for experimental purposes.

2.2.4 Preparation in a pharmacy in individual cases of a medicine in accordance with a prescription, or acts carried out with a medicine so prepared.

2.2.5A Acts done in reliance upon them not being prohibited by a valid claim present in a patent as initially granted, but subsequently becoming prohibited by a valid claim of that patent changed in accordance with procedures for effecting changes to patents after grant.

2.2.6B Acts done by government for purposes merely of its own use."

2.2.2 The Brussels Draft

The Brussels Draft was essentially identical to Article 30. Compared to the list of specific exceptions under the Anell Draft, both the Brussels Draft and the final TRIPS text adopted more general language, modelled on Article 9(2) of the Berne Convention, without specification of the particular acts that could be exempted.

3. Possible interpretations

3.1 The conditions of Article 30

The admissibility of exceptions to patent rights is subject, under Article 30, to three conditions which in the view of the panel in *Canada-Patent Protection of Pharmaceutical Products*[802] (hereinafter *"EC-Canada"*), are "cumulative, each

[798] See MTN.GNG/NGII/W/26, 7 July 1988 (Section D.a.(i)).

[799] See MTN.GNG/NGII/W/57, 11 December 1989.

[800] See MTN.GNG/NGII/W/47, 25 October 1989.

[801] The U.S. proposal did not address this issue. According to the U.S. delegation, Contracting Parties could "limit the patent owner's rights solely through compulsory licences" (see MTN.GNG/NGII/W/70, 11 May 1990).

[802] WT/DS114/R, 17 March 2000.

being a separate and independent requirement that must be satisfied. Failure to comply with any one of the three conditions results in the Article 30 exception being disallowed."[803] The panel added that

> "The three conditions must, of course, be interpreted in relation to each other. Each of the three must be presumed to mean something different from the other two, or else there would be redundancy.[804] Normally, the order of listing can be read to suggest that an exception that complies with the first condition can nevertheless violate the second or third, and that one which complies with the first and second can still violate the third. The syntax of Article 30 supports the conclusion that an exception may be "limited" and yet fail to satisfy one or both of the other two conditions. The ordering further suggests that an exception that does not "unreasonably conflict with normal exploitation" could nonetheless "unreasonably prejudice the legitimate interests of the patent owner."[805]

Members may provide limited exceptions to the exclusive rights conferred by a patent, . . .

The first condition to be met is that the exception must be "limited". According to its ordinary meaning, "limited" is "confined within definite limits; restricted in scope, extent, amount, etc. It is also "small" in relation to an amount or number; or "low" in relation to an income.[806]

An exception may be deemed limited when it is subject to certain boundaries, for instance, with regard to the acts involved (e.g., importation, exportation, evaluation), the purpose of the use (e.g., for private purposes or education), the outcome of the invention's use (e.g., preparation of individual medicinal prescriptions), the persons that may invoke the exception, or its duration. An exception may be limited in relation to a field of technology as well (e.g., food or pharmaceuticals). While the consistency of this latter kind of limitations with the non-discrimination clause of Article 27.1 was addressed by the panel in the *EC-Canada* case, the panel did not give a definite interpretation of the issue.[807]

[803] Ibid., para. 7.20.

[804] See *United States – Standards for Reformulated and Conventional Gasoline*, WT/DS2/AB/R, p. 23 (adopted 20 May 1996).

[805] *EC-Canada*, WT/DS114/R, 17 March 2000, para. 7.21. The report of the drafting committee for Article 9(2) of the Berne Convention, from which this text was derived, concluded that measures not in conflict with "normal exploitation" could nonetheless prejudice the "legitimate interests" of the copyright owner. The report is quoted in paragraph 7.72 of the *EC-Canada* panel's report.

[806] New Shorter Oxford Dictionary, p. 1592.

[807] The panel held that "Article 27 prohibits only discrimination as to the place of invention, the field of technology, and whether products are imported or produced locally. Article 27 does not prohibit bona fide exceptions to deal with problems that may exist only in certain product areas. Moreover, to the extent the prohibition of discrimination does limit the ability to target certain products in dealing with certain of the important national policies referred to in Articles 7 and 8.1, that fact may well constitute a deliberate limitation rather than a frustration of purpose. It is quite plausible, as the EC argued, that the TRIPS Agreement would want to require governments to apply exceptions in a non-discriminatory manner, in order to ensure that governments do not succumb to domestic pressures to limit exceptions to areas where right holders tend to be foreign producers" (para. 7.92).

The panel provided an interpretation of what "limited" means in Article 30:

> "[. . .] The word 'exception' by itself connotes a limited derogation, one that does not undercut the body of rules from which it is made. When a treaty uses the term "limited exception", the word "limited" must be given a meaning separate from the limitation implicit in the word "exception" itself. The term "limited exception" must therefore be read to connote a narrow exception – one which makes only a small diminution of the rights in question.[808]
>
> [. . .] In the absence of other indications, the Panel concluded that it would be justified in reading the text literally, focusing on the extent to which legal rights have been curtailed, rather than the size or extent of the economic impact. In support of this conclusion, the Panel noted that the following two conditions of Article 30 ask more particularly about the economic impact of the exception, and provide two sets of standards by which such impact may be judged.[footnote omitted] The term "limited exceptions" is the only one of the three conditions in Article 30 under which the extent of the curtailment of rights as such is dealt with."[809]

In adopting a narrow concept of "limited", the panel has focused on the extent of the curtailment and not on the extent of the economic implications thereof. Hence, an exception with little economic effects might be disallowed under this doctrine even if the patent owner is not negatively affected in practice. In the panel's view, the economic impact of the exception must be evaluated under the other conditions of Article 30.

Given that panel reports do not create binding precedents (and the fact that this particular report was not subject to appeal), nothing would prevent future panels and the Appellate Body from adopting a broader concept in this matter, as suggested by Canada in its submission.[810]

> . . . provided that such exceptions do not unreasonably conflict with normal exploitation of the patent . . .

The second condition established by Article 30 is that the exception should not "unreasonably conflict with the normal exploitation" of the patent. This language, substantially borrowed from Article 9(2) of the Berne Convention, requires a determination of what is "unreasonable" in certain circumstances and when there is a "conflict" with the "normal" exploitation of a patent. The literal method of interpretation followed by GATT/WTO panels requires a careful understanding of these key elements.

The concept of "unreasonable" indicates acts that go "beyond the limits of what is reasonable or equitable."[811] "Conflict" means "struggle, clash, be

[808] *EC-Canada*, para. 7.30.

[809] *EC-Canada*, para. 7.31.

[810] See Canada's submission in the *EC-Canada* case relating to limited nature of the products, the persons that may invoke the exception and its duration, and the panel's critical position on these arguments in relation to Article 52.2(2) of the Canadian Patent law (para. 7.37).

[811] The Concise Oxford Dictionary, p. 1176.

incompatible,[812] and "normal" "conforming to standard, regular, usual, typical."[813] Finally, "exploitation" means utilization.[814]

The panel in *EC-Canada* did not address what "unreasonably" means, since its analysis led to the conclusion that there was no "conflict" with the normal exploitation of a patent, and therefore it was not necessary to elucidate whether the Canadian exception was reasonable or not. If a conflict of such kind were found, however, the way in which "unreasonably" were to be interpreted would acquire crucial importance and become a delicate issue.

Members have considerable latitude to interpret what "unreasonable" is. In the last instance, the unreasonableness of an exception will depend on the conceptual framework under which a decision is made. The panel in *EC-Canada*, for instance, took the view that

> "Patent laws establish a carefully defined period of market exclusivity as an inducement to innovation, and the policy of those laws cannot be achieved unless patent owners are permitted to take effective advantage of that inducement once it has been defined."[815]

This statement hints at the panel's conception on the role and objectives of the patent system, a subject on which different positions and theories have been elaborated.[816] It may be argued that while emphasizing stimulation to innovation, the panel's view fails to consider other equally essential objectives of the patent system. The diffusion of knowledge and its continuous improvement are equally important objectives of that system, which in the last instance was instituted to serve the public interest.[817] It is important to note in this regard that in the Doha Ministerial Declaration on the TRIPS Agreement and Public Health, Members stated that

> "In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles."[818]

Developing countries have, in particular, stressed the need to construe the "purpose" of the Agreement and of the protection conferred thereunder on the basis of Article 7 of the Agreement.[819]

[812] The Concise Oxford Dictionary, p. 197.

[813] The Concise Oxford Dictionary, p. 690.

[814] The Concise Oxford Dictionary, p. 340.

[815] *EC-Canada*, WT/DS114/R, 17 March 2000, para. 7.55.

[816] Alan Gutterman, *Innovation and competition policy: a comparative study of regulation of patent licensing and collaborative research & development in the United States and the European Community*, Kluwer Law International, London 1997.

[817] Paul Welfens; John Addison; David Audretsch; Thomas Gries and Hariolf Grupp, *Globalization, Economic Growth and Innovation Dynamics*, Springer, Berlin 1999, p. 138.

[818] Declaration on the TRIPS Agreement and Public Health, WTO document WT/MIN/(01)/DEC/2 of 20 November 2001, para. 5 (a).

[819] See the submission by the African Group, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka,

Another important issue for the interpretation of Article 30 is what is meant by "normal" exploitation. As noted by the panel in *EC-Canada*, "normal" is "regular, usual, typical, ordinary, conventional."[820] The panel also noted

> "the term can be understood to refer either to an empirical conclusion about what is common within a relevant community, or to a normative standard of entitlement. The Panel concluded that the word "normal" was being used in Article 30 in a sense that combined the two meanings."[821]

Patents confer negative rights, that is, the right to exclude any unauthorized use of the invention. In the *EC-Canada* case the panel held that

> "'exploitation' refers to the commercial activity by which patent owners employ their exclusive patent rights to extract economic value from their patent."[822] "The normal practice of exploitation by patent owners, as with owners of any other intellectual property right, is to exclude all forms of competition that could detract significantly from the economic returns anticipated from a patent's grant of market exclusivity. The specific forms of patent exploitation are not static, of course, for to be effective exploitation must adapt to changing forms of competition due to technological development and the evolution of marketing practices. Protection of all normal exploitation practices is a key element of the policy reflected in all patent laws."[823]

. . . and do not unreasonably prejudice the legitimate interests of the patent owner, . . .

Thailand and Venezuela (IP/C/W/296) [hereinafter developing country proposal IP/C/W/296]: "Each provision of the TRIPS Agreement should be read in light of the objectives and principles set forth in Articles 7 and 8. Such an interpretation finds support in the Vienna Convention on the Law of Treaties (concluded in Vienna on 23 May, 1969), which establishes, in Article 31, that "[a] treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose" (para 17). "Article 7 is a key provision that defines the objectives of the TRIPS Agreement. It clearly establishes that the protection and enforcement of intellectual property rights do not exist in a vacuum. They are supposed to benefit society as a whole and do not aim at the mere protection of private rights. Some of the elements in Article 7 are particularly relevant, in order to ensure that the provisions of TRIPs do not conflict with health policies: the promotion of technological innovation and the transfer and dissemination of technology; the mutual advantage of producers and users of technological knowledge; social and economic welfare; and the balance of rights and obligations" (para. 18).

[820] The New Shorter Oxford English Dictionary, p. 1940.

[821] *EC-Canada*, WT/DS114/R, 17 March 2000, para. 7.54. It may be argued, however, that what is "normal" or not entirely depends on an empirical analysis, since the right to exclude the unauthorized making of an invention is not a just a "normal" way of operating, but a legal faculty established by law.

[822] *EC-Canada*, para. 7.54. As the panel explained, "Canada took the position that "exploitation" of the patent involves the extraction of commercial value from the patent by "working" the patent, either by selling the product in a market from which competitors are excluded, or by licensing others to do so, or by selling the patent rights outright. The European Communities also defined "exploitation" by referring to the same three ways of "working" a patent. The parties differed primarily on their interpretation of the term 'normal'" (para. 7.51).

[823] Ibid, para. 7.55.

A further condition of Article 30 requires that the exception does "not unreasonably prejudice the legitimate interests of the patent owner". To "prejudice" means to "impair validity or strength of (right, claim, statement, one's chances, etc)."[824] "Legitimate" means "lawful, proper; regular, conforming to standard type; logically admissible."[825] The *EC-Canada* panel rejected the EC interpretation that "legitimate interests" are essentially "legal" interests. It considered that

> "To make sense of the term "legitimate interests" in this context, that term must be defined in the way that it is often used in legal discourse – as a normative claim calling for protection of interests that are "justifiable" in the sense that they are supported by relevant public policies or other social norms. This is the sense of the word that often appears in statements such as "X has no legitimate interest in being able to do Y".[826]

. . . taking account of the legitimate interests of third parties.

The last condition of Article 30 was absent in the text of Berne Article 9(2) which inspired drafters of Article 30. According to the *EC-Canada* panel,

> "[A]bsent further explanation in the records of the TRIPS negotiations, however, the Panel was not able to attach a substantive meaning to this change other than what is already obvious in the text itself, namely that the reference to the 'legitimate interests of third parties' makes sense only if the term 'legitimate interests' is construed as a concept broader than legal interests."[827]

3.2 Acts that may be exempted

The specification of several particular exempted acts was considered during negotiations (see 2.1, above), but the final text of Article 30 only included a general rule. An analysis of comparative law suggests different types of exemptions that may be provided for in national legislation.

3.2.1 Research and experimentation

Exceptions may be granted for scientific research, that is, for acts made without a commercial intent but merely to generate new knowledge. It may also be possible to exempt acts of experimentation on the invention even if made with commercial purposes,[828] such as in order to "invent around", improve on the protected invention, evaluate an invention in order to request a licence, or for other legitimate purposes, such as to test whether the invention works and the patent granted is valid.

[824] The Concise Oxford Dictionary, p. 810.

[825] The Concise Oxford Dictionary, p. 574.

[826] *EC-Canada*, WT/DS114/R, 17 March 2000, para. 7.69.

[827] Ibid, para 7.71.

[828] The Community Patent Convention, for instance, provides that there is no infringement in case of "acts done for experimental purposes relating to the subject-matter of the patented invention" (Article 27.b).

Without providing a final judgment on the consistency of research exemptions with Article 30, in *EC-Canada*, the panel considered this exception.

> "... as an illustration one of the most widely adopted Article 30-type exceptions in national patent laws – the exception under which use of the patented product for scientific experimentation, during the term of the patent and without consent, is not an infringement. It is often argued that this exception is based on the notion that a key public policy purpose underlying patent laws is to facilitate the dissemination and advancement of technical knowledge and that allowing the patent owner to prevent experimental use during the term of the patent would frustrate part of the purpose of the requirement that the nature of the invention be disclosed to the public. To the contrary, the argument concludes, under the policy of the patent laws, both society and the scientist have a 'legitimate interest' in using the patent disclosure to support the advance of science and technology."[829]

3.2.2 Early working

Another important application of Article 30 may be the "early working" or "Bolar exception".[830] Its purpose is to allow generic drug producers to place their products on the market as soon as a patent expires, and thereby allow consumers to obtain medicines at lower prices immediately thereafter. The *EC-Canada* case confirmed the consistency of an exception of this type with Article 30 (see Section 4, below).

3.2.3 Individual prescriptions

An exception allowing for the preparation of medicines under individual prescriptions also seems compatible with Article 30, and has been in fact provided for in many national laws. This type of exception is generally limited to on-demand medicines prepared for an individual case in a pharmacy or by a medical professional.

3.2.4 Prior use

The *bona fide* use of an invention by a third party before the date of application of the patent is also a common ground for exceptions to the patent exclusive rights. Given the redundancy in science and technology activities, two or more firms or researchers may obtain substantially similar results. In fact, many people are looking for solutions to the same problems, often racing to be the first in reaching a viable (and patentable) solution. The prior use was recognized as valid ground for an exception in the context of the WIPO draft treaty for the harmonization of patent law.[831] The recognition of prior user rights (as provided for, e. g., in Section 64 of the UK Patents Act 1977) has been deemed consistent with the European Patent Convention,[832] and is to be considered compatible with TRIPS.

[829] *EC-Canada*, para. 7.69.

[830] For an explanation of this term, see above, Section 2 of this chapter.

[831] See Article 20 of the draft treaty presented at the Diplomatic Conference held in The Hague in 1991.

[832] Some member states of the European Patent Convention recognise prior user rights, and some do not. Since this situation may inhibit the free movement of goods between member states of the European Union and the European Economic Area, the European Parliament and Council could

3.2.5 Parallel imports

Article 30 may also allow derogations with regard to the exclusive right to import, when a patented product has been lawfully marketed in a foreign country (generally called "parallel imports"). Article 28 states that a patent shall confer on its owner, where the subject matter is a product, the exclusive right to prevent unauthorized third parties from "importing" the product for the purposes of making, using, offering for sale, or selling. In a footnote, however, it is clarified that the exclusive right of importation, "like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6."[833]

4. WTO jurisprudence

4.1 EC-Canada

In the *EC-Canada* case, the interpretation of Article 30 was extensively addressed by the panel,[834] in relation to the "Bolar exception" as contemplated in Section 55.2 of Canadian patent law, which provided:

> "(1) It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.
>
> (2) It is not an infringement of a patent for any person who makes, constructs, uses or sells a patented invention in accordance with subsection (1) to make, construct or use the invention, during the applicable period provided for by the regulations, for the manufacture and storage of Articles intended for sale after the date on which the term of the patent expires."

The panel found consistent with TRIPS obligations paragraph (1) of this Article, but inconsistent the stockpiling provision as contained in paragraph (2).

The panel noted that, in the framework of TRIPS,

> "[. . .] which incorporates certain provisions of the major pre-existing international instruments on intellectual property, the context to which the Panel may have recourse for purposes of interpretation of specific TRIPS provisions, in this case Articles 27 and 28, is not restricted to the text, Preamble and Annexes of the TRIPS Agreement itself, but also includes the provisions of the international instruments on intellectual property incorporated into the TRIPS Agreement [. . .]."[835]

legislate for their member states to remove inhibitions hindering the free movement of goods between their member States.

[833] Article 6 of the TRIPS Agreement states that: "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." For details, see Chapter 5.

[834] *Canada – Patent Protection of Pharmaceutical Products*, WT/DS114/R, 17 March 2000. However, as mentioned, the panel did not consider necessary to examine all elements in Article 30 in order to reach its conclusion. It neither addressed when a conflict with the patent owner would be "unreasonable", nor the meaning of the final phrase of the Article (relating to the legitimate interests of third parties).

[835] *EC-Canada*, para. 7.14.

On this basis, the panel considered that Article 9(2) of the Berne Convention for the Protection of Literary and Artistic Works (1971)

> "[. . .] is an important contextual element for the interpretation of Article 30 of the TRIPS Agreement."[836]

As a consequence of the extended context that the panel took into account, it concluded that

> "the interpretation may go beyond the negotiating history of the TRIPS Agreement proper and also inquire into that of the incorporated international instruments on intellectual property."[837]

Though according to the EC, Articles 7 and 8 were to be deemed statements that describe the balancing of goals that had already taken place in negotiating the final texts of TRIPS, in the panel's view:

> "Article 30's very existence amounts to a recognition that the definition of patent rights contained in Article 28 would need certain adjustments. On the other hand, the three limiting conditions attached to Article 30 testify strongly that the negotiators of the Agreement did not intend Article 30 to bring about what would be equivalent to a renegotiation of the basic balance of the Agreement. Obviously, the exact scope of Article 30's authority will depend on the specific meaning given to its limiting conditions. The words of those conditions must be examined with particular care on this point. Both the goals and the limitations stated in Articles 7 and 8.1 must obviously be borne in mind when doing so as well as those of other provisions of the TRIPS Agreement which indicate its object and purposes."[838]

The panel found that the exception contained in 55.2(1) of the Canadian law - including activities seeking product approvals in foreign countries – was "limited" within the meaning of Article 30:

> "The exception is 'limited' because of the narrow scope of its curtailment of Article 28.1 rights. As long as the exception is confined to conduct needed to comply with the requirements of the regulatory approval process, the extent of the acts unauthorized by the right holder that are permitted by it will be small and narrowly bounded. Even though regulatory approval processes may require substantial amounts of test production to demonstrate reliable manufacturing, the patent owner's rights themselves are not impaired any further by the size of such production runs, as long as they are solely for regulatory purposes and no commercial use is made of resulting final products."[839]

Though the EC argued that an early working obligation, as provided by the Canadian law, should be linked to an extension of the patent term, as conferred in

[836] Ibid.
[837] Ibid, para. 7.15.
[838] Ibid, para. 7.26.
[839] Ibid, para. 7.45.

Europe, Switzerland and the USA, the panel dismissed this argument. It stressed that

> "the interest claimed on behalf of patent owners whose effective period of market exclusivity had been reduced by delays in marketing approval was neither so compelling nor so widely recognized that it could be regarded as a 'legitimate interest' within the meaning of Article 30 of the TRIPS Agreement. Notwithstanding the number of governments that had responded positively to that claimed interest by granting compensatory patent term extensions, the issue itself was of relatively recent standing, and the community of governments was obviously still divided over the merits of such claims. Moreover, the Panel believed that it was significant that concerns about regulatory review exceptions in general, although well known at the time of the TRIPS negotiations, were apparently not clear enough, or compelling enough, to make their way explicitly into the recorded agenda of the TRIPS negotiations. The Panel believed that Article 30's 'legitimate interests' concept should not be used to decide, through adjudication, a normative policy issue that is still obviously a matter of unresolved political debate."[840]

In relation to the "stockpiling provision", Canada argued that the curtailment of the patent owner's legal rights was "limited" just so long as the exception preserved the exclusive right to sell to the ultimate consumer during the patent term. However, in the panel's view

> "the question of whether the stockpiling exception is a 'limited' exception turns on the extent to which the patent owner's rights to exclude 'making' and 'using' the patented product have been curtailed. The right to exclude 'making' and 'using' provides protection, additional to that provided by the right to exclude sale, during the entire term of the patent by cutting off the supply of competing goods at the source and by preventing use of such products however obtained. With no limitations at all upon the quantity of production, the stockpiling exception removes that protection entirely during the last six months of the patent term, without regard to what other, subsequent, consequences it might have. By this effect alone, the stockpiling exception can be said to abrogate such rights entirely during the time it is in effect."[841]

Another important issue considered by the Panel was whether the market advantage gained by the patent owner in the months after expiration of the patent could also be considered a purpose of the patent owner's rights to exclude "making" and "using" during the term of the patent. It held that

> "[I]n both theory and practice, the Panel concluded that such additional market benefits were within the purpose of these rights. In theory, the rights of the patent owner are generally viewed as a right to prevent competitive commercial activity by others, and manufacturing for commercial sale is a quintessential competitive commercial activity, whose character is not altered by a mere delay in the commercial reward. In practical terms, it must be recognized that enforcement of the

[840] Ibid, para. 7.82.

[841] Ibid, para. 7.34.

> right to exclude 'making' and 'using' during the patent term will necessarily give all patent owners, for all products, a short period of extended market exclusivity after the patent expires. The repeated enactment of such exclusionary rights with knowledge of their universal market effects can only be understood as an affirmation of the purpose to produce those market effects."[842]

The panel dismissed Canada's argument that the fact that the exception could only be used by those persons having utilized the regulatory review exception of Section 55.2(1) limited the scope of the exception both to those persons and to products requiring regulatory approval, and that the stockpiling exception was also "limited" because it only applied for six months before the expiry of the patent. The panel held that "each exception must be evaluated with regard to its impact on each affected patent, independently" and that the fact that the exception applied only to the last six months of the patent term obviously reduced its impact on all affected patented products. It agreed with the EC that six months was a commercially significant period of time, especially since there were no limits at all on the volume of production allowed, or the market destination of such production.

Finally, it is important to note that, in the panel's view, both Articles 30 and 31 are subject to the non-discrimination clause contained in Article 27.1.[843] This interpretation has been contested, however, by a number of developing countries.[844]

4.2 United States-Section 110(5) of the US Copyright Act

In *United States-Section 110(5) of the US Copyright Act*,[845] a panel examined the three criteria under Article 13 (the exception clause in the copyright Section of the Agreement).[846] Given that both provisions were inspired by Article 9(2) of the Berne Convention (1971), some considerations made in such analysis may also be relevant to the interpretation of exceptions under Article 30.

[842] Ibid, para. 7.35.

[843] "Article 27.1 prohibits discrimination as to enjoyment of 'patent rights' without qualifying that term. Article 30 exceptions are explicitly described as 'exceptions to the exclusive rights conferred by a patent' and contain no indication that any exemption from non-discrimination rules is intended. A discriminatory exception that takes away enjoyment of a patent right is discrimination as much as is discrimination in the basic rights themselves. The acknowledged fact that the Article 31 exception for compulsory licences and government use is understood to be subject to the non-discrimination rule of Article 27.1, without the need for any textual provision so providing, further strengthens the case for treating the non-discrimination rules as applicable to Article 30. Articles 30 and 31 are linked together by the opening words of Article 31 which define the scope of Article 31 in terms of exceptions not covered by Article 30" (para. 7.91 of the panel's report). The panel considered an "acknowledged fact" the application of the non-discrimination clause to Article 31, because both Canada and the EC agreed on this interpretation of Article 31. See Chapter 25.

[844] See para. 33 of developing country proposal IP/C/W/296.

[845] WT/DS160/R of 15 June 2000. For a detailed analysis of this case, see Chapter 12 of this book.

[846] This provision stipulates that: "Members shall 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."

5. Relationship with other international instruments

5.1 WTO Agreements

5.2 Other international instruments

As pointed out in this chapter of the book, Article 30 has a clear link with Article 9 (2) of the Bern Convention.

6. New developments

6.1 National laws

National patent laws adopted or amended after the adoption of TRIPS have established different types of exceptions to the patent holder's exclusive rights. A general review of patent laws in developing countries, however, reveals that the room left by Article 30 has only been used in a limited manner so far.

In many countries an explicit exception has been provided for research conducted for "scientific purposes".[847] In other countries, acts for experimental purposes have been specifically exempted, under different conditions. In Mongolia, for instance, it is not an infringement to make use of an invention "for scientific research or experimental purposes."[848] In Taiwan Province of China a third party is allowed to use the invention for "research or experimental purposes only, with non-profit acts or intention involved therein."[849]

The laws of many countries also included exceptions for "experimental purposes", without limiting them to non-commercial acts, such as the law of Botswana,[850] Turkey,[851] Trinidad and Tobago,[852] Bhutan,[853] El Salvador,[854] and Singapore.[855]

Argentina implemented a "Bolar exception" under Law 24.766 of 1996, allowing for experimentation and application for approval of a generic product before the expiration of the respective patent (Article 8). This exception is not linked to the extension of the patent term.

Israel introduced in 1998 provisions, modelled on the U.S. law,[856] allowing third parties to experiment, before the expiration of a patent, for obtaining registration for marketing in Israel or in a foreign country with a similar exception. The law not only permits the use of the invention to undertake local trials but the export

[847] E.g., Guinea-Bissau, Decreto-Ley of 1996, Article 4.c.

[848] Patent Law of 1993, as amended in 1997, Article 18.2.1.

[849] Patent Law, as amended in 1994 and 1997, Article 57.1.

[850] As amended in 1997, Article 24.3.a.iii.

[851] Law of 1996, Article 75.b.

[852] Act No. 21 of 1996, Article 42.b.

[853] The Industrial Property Regulations, 1997, Article 4.a.iii.

[854] Law No. 35, 1996, Article 19.2.

[855] Patents Act, 1994, as amended in 1995, Article 66.2.b.

[856] The U.S. Drug Price Competition and Patent Term Restoration Act of 1984, which adopted the "Bolar exception", permitted the extension of the patent term so as to compensate pharmaceutical patent owners for the time consumed by the marketing approval of a drug, up to five years.

of materials in small quantities to initiate approval procedures before the expiry of the patent in the countries that allow it. It also grants an extension of the life of the patent for up to five years (or for 14 years from first registration worldwide or upon expiration of an extension granted elsewhere, whichever terminates the earliest). Australia also adopted an exception of this kind, linked to the extension of the patent term.

The "Bolar exception" was also incorporated into Article 43 of the Brazilian Industrial Property Code by Law 10.196 of 14 February 2001.

Though in Europe this exception has not been formally introduced yet,[857] the German Federal Supreme Court accepted a "Bolar" type exception in *Boehringer Ingelheim Int. GmbH v. Dr. Rentschler Arzneimittel GmbH and others* (11.7.95). The Court stated that "... it is not contrary to the permissibility of clinical tests that the defendants are carrying out or supporting these with the further aim of licensing under the laws relating to pharmaceuticals". In another decision (*Wellcome Foundation Ltd. vs. Parexel International and others* (1.1.98)), the Paris Court of Appeal held that undertaking tests for obtaining marketing approval did not constitute infringement as such.

Explicit derogations to the exclusive right to import have been provided for in some laws under the principle of "exhaustion of rights". This is the case, for instance, of Argentina,[858] the Andean Group countries (Decision 486), South Africa (for medicines),[859] and Kenya.

6.2 International instruments

6.3 Regional and bilateral contexts

6.3.1 Regional

6.3.2 Bilateral

The USA-Jordan agreement explicitly permits the parties to adopt a "Bolar" type exception, including for exports when made to meet regulatory requirements in a foreign country. Article 19 of the agreement states that

> "If a Party permits the use by a third party of a subsisting patent to support an application for marketing approval of a product, the Party shall provide that any product produced under this authority shall not be made, used or sold in the territory of the Party other than for purposes related to meeting requirements

[857] The European Parliament has expressed its opinion in favour of the admission of a "Bolar" type exception. In its resolution of 16 April 1996, paragraph 17, it stated that: "Measures should be introduced which enable pharmaceutical companies to begin, in advance of patent or supplementary protection certificate (SPC) expiry, such laboratory experiments and regulatory preparations as may be required only for the registration of generic pharmaceuticals developed in the EU, to be available on the market immediately, but only after the expiry of a patent or SPC for a proprietary product".

[858] The implementing regulation (Decree 260/96), however, significantly reduces the scope of such exception.

[859] The permission to parallel import is incorporated in the Medicines Act, which was challenged before the South African Supreme Court on this and other grounds by the pharmaceutical industry. The complaint, nevertheless, was withdrawn in April 2001.

> for marketing approval, and if export is permitted, the product shall only be exported outside the territory of the Party for purposes of meeting requirements for marketing approval in the Party or in another country that permits the use by a third party of a subsisting patent to support an application for marketing approval of a product".

The same type of exception is permitted under Article 17.9.4 of the USA-Chile FTA.

6.4 Proposals for review

There have been no proposals for review of Article 30.

7. Comments, including economic and social implications

The economic and social implications of the exceptions allowed under Article 30 are significant. The exceptions mitigate the potential anti-competitive effects of the exclusive rights and may thereby increase static or dynamic efficiency.

Thus, the experimental use exception, particularly if permitted for *commercial* purposes, may speed up follow-on innovation and further technological progress. It may clearly enhance dynamic efficiency, without reducing static efficiency.

The "Bolar exception", as indicated above, permits an early introduction of competitive products, normally pharmaceuticals, as soon as the patent expires and thereby allows consumers to gain access to medicines at lower prices. In the absence of such exception, the introduction of generic copies may be delayed for several months or years, during which the patent owner might charge high prices despite the expiry of the patent. This exception increases static efficiency; since the patent holder will be able to keep its monopoly till the expiry of the patent, it is unlikely to reduce dynamic efficiency. An analysis of the welfare implications of the Act that introduced this exception in the USA indicated that

> "... from the perspective of economic welfare, the Act is the source of large potential positive gains of two types. First, it eliminated costly scientific testing which served no valid purpose. Second, the Act lowered prices to consumers with some elimination of deadweight losses and large transfers from producers to consumers."[860]

The exception of prior use is based on reasons of justice (it is not fair to prevent the use of an invention to those who possessed it and did not apply for a patent) as well as static efficiency. The existence of an alternative supply to the patent owner may drive prices down and benefit consumers.[861]

[860] See, e.g., W. Viscusi; John Vernon and Joseph Harrington, *Economics of regulation and antitrust*, Second Edition, The MIT Press, Cambridge 1997, p. 857.

[861] Note that several of the above exceptions were also referred to by the IPR Commission report (p. 119). In addition to those exceptions, the Commission also proposed an exception for *teaching purposes* (ibid.) and highlights the importance of such exemption, due to the increasing encroachment of patent rights into traditional copyright areas such as computer programs.

Finally, parallel imports as an exception to exclusive patent rights may be a powerful tool to increase allocative efficiency.[862] If consumers can acquire from a foreign country legitimate products at lower prices than those locally charged by the patent holder, there is an increase in static efficiency without necessarily reducing dynamic efficiency: the patent holder has been remunerated (in the foreign market) for the intellectual contribution he has made. Of course, the levels of profit obtained by the patent holder may be lower than those obtainable if he/she were able to fragment markets and charge a higher price in the importing country, but this does not mean that the owner would not be able to recover R&D expenditures.

The pharmaceutical industry has claimed that the admission of parallel imports may endanger future R&D. It has argued that the exports of drugs sold at low cost in developing countries to higher-priced markets would affect the industry's ability to fund future R&D.[863] It has been argued, however, that trade in medicines is subject to quite stringent national regulations that erect effective barriers to market access. Moreover, parallel imports would only take place where significant price differentials exist. Pharmaceutical firms may reduce such differentials or sell the patented products under different trademarks or packaging in major markets, in order to make parallel importation difficult or unattractive.[864] Developed countries that consider their industries to be jeopardized by "parallel exports" from low price countries may adopt measures to prevent parallel imports under their national legislation. Thus, the IPR Commission in its Report recommended that

> "Developed countries should maintain and strengthen their legislative regimes to prevent imports of low priced pharmaceutical products originating from developing countries."[865]

At the same time, it has been suggested that in order to keep a system of tier pricing and prevent low-priced medicines in developing countries from flowing to developed countries, the former should adopt measures to prevent their exportation.[866]

[862] For a general analysis of the exhaustion doctrine under the TRIPS Agreement, see Chapter 5. For a discussion of parallel imports in the trademark context, see Chapter 14.

[863] Arguments against parallel trade also include the objection that it will increase opportunities for "counterfeit and substandard products to enter the market" (Harvey Bale, *TRIPS, Pharmaceuticals and Developing Countries: Implications for Drug Access and Drug Development*, paper presented at the WHO Workshop on the TRIPS Agreement and its Impact on Pharmaceuticals, IFPMA, Jakarta 2000, p. 18), but this is essentially a problem of law enforcement that can be addressed under normal procedures.

[864] See, e.g., Jayashree Watal, *Pharmaceutical patents, prices and welfare losses: a simulation study of policy options for India under the WTO TRIPS Agreement*, Washington DC 2000 (mimeo).

[865] See IPR Commission report, p. 41. This could be done by the adoption or maintenance in developed countries of a system of national or regional exhaustion of intellectual property rights. For more details on the principle of exhaustion, see Chapter 5.

[866] Thus, the U.S. delegation held at the Council for TRIPS Special Session of June 21, 2001, that "In our view, advocates of parallel importation overlook the fact that permitting such imports discourages patent owners from pricing their products differently in different markets based upon the level of economic development because of the likelihood that, for example, products sold for low prices in a poor country will be bought up by middle men and sent to wealthiest country markets and sold at higher prices, for the benefit primarily of the middle men. The lack of parallel

Finally, as far as the situation in developing countries is concerned, the IPR Commission recommended that:

> "Developing countries should not eliminate potential sources of low cost imports, from other developing or developed countries. In order to be an effective pro-competitive measure in a scenario of full compliance with TRIPS, parallel imports should be allowed whenever the patentee's rights have been exhausted in the foreign country. Since TRIPS allows countries to design their own exhaustion of rights regimes (a point restated at Doha), developing countries should aim to facilitate parallel imports in their legislation."[867]

import protection can also have significant health and safety implications. Our law enforcement and regulatory agencies, especially FDA, have commented on how very difficult it is for them to keep counterfeit and unapproved drugs out of our country even with the strong parallel import protection provided in the United States. Advocating parallel imports, therefore, could work to the disadvantage of the very people on behalf of whom the advocates purport to be speaking." As Dr. Brundtland in Oslo noted, "For differential pricing to work on a large scale, I think we can all agree that there must be watertight ways of preventing lower priced drugs from finding their way back into rich country markets."

[867] IPR Commission report, p. 42. A possible means to realize this objective would be the adoption in developing countries of an international regime of exhaustion, contrary to the national/regional exhaustion regimes recommended for developed countries, see above.

24: Patents: Disclosure Obligations

> 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.

1. Introduction: terminology, definition and scope

A patent application includes the specification, the claims and the summary of the invention. The specification (or description) of the invention is generally written like a science or engineering report describing the problem the inventor faced, the prior art and the steps taken to solve the problem. In some jurisdictions, the applicant must also provide a characterization of the "best mode" of solving the problem, in order to facilitate others' practicing the invention upon the expiry of the patent by revealing the best-known way (at the time of the patent application) of doing so.[868]

The essential goals of the specification are to substantiate the evidence of completion of the act of invention,[869] that is, whether the inventor has effectively made a patentable invention; and to make new technical information available to the public so others are able to recreate the invention and improve upon it.[870]

[868] See, e.g. Jay Dratler (Jr.), *Intellectual property law: commercial, creative and industrial property*, vol. 1, Law Journal Seminars-Press, New York 1996, p. 2-85 [hereinafter Dratler, 1996].

[869] See, e.g., Mark Janis, *On courts herding cats: contending with the "written description" requirement (and other unruly patent disclosure doctrines)*, Washington University Journal of Law and Policy 2000, vol. 2, p. 68 [hereinafter Janis].

[870] See, e.g., Robert Merges and Richard Nelson, *On limiting or encouraging rivalry in technical progress: the effect of patent-scope decisions*, The Journal of Economic Behaviour and Organization 1994, No. 25, p. 129 [hereinafter Merges and Nelson].

Disclosure has historically been one of the fundamental principles of patent law. It provided one of the early justifications for the granting of patents.[871] The justification of patent rights based on disclosure was in some cases put in the form of a "social contract" theory: "society makes a contract with the inventor by which it agrees to grant him the exclusive use of the invention for a period and in return the inventor agrees to disclose technical information in order that it will later be available to society."[872]

Another part of the patent application is a set of claims which should define, in precise terms, what the inventor considers to be the specific scope of the invention.[873] The patent claims serve a quite different function from the specification: they distinguish the inventor's intellectual property from the surrounding terrain,[874] that is, they define the technological territory that cannot be invaded by third parties without risking an infringement suit. The way this is done varies from jurisdiction to jurisdiction. As explained in Chapter 17 (Section 1), some countries take a literal approach, whereas others rely on the doctrine of functional equivalents.

The specification and claims are closely related. There must be a correlation between the scope of the disclosure and the scope of the claims. The former should "support" the latter, in order to ensure that the exclusivity granted to the patent owner is justified by the actual technical contribution to the art.[875]

TRIPS includes specific obligations on the disclosure of the invention, but leaves WTO Members the freedom to determine its relationship with the claims and, in particular, the complex issue of claims interpretation.[876]

2. History of the provision

2.1 Situation pre-TRIPS

While the specific requirements of the obligation to disclose the invention and their practical enforcement (by patent offices and courts) vary among countries,

[871] "In the absence of protection against imitation by others, an inventor will keep his invention secret. This secret will die with the inventor and society will lose the new art. Hence, a means must be devised to induce the inventor to disclose his secret for the use of future generations. This can best be done by granting him an exclusive patent which protects him against imitation" (Edith T. Penrose, *The economics of the international patent system*, The Johns Hopkins Press, Baltimore 1951, p. 32 [hereinafter Penrose]).

[872] Penrose, p. 32. Lord Mansfield was perhaps the first jurist to formulate the social contract theory when, in a 1778 case, he pronounced that "the law relative to patents requires, as a price the individual should pay the people for his monopoly, that he should enrol, to the very best of his knowledge and judgment, the fullest and most sufficient description of all the particulars on which the effect depended, that he was at the time able to do". *Liardet v. Johnson*, [1778] 1 WPC 52 at 54.

[873] The claims are the "metes and bounds" of patent rights, see *Markman v. Westview Instruments Inc.*, 517 US, 370, 372 (1996).

[874] See, e.g., Merges and Nelson, p. 129.

[875] For a discussion on this relationship under U.S. and European law, see Janis, pp. 55–108.

[876] See, e.g., John Duffy, *On improving the legal process of claims interpretation: administrative alternatives*, Washington University Journal of Law and Policy 2000, vol. 2, reproduced in Richard R. Nelson, *The sources of economic growth*, Harvard University Press, Cambridge (USA)-London (UK), 1996, pp. 109–166; Carlos Correa, *Integrating Public health Concerns into Patent Legislation in Developing Countries*, South Centre 2000, p. 81 [hereinafter Correa, 2000a].

such obligation was a well established element in patent law at the time of the negotiation of TRIPS.

The best mode requirement (which, as discussed below, is not mandatory under the Agreement) was well established under U.S. law, despite some ambiguities,[877] but it was not provided for in the legislation of most other countries, including in Europe and Japan. Moreover, the obligation (also non-mandatory) to provide information concerning the applicant's corresponding foreign applications and grants had no significant precedents, if any.

2.2 Negotiating history

2.2.1 The Anell Draft

"3. Obligations of Patent Owners

The owner of the patent shall have the following obligations:

3.1 to disclose prior to grant the invention in a clear and complete manner to permit a person versed in the technical field to put the invention into practice [and in particular to indicate the best mode for carrying out the invention];

(See also point 1.3 above)[878]

3.2 to give information concerning corresponding foreign applications and grants;

3.3B to work the patented invention in the territory of the Party granting it within the time limits fixed by national legislation;

3.4B in respect of licence contracts and contracts assigning patents, to refrain from engaging in abusive or anticompetitive practices adversely affecting the transfer of technology, subject to the sanctions provided for in Sections 8 and 9 below."

The draft provision on "obligations of the patent owner" was one of the most controversial in the whole TRIPS negotiations, since developing countries tried to incorporate an obligation to work the patented invention locally (see paragraph 3.3B, above). Equally, developing countries sought to include a clause against abusive or anticompetitive licensing practices on the part of patent holders (see paragraph 3.4B, above).

2.2.2 The Brussels Draft

The first two draft paragraphs were essentially the same as under the current Article 29. In addition, the Brussels Draft still contained references to a local working obligation and abusive or anti-competitive licensing practices. By contrast to

[877] See, e.g., Dratler, 1996, pp. 2–85; Charles Hauff, *The best mode requirement of the U.S. patent system*, in Michael Lechter (Ed.), *Successful Patents and Patenting for Engineers and Scientists*, IEEE Press, New York 1995, p. 219.

[878] Point 1.3 of the Anell Draft referred to patentable subject matter and provided: "Requirements such as filing of an adequate disclosure in a patent application and payment of reasonable fees shall not be considered inconsistent with the obligation to provide patent protection." See Chapter 17.

the Anell Draft, however, these obligations were optional:

> "3. PARTIES may provide that a patent owner shall have the following obligations:
>
> (a) To ensure the [working] [exploitation] of the patented invention in order to satisfy the reasonable requirements of the public. [For the purposes of this Agreement the term "working" may be deemed by PARTIES normally to mean manufacture of a patented product or industrial application of a patented process and to exclude importation.]
>
> [(b) In respect of licensing contracts and contracts assigning patents, to refrain from engaging in abusive or anti-competitive practices adversely affecting the transfer of technology.]
>
> 4. PARTIES may adopt the measures referred to in Articles [31, 32 and 40][879] below to remedy the non-fulfillment of the obligations mentioned in paragraph 3 above."

In the subsequent negotiations, the working obligation disappeared from the final text of Article 29 as a result of the compromise struck in December 1991, which was reflected in the wording of Article 27.1 *in fine*. Article 29, as adopted, was finally limited to matters relating to the disclosure of the invention for purposes of examination and of execution of the invention after the expiry of the patent term. The clause on anti-competitive licensing practices was moved to the more general provision under Article 40, TRIPS, thus disconnecting it from the patent application procedure.

3. Possible interpretations

Article 29 contains one mandatory and two facultative elements. First, it requires Members to disclose the invention "in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art". It, thus, unsurprisingly incorporates the "enablement" requirement, as usually established in national patent laws.[880] Such requirement aims at ensuring that patents perform their informative function, by demanding that the patent specification enable those skilled in the art to make and use the full scope of the invention without undue experimentation.[881]

Second, Article 29.1 introduces, in a facultative manner, the best mode requirement inspired by U.S. law. This requirement aims at preventing inventors from obtaining protection while concealing from the public the preferred embodiments

[879] As in the final TRIPS text, the referenced Articles referred to compulsory licensing, revocation/forfeiture of patents and the control of anti-competitive licensing practices.

[880] Under current U.S. law, for instance, the enablement doctrine is codified in 35 U.S.C. No. 112, para. 1 (1984) which provides that "[T]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention".

[881] The directions given in the specification for performing the invention must be such as to enable the invention to be carried into effect without an excessive number of experiments. See, for instance, the English case of *Plimpton v Malcolmson* (1876) 3 Ch D 531, 576.

of their inventions. Unlike the enablement requirement, which requires an objective analysis, the best mode requirement is a subjective one: what constitutes the best mode of executing the invention depends upon what the inventor knew and considered to be the best way of executing his invention, at the time of the filing of the patent application[882] or the priority date.[883] This information rarely includes the actual know-how for the execution of the invention, since at the time of filing there is seldom production experience.

Third, Article 29 allows Members to require information concerning the applicant's corresponding foreign applications and grants. Such information may be important, particularly for patent offices in developing countries, in order to improve and speed up the examination process. However, such requirement does not affect the basic principle of independence of patent applications.[884] The Agreement does not refer to the consequences of the failure to comply with this requirement. However, since this requirement may be a condition imposed on patent applicants, an application may be rejected if the applicant fails to provide the referred to information.

The Agreement leaves considerable room for the implementation of the standards provided for in Article 29. WTO Members could for example strictly implement these standards with a view to facilitating competitive innovation, adapting protected inventions to local conditions, or merely practicing them once the term of protection expires.[885]

Another aspect left to WTO Members is the extent to which the applicant would be obliged, if several embodiments of the invention were claimed, to provide sufficient information to enable the reproduction of *each* embodiment for which the applicant seeks patent protection. A strict enablement requirement may mandate disclosure of each embodiment.[886] This approach would prevent excessively broad patents covering embodiments of the invention that have not been described

[882] See, e.g., Dratler, 1996, pp. 2–86.

[883] The priority date means the date on which the first application was made, in accordance with Article 4 of the Paris Convention. The purpose of this right is to enable someone who has filed a patent application in one country to file posterior applications for the same patent in the other countries of the Paris Union. In this scenario, it is possible that a third person in one of these other countries files an application for the same patent before the original applicant has a chance to deposit his application for that country. The priority date results in the recognition of the original filing in all the other Paris Union countries. Thus, any applications by third persons intervening between the original filing in one country and any subsequent filings by the original applicant in the other countries will be considered posterior to the original filing. The condition is, however, that the subsequent filings in the other countries be effectuated within 12 months from the date of filing of the first application. For details, see Article 4A, B, C of the Paris Convention.

[884] "Patents applied for in the various countries of the Union by nationals of countries of the Union shall be independent of patents obtained for the same invention in other countries, whether members of the Union or not" (Paris Convention for the Protection of Industrial Property, Article 4*bis*(1) (1967)).

[885] See, e.g., UNCTAD, 1996, p. 33.

[886] However, some patent offices, such as the European Patent Office, accept that, in order to be valid, the description need not include specific instructions as to how all possible variants within the claim definition can be obtained. See, e.g., Trevor Cook, Catherine Doyle, and David Jabbari, *Pharmaceuticals biotechnology & The Law*, Stockton Press, New York 1991, p. 80.

by the applicant in a form that effectively allows their reproduction by a third party.

It may also be possible for Members to introduce a written description requirement in order to determine whether patent disclosure reasonably conveys to one skilled in the art that the inventor possessed the claimed subject matter at the time of filing the application.[887]

Further, Members may define how the relationship between the specification and the claims is to be considered,[888] as well as the method of interpretation of claims. Moreover, WTO Members may decide whether such requirements would be applied during original examination of the application by the patent office and/or on occasion of post-grant opposition procedures.[889]

One important issue not addressed by TRIPS relates to the disclosure of inventions relating to micro-organisms[890] and other biological materials. In these cases, the written description is insufficient; access to the relevant knowledge is only possible through access to the biological material itself.[891] Such access may be permitted to third parties (for experimental purposes) after the publication of the patent application, as provided under European law, or after the patent grant, such as in the case of the USA.

Finally, a controversial issue is whether national laws may require that the patent applicant inform the country of origin of the biological material, and/or demonstrate that the applicant has complied with the relevant rules with regard to access to such material. This requirement[892] would help to ensure compliance with the benefit sharing provisions of the Convention on Biological Diversity, and to avoid possible misappropriation ("biopiracy") of genetic resources and associated knowledge.

The consistency of such additional requirement[893] with Articles 27.1 and 29 has been questioned, particularly if non-compliance would lead to the rejection of the patent application or the invalidation of a granted patent.[894] According to the U.S.

[887] The negotiating history of Article 29.1 would indicate, however, that there was not intention to incorporate a "written description" requirement. See, e.g. Janis, p. 59 and 88, fn. 133.

[888] For instance, under the European Patent Convention the claims must be "clear and concise and be supported by the description" ("support requirement") (Article 84).

[889] This means that a third party may challenge a patent granted by arguing that the disclosure is not sufficient for a person skilled in the art to carry out the invention. See Janis, p. 89.

[890] The Budapest Treaty (1977) has created a system for the international recognition of the deposit of microorganisms that facilitates the tasks of patent offices and provides guarantees to the applicants/patent holders.

[891] It is important to ensure that the scope of protection for biological material patents corresponds to the material actually deposited. If there is no correspondence between the description and the deposited material, the patent (or claim) may be deemed void.

[892] An obligation of this type was incorporated in the draft of the European Union Directive relating to patents on biotechnology, as recommended by the European Parliament in July 1997. Though it was removed from the finally approved text, Recital 27 of the Directive mentions an obligation to provide information as to geographical origin of biological material where this is known, without prejudice to patent validity. See European Directive on Biotechnological Inventions No. 96/9/EC of March 11, 1996.

[893] Which has been established in some national laws (see Section 6.1 below).

[894] "The origin of the genetic resources and of other circumstances related to their acquisition is not generally necessary for the invention to be carried out by a person skilled in the art", Pires de

government, imposing such requirement would be

> "an extremely ineffective way for countries that are the source of genetic resources or traditional knowledge . . . In addition, imposing additional requirements on all patent applicants only increases the cost of obtaining patents that would have a greater adverse effect on individual inventors, non-profit entities, and small and medium sized businesses, including those in developing countries."[895]

For some WTO Members, this matter would require an amendment of the Agreement (see Section 6.4 below). It has also been suggested that the acquisition and enforcement of rights in inventions, knowingly derived directly or indirectly from an illegal act, such as the unauthorized acquisition of genetic resources, may be deemed abusive. As a result, patents so obtained may be deemed valid but not enforceable.[896]

4. WTO jurisprudence

There have been no cases under the DSU on this matter.

5. Relationship with other international instruments

5.1 WTO Agreements

There are no other WTO Agreements relevant to this subject.

5.2 Other international instruments

The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (1977), amended in 1980[897] constitutes a union for the international recognition of the deposit of micro-organisms for the purposes of patent procedure. Contracting States allowing or requiring the deposit of micro-organisms for the purposes of patent procedure shall recognize, for such purposes, the deposit of a micro-organism with any international depositary authority.

It is also interesting to note that at the meeting of the WIPO Standing Committee on the Law of Patents on September 6–14, 1999, Colombia proposed the

Nuno Carvalho, *Requiring disclosure of the origin of genetic resources and prior informed consent in patent applications without infringing the TRIPS Agreement: The problem and the solution*, Re-Engineering Patent Law 2000, vol. 2, p. 380 [hereinafter Pires de Carvalho].

[895] See WTO DOC. IP/C/W/162 (Oct. 29, 1999).

[896] See, e.g. Pires de Carvalho, p. 395 and 399. This option would be based on the "fraudulent procurement doctrine": "if patent applicants fail to be candid on matters that may have an impact on the final decision on patentability, such as novelty or inventiveness, then the patent may be invalidated. When the lack of candor regards matters that are not essential to the grant or rejection of the patent, then fraudulent procurement is sanctioned by non-enforceability. Enforceability is restored when the patent owner corrects the misrepresentations or other inequitable conducts-in other words, when *he cleans his hands"*. (ibidem, p. 397).

[897] With a membership of 59 countries as of 15 July 2004 (see <http://www.wipo.int/treaties/en/registration/budapest/index.html>).

following language (not finally adopted) to be included in the proposed Patent Law Treaty:

> "1. All industrial property protection shall guarantee the protection of the country's biological and genetic heritage. Consequently, the grant of patents or registrations that relate to elements of that heritage shall be subject to their having been acquired legally.
>
> 2. Every document shall specify the registration number of the contract affording access to genetic resources and a copy thereof where the goods or services for which protection is sought have been manufactured or developed from genetic resources, or products thereof, of which one of the member countries is the country of origin."

6. New developments

6.1 National laws

In the Indian Patents (Second Amendment) Act, 2002, the grounds for rejection of the patent application, as well as revocation of the patent, include non-disclosure or wrongful disclosure of the source of origin of biological resource of knowledge in the patent application, and anticipation of knowledge, oral or otherwise. It has also been made incumbent upon patent applicants to disclose in their patent applications the source of origin of the biological material used in the invention.[898]

In 2000, Denmark amended the Patent Act, in part to implement the EC Directive on Biotechnological Inventions (see 6.3.1 below). Accordingly, based on the Act, the existing ministerial regulation on patents was amended by supplementing its paragraph 3 with the following provision:

> "If an invention concerns or makes use of biological material of vegetable or animal origin, the patent application shall include information on the geographical origin of the material, if known. If the applicant does not know the geographical origin of the material, this shall be indicated in the application. Lack of information on the geographical origin of the material or on the ignorance hereon does not affect the assessment of the patent application or the validity of the rights resulting from the granted patent.
>
> Breach of this provision could imply a violation of the obligation in the Danish Penal Code (par. 163) to provide correct information to a public authority."

Article 31 of Brazil's Provisional Measure No. 2.186–16 on access and benefit sharing (23 August 2001) provides that:

> "The grant of industrial property rights by the competent bodies for a process or product obtained using samples of components of the genetic heritage is

[898] In addition, Section 6 of the Indian Biological Diversity Act, 2002, states that anybody seeking any kind of intellectual property rights on a research based upon biological resource or knowledge obtained from India, needs to obtain prior approval of the National Biodiversity Agency (NBA). The NBA will impose benefit-sharing conditions. Section 18 (iv) stipulates that one of the functions of NBA is to take measures to oppose the grant of IPRs in any country outside India on any biological resource obtained from India or knowledge associated with such biological resource.

> contingent on the observance of this Provisional Measure, the applicant being obliged to specify the origin of the genetic material and the associated traditional knowledge, as the case may be."

In a similar vein, Article 13 of the Egyptian Law on the protection of intellectual property rights, 2002, provides as follows:

> "Where the invention involves biological, plant or animal product, or traditional medicinal, agricultural, industrial or handicraft knowledge, cultural or environmental heritage, the inventor should have acquired the sources in a legitimate manner."

6.2 International instruments

Article 3 of the draft Substantive Patent Law Treaty[899] contains rules on disclosure and description of the inventions. Paragraph 1 of Article 3 establishes that:

> "[. . .] The disclosure of the invention in the application as a whole shall be adequate, if, as of the date of filing of the application, it sets forth the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art, as prescribed in the Regulations."

In addition, paragraph 2 of Article 3 establishes that

> "[. . .] In respect of the disclosure, no requirement additional to or different from those provided for in paragraph (1) may be imposed."

6.3 Regional and bilateral contexts

6.3.1 Regional

Under the "Common Regime on Access to Genetic Resources" of the Andean Group patent applicants are obliged to provide patent offices with information concerning the origin of the genetic resource in question and some proof of prior informed consent from government authorities as well as traditional knowledge holders.[900] Any intellectual property right or other claims to resources shall not be considered valid, if they were obtained or used in violation of the terms of a permit for access to biological resources residing in any of the Andean countries, as regulated under that Decision.

[899] Draft 5 of 19 December 2000, available at <http://www.wipo.org/scp/en/documents/session_5/pdf/splt_5.pdf>. Note that this draft has not yet turned into any legally binding agreement. Contrary to the TRIPS Agreement, which only sets up *minimum standards* for patents, this exercise aims at the international *harmonization* of substantive patent law. On an earlier draft of 1991 see WIPO, *Records of the Diplomatic Conference for the Conclusion of a Treaty Supplementing the Paris Convention as far as Patents are Concerned*, vol. 1: "First Part of the Diplomatic Conference, the Hague", Geneva 1991, pp. 15–16 [hereinafter WIPO, 1991]. The draft Substantive Patent Law Treaty has to be distinguished from the WIPO "Patent Law Treaty", adopted on 1 June, 2000. The latter constitutes a legally binding agreement, but it is limited to *procedural* provisions and does not make any attempt to harmonize *substantive* patent law. It is available at <http://www.wipo.int/clea/docs/en/wo/wo038en.htm>.

[900] See Common Regime on Access to Genetic Resource, Andean Decision 391 of 02 July 1996. See also in this context the Biodiversity Law (No. 7788) of Costa Rica, enacted on 27 May 1998.

The EC Directive on Biotechnological Inventions[901] alludes in Recital 27 to an obligation to provide information as to the geographical origin of biological material where this is known, without prejudice to patent validity.

6.4 Proposals for review

As analyzed in Chapter 21, Members of the Council for TRIPS have been discussing ways to address the unauthorized patenting of genetic material and associated traditional knowledge. In this context, developing country Members have been advocating the amendment of TRIPS to include, as a requirement for the granting of the patent, the applicant's obligation to disclose the origin of the genetic material at issue.[902] The African Group has proposed an amendment of Article 29 that would result in a *mandatory* disclosure requirement:

> "Compared to other alternatives, Article 29 of the TRIPS Agreement seems to be the most suitable for an appropriate modification to contain these rights and obligations, by including the requirements for equity, disclosure of the community of origin of the genetic resources and traditional knowledge, and a demonstration of compliance with applicable domestic procedures. These requirements would formalise what in the view of the Group should be expected of all such patent applications. Given the failure of certain domestic systems to prevent patents that constituted a misappropriation of genetic resources and traditional knowledge, these requirements would be useful in preventing or minimising the repetition or even the increase of such cases.
>
> The Group suggests that Article 29 be modified by adding the following as paragraph 3: 3. Members shall require an applicant for a patent to disclose the country and area of origin of any biological resources and traditional knowledge used or involved in the invention, and to provide confirmation of compliance with all access regulations in the country of origin."[903]

Some developed country Members, on the other hand, have expressed their opposition to enforcing disclosure of origin of genetic resources through the patent system (see Chapter 21).[904] Switzerland, while acknowledging that a disclosure obligation should be dealt with under the patent system, has proposed to pursue the matter outside the WTO, i.e. through an amendment of the WIPO Patent

[901] No. 96/9/EC of March 11, 1996.

[902] Next to the disclosure of origin requirement, these proposals also include obligations for the patent applicant to prove evidence of prior informed consent and fair and equitable benefit sharing in respect of the country where the genetic material originates. See the Joint Communication from the African Group, IP/C/W/404 of 26 June 2003 [hereinafter African Group June 2003] and the Submission by Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, India, Peru, Thailand, Venezuela, IP/C/W/403 of 24 June 2003. See also the checklist submitted to the Council for TRIPS on 2 March 2004 by Brazil, Cuba, Ecuador, India, Peru, Thailand and Venezuela (IP/C/W/420).

[903] See African Group June 2003, p. 6.

[904] The EC has signalled agreement to discuss a disclosure requirement, but is opposed to treating this issue under the patent system. See Communication from the European Communities and their Member States to the Council for TRIPS of 17 October 2002, IP/C/W/383.

Cooperation Treaty, making disclosure a *voluntary* requirement for the patent grant.[905]

7. Comments, including economic and social implications

The nature of the patent bargain requires the patent applicant to make a full disclosure of the matter claimed for his benefit.[906] This serves two purposes.

First, the information contained in patent specifications is an important tool for research and the advancement of technology. Access to this information, nowadays facilitated by the availability of several on-line and off-line databases, provides a useful tool to industry and scientific institutions.

Second, the technical information carried in a patent has to be put at the unrestricted disposal of the public at the expiry of the term of protection. The patent owner obtains a temporary monopoly, subject to the condition that the society at large may benefit from full use of the information once that term has elapsed.

The achievement of these two purposes critically depends on the completeness and quality of the patent description. If the applicant were able to conceal from the public the information necessary to execute the invention, these purposes would be defeated.

Moreover, the grant of a right to exclude is only justified when the inventor can prove actual possession of the information claimed to be inventive. The description, therefore, may play the dual role of ensuring full disclosure as well as limiting the scope of protection to what the applicant has actually invented.[907]

Ensuring the completeness and quality of patent disclosure, in a manner accessible to local researchers and industry, is essential in developing countries. Patent offices should pay attention to the quality of translation into the domestic language. However, the mere translation of patent applications as originally filed in other countries may not be sufficient in some developing countries to enable third parties to practice the invention.[908] Patent offices may, hence, adopt rules requiring the proper identification and description of inventions in a manner understandable to local people skilled in the art.

Compliance by Members with Article 29 does not seem problematic, since the mandatory elements contained therein are in line with well-established practice in patent law. Members are free to introduce into national laws the non-mandatory elements of that provision. They would in general benefit from incorporating the

[905] See IP/C/W/400l, p. 2: "Based on the PLT, national law may foresee that the validity of granted patents is affected by a lacking or incorrect declaration of the source, if this is due to fraudulent intention." Reiterated in IP/C/W/423 and the June 2004 Meeting of the TRIPS Council.

[906] See, e.g. Peter Groves, *Source Book on Intellectual Property Law*, Cavendish Publishing Limited, London 1997, p. 202.

[907] The importance of this limitation of the scope of protection was also stressed by the IPR Commission in its report, in particular with respect to the patenting of genetic material. The Commission recommended (p. 118): "If developing countries allow patents over genes as such, regulations or guidelines should provide that claims be limited to the uses effectively disclosed in the patent specification, so as to encourage further research and commercial application of any new uses of the gene."

[908] See, e.g., UNCTAD, 1996, para. 132.

best mode requirement,[909] as well as the obligation to provide information about foreign applications and grants. In addition, Members enjoy considerable room to determine the specific contours of the disclosure obligations, as well as the relationship between description and claims and the form of interpretation of the latter.

Wherever this is possible, manufacturers prefer to keep processes secret. Indeed the sum total of know-how, both patentable and non-patentable, is often what gives the competitive edge, enabling the production of better products at affordable prices. Furthermore, trade secrets have the major advantage that they are unlimited in duration. For example, the secret process used for producing a well-known brand of Swiss spreading cheese goes back many generations, and the Swiss parent company goes to considerable lengths to ensure that its licensees around the world do not learn the secret. Thus, manufacturers will tend to disclose only to the extent that competitors could themselves reproduce the product were it not covered by a patent. It is this fact that weakens the utility of the patent systems as a source of information for developing countries.

As mentioned above, the disclosure of the origin of biological materials claimed in patent applications may have important economic implications. Such a disclosure would not be a necessary condition to but would facilitate claims of benefit sharing (under national access legislation in line with the CBD) by states from which the materials have been acquired. Many developing countries have significant expectations (albeit not confirmed in practice so far) about the income that compliance with benefit sharing obligations may generate.

Disclosure of the origin of biological materials may also facilitate the monitoring of patent grants in order to eventually challenge their validity, when states or other stakeholders consider that a misappropriation ("biopiracy") has taken place. A critical issue in relation to the disclosure of origin is the extent to which such disclosure, if made compulsory, would be deemed compatible with obligations under TRIPS, particularly if non-compliance may lead to the revocation of a patent.

[909] See also the IPR Commission recommendation (on p. 117 of the report) that "Developing countries should adopt the best mode provision to ensure that the patent applicant does not withhold information that would be useful to third parties."

25: Patents: Non-Voluntary Uses (Compulsory Licences)

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:

(a) authorization of such use shall be considered on its individual merits;

(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;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

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

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

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

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(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;

(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

[Footnote]*: "Other use" refers to use other than that allowed under Article 30.

1. Introduction: terminology, definition and scope

Article 31 regulates the practice commonly known as compulsory licensing. A compulsory licence is an authorization granted by a government to a party other than the holder of a patent on an invention to use that invention without the consent of the patent holder. The patent itself is a charter from a government in favour of a particular person that gives that person certain rights. The compulsory licence acts to restrain the exercise of those private rights in the public interest. The compulsory licence is one mechanism through which governments limit the private power that resides in the grant of patents. It acknowledges that in various contexts the public interest in having technical knowledge more immediately accessible should take precedence over other patent interests.

Article 31 addresses "Other Use Without the Authorization of the Right Holder", and refers in its introductory clause to "other use [footnote: "Other use" refers to use other than that allowed under Article 30] of the subject matter of a patent without the authorization of the right holder". This awkward formulation reflects

the effort by the drafters to distinguish between "limited exceptions" that are authorized under Article 30, and compulsory licensing authorized under Article 31. Article 31 (compulsory licensing) addresses the interests of patent holders in particular cases – a compulsory licence is directed to an identified patent and authorized party – while Article 30 exceptions may involve legislation of more general effect on patent holders and authorized parties.

Article 31 does not attempt to specify or limit in any way the grounds upon which such licences may be granted. It sets up procedures that governments are expected to follow when they grant a licence, and describes certain terms that compulsory licences should embody. The procedures and terms vary depending on the contexts in which the compulsory licence is employed.

The Declaration on the TRIPS Agreement and Public Health adopted at the Doha Ministerial Conference states:

> "Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted."[910]

2. History of the provision

2.1 Situation pre-TRIPS

Prior to TRIPS, countries throughout the world maintained legislation authorizing the grant of compulsory licences. The terms of this legislation varied considerably. A number of countries, such as Canada[911] and India,[912] provided for "licences of right" in certain subject matter areas, such as food and pharmaceutical patents, so that after a minimum time period prescribed by the Paris Convention, any person with an interest in exploiting a patent was automatically entitled to a compulsory licence.[913] The laws of most or all countries allowed the government to use any patent for national security purposes. Patent laws included various other public interest grounds on which compulsory licences might be granted. These grounds included non-working of the patent within the national territory, failure to meet demand for the patented invention on reasonable terms, and as remedy for anticompetitive practices. For instance, a large number of compulsory licences have been granted in the USA in order to remedy anticompetitive practices.[914]

[910] Declaration on TRIPS and Public Health, WTO Ministerial Conference, Fourth Session, Doha, 9–14 Nov. 2001, WT/MTN(01)/DEC/W/2, 14 Nov. 2001, at para. 5(b).

[911] See description of Canada's pre-1993 compulsory licensing system in *Canada – Patent Protection of Pharmaceutical Products*, Report of the Panel, WT/DS114/R, March 17, 2000 (hereinafter "*EC-Canada*"), at para. 4.6. See in particular Reichman, Hasenzahl, *The Canadian Experience*. See also the "Common Industrial Property Regime" (Decision 85) of the Andean Community.

[912] See Elizabeth Henderson, *TRIPs and the Third World: The Example of Pharmaceutical Patents in India*, 19 EUR J. INT. PROP. REV. 651, 658–59 (1997), discussing Patents Act of 1970. Note that since India did not grant food and pharmaceutical product patents, the licence of right related only to process patents in these areas.

[913] Canada's legislation was modelled on British patent law that provided for licences of right in the pharmaceutical and food sectors prior to amendment in 1977. See Cornish, 1998, pp. 7–43

[914] See, e.g., Carlos Correa, *Intellectual property rights and the use of compulsory licences: options for developing countries*, Trade-Related Agenda, Development and Equity, Working Papers,

The principal international agreement concerning patents, the Paris Convention, recognizes the right of its state parties to grant compulsory licences to remedy abuses of patent rights, including failure to work the patent (Paris Convention, Article 5A). Although the Paris Convention prescribes a minimum period of time before a compulsory licence may be applied for (3 or 4 years depending on the circumstances), it does not otherwise limit the grant of such licences, and does not establish a right of compensation on behalf of patent holders. Controversy over the appropriate scope of compulsory licensing is cited as one of the reasons TRIPS negotiations were initiated.[915] In the late 1970s and early 1980s, developing country demands for a New International Economic Order included greater access to technology. These demands were manifest in negotiations on revision of the Paris Convention. These negotiations broke down in 1982, in significant part because of competing demands concerning compulsory licensing. The failure of these negotiations convinced industry interests that they would not succeed in solving what they viewed as the "intellectual property problem" at WIPO. This led to a refocusing of IPR efforts towards the GATT.

2.2 Negotiating history

2.2.1 Early national proposals

The United States played a major role in the inclusion of the TRIPS negotiations in the Uruguay Round, and its initial November 1987 "Proposal for Negotiations on Trade-Related Aspects of Intellectual Property Rights" stated in regard to compulsory licensing:

> "Governments should generally not grant compulsory licenses to patents and shall not grant a compulsory license where there is a legitimate reason for not practicing the invention such as government regulatory review. If a government grants a compulsory license, it shall not discriminate against inventions in particular fields of technology and it shall provide for full compensation to the patentee for the license. No compulsory license shall be exclusive."[916]

In July 1988, the European Community submitted to the TRIPS Negotiating Group an alternate proposal regarding an agreement, stating in respect to compulsory licensing:

> "The granting of compulsory licences for lack or insufficiency of exploitation, compulsory licences in respect of dependent patents, official licences, and any

South Centre, Geneva 1999. See also UNCTAD-ICTSD, Jerome H. Reichman and Catherine Hasenzahl, *Non-Voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the United States of America*, also available at <http://www.iprsonline.org/unctadictsd/projectoutputs.htm#casestudies>. See also the case study by the same authors specifically focusing on the U.S experience, forthcoming.

[915] *Id.*, at 3–17 to 3–18. See also Frederick Abbott, Thomas Cottier, and Francis Gurry, *The International Intellectual Property System: Commentary and Materials*, Kluwer Law 1998, pp. 717–718.

[916] Suggestion by the United States for Achieving the Negotiating Objective, United States Proposal for Negotiations on Trade-Related Aspects of Intellectual Property Rights, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, MTN.GNG/NG11/W/14, 20 Oct. 1987, Nov. 3, 1987.

right to use patented inventions in the public interest shall, in particular in respect of compensation, be subject to review by a court of law."[917]

In July 1989, India submitted a detailed paper that proposed an approach to compulsory licensing that would authorize licensing for non-working, and licences of right in areas such as food, pharmaceuticals and agricultural chemicals.[918] Fair compensation under a licence of right would be determined as a matter of local law.[919]

At a meeting of the TRIPS Negotiating Group in July 1989, the subject of compulsory licensing was discussed extensively, particularly in relation to the issue of non-working of patents,[920] and it was further considered at a meeting in October-November 1989.[921]

2.2.2 The Anell Draft

Under the Anell Draft, the "A" text introductory clause on compulsory licensing stated: "PARTIES shall minimize the grant of compulsory licences in order not to impede adequate protection of patent rights".[922] It listed specific and limited grounds on which licences might be granted, including "On the grounds of the public interest concerning national security, or critical peril to life of the general public or body thereof".[923] This text specifically addressed the local working requirement, providing "Compulsory licences for non-working or insufficiency of working on the territory of the granting authority shall not be granted if the right holder can show that the lack or insufficiency of local working is justified by the existence of legal, technical or commercial reasons".[924] Compulsory licensees would have been allowed only to supply the local market ("Compulsory licences shall be granted to permit manufacture for the local market only").[925] At this stage, the authority that would be responsible for reviewing the grant was bracketed: ("Any decision relating to the grant and continuation of compulsory licences and the compensation provided therefore shall be subject to [judicial review] [review by a distinct higher authority]").[926]

[917] Guidelines and Objectives Proposed by the European Community for the Negotiations on Trade-Related Aspects of Substantive Standards of Intellectual Property Rights, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, MTN.GNG/NG11/W/26, July 1988, at III.D.3.a(iv).

[918] Communication from India, Standards and Principles Concerning the Availability, Scope and Use of Trade-Related Intellectual Property Rights, MTN.GNG/NG11/W/37, 10 July 1989.

[919] At that stage in the TRIPS negotiations, India objected to the establishment of "any new rules and disciplines pertaining to standards and principles concerning the availability, scope and use of intellectual property rights."

[920] Note by the Secretariat, Meeting of Negotiating Group of 12–14 July 1989, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, MTN.GNG/NG11/14, 12 September 1989.

[921] Note by the Secretariat, Meeting of Negotiating Group of 30 October–2 November 1989, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, MTN.GNG/NG11/16, 4 December 1989, at para. 34.

[922] See document MTN.GNG/NG11/W/76, Section 5: Patents, 5A.1.

[923] Section 5A.2.2b.

[924] Section 5A.3.2.

[925] Section 5A.3.5.

[926] Section 5A.3.10.

In the Anell Draft, the only compulsory licensing text specifically designated "B" was the following:

> "5B Nothing in this Agreement shall be construed to prevent any PARTY from taking any action necessary: (i) for the working or use of a patent for governmental purposes; or (ii) where a patent has been granted for an invention capable of being used for the preparation or production of food or medicine, for granting to any person applying for the same a licence limited to the use of the invention for the purposes of the preparation or production and distribution of food and medicines. (See also point 2.1B(c) above and Section 8 below)"

Records of the meeting of the TRIPS Negotiating Group subsequent to the Chairman's summary indicate substantial resistance on the part of developing countries to the strict limits suggested by the developed countries regarding grounds for compulsory licensing.

2.2.3 The Brussels Draft

The Brussels Ministerial Text[927] included an article on compulsory licensing (Article 34) that approximated the Dunkel Draft and final TRIPS Agreement text, but with several important differences.[928] The Brussels Draft eliminated any enumeration of permissible grounds for granting compulsory licences, and instead

[927] Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Revision, Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, MTN.TNC/W/35/Rev. 1, 3 Dec. 1990.

[928] Article 34, Brussels Draft, provided:

"Article 34: Other Use Without Authorisation of the Right Holder

Where the law of a PARTY allows for other use[6] of the subject matter of a patent without the authorisation of the right holder, including use by the government or third parties authorised by the government, the following provisions shall be respected:

(a) Each case of such use shall be considered on its individual merits.

(b) Such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorisation 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 PARTY in the case of a national emergency or other circumstances of extreme urgency. In such situations, the right holder shall, nevertheless, be notified as soon as is reasonably practicable.

(c) The scope and duration of such use shall be limited to the purpose for which it was authorised.

(d) Such use shall be non-exclusive.

(e) Such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use.

(f) Any such use shall be authorised predominantly for the supply of the domestic market of the PARTY authorising such use.

(g) Authorisation for such use shall be liable to be terminated when the circumstances which led to it cease to exist and are unlikely to recur, subject to adequate protection of the legitimate interests of the persons so authorised. The competent authority shall have the authority to review, upon request, the continued existence of these circumstances.

(h) The right holder shall be paid fair and equitable adequate remuneration in the circumstances of each case, taking into account the economic value of the licence.

(i) The legality of any decision relating to the authorisation of such use shall be subject to judicial review or other independent review by a distinct higher authority in that PARTY.

(j) Any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that PARTY.

(k) Laws, regulations and requirements relating to such use may not discriminate between fields of technology or activity in areas of public health, nutrition or environmental protection or where necessary for the purpose of ensuring the availability of a product to the public at the lowest possible price consistent with giving due reward for the research leading to the invention.

focused on the processes by which such licences might be granted and the terms that such licences should contain.

In the Brussels Draft, "public non-commercial use" is addressed in a clause (Article 34(o)), separate from the provision regarding national emergency and circumstances of extreme urgency (compare Article 31(b), TRIPS Agreement). It was envisaged that public non-commercial use might provide exemption from at least some requirements of the compulsory licensing rules applicable in other contexts. Language intended to address U.S. legislation under which notice to the patent holder is not required was included.

The terms "fair and equitable" appeared before "adequate" in the general clause on remuneration of the patent holder (Article 34(h), Brussels Draft), as well as in the clause on public non-commercial use.

At the Brussels Draft stage, the principle that reviews would be undertaken either by a judicial authority or a distinct higher authority was accepted.

A provision on non-discrimination was at this stage incorporated directly in the draft article on compulsory licensing, rather than in the draft article on patentable subject matter (as it appears in the final TRIPS Agreement text). That clause of Article 34, Brussels Draft, provided:

> "(k) Laws, regulations and requirements relating to such use may not discriminate between fields of technology or activity in areas of public health, nutrition or environmental protection or where necessary for the purpose of ensuring the availability of a product to the public at the lowest possible price consistent with giving due reward for the research leading to the invention."

The language of draft clause (k) is ambiguous. For example, it is not clear what the phrase beginning "or where necessary for the purpose of ensuring the

(l) PARTIES are not obliged to apply the conditions set forth in sub-paragraphs (b) and (f) above where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. Appropriate remuneration may be awarded in such cases.
(m) Where such use is authorised to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:
(i) the invention claimed in the second patent shall involve an important technical advance in relation to the invention claimed in the first patent and, where the invention claimed in the second patent is a process, such process shall be one of considerable economic significance;
(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and
(iii) the use authorised in respect of the first patent shall be non-assignable except with the assignment of the second patent.
(n) Authorisation by a PARTY of such use on grounds of failure to work or insufficiency of working of the patented product or process shall not be applied for before the expiration of a period of four years from the date of filing of the patent application or three years from the date of grant of the patent, whichever period expires last. Such authorisation shall not be granted where importation is adequate to supply the local market or if the right holder can justify failure to work or insufficiency of working by legitimate reasons, including legal, technical or economic reasons.
(o) Notwithstanding the provisions of sub-paragraphs (a)–(k) above, where such use is made for public non-commercial purposes by the government or by any third party authorised by the government, PARTIES are not obliged to apply the conditions set forth in sub-paragraphs . . . above in such cases. Where it comes to the knowledge of the government that a patent is being exploited under the provisions of this sub-paragraph, the government shall ensure that the patent owner is informed and is fairly and equitably adequately compensated."

availability. . . " is directed toward. It might have been intended to prohibit the use of compulsory licensing to address pricing in particular fields, such as pharmaceutical products. Yet the combination of the phrase "may not discriminate" with "where necessary" produces a confusing result. Exceptions under Article XX, GATT 1947, were typically framed in the context of "necessity". The preclusion of "necessary" measures for public health would seem a result inconsistent with GATT practice. In the final TRIPS Agreement text, language requiring consistency of "necessary" public health measures with the terms of TRIPS appears in Article 8 (Principles).

Clause (l), Brussels Draft, provides in relation to remedying anticompetitive practices that Members "may" award appropriate remuneration. In Article 31(k), TRIPS, the need to correct anticompetitive practices "may be taken into account" in determining remuneration.

Clause (n), Brussels Text, expressly addressed non-working of patents, providing:

> "(n) Authorisation by a PARTY of such use on grounds of failure to work or insufficiency of working of the patented product or process shall not be applied for before the expiration of a period of four years from the date of filing of the patent application or three years from the date of grant of the patent, whichever period expires last. Such authorisation shall not be granted where importation is adequate to supply the local market or if the right holder can justify failure to work or insufficiency of working by legitimate reasons, including legal, technical or economic reasons."

This clause was not included in the Dunkel Draft or final TRIPS Agreement text. The first sentence would have essentially incorporated the time period prescribed by Article 5A(4), Paris Convention (which was effectively incorporated by reference in Article 2, Brussels Text, and Article 2, TRIPS Agreement text). The second sentence would have substantially affected "local working" requirements. The final TRIPS text, as discussed above, incorporates in Article 27.1 a rule that patent rights shall be enjoyable without discrimination as to whether products are imported or locally produced.

There were virtually no changes between the Dunkel Draft and the final TRIPS text on compulsory licensing.

As reflected in the statements by delegations, one of the main obstacles to conclusion of the text on compulsory licensing concerned debate over the right of governments to grant such licences on grounds of non-working. There were a number of negotiating texts on this subject proposed throughout the negotiations, but negotiators could not agree on a direct solution. The issue was indirectly addressed by Articles 27.1[929] and Article 70.6 of TRIPS.[930]

[929] See Chapter 18.

[930] This Article states that "Members shall not be required to apply Article 31, or the requirement in paragraph 1 of Article 27 that patent rights shall be enjoyable without discrimination as to the field of technology, to use without the authorization of the right holder where authorization for such use was granted by the government before the date this Agreement became known."

3. Possible interpretations

Article 31 does not purport to limit the grounds on which compulsory licences may be granted. If a WTO Member chooses to provide for such licences, then certain conditions must be fulfilled.

3.1 Individual merits

> (a) authorization of such use shall be considered on its individual merits;

The first of these conditions is that each licence should be considered on its individual merits (Article 31(a)). The ordinary sense of this would be that governments should not attempt to grant blanket authorizations of compulsory licences pertaining to types of technologies or enterprises, but instead should require each application for a licence to undergo a process of review to determine whether it meets the established criteria for the granting of a licence.

The practice of the United States in authorizing government use of patents, well known at the time of the adoption of Article 31 (and accounting for much of its peculiar language), indicates that the requirement of review of individual merits may be interpreted flexibly. Under U.S. law, the government may use any patented invention (or authorize its contractor to use such invention) without providing prior notification to the patent holder, subject only to the patent holder's right to initiate a proceeding before the Court of Claims for compensation. The U.S. patent holder may not obtain an injunction against such government use. This suggests that in cases of government use of a patent the consideration of individual merits can take place after the licence is granted and relate only to the question of compensation.

The requirement that licences be considered on their individual merits does not mean that presumptions may not be established in favour of granting licences in particular contexts, placing the burden on patent holders to overcome the presumptions. For example, a compulsory licensing statute might provide that the absence of supply on the local market of a patented product at an affordable price justifies the grant of a compulsory licence, placing the burden on the patent holder to demonstrate that there are adequate supplies of products on the local market at affordable prices.

The question of who must consider the individual merits of the licence is addressed below.

3.2 Prior negotiations

> (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;

Article 31 generally requires that a party seeking a compulsory licence first undertake negotiations with the patent holder for a voluntary licence on "reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time". This requirement is inherently flexible since the concept of reasonable terms and period of time will depend on context.

3.2.1 Commercial terms and conditions

If the applicant for a compulsory licence claims that it sought and failed to obtain a licence from the patent holder on reasonable commercial terms, the authority considering the application may need to decide whether the patent holder's position on compensation was reasonable.

Patent licences generally involve the payment of a royalty from the licensee to the patent holder. A royalty is a usage fee the amount of which may be calculated on different bases. As examples, a royalty may be payable based on the number of units of a licensed product made or sold, or it may be payable based on the licensee's net income from sales of the product. A royalty may be a fixed amount payable at periodic intervals.

The customary royalty for licensing of a patented product or process will vary from industry to industry, and within each industry, depending on the value of the particular technology involved. The royalty on a highly advanced new technology that was developed through substantial expenditures on research and development (R&D) is generally going to be higher than the royalty on a mature technology that might be nearing the end of its life-cycle. The level of royalty will also depend upon either the proven or anticipated success of the product in the market place.

Much of the global flow of patent royalties is internal to multinational enterprises that are transferring income and expenses among their operating units in different countries, and will often depend on factors such as minimization of tax burdens. In order to derive a reasonable royalty based on customary practices in an industry, it may be necessary to disregard evidence of intra-enterprise royalty payments.[931]

Royalty rates are discussed further below in regard to payment of compensation to patent holders.

[931] Typically, the negotiator seeking a commercial patent licence will seek to minimize the level of payments to the patent holder, and the patent holder will seek to maximize its stream of income. The patent holder might not seek the highest possible royalty rate since the aggregate amount of its income stream may depend on the level of sales of the patented product, and an excessive royalty might diminish its overall return.

The rate of royalty to be paid is not the only commercial term or condition that is important to a party seeking a licence. Other important elements include:

1. Duration of the licence term. The licensee must make sure that it will be able to use the technology for as long as is necessary to recover and earn a reasonable return on any investments it will be making.

2. Additional technology. Patent applications often do not disclose enough information to allow the practical exploitation of the technology without additional trade secret or other knowledge gained by the patent holder through practical experience. The extent to which the patent holder will aid in the implementation of technological solutions may substantially affect the value of the patent to the licensee.

3. Grant-backs. Patent licensees often develop improvements on inventions which have substantial commercial value. A patent licensor may seek to require that the licensee "grant back" to it any improvement on the invention. The extent of the licensee's obligations in this area will affect the value of the licence to both parties.

4. Tying Arrangements. Patent holders may seek to require licensees to purchase components of the patented product, ancillary products, unrelated products, or support services as conditions of granting a licence. Licensees risk being locked into higher than market commitments through these kinds of arrangements, and demands for undertaking such commitments will affect the value of a licence.

5. Export restrictions. Patent owners often impose on voluntary licences restrictions on the export of the licensed product. This may limit the ability of the licensee to achieve economies of scale in its production facilities.

3.2.2 Reasonable period of time

A patent holder that does not wish to licence its technology, but that also does not wish to see a compulsory licence granted, may well attempt to prolong negotiations using a variety of tactics. Such tactics may include appearing to be engaged in serious negotiations over detailed terms and conditions that do not reach a conclusion. Negotiators seeking licences on reasonable commercial terms are perfectly justified in setting an outer limit for successfully concluding licences, and refusing to negotiate beyond that point.

The reasonable time for negotiations may depend on the purpose for which the licence is sought. As example, a negotiator seeking to commence production of a life-saving pharmaceutical would be justified in seeking a more rapid conclusion of negotiations than a negotiator seeking to commence production of an improved fishing rod.

3.2.3 Waiver of prior negotiations

Under certain conditions, prior negotiation with the patent holder need not be pursued. These are the cases of:

1. "national emergency";
2. "other circumstances of extreme urgency"; or
3. "public non-commercial use".

The language used to define each of these cases leaves room for interpretation. Many countries have laws under which the executive or other authority may formally declare a situation of national emergency, and this declaration may lead to the suspension of certain otherwise applicable constraints. For example, in a situation of national emergency the executive may be able to rule by decree in areas that would normally require parliamentary assent. The terms "other circumstances of extreme urgency" make clear that a waiver of the prior negotiations requirement does not depend upon a formal declaration of national emergency. Even if a country's laws make specific provision for declarations of national emergency from which defined consequences flow, this does not mean that this specific provision needs to be invoked. As example, a government might declare the pandemic spread of a disease to constitute a national emergency, although it is not generally intending to alter the normal pattern of constitutional government.

The use of the term "extreme" in connection with "urgency" suggests that more than a preference to move quickly to authorize a licence is involved in invoking this waiver. The term "extreme" refers to the far end of the spectrum of urgency, but it is not possible to lay out a general rule as to what differentiates extreme urgency from moderate urgency.

The waiver of prior negotiations in the context of national emergency or extreme urgency applies to grants of compulsory licences for private commercial as well as public purposes.

The waiver of prior negotiations also applies when patents are used for public purposes. In many cases it will not be necessary to rely on "national emergency" or "extreme urgency" as the basis for a waiver. There are many ways that the terms "public non-commercial use" may be defined in good faith. The term "public" could refer to use by a government, as opposed to private, entity.[932] The term may refer also to the purpose of the use, that is, use for "public" benefit. A private entity could be charged with exploiting a patent for the benefit of the public.

"Non-commercial use" may be defined either in relation to the nature of the transaction, or in relation to the purpose of the use. Regarding the nature of the transaction, "non-commercial" may be understood as "not-for-profit" use. A commercial enterprise does not ordinarily enter the market without intending to earn a profit. Regarding the purpose of the use, "non-commercial" may refer to the supply of public institutions that are not functioning as commercial enterprises. The supply of a public hospital operating on a non-profit basis may be a "non-commercial" use of the patent.

"Public non-commercial use" is a flexible concept, leaving governments with considerable flexibility in granting compulsory licences without requiring

[932] For example, in the United States, a private contractor for the government may be authorized to use a third party's patent without prior negotiation.
There are many instances where the WTO Agreements refer to "governmental" use. For example GATT Article III:8(a) provides: "The provisions of this Article shall not apply to laws, regulations or requirements governing the procurement by governmental agencies of products purchased for governmental purposes and not with a view to commercial resale or with a view to use in the production of goods for commercial sale."
The Agreement on Government Procurement refers to identified "government" entities, not to "public" entities.

commercial negotiations in advance. Note, however, that the waiver of prior negotiations does not extinguish the requirement that adequate compensation in the circumstances be paid to the patent holder (discussed later).

3.2.4 Notification

In cases of national emergency or extreme urgency, the government is obligated to notify the patent holder of the grant of the compulsory licence as soon as reasonably practicable. Reasonable practicability will depend on the circumstances of the case, and need not precede grant of the license. Regarding public non-commercial use, Article 31(b) says: "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." The peculiar wording derives from law and practice in the United States that allows the government and its contractors to make use of patents without advance notice to patent holders.[933] Although U.S. law does not require that a patent holder be notified even if the government knows of a valid patent, it would nonetheless appear that if a government or a private entity is aware of the existence of a valid patent (without a patent search) when a compulsory licence is to be granted for public non-commercial use, it should notify the patent holder.

3.2.5 Competition law remedy

It is important to note that, pursuant to Article 31(k), when compulsory licences are used by the governments to remedy anticompetitive practices[934] (pursuant to findings by judicial or administrative bodies) there is no requirement of prior negotiations with or notification of the patent holders under Article 31(b).

3.3 Scope and duration

> (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;[935]

The purpose of the authorization is intended to determine the scope of the licence. This suggests that compulsory licences should not necessarily provide the licensee with an unencumbered field of application. A compulsory licence granted to an aircraft parts supplier regarding military aircraft components might not, for example, authorize the supplier to sell the same patented parts for use in civilian aircraft.

[933] But subsequently allowing the patent holders to seek compensation.

[934] On the relationship between competition law and intellectual property in developing countries, see Carlos Correa, *The strengthening of IPRs in developing countries and complimentary legislation* (2000), prepared upon the request of DFID (UK), available at <www.dfid.gov.uk>.

[935] The special provision regarding semiconductor technology is of limited application and not discussed further here.

The duration of the licence should also be limited in terms of purpose, but this does not prevent a compulsory licensee from receiving a grant that is of sufficiently long duration to justify its investment in production from a commercial standpoint. A licence grant should in any case be long enough to provide adequate incentive for production. Otherwise the purposes of Article 31 will be frustrated.

3.4 Non-exclusivity

> (d) such use shall be non-exclusive;

In the ordinary commercial context, when a patent holder grants a licence for a particular territory, it may agree to refrain from conferring marketing rights over the product covered by the licence in that territory to other parties (i.e., it grants an exclusive licence). Otherwise, the licensee will face the risk of competition from other licensees that might reduce the value of the licence and any investment in exploiting it. The licensee may also face competition by the patent owner, unless he also agrees to exclude himself from the territory.

The requirement that a compulsory licence be non-exclusive raises difficulties from the standpoint of prospective compulsory licensees. They face the possibility that patent holders and possibly other licensees will seek to undercut them in the market, and this will reduce their incentive to invest.

In some contexts it may be possible to alleviate this concern by providing a government contract for assured purchase of the licensed product. In other contexts, the prospective licensee will have to assure itself, for example by negotiating commercial commitments in advance, that its investment in exploiting a compulsory licence will not involve an unreasonable level of risk.

3.5 Non-assignment

> (e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

The objective of this provision is to prevent the development of a market in compulsory licences as instruments with independent value. The creation of such a market would generally enhance the value of compulsory licences, and might encourage parties to seek them. This requirement does not prevent the sale or transfer of businesses that have obtained compulsory licences, and thereby allows investments in the licences to be sustained.

The reference to assignment of the goodwill means that there need not be any tangible assets constituting the party holding the licence. This adds an element of flexibility to the rule against non-assignment. If a party seeking a compulsory licence establishes a legal entity whose assets are largely comprised of the compulsory licence, it would be feasible to assign and transfer the entire entity ("goodwill") as part of a secondary market transaction.

3.6 Predominantly for the domestic market

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

The word "predominantly" refers to the majority part, and would generally suggest that more than fifty percent of the production by a compulsory licensee should be intended for the supply of the domestic market.

It is clear that a government may authorize a compulsory licensee to produce for export, provided that the licence includes an undertaking to predominantly produce for the domestic market.

It is generally accepted that a country may issue a compulsory licence within its territory, and allow the licensee to fulfil the terms of the authorization through importation. Thus, if there are off-patent products available outside the country the compulsory licensee may import those products without the consent of the patent holder.

On August 30, 2003, the General Council of the WTO adopted the Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (the "Decision").[936] Adoption of the Decision was preceded by reading of a Chairperson's Statement that expressed certain "shared understandings" of the Members regarding the way it would be interpreted and implemented. The Decision establishes a mechanism under which the restriction of Article 31(f) will be waived for an exporting Member when it is requested by an eligible importing Member to supply products under compulsory license issued in the exporting country. Details regarding this waiver are discussed under New developments (Section 6.2 of this chapter).

It is important to note that, pursuant to Article 31(k), when compulsory licences are used by the governments to remedy anticompetitive practices (pursuant to findings by judicial or administrative bodies) there is no requirement that those licences be granted predominantly for supply of the domestic market.

3.7 Termination

> (g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

As noted above in regard to the terms and conditions of a licence, the compulsory licensee may be required to undertake substantial investment in connection with producing and distributing under a licence. If compulsory licensing

[936] Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health WT/L/540, 2 September 2003 (hereinafter "Decision").

is going to be successful, it must provide sufficient economic incentive for the licensee.

There are a number of mechanisms that might be considered to allow for the termination of a licence under conditions that would adequately protect the legitimate interests of the licensee. For example, the initial grant of the licence could establish the minimum term necessary for the licensee to recover its costs and earn a reasonable return, and also provide for automatic extensions of the licence absent a showing by the patent holder that the conditions that led to the granting of the licence have ceased to exist and are unlikely to recur. The licence could not be terminated during the initial term in which protection of the licensee's interests is assured. Alternatively, the patent holder might be required to compensate the licensee for the remaining value of the licence if the patent holder desires to step in and supply the market in place of the licensee.

A country's compulsory licensing rules should include some mechanism by which the patent holder can petition for a review by the competent authority as to whether the circumstances leading to the granting of the licence have ceased and are unlikely to recur. The compulsory licensee may, of course, be permitted to present its own evidence and justifications for continuing the licence, and might well be entitled to appeal any decision on this matter to the courts.

3.8 Adequate remuneration

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

The requirement of payment of adequate compensation was not part of the Paris Convention rules on compulsory licensing. The requirement applies to government use as well as private party use of the patent.

The TRIPS Agreement rules on compensation embody substantial flexibility as a consequence of use of the terms "in the circumstances of each case", indicating that factors relating to the underlying reasons for the grant of the licence may be taken into account in establishing the level of compensation. Granting authorities are instructed to "take into account the economic value of the authorization", but are not required to base the royalty payable to the patent holder on that value.

The term "adequate" generally is used to indicate something that is sufficient, or meets minimum standards, but not more than that.[937] In the context of payments to patent holders, adequate payment may be defined in a variety of ways.

Granting a compulsory licence is not the same as ordering forfeiture or revocation of a patent. Compulsory licences must be non-exclusive, and the grant of a compulsory licence to a third party (including the government) does not preclude the patent holder from exploiting the national market or exporting the patented product.

[937] A student who does "adequate" work is a student whose work meets the basic minimum standards, but whose work does not demonstrate qualities above that.

One way to approach adequacy of compensation is to ask what the licensee would have been required to pay as compensation to the patent holder for a commercial licence under ordinary circumstances. Assuming that there is a market for licences regarding the type of technology involved in the particular case, the market rate would provide an indication at least as to what patent holders might expect from licensing their technology.

However, the "market rate" may be difficult to determine or misleading for a number of reasons. First, in a market characterized by a limited number of patent-holder actors, there may be active or passive collusion among the patent holders that results in a market rate that is higher than would be the case if the market were functioning efficiently. Second, many, if not most, patent licences are granted among members of the same enterprise group. It may well be in a group's interest to charge high inter-enterprise patent royalties to reduce tax burdens, and it may be very difficult to disaggregate available data so as to establish what market rates would look like without reference to intra-group licences. Even in regard to transactions involving nominal competitors, there may be factors such as joint venture interests that affect what might otherwise be presumed to be market-rate transactions.

Another possible approach involves requiring each patent holder to present a detailed justification for its royalty request. The patent holder could be asked to provide specific data on its research and development costs (including any offsetting tax or accounting benefits), whether it received or made use of any government-supported research in developing its invention, its total global market for the patented invention, the percentage of the global market represented by the country granting the compulsory licence, the average rate of return on its patented products, and so forth. The granting authority could on the basis of this data determine what level of royalty would adequately reflect the patent holder's interest in the country in question.

An international organization might be relied upon to establish royalty guidelines on an industry or product/process basis that might be used as a benchmark by authorities granting compulsory licences.

The licensee's royalty obligation may be calculated as a percentage of its income from sales of the licensed product. That income may be represented, for example, by its wholesale sales, and may be net of tax liabilities.

The level of compensation depends on the circumstances of each case, and there are a number of factors that this potentially brings into play. If a compulsory licence is used to remedy an anticompetitive practice, the level of compensation may be adjusted to reflect the need to remedy past misconduct and to affirmatively promote the entry of new competitors in the market. Although Article 31 does not eliminate the requirement of compensation for compulsory licences to remedy anticompetitive practices, neither does it in any way suggest that this compensation may not be strictly limited to reflect governmental objectives. Article 31(k) expressly recognizes that "The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases."

The authorities granting a compulsory licence may also take into account the public interest in effective exploitation of the licence as compared with the private interest in earning a particular level of return. For example, if a developing country

government is granting a compulsory licence to address a public health crisis that affects a large segment of its population, the government could justify the payment of a minimal royalty on grounds that the public interest in the circumstances of the case warrants a reduced royalty.

The economic value of the authorization is to be "taken into account" in establishing the level of compensation. In cases where a compulsory licence is granted to achieve an industrial policy objective, the value of the licence in the hands of the licensee may be a significant factor in determining the level of payment. Where the licence is granted to address urgent public needs, the economic value of the licence to the licensee may be a much less significant factor.

The Decision on Implementation of Paragraph 6 of the Doha Declaration also provides for a waiver of the requirement for adequate remuneration in the eligible importing Member when remuneration is paid in the exporting Member (Decision, para. 3). This waiver was included to avoid the result that the patent holder would receive double compensation when the system established by the Decision is used. Paragraph 3 of the Decision states that remuneration in the export Member will be established "taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member". The concept of economic value to the importing Member could be understood in a number of ways. The idea for avoiding double remuneration was that the level of compensation should be determined based on the level of economic development and financial capacity in the importing Member, and not the level of economic development and budget capacity in the exporting Member. The approach to remuneration taken by Canada in its implementation of the Decision, discussed in Section 6.1 of this chapter, illustrates one constructive approach to the remuneration issue.

3.9 Review by Judicial or Distinct Higher Authority

> (i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
>
> (j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member.

The procedures adopted for the review of decisions are likely to play a critical role in determining whether compulsory licences are applied for and used. No sensible enterprise deciding whether to seek a compulsory licence is interested in investing a large measure of resources in protracted court battles that represent not only a financial drain, but also a substantial imposition on managerial resources.

Because the legal institutions and procedures of nations differ fairly substantially, the requirements for review are set out in general terms, and provide substantial discretion to countries in implementation.

The review of grant and remuneration decisions may be undertaken by a court, or may be undertaken as an "independent review" by a "distinct higher authority".

Article 31 does not address the nature of the authority that may initially grant a compulsory licence or determine the level of compensation. This decision may be placed in the hands of an executive administrator. Since the WTO Agreements, including TRIPS, require transparency and basic fairness, governments should develop and publish regulatory procedures pursuant to which compulsory licences will be granted. However, since it is anticipated that governments may act to grant compulsory licences under conditions of urgency, there is nothing to prevent them from providing for waivers of generally applicable rules in such circumstances.

The use of a court as an independent review body is fairly self-explanatory. Court systems typically involve courts of first instance, and one or more levels of courts of appeal. Many legal systems employ specialized courts for particular subject matters, and this may include patent courts. Article 31 does not suggest a preference for the character of the court that is to review decisions regarding compulsory licences, and it may be preferable, because of the general-purpose objectives of this provision, that a court other than a specialized court be used for such review.

Article 31(i) and (j) also allow for "independent" review by a "distinct higher authority". "Independent" means that the reviewing person or body should not be subject to control by the person or body that initially grants the licence or determines the payment. Independence implies that the reviewer should be able to modify or reverse the initial decision without threat of political or economic reprisal. The term "higher authority" refers to a more senior level government person or body than the granting person or body. The term "distinct" could refer to a person or body within the same government agency that initially grants the licence, provided that there is adequate separation of personnel and function among the two persons or bodies. If the initial granting authority within a government is an administrator within the patent office, and the patent office is under the jurisdiction of the Minister of Economy and Trade, the Minister might serve as an authority "distinct" from the patent office administrator.

These provisions should be read in conjunction with Article 44.2, TRIPS Agreement, regarding injunctions. Article 44.2 provides in its first sentence that, with respect to government use licensing, remedies may be limited to the payment of remuneration. This means that the government may not be enjoined from using a patent without the consent of the patent holder, subject to the payment of remuneration, as long as it complies with the requirements as to government use licensing set out in Article 31. Since a government may use a patent without prior notice to or negotiations with the patent holder, this means that a patent holder need not have an opportunity to block the grant or use of a license. The drafting of this provision takes into account the U.S. approach to government use licensing.

The second sentence of Article 44.2 states "In other cases, the remedies under this Part shall apply or, where these remedies are inconsistent with a Member's law, declaratory judgments and adequate compensation shall be available." Once a compulsory license is granted, the licensee is not engaging in infringement of the patent holder's rights. Assuming the license is properly granted, there is no basis for injunctive relief. Nevertheless, before the grant of the license the patent holder might seek a court injunction to prevent the patent office from issuing it and, even after the grant, the patent holder might seek a temporary injunction pending a final determination by a court or distinct higher authority. The second sentence of Article 44.2 provides that injunctive remedies need not be available

when they are "inconsistent with a Member's law". This is an ambiguous formulation. One interpretation is that injunctions need not be made available if they are not generally provided for in national law. This would be a strained interpretation since Article 44.1 requires that injunction relief be made available in certain cases. A Member would not be in compliance with its general TRIPS obligations if it did not allow for such remedy in those cases. A second and more coherent interpretation is that a compulsory licensing statute need not allow for preliminary or temporary injunctions pending a determination whether the license is lawful. Instead, the courts or distinct higher authority may be asked to render a declaratory judgement, which means they will set out the rights of the parties without ordering relief, and to provide for compensation.

3.10 Remedies for anticompetitive practices

> (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;

As previously discussed, when a compulsory licence is granted based upon a judicial or administrative finding of anticompetitive practices, the otherwise applicable requirements of prior negotiations, notice and limiting the licence to predominant supply of the domestic market do not apply. In addition, the finding may be reflected in the level of payment to the patent holder. Finally, if it is likely that the anticompetitive conditions that led to the initial grant will recur, competent authorities may refuse to terminate the licence.

In individual cases, authorities considering applications for compulsory licences may be presented with several potential grounds for granting them.[938] A finding of anticompetitive conduct on the part of the patent holder provides flexibility regarding the potential terms of a compulsory licence, and should be made when anticompetitive practices are evidenced.

3.11 Dependent Patents

> (l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:
>
> (i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

[938] A useful listing of potentially anticompetitive practices may be found in the *Set of Multilaterally Agreed Equitable Principles and Rules for the Control of Restrictive Business Practices*, adopted by the UN General Assembly.

(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

Article 31(l) addresses the context in which a compulsory licence is granted to permit the exploitation of a second patented invention that depends upon rights to use an existing patented invention. It requires that the second invention involve an important technical advance of considerable economic significance, that the holder of the first patent be granted a cross-licence on reasonable terms to use the second patent, and that the compulsory licence not be assignable except with the assignment of the second patent.

The question whether an invention is an important technical advance involves a subjective judgment that necessarily involves a range of discretion. Patents are granted only if a claimed invention evidences a sufficient "inventive step" over prior art, so a second patent should not be granted in the first place unless there is an inventive step. The idea of an important technical advance is reminiscent of former German patent law that required a vaguely defined quantum of technical progress as a condition of patentability.[939] This idea was abandoned in European patent law because, among other reasons, it is exceedingly difficult to distinguish important and unimportant technical advances.

4. WTO jurisprudence

4.1 EC-Canada

As of today, there is no decision of a WTO dispute settlement panel or the Appellate Body that directly interprets Article 31. As noted above, in the *EC-Canada* decision, in the context of interpreting Article 30, the panel accepted the presumption of the EC and Canada that Article 31 is subject to the rule of non-discriminatory treatment of patents with respect to place of invention, field of technology and whether products are imported or locally produced.[940] Yet the panel in that case left a considerable degree of flexibility in the interpretation of Article 27.1. The panel said:

> "The primary TRIPS provisions that deal with discrimination, such as the national treatment and most-favoured-nation provisions of Articles 3 and 4, do not use the term "discrimination". They speak in more precise terms. The ordinary meaning of the word "discriminate" is potentially broader than these more specific definitions. It certainly extends beyond the concept of differential treatment. It is a normative term, pejorative in connotation, referring to results of the unjustified imposition of differentially disadvantageous treatment."[941] [emphasis added]

[939] See Friedrich-Karl Beier, *The European Patent System*, 14 VAND. J. TRANSNAT'L L. 1 (1981).

[940] The proposition that Article 31 is subject to Article 27.1 was accepted by the parties in the *EC-Canada* case, and the panel confirmed the parties' understanding. *EC-Canada* (WT/DS114/R), at paras. 7.90–7.91.

[941] *Id.*, para. 7.94.

The panel makes clear that the conduct prohibited by Article 27.1 is discrimination, and that "discrimination" is not the same as "differentiation". The panel suggests that governments are permitted to adopt different rules for particular product areas or locations of production, provided that the differences are adopted for *bona fide* purposes. The panel did not attempt to provide a general rule regarding what differences will be considered *bona fide*.

The panel's reasoning is of considerable importance in the implementation of Article 31 because it indicates that there may be distinctions regarding fields of technology, and distinctions regarding imported and locally produced products, made when adopting rules and granting compulsory licences. WTO Members are precluded from adopting or applying rules in a manner that "discriminate". This implies adopting or applying a rule for an improper purpose, such as solely to confer an economic advantage on local producers. There may, however, be *bona fide* reasons for drawing distinctions, such as assuring that compelling public interests are satisfied.

Strongly reinforcing the panel's view that Members may adopt *bona fide* distinctions among fields of technology are paragraphs 6 and 7 of the Doha Declaration on the TRIPS Agreement and Public Health. Paragraph 6 directs the TRIPS Council to specifically consider a situation affecting manufacturing capacity in the "pharmaceutical sector", and paragraph 7 specifically addresses the implementation and enforcement of TRIPS rules relating to "pharmaceutical products".

Moreover, it can be argued that Article 27 deals with patentable subject matter and that Article 31 is a self-standing Article. To affirm that Article 31 is *generally subject* to Article 27 could limit its application in ways that were not intended either by the negotiators or indeed by the text. In fact, the *EC-Canada* case was not about compulsory licensing and the panel's report cannot be considered as definite jurisprudence.[942]

4.2 United States – Brazil

On May 30, 2000, the United States requested consultations with Brazil under the WTO Dispute Settlement Understanding, stating:

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

[942] In addition, the view of the panel was not shared by all Members, as reflected by the proceedings of the DSB meeting when the report was submitted for adoption.

requirement is inconsistent with Brazil's obligations under Articles 27 and 28 of the TRIPS Agreement, and Article III of the GATT 1994."[943]

The request for consultations was followed by a U.S. request for establishment of a panel.[944] The United States withdrew its complaint in this matter prior to the submission of written pleadings by either party.[945] However, the request for consultations illustrates that provisions authorizing compulsory licensing for "non-working" may be subject to challenge under Article 27.[946]

The Paris Convention authorizes the grant of compulsory licences for failure to work a patent. A major issue in a case such as that brought by the United States against Brazil is whether Article 27.1 was intended to prohibit WTO Members from adopting and implementing local working requirements, and effectively to supersede the Paris Convention rule. The negotiating history of TRIPS indicates that Members differed strongly on the issue of local working. Several delegations favoured a direct prohibition of local working requirements, but TRIPS did not incorporate a direct prohibition. Instead, it says that patent rights shall be enjoyable without discrimination as to whether goods are locally produced or imported. Under the jurisprudence of *EC-Canada*, this leaves room for local working requirements adopted for *bona fide* (*i.e.*, non-discriminatory) purposes.

5. Relationship with other international instruments

5.1 WTO Agreements

5.2 Other international instruments

Article 5.A.2 of the Paris Convention provides:

> "Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licences to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work."

Article 5.A.4 of the Paris Convention provides:

> "A compulsory licence may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date

[943] Request for Consultations by the United States, *Brazil – Measures Affecting Patent Protection*, WT/DS199/1, G/L/385, IP/D/23, 8 June 2000.

[944] Request for the Establishment of a Panel by the United States, *Brazil – Measures Affecting Patent Protection*, WT/DS199/39, January 2001.

[945] See Joint Communication Brazil-United States, June 25, 2001. Following notification of the U.S. decision to withdraw its complaint (without prejudice), the communication stated:

> "the Brazilian Government will agree, in the event it deems necessary to apply Article 68 to grant a compulsory licence on a patent held by a U.S. company, to provide advance notice and adequate opportunity for prior talks on the matter with the United States. These talks would be held within the scope of the U.S.-Brazil Consultative Mechanism, in a special session scheduled to discuss the subject.
>
> "Brazil and the United States consider that this agreement is an important step towards greater cooperation between the two countries regarding our shared goals of fighting AIDS and protecting intellectual property rights."

[946] Article 28, TRIPS Agreement, sets out the basic rights of patent holders. Article III of GATT 1994 is the national treatment provision applicable to trade in goods.

of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory licence shall be non-exclusive and shall not be transferable, even in the form of the grant of a sub-licence, except with that part of the enterprise or goodwill which exploits such licence."

The Paris Convention authorizes the grant of compulsory licences, and sets out limited conditions to be applied in cases of non-working.[947] The Paris Convention does not otherwise establish specific conditions or restrictions on the granting of compulsory licences.

6. New developments

6.1 National laws

The entry into force of TRIPS has resulted in the revision of patent laws by a substantial number of countries, including those that anticipate accession to the WTO. Many of these countries have consulted with the World Intellectual Property Organization (WIPO) concerning the terms of their revised intellectual property laws. The model patent law that is generally proposed by WIPO includes provision for compulsory licensing of patents taking into account the rules of Article 31.

6.1.1 Canada

Since the adoption of the Decision on Implementation of Paragraph 6, Canada and Norway have passed implementing legislation, and a number of other countries are proposing to do so. Canada's legislation prescribes a list of products eligible for export under license, but permits additions to the list by action of the executive (in consultation with an expert advisory committee).[948] Remuneration will be based on the level of economic development of the importing country, and royalties will range from less than one percent to four percent. Canada will authorize exports to non-WTO Member countries with an undertaking from the importing country to comply with the rules of the Decision. If exports are priced above a certain threshold in relation to Canadian prices, the patent holder will have the opportunity to challenge the grant and terms of the license.

6.1.2 Norway

The legislation and regulations adopted by Norway do not limit the products that may be exported, relying on the decision of the importing country.[949] Like Canada,

[947] Article 2.1 of the TRIPS Agreement states that the Agreement does not derogate from existing obligations of Members under the Paris Convention. If, for the sake of argument, Article 27.1 were to be construed to restrict or preclude compulsory licensing for non-working, this would derogate from a "right" of Members, not an "obligation". As such, this interpretation would not be precluded by Article 2.2 of TRIPS.

[948] Bill C-9, An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa), passed by the House of Commons, May 4, 2004, by the Senate without amendment, May 13, 2004, receiver Royal Assent, May 14, 2004).

[949] Regulations Amending The Patent Regulations (in accordance with the Decision of the WTO General Council of 30 August 2003, pursuant to sections 49 and 69 of the Act of 15 December 1967 No. 9 relating to patents, the Ministry of Justice and the Police laid down the following regulations by Royal Decree of 14 May 2004). See Consultation – Implementation of paragraph 6

Norway will permit exports to non-WTO Members with an appropriate commitment to abide by the rules of the Decision. Remuneration will be determined on a case-by-case basis.

6.2 International instruments

6.2.1 The decision on implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health[950]

Paragraph 6 of the Doha Declaration recognized the problem that countries with insufficient or no manufacturing capacity in the pharmaceutical sector have in making effective use of compulsory licensing, and directed the TRIPS Council to recommend an expeditious solution.[951] On August 30, 2003, following nearly two years of negotiations, the General Council adopted the Decision, preceded by the reading of a Chairperson's Statement. The Decision is intended to allow countries with manufacturing capacity to make and export pharmaceutical products to countries with public health needs, notwithstanding Article 31(f) of TRIPS that limits compulsory licensing predominantly to the supply of the domestic market. It does this by establishing a mechanism under which the restriction of Article 31(f) is waived for the exporting country, and Article 31(h) (remuneration) is waived for the importing country.

Paragraph 1 of the Decision defines "pharmaceutical product" broadly, and does not limit application of the solution to specific disease conditions. The definition expressly covers active pharmaceutical ingredients (APIs), and diagnostic kits. The definition is sufficiently broad to encompass vaccines. It requires Members other than least-developed country Members (which are automatically included) to submit a notification of their intention to use the system in whole or in part, which notification may be modified at any time. This notification establishes the Member as an "eligible importing Member", and several developed Members have opted out of the system in whole or in a limited way.

Paragraph 2 of the Decision establishes conditions for use of the waiver. The importing Member must notify the TRIPS Council of its needs, and (except for least developed country Members), must indicate that it has determined that it has insufficient or no manufacturing capacity for the product(s) in question. The latter determination is made in accordance with an Annex to the Decision. When there is a patent in the importing Member, it must indicate that it has issued, or intends to issue, a compulsory license (except for least developed country Members that elect not to enforce patents pursuant to Paragraph 7 of the Doha Declaration). The

of the Doha Declaration on the TRIPS Agreement and Public Health in Norwegian law, available at <http://www.dep.no/ud/engelsk/>.

[950] WT/L/540, the "Decision" (reproduced as Annex 1, including Chairperson's Statement).

[951] See Frederick M. Abbott, *The Containment of TRIPS to Promote Public Health: A Commentary on the Decision on Implementation of Paragraph 6 of the Doha Declaration*, manuscript with reference to be provided (forthcoming 2004); Carlos Correa, *Implementation Of The WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WHO 2004 (forthcoming) (hereinafter "Correa 2004"), and; Paul Vandoren and Jean Charles Van Eeckhaute, *The WTO Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, 6* J. World Intell. Prop. 779 (2003).

exporting Member must notify the TRIPS Council of the terms of the export license it issues, including the destination, quantities to be supplied and the duration of the license. The products supplied under the license must be identified by special packaging and/or colouring/shaping. Before quantities are shipped, the licensee must post on a publicly accessible website the destination and means it has used to identify the products as supplied under the system.

Paragraph 3 provides for a waiver of the remuneration requirement for the importing country, discussed above in Section 3 of this chapter.

Paragraph 4 requires importing Members to implement measures proportionate to their means to prevent diversion of products imported under the system. Paragraph 4 does not specify the nature of such means, which might include mechanisms pursuant to which patent holders can obtain remedies.

Paragraph 5 requires other Members to take measures already provided for under TRIPS to prevent the importation of diverted products into their territories.

Paragraph 6 provides an additional waiver of Article 31(f) for regional trading arrangements in Africa (i.e., more than half of which were least developed countries when the Decision was adopted). This waiver allows a Member to export to countries throughout the region under a single compulsory license, although it does not expressly waive the requirement for licenses to be issued by importing countries of the region. The main benefit of the waiver may be to allow the import of APIs, formulation into finished products, and export throughout the African region.

Paragraph 7 refers in a general way to transfer of technology.

Paragraph 8 makes clear that the waiver does not require annual renewal.

Paragraph 9 indicates that the Decision is without prejudice to rights that Members may otherwise have under TRIPS (such as the potential for exports under Article 30).

Paragraph 10 precludes non-violation nullification or impairment causes of action with respect to the Decision.

Paragraph 11 provides that the waiver will remain effective for each Member until an amendment has come into effect to replace it there, and that Members will commence negotiations for an amendment to be based, where appropriate, on the waiver. Although the Decision stated that the negotiations would have a view to completion within six months following the end of 2003, in June 2004 the TRIPS Council extended that tentative completion date until the end of March 2005.

The Chairperson's Statement indicates, *inter alia*, that Members will act in good faith in using the Decision, providing:

> "First, Members recognize that the system that will be established by the Decision should be used in good faith to protect public health and, without prejudice to paragraph 6 of the Decision, not be an instrument to pursue industrial or commercial policy objectives."

This statement of good faith does not in any way preclude enterprises from acting for commercial gain. Since it is unlikely that a Member would use importation as the means to effect an industrial or commercial policy, it seems doubtful that this statement of good faith will inhibit use of the system.

6.2.2 Paragraph 5 of the Doha Declaration

Paragraph 5 of the WTO Doha Ministerial Declaration on the TRIPS Agreement and Public Health (Doha Declaration) states in its relevant part:

> "5. [. . .], while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities [i.e. the ones contained in the TRIPS Agreement] 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, . . . "

This statement does not provide for any substantive modifications of TRIPS but only reiterates what is already stipulated therein. Paragraph (b) relates to Members' discretion with regard to the grounds upon which compulsory licences are granted. Paragraph (c) refers to Article 31(b), making clear that the definition of the terms "national emergency" and "other circumstances of extreme urgency" is up to Members' discretion. This leaves Members considerable room for the pursuit of public policy objectives, especially those related to public health.

6.3 Regional context

6.3.1 FTAA

Countries of the western hemisphere have proposed to enter into a Free Trade Area of the Americas (FTAA) Agreement by 2005. A preliminary draft text of the FTAA includes a chapter on intellectual property rights.[952] That chapter includes a number of proposals regarding compulsory licensing.

6.3.2 The Andean Community

In September 2000, the Andean Community (Bolivia, Colombia, Ecuador, Peru and Venezuela) adopted Decision 486 establishing a new IPR system. This Decision contains a separate chapter on compulsory licensing.[953]

6.3.3 The Bangui Agreement

Finally, the African Intellectual Property Organization (OAPI) in 1999 revised the 1977 Bangui Agreement on the Creation of an African Intellectual Property Organization. Annex 1, Title IV to the 1999 Agreement regulates non-voluntary licenses.[954]

6.4 Proposals for review

As noted earlier, the Decision on Implementation of Paragraph 6 provides for negotiation of an amendment to be based, where appropriate, on the Decision. It

[952] FTAA – Free Trade Area of the Americas, Draft Agreement, Chapter on Intellectual Property Rights, Derestricted, FTAA.TNC/w/133/Rev.1, July 3, 2001.

[953] See <http://www.ftaa-alca.org/intprop/natleg/Decisions/dec486_e.asp>.

[954] See <http://www.oapi.wipo.net/en/textes/pdf/accord_bangui.pdf>.

is expected that some developing Members will propose changes to the Decision, but as of July 2004, no formal proposals to this effect had been made to the TRIPS Council.[955]

7. Comments, including economic and social implications

Compulsory licensing of patents is one of the most important economic instruments for developing countries attempting to address the technology gap with developed countries. In her classic 1951 work, *The Economics of the International Patent System*, Edith Penrose observed:

> "The second method of reducing the cost of the patent monopoly is that of compulsory licensing. This is by far the most effective and flexible method and enables the state to prevent most of the more serious restrictions on industry. It could be used very effectively to undermine the monopoly power of several of the more powerful international cartels whose position is largely based on their control of the patent rights to industrial processes in the larger industrial countries; and it could be used to ensure that patented new techniques developed abroad are available to domestic industries wishing to use them.
>
> The International [Paris] Convention places restrictions on the right of countries to subject patents to compulsory licensing. These restrictions should be eliminated and countries should be encouraged to use this device to break up some of the more serious of the monopolistic restrictions on the use of new techniques."[956]

Ownership of technology remains concentrated in the developed countries where large amounts of capital are invested in research and development (R&D). Industries in developing countries have great difficulty in competing in R&D because of persistent structural imbalances. Developed country enterprises are often reluctant to licence new technology on terms and conditions that will permit developing country enterprises to effectively compete in world markets. Although TRIPS makes a number of references to encouraging transfers of technology, there is little evidence that programmes to accomplish this are being implemented. Compulsory licensing, and the threat of compulsory licensing, are necessary to make transfer of technology a reality.

Developing countries that grant compulsory licences run the risk of economic retaliation by developed countries. For this reason, compulsory licensing should be undertaken in accord with international obligations. The adoption of the Doha Declaration has unambiguously confirmed the right of Members to define the grounds for granting compulsory licences.

[955] Note that as of August 2004, Members in the Council for TRIPS have not been able to agree on a common approach to amending Article 31, TRIPS Agreement. Main areas of controversy relate to the content of the amendment and its form. As to the content, delegations disagree whether the Chair's statement, issued together with the Decision of 30 August 2003, should be incorporated into the amendment of the TRIPS Agreement. Some Members have expressed concern about enhancing the Chair's statement's legal status by such incorporation. As to the legal form of the envisaged TRIPS amendment, some Members favour a footnote to Article 31 TRIPS, referring to the Decision as a separate document. Others support the inclusion into the TRIPS Agreement of the full text of the Decision, either under a new Article 31*bis*, or as an Annex, or as a footnote.

[956] Penrose.

The argument is made that compulsory licensing reduces incentives for developed country enterprises to engage in R&D, and that reduced R&D diminishes global welfare by lowering the future stock of useful inventions. However, the benefit to developing countries of increased R&D in the developed countries is often remote, and there is no evidence that the granting of compulsory licences has led to a reduction in R&D investment.[957] Compulsory licensing stresses the interest of developing countries in raising current standards of living.

[957] F. M. Scherer, *Comments* in Robert Anderson and Nancy Gallini (Eds.), *Competition policy and intellectual property rights in the knowledge-based economy*, University of Calgary Press, Alberta 1998.

Annex 1: The Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (the "Decision"), including Chairperson's Statement

Decision of 30 August 2003*

The General Council,

Having regard to paragraphs 1, 3 and 4 of Article IX of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");

Conducting the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the WTO Agreement;

Noting the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the "Declaration") and, in particular, the instruction of the Ministerial Conference to the Council for TRIPS contained in paragraph 6 of the Declaration to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement and to report to the General Council before the end of 2002;

Recognizing, where eligible importing Members seek to obtain supplies under the system set out in this Decision, the importance of a rapid response to those needs consistent with the provisions of this Decision;

Noting that, in the light of the foregoing, exceptional circumstances exist justifying waivers from the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products;

Decides as follows:

For the purposes of this Decision:

(a) "pharmaceutical product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included[958];

(b) "eligible importing Member" means any least-developed country Member, and any other Member that has made a notification[959] to the Council for TRIPS of its intention to use the system as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system set out in this Decision as importing Members[960]

* This Decision was adopted by the General Council in the light of a statement read out by the Chairman, which can be found in JOB(03)/177. This statement will be reproduced in the minutes of the General Council to be issued as WT/GC/M/82.

[958] This subparagraph is without prejudice to subparagraph 1(b).

[959] It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.

[960] Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom and the United States.

and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;

(c) "exporting Member" means a Member using the system set out in this Decision to produce pharmaceutical products for, and export them to, an eligible importing Member.

2. The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out below in this paragraph:

(a) the eligible importing Member(s)[961] has made a notification[959] to the Council for TRIPS, that:

(i) specifies the names and expected quantities of the product(s) needed[962];

(ii) confirms that the eligible importing Member in question, other than a least-developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex to this Decision; and

(iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Article 31 of the TRIPS Agreement and the provisions of this Decision[963];

(b) the compulsory licence issued by the exporting Member under this Decision shall contain the following conditions:

(i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;

(ii) products produced under the licence shall be clearly identified as being produced under the system set out in this Decision through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and

(iii) before shipment begins, the licensee shall post on a website[964] the following information:

- the quantities being supplied to each destination as referred to in indent (i) above; and
- the distinguishing features of the product(s) referred to in indent (ii) above;

[961] Joint notifications providing the information required under this subparagraph may be made by the regional organizations referred to in paragraph 6 of this Decision on behalf of eligible importing Members using the system that are parties to them, with the agreement of those parties.

[962] The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision.

[963] This subparagraph is without prejudice to Article 66.1 of the TRIPS Agreement.

[964] The licensee may use for this purpose its own website or, with the assistance of the WTO Secretariat, the page on the WTO website dedicated to this Decision.

(c) the exporting Member shall notify[965] the Council for TRIPS of the grant of the licence, including the conditions attached to it.[966] The information provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

3. Where a compulsory licence is granted by an exporting Member under the system set out in this Decision, adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement shall be paid to that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall be waived in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

4. In order to ensure that the products imported under the system set out in this Decision are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country Member experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.

5. Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system set out in this Decision and diverted to their markets inconsistently with its provisions, using the means already required to be available under the TRIPS Agreement. If any Member considers that such measures are proving insufficient for this purpose, the matter may be reviewed in the Council for TRIPS at the request of that Member.

6. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products:

(i) where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least-developed countries, the obligation of that Member

[965] It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.

[966] The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision.

under Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least-developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question;

(ii) it is recognized that the development of systems providing for the grant of regional patents to be applicable in the above Members should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of the TRIPS Agreement, including in conjunction with other relevant intergovernmental organizations.

7. Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem identified in paragraph 6 of the Declaration. To this end, eligible importing Members and exporting Members are encouraged to use the system set out in this Decision in a way which would promote this objective. Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of the TRIPS Agreement, paragraph 7 of the Declaration and any other relevant work of the Council for TRIPS.

8. The Council for TRIPS shall review annually the functioning of the system set out in this Decision with a view to ensuring its effective operation and shall annually report on its operation to the General Council. This review shall be deemed to fulfil the review requirements of Article IX:4 of the WTO Agreement.

9. This Decision is without prejudice to the rights, obligations and flexibilities that Members have under the provisions of the TRIPS Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration, and to their interpretation. It is also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the present provisions of Article 31(f) of the TRIPS Agreement.

10. Members shall not challenge any measures taken in conformity with the provisions of the waivers contained in this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.

11. This Decision, including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member. The TRIPS Council shall initiate by the end of 2003 work on the preparation of such an amendment with a view to its adoption within six months, on the understanding that the amendment will be based, where appropriate, on this Decision and on the further understanding that it will not be part of the negotiations referred to in paragraph 45 of the Doha Ministerial Declaration (WT/MIN(01)/DEC/1).

ANNEX [to the Decision]

Assessment of Manufacturing Capacities in the Pharmaceutical Sector Least-developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector. For other eligible importing Members

insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways:

(i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector;

OR

(ii) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply.

The General Council's Chairperson's Statement

The General Council has been presented with a draft Decision contained in document IP/C/W/405 to implement paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. This Decision is part of the wider national and international action to address problems as recognized in paragraph 1 of the Declaration. Before adopting this Decision, I would like to place on the record this Statement which represents several key shared understandings of Members regarding the Decision to be taken and the way in which it will be interpreted and implemented. I would like to emphasize that this Statement is limited in its implications to paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.

First, Members recognize that the system that will be established by the Decision should be used in good faith to protect public health and, without prejudice to paragraph 6 of the Decision, not be an instrument to pursue industrial or commercial policy objectives.

Second, Members recognize that the purpose of the Decision would be defeated if products supplied under this Decision are diverted from the markets for which they are intended. Therefore, all reasonable measures should be taken to prevent such diversion in accordance with the relevant paragraphs of the Decision. In this regard, the provisions of paragraph 2(b)(ii) apply not only to formulated pharmaceuticals produced and supplied under the system but also to active ingredients produced and supplied under the system and to finished products produced using such active ingredients. It is the understanding of Members that in general special packaging and/or special colouring or shaping should not have a significant impact on the price of pharmaceuticals.

In the past, companies have developed procedures to prevent diversion of products that are, for example, provided through donor programmes. "Best practices" guidelines that draw upon the experiences of companies are attached to this statement for illustrative purposes. Members and producers are encouraged to draw from and use these practices, and to share information on their experiences in preventing diversion.

Third, it is important that Members seek to resolve any issues arising from the use and implementation of the Decision expeditiously and amicably:

• To promote transparency and avoid controversy, notifications under paragraph 2(a)(ii) of the Decision would include information on how the Member

in question had established, in accordance with the Annex, that it has insufficient or no manufacturing capacities in the pharmaceutical sector.

- In accordance with the normal practice of the TRIPS Council, notifications made under the system shall be brought to the attention of its next meeting.
- Any Member may bring any matter related to the interpretation or implementation of the Decision, including issues related to diversion, to the TRIPS Council for expeditious review, with a view to taking appropriate action.
- If any Member has concerns that the terms of the Decision have not been fully complied with, the Member may also utilise the good offices of the Director General or Chair of the TRIPS Council, with a view to finding a mutually acceptable solution.

Fourth, all information gathered on the implementation of the Decision shall be brought to the attention of the TRIPS Council in its annual review as set out in paragraph 8 of the Decision.

In addition, as stated in footnote 3 to paragraph 1(b) of the Decision, the following Members have agreed to opt out of using the system as importers: 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 United States of America. Until their accession to the European Union, Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic and Slovenia agree that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency. These countries further agree that upon their accession to the European Union, they will opt out of using the system as importers.

As we have heard today, and as the Secretariat has been informed in certain communications, some other Members have agreed that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency: Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey, United Arab Emirates.

Attachment:

"Best Practice" guidelines

Companies have often used special labelling, colouring, shaping, sizing, etc. to differentiate products supplied through donor or discounted pricing programmes from products supplied to other markets. Examples of such measures include the following:

- Bristol Myers Squibb used different markings/imprints on capsules supplied to sub-Saharan Africa.
- Novartis has used different trademark names, one (Riamet®) for an antimalarial drug provided to developed countries, the other (Coartem®) for the same products supplied to developing countries. Novartis further differentiated the products through distinctive packaging.
- GlaxoSmithKline (GSK) used different outer packaging for its HIV/AIDS medications Combivir, Epivir and Trizivir supplied to developing countries. GSK

further differentiated the products by embossing the tablets with a different number than tablets supplied to developed countries, and plans to further differentiate the products by using different colours.

- Merck differentiated its HIV/AIDS antiretroviral medicine CRIXIVAN through special packaging and labelling, i.e., gold-ink printing on the capsule, dark green bottle cap and a bottle label with a light-green background.
- Pfizer used different colouring and shaping for Diflucan pills supplied to South Africa.

Producers have further minimized diversion by entering into contractual arrangements with importers/distributors to ensure delivery of products to the intended markets.

To help ensure use of the most effective anti-diversion measures, Members may share their experiences and practices in preventing diversion either informally or through the TRIPS Council. It would be beneficial for Members and industry to work together to further refine anti-diversion practices and enhance the sharing of information related to identifying, remedying or preventing specific occurrences of diversion.

26: Process Patents: Burden of Proof

Article 34 Process Patents: Burden of Proof

1. For the purpose of civil proceedings in respect of the infringement of the rights of the owner referred to in paragraph 1(b) of Article 28, 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. Therefore, Members shall provide, in at least one of the following circumstances, that any identical product when produced without the consent of the patent owner shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process:

(a) if the product obtained by the patented process is new;

(b) if there is a substantial likelihood that the identical product was made by the process and the owner of the patent has been unable through reasonable efforts to determine the process actually used. Any Member shall be free to provide that the burden of proof indicated in paragraph 1 shall be on the alleged infringer only if the conditions referred to in subparagraph (a) is fulfilled or only if the condition referred to in subparagraph (b) is fulfilled.

2. In adduction of proof to the contrary, the legitimate interests of the defendants in protecting their manufacturing and business secret shall be taken into account.

1. Introduction: terminology, definition and scope

Article 34 is concerned with patents the subject matter of which is a claim or claims to a process for the manufacture of a product, which may itself be the subject of a patent though it does not necessarily have to be.

Article 34 reverses the procedural principle under which the person asserting a fact must prove it. Its purpose is to meet the so called *"probatio diabolica"*: it is always difficult for a plaintiff owning a process patent to prove whether or not the process used by the alleged infringer to manufacture an identical product to the one resulting from the patented process infringes his exclusive

right, unless the plaintiff gains access to the manufacturing process of the alleged infringer.[967]

The conditions on which the onus of proof should be reversed are as follows:[968]

1. The alleged infringer's product must be identical for material purposes to the product produced by the patented process.

2. If this is the case, Members should implement a presumption that such product has been obtained by the patented process if –

(a) the product obtained by the patented process is new; or

(b) if there is a substantial likelihood that the identical product (new or existing) was made by such process and the owner of the patent was unable through reasonable efforts to determine the process actually used, and the patent owner produces evidence that he/she has used reasonable efforts to try to determine the process used and was unable to do so.

2. History of the provision

2.1 Situation pre-TRIPS

The rule on the reversal of the burden of proof was introduced by the 1891 German patent law (Article 139). It was also incorporated in the patent laws of Italy, Belgium and Spain. It was also included in the Community Patent Convention (Article 35), as well as in the proposed WIPO treaty for harmonization of patent law (Article 24)[969] on terms substantially similar to the text adopted later on under TRIPS.

2.2 Negotiating history

Negotiations on this provision were based on the proposals submitted in 1990 by the European Communities, the USA and Switzerland. Equivalents of this provision existed in both the Brussels Draft of TRIPS and in the Anell Draft of July 23, 1990. The two conditions for the reversal of the *onus probandi* were similar in both drafts, but in its final version Article 34.2 makes it clear that Members may provide that the onus shall be on the alleged infringer if *either* of the conditions is fulfilled. During the negotiations the European Commission favoured the first condition and the United States the second.[970]

2.2.1 The Anell Draft

"2.3 Reversal of Burden of Proof

2.3A.1 If the subject matter of a patent is a process for obtaining a product, the same product when produced by any other party shall, in the absence of proof to

[967] See, e.g., Miguel Vidal-Quadras Trias des Bes, *Process patents on new products and reversal of the burden of proof: factors contributing to the interpretation of its scope*, European Intellectual Property Review 2002, vol. 24, No. 5, p. 237–243 (237) [hereinafter Vidal-Quadras Trias des Bes].

[968] See Gervais, p. 171.

[969] See WIPO, 1991, p. 32.

[970] See Gervais, p. 172.

the contrary, be deemed to have been obtained by the patented process in [at least one of] the following situation[s]:

(a) if the product is new, [or,

(b) where the product is not new, if there is a substantial likelihood that the product was made by the process [and the owner of the patent has been unable through reasonable efforts to determine the process actually used].

2.3A.2 In the adduction of proof to the contrary, the legitimate interests of the defendant in protecting his manufacturing and business secrets shall be taken into account.

2.3B Where the subject matter of a patent is a process for obtaining a product, whether new or old, the burden of establishing that an alleged infringing product was made by the patented process shall always be on the person alleging such infringement."

Alternative 2.3B, introduced by developing countries, was clearly intended to counter the proposals for reversal of the burden of proof. But this strategy was not successful, as is obvious from the text finally adopted.

2.2 The Brussels Draft

"Reversal of Burden of Proof

1. For the purpose of civil proceedings in respect of the infringement of the rights of the owner referred to in Article [28](1)(b), if the subject matter of a patent is a process for obtaining a product, PARTIES [shall] [may] provide in at least one of the following circumstances that any identical product when produced by any party not having the consent of the patent owner shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process:

(a) if the product obtained by the patented process is new;

(b) if there is a substantial likelihood that the identical product was made by the process and the owner of the patent has been unable through reasonable efforts to determine the process actually used.

2. In the adduction of proof to the contrary, the legitimate interests of the defendant in protecting his manufacturing and business secrets shall be taken into account."

3. Possible interpretations

> 1. For the purpose of civil proceedings in respect of the infringement of the rights of the owner referred to in paragraph 1(b) of Article 28, if the subject matter of a patent is a process for obtaining a product, . . .

The reversal of burden of proof logically applies to civil procedures only, since the presumption of innocence generally governs in criminal cases. The subject of the patent for the reversal to proceed should be a "patent for obtaining a process". It is left to Members, however, to determine whether such a process should be the

sole object of the patent, or whether "hybrid" patents (including claims over both a process and a product) should also be subject to Article 34.

This Article only applies, further, in cases where an infringement of the acts described in Article 28.1(b) of TRIPS is alleged, that is, whenever the identical product has been directly obtained with the patented process. It is not enough, hence, to argue that the product is *obtainable* with such a process.

> . . . 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.

Article 34.1 requires Members to empower their judicial authorities to order the reversal of the burden of proof. It is not an operative, self-executing provision, but requires positive action both by the Members and, in a particular case, the competent judge. The defendant can be obliged to prove that the process is different from the patented process, but cannot be obliged to prove that the process has not been infringed. If the defendant proves that the process used by himself on the one hand and the patented process on the other hand are different, the proof of infringement, which would normally require the application of the "doctrine of equivalents",[971] remains a plaintiff's burden, according to general principles of procedural law.[972]

> Therefore, Members shall provide, in at least one of the following circumstances, that any identical product when produced without the consent of the patent owner shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process:

Whether a product is "identical" to the product obtained by a patented process is to be determined on the basis of its structural composition. Similarity, therefore, is not sufficient to trigger the reversal of proof.[973]

[971] This doctrine provides a conceptual framework to determine if a violation of a patent exists when there is no literal infringement of patent claims. See, e.g., Correa, 2000a, p. 85.

[972] See the decision of the Barcelona Provincial Appellate Court of September 18, 2000, in *Enaaprile II*, according to which the defendant's burden of proving the contrary "is confined to disclosing the process actually used by the defendant (which would convert the proceedings into a mere comparison of both processes) and to show that the two processes are not identical, but not that the presumption also involves proof that the processes are not equivalent". See also the judgment of the German Federal Court of June 25, 1976, in *Alkylendiamine II*, which held that a similar rule under German law did not shift the responsibility for determining the scope of the plaintiff's right on the defendant; but merely required the defendant to provide sufficient proof of the process actually used in manufacturing the product. G.R.U.R 1997, p.103 (cases quoted in Vidal-Quadras Trias des Bes, p. 240).

[973] The German Federal Supreme Court in the *Alkylenediamine II* case clarified that the notion of "same substance" under the old Patents Act Section 47(3) applied also when established differences exist between two substances within the limits that technical experience shows to be attributable to a variation of the patented process, but not the application of a different process. See Straus, p. 820.

In addition to requiring that judges be empowered to order the reversal, Article 34 provides for the establishment of a *juris tantum* presumption that the patented process has been effectively used. This presumption admits proof to the contrary.

As mentioned, the conditions stipulated in Article 34.1 for the reversal to proceed constitute options for Members. They may opt for establishing one or the other,[974] at their discretion.

3.1 Article 34.1(a)

> (a) if the product obtained by the patented process is new;

This condition, probably inspired by European law, requires the "newness" of the product obtained through the protected process. In many cases, the product may be new but not inventive and, hence, not patentable. In the case of countries that did not grant product patent protection for pharmaceuticals or other products, there exist many instances in which the inventor was able to patent the process, but not the product. The rationale for this option is that when a product is new, it is unlikely that competitors had the time to develop alternative processes to obtain the same product. The older the product, the higher the possibility that such alternatives have been developed.[975]

For countries that opt for alternative (a), there is no obligation to order the reversal of the burden for products which are not new.

TRIPS does not determine when a product should be considered new for the purposes of this provision. Members enjoy considerable room for manoeuvre in this respect. They may, for instance, establish that newness be judged:

(1) according to the novelty requirement under the patent law on the date of the application (or the priority date). This solution is significantly advantageous to the patent owner: though a long period may have passed between that date and the date of infringement, the product would still be considered new for the purposes of the burden of proof. Under this approach the attribute of new is fixed once and forever ignoring that, as time passes, it may be reasonably presumed that other processes to obtain the product may have been developed.[976]

[974] A "TRIPS-plus" solution may obviously be to order reversal of the burden of proof when *any* of the conditions are met, as originally sought by the USA during TRIPS negotiations.

[975] Thus, it has been noted that "it seems to be reasonable to assume that, where subsequent processes have been described for obtaining the product resulting from the claimed patented processes to the extent that such processes may vary to a greater or lesser extent, bring different advantages or simply be practicable, when the patent invoked is close to expiry and alternative processes have been described, these circumstances must be taken into account in order to undermine the grounds for presuming that the patented process has been used" (Vidal-Quadras Trias des Bes, p. 242).

[976] The District Court of Munich considered (as long ago as 1963) that the "new product" characteristic required by the article of the Patent Law relating to the reversal of the burden of proof did not necessarily have to be interpreted as having the same meaning as novelty for the purpose of patentability. More recent German authors have taken the same view since such an interpretation

Or:

(2) at the time the product is introduced into the market. If other products obtained by non-infringing processes were available at that time, it would be *prima facie* proven that other processes existed for obtaining the product and, therefore, there would be no logical basis for the legal presumption to operate. This solution was proposed in one of the texts considered in the preparatory work of the WIPO Diplomatic Conference for the adoption of a Patent Law Treaty,[977] and has also been suggested by some authorities in Europe.[978]

3.2 Article 34.1(b)

> (b) if there is a substantial likelihood that the identical product was made by the process and the owner of the patent has been unable through reasonable efforts to determine the process actually used. Any Member shall be free to provide that the burden of proof indicated in paragraph 1 shall be on the alleged infringer only if the condition referred to in subparagraph (a) is fulfilled or only if the condition referred to in subparagraph (b) is fulfilled.

A "substantial likelihood" is more than the mere "possibility". The plaintiff must be able to prove that, in the circumstances of the particular case, the identical product is likely to have been obtained with his patented process. Under this option, the plaintiff would also have to prove that he has made reasonable and unsuccessful efforts to determine what process was used, for instance, by undertaking the chemical analysis of the product, requesting information from the product manufacturer (if known and different from the alleged infringer), or other measures that the owner could undertake at a reasonable cost and within a reasonable time.

3.3 Article 34.2

> 2. In adduction of proof to the contrary, the legitimate interests of the defendants in protecting their manufacturing and business secret shall be taken into account.

As noted, Article 34.2 makes it clear that the obligation to reverse the burden of proof may apply in *either* the circumstances specified in Article 34.1(a) or (b) set out above. If the product has in fact been produced by a different process, the alleged infringer will not want to disclose his process to competitors. Article 34.2

would be contrary to the purpose of the procedural rule contained in German law (Vidal-Quadras Trias des Bes, p. 242).

[977] Article 301(1)(b) of the 1987 Draft Patent Law Treaty disregarded the presumption of infringement "if, at the time of the alleged violation, an identical product emanating from a source other than the owner of the patent and the defendant was already known in commerce in the country in which the patent applies". See, e.g., Harold Wegner, *Patent Harmonization*, Sweet & Maxwell, London 1993, p. 334.

[978] See, e.g., authors quoted by Straus, p. 821.

provides that in the presentation of evidence to the contrary, the legitimate interests of the defendants in protecting their manufacturing and business secret shall be taken into account. Obviously, those legitimate interests include not disclosing the defendant's trade secrets to the other side, including technical and commercial information (e.g., the source of a given intermediate used in the process).

However, the defendant will be bound to disclose the process that has actually been used in order to rebut the *juris tantum* presumption. Otherwise, he will be deemed as infringing the patent. A possible strategy to protect the defendant's trade secrets is for the rules of court procedure of a Member to require the trade secrets to be disclosed only to an independent expert, who is under an obligation of secrecy, and who will advise the court under conditions of confidentiality. Another strategy which is perhaps more appropriate to adversarial (as opposed to inquisitorial) court procedures is to require the information to be disclosed to one member of the plaintiff's team who is similarly bound by an obligation of secrecy. That person will communicate the information to the plaintiff's independent lawyers (who are similarly under an obligation of confidentiality), who will then advise whether the proceedings are to continue or to be discontinued.

"Legitimate interests", as defined by the panel in *Canada-Patent protection of pharmaceutical products*, must be "construed as a concept broader than legal interests",[979] encompassing any business interest that the defendant may legitimately wish to protect.

4. WTO jurisprudence

There is no WTO jurisprudence on this provision. In a case settled between USA and Argentina after consultations, the Argentine government agreed to amend its patent law in order to comply with Article 34.1. The proposed amendment opts for the alternative provided for under Article 34.1 (a).[980]

5. Relationship with other international instruments

This provision has no counterpart in either the Paris Convention or the European Patent Convention, both of which leave the question of onus of proof to national law. However, Article 35 of the Community Patent Convention provides that

> "1. If the subject-matter of a Community patent is a process for obtaining a new product, the identical product when produced by any other party shall, in the

[979] WT/DS114/R, 17 March 2000, at para 7.71.

[980] With regard to the definition of "new", the proposed amendment reads as follows: "[I]t shall be presumed that, in the absence of proof to the contrary, the product obtained by the patented process is not new if the defendant or if an expert appointed by the court at the request of the defendant is able to show that, at the time of the alleged infringement, there exists in the market a non-infringing product identical to the one produced by the patented process that originated from a source different from the right owner or the defendant". See WT/DS171/3, WT/DS196/4, IP/D/18/Add.1, IP/D/22/Add.1 of 20 June 2002.

absence of proof to the contrary, be deemed to have been obtained by the patented process.

2. In the adduction of proof to the contrary, the legitimate interests of the defendant in protecting his manufacturing and business secrets shall be taken into account".

6. New developments

In implementing the rule on reversal of burden of proof mandated by TRIPS, some countries opted for alternative (a),[981] others for alternative (b),[982] while many incorporated both conditions set out in Article 34.1.[983]

7. Comments, including economic and social implications

Process patents are a weak form of protection, because of the difficulties involved in proving infringement. As noted above, formerly some countries while barring the patenting of pharmaceutical products would allow the patenting of processes. The effect was that for practical purposes pharmaceutical products were not fully protected, because the key feature of a pharmaceutical product is usually its molecule, and in practice the composition of this is fairly easy to analyse, though the same molecule must be manufactured by an alternative method in order not to infringe the process patent. Article 34 attempts to ameliorate this weakness by reversing the onus of proof, so that if the defendant has produced an identical product to that produced by the process patent, the onus shifts to the defendant to show that the product was produced without use of the process covered by the patent. It is, of course, no defence in patent law that the defendant independently developed the identical process. Independent creation is a defence in copyright and trade secrets law, but a patent confers an exclusive right on the patentee.

The reversal of the burden of proof, hence, may be of particular importance in developing countries and economies in transition that did not recognize product patents for pharmaceuticals or in other fields of technology prior to the implementation of TRIPS. With the universal introduction of product patent protection for pharmaceuticals and chemical products under Article 27.1, the practical importance of such principle will diminish, since infringement of product patents would be easier to prove. However, Article 34 will provide a valuable procedural tool to patent holders that have only been able to obtain process and not product protection.

Those countries that opted, in implementing Article 34.1, for alternative (a) generally aimed at excluding the application of such a rule for products already in the market. The extent to which this will be achieved, however, would depend

[981] See, e.g., Argentine patent law 24.481 (Article 88).

[982] This alternative is often found, for instance, in bilateral agreements concluded between the USA and former centrally managed economies (Straus, p. 810).

[983] See, e.g., Indonesian patent law No. 14 of year 2000 (Article 119); Industrial Property Common Regime of the Andean Community, Decision 486 (Article 240).

on the way in which the concept of "new" is defined by law and jurisprudence. If "new" is assimilated to the "novelty" standard for patentability, and a product was new at the time of the patent application, it would remain "new" for the purposes of the reversal of the burden of proof until the patent expires, possibly many years after its introduction into commerce.