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.