

MODULE V

PATENTS

A Introduction

This module explains the provisions of Section 5 of Part II of the TRIPS Agreement entitled 'Patents'. Section 5, which contains eight articles, from Article 27 to Article 34, sets out the obligations of members with respect to standards concerning the availability, scope and use of patents. Starting with a general explanation of terms, this module goes on to explain each specific provision in this Section of the TRIPS Agreement.

1 What are patents?

The term 'patent' is not specifically defined in the TRIPS Agreement. A patent is the title given to the IPR that is granted to protect new inventions. A patent, which is granted by the authorities in a specified jurisdiction, gives its owner an exclusive right to prevent others from exploiting the patented invention in that jurisdiction for a limited period of time without his or her authorization, subject to a number of exceptions.

The term 'invention' is not defined in the TRIPS Agreement. One informal definition (used, for example, in some WIPO capacity building materials) characterizes an invention as a new solution to a technical problem. Other approaches to defining 'invention' can also be found in national laws. Many national laws exclude such material as scientific theories, aesthetic creations, schemes, and rules and methods for performing mental acts. These activities do not aim at any direct technical result but are rather of an abstract and intellectual character.

Unlike copyright, where protection does not require meeting with prior formalities, a patent is not automatically available for eligible inventions. In order to get a patent, an inventor or other eligible person has to file an application for each jurisdiction in which he or she wants protection and meet certain substantive and formal requirements. Patents in each jurisdiction are independent of each other, i.e. the application, grant or cancellation of a patent in one jurisdiction does not have an automatic effect for the same invention in any other jurisdiction (Article 4*bis* of the Paris Convention).

The social purpose of patent protection is to provide an incentive for technological change, and in particular for further investment into research and development (R&D) in order to stimulate new inventions. As a condition of obtaining protection, patent applicants must disclose certain details of the invention covered in the application for protection. This would, for example, help others to study the invention and thus build on the technology contained in it. The patent system thus aims to contribute to the promotion of technological innovation and to the transfer and dissemination of

technology (as set out in Article 7 of the TRIPS Agreement). However, as mentioned above, the patent system also enables the patent owner to limit the extent to which others can use the patented invention during its term of protection. Thus, it is vital to find in the patent system a proper balance between these considerations. Such a balance can be found, *inter alia*, through appropriate ways of defining and structuring commercial relationships and other mechanisms for the development, transfer and dissemination of technology, including various approaches to licensing and R&D contracts.

2 What is the relationship of TRIPS with the Paris Convention?

As seen in Module I, the main provisions of the Paris Convention (Articles 1 to 12 and 19), which is the relevant pre-existing treaty in the case of patents, are incorporated into the TRIPS Agreement by reference.

The Paris Convention refers to patents as an object of the protection of industrial property (Article 1.2). It contains a number of other important provisions, details of which are provided below. However, the Paris Convention is silent on some important issues relating to what subject matter has to be patentable, the scope of patent rights and their duration.

B TRIPS provisions on patents

The patent provisions of the TRIPS Agreement have to be read along with other parts of the Agreement, including the transitional arrangements given in Part VI of the TRIPS Agreement, which are explained in Module I. This Section attempts to strike the aforementioned balance between the long-term objective of providing incentives for future inventions, and the short-term cost of restricting access to existing inventions.

Also of importance are the provisions in Article 70 which cover the extent to which members are required to apply the new rules of IP to protect subject matter existing at the time they come under an obligation to apply the TRIPS Agreement. See the discussion on Article 70 in Module I, section D2.

1 What subject matter is to be protected?

Each IPR covered by the TRIPS Agreement relates to a different kind of subject matter. As explained in the introductory section above, in the case of patents the subject matter of protection is an invention. In order to answer the question posed above, the TRIPS Agreement has provisions on:

- (1) the areas in which inventions must be eligible for protection;
- (2) the substantive conditions and formal requirements to be met in order for these inventions to be protected; and

(3) the inventions which may be excluded from patent grant, even when they meet the general conditions of eligibility.

These issues will be dealt with below in turn.

(a) In which areas must inventions be eligible for protection?

TRIPS Article 27.1 obliges members to make patents available⁵⁹ for inventions:

- whether products or processes
- in all fields of technology without discrimination (subject to optional exclusions set out in paragraphs 2 and 3 of Article 27 as explained further below).

This means that those interested in obtaining a patent for their invention must have the legal means to do so in every member's jurisdiction irrespective of whether the invention is a product or a process (for example, whether it is a toothpaste with a new formulation or a new process for making the toothpaste) and irrespective of the field of technology (for example, whether it pertains to chemistry or mechanical engineering). Thus, members cannot exclude from patenting classes of inventions, for example those pertaining to the field of medical technologies, unless there is a specific exclusion allowed under the TRIPS Agreement (see below).

(b) What conditions must inventions meet to be eligible for patent protection?

There are two types of conditions on patent applicants under the TRIPS Agreement:

- substantive conditions linked with the nature of the invention to be protected; and
- formal conditions linked with the fulfilment of certain formalities in the patent grant process.

Article 27.1 states, *inter alia*, that 'patents shall be available for any inventions, provided that they are new, involve an inventive step and are capable of industrial application'. These three substantive conditions are recognized as the basic tests of patentability, namely novelty, inventive step and industrial applicability, which were already present in some form in many countries' laws prior to the TRIPS Agreement. In addition to these three tests of patentability, there is one other condition that is considered to be substantive, namely that of disclosure of the invention.

⁵⁹ Since, as explained earlier, patent protection is not automatically granted but accorded to applicants that meet some substantive and formal conditions, the TRIPS provisions that are set out below are couched in terms of the patent protection that is to be made 'available'.

(i) Novelty, inventive step and industrial applicability

Novelty To be eligible for patent protection, the invention must be ‘new’. The term ‘new’ is not defined in the TRIPS Agreement but the concept is understood in many jurisdictions to mean that the claimed invention shows a new characteristic which has not already been disclosed to the public before the relevant date in the body of existing knowledge in its technical field (called ‘prior art’ or ‘state of the art’). In other words, the invention must not have been disclosed to the public through having been made, carried out or used before. The ingredients of an invention may not all be new, but the way of applying them must not have been made public before: for example, a new type of electrical battery that uses materials not previously used for this purpose may be considered as a novel invention. This criterion of ‘novelty’ is generally understood to safeguard against patenting of technologies that are already available to the public, to ensure that a patented invention is a genuine contribution to existing knowledge.

Inventive step To be eligible for patent protection, in addition to being new, the invention must involve an inventive step. There is no definition of this term in the TRIPS Agreement except that the TRIPS Agreement says in footnote 5 that ‘inventive step’ may be deemed by a member to be synonymous with the term ‘non-obvious’. This requirement is understood in many jurisdictions to mean that the invention must represent a sufficient advance in relation to the state of the art, i.e. an advance from what has been used or described before, such that it could not be obvious to a person working in the technical field related to the invention with ‘ordinary skill’ or average knowledge. Sometimes, this is also described as an ‘unexpected’ or ‘surprising’ effect that is not evident to the average person familiar with that area of technology.

For example, a new type of washing machine is invented that includes a particular type of motor coupled to a particular type of pump. For the inventive step to be denied, it is necessary that not only the combination, but also the choice of the combined elements, is obvious. It is the sum of the differences that have been discovered which must be compared with the prior art and judged as to obviousness, and not each of the new elements taken individually, except where there is no technical link between them.

This criterion of ‘inventive step’ or ‘non-obviousness’ is generally understood to safeguard against patents being granted for inventions which – while strictly new in the sense of not having been disclosed before – only represent a trivial or routine advance on existing knowledge, reserving patents for inventions that represent a clear and non-obvious advance on the state of the art.

Industrial applicability To be eligible for protection, the invention must also be capable of industrial application. There is no further definition of this term except that the TRIPS Agreement says that ‘capable of industrial application’ may be deemed by a member to be synonymous with the term ‘useful’. In some countries this is also termed ‘utility’. This requirement is interpreted in many jurisdictions to mean that the invention has to

be susceptible of practical use in some way in any kind of industry, including agriculture.

Activities that do not aim at any direct technical result but are rather of an abstract and intellectual character are generally excluded from patent grant. This criterion of 'industrial applicability' or 'utility' is generally viewed as reserving patents for technologies that actually achieve a practical purpose, and do not represent a mere abstract theory or speculative notion.

Priority A patent is often assessed as to whether the claimed invention is new and involves an inventive step, including whether it has been anticipated by an earlier patent application, long after the original patent application was filed. Generally, the novelty or inventive step of the claims is assessed against the existing technology not at the time of this examination, but rather as of the date of filing of the original patent. In this regard, Article 4 of the Paris Convention, as incorporated in the TRIPS Agreement, provides for a right of priority to benefit applicants from members who file patent applications abroad after an initial original filing. The right of priority entitles a patent applicant, when filing applications abroad, to claim priority on the basis of a regular first application filed in any member, provided the later applications are filed within twelve months. If recognized, the claim of priority means that the later applications are treated as if they had been filed on the same day as the first application, in particular when determining whether the claimed inventions are patentable. That is to say that that priority date will be used for the purpose of determining the relevant body of prior art.

(ii) Disclosure Article 29 of the TRIPS Agreement requires members to oblige patent applicants 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. This is held to mean in many domestic legislations that a person of ordinary knowledge or skills in the technical field to which the invention pertains must be able, from the information disclosed, to understand how to carry out the invention, for example how to make the product or use the process. Sometimes this is called the 'teaching' or 'enabling' function of the patent document. Patent authorities may additionally require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application (Article 29.1). Thus, if there are several ways in which the invention may be put into practice, the applicant can be required to disclose that which is most practicable. The 'best mode' requirement is optional, i.e. members have the choice of deciding whether or not to impose it on patent applicants.

The disclosure requirement is generally viewed as forming part of a contract between the patent holder and society at large where a period of exclusive rights is granted to a patent holder on the basis of a transfer of the knowledge about the invention to the public. This has long been the policy function of the patent system and indeed lies behind the very word 'patent', which means 'laid open'.

Formal conditions As outlined in Module I, Part IV of the TRIPS Agreement contains some general rules concerning acquisition and maintenance of IPRs. Article 62 permits members to impose reasonable procedures and formalities as a condition for granting a patent, such as requiring application forms to be filled and fees to be paid before a patent is granted. Thus, as mentioned before, patent protection is not automatic but made available to applications that meet the applicable formal and substantive requirements.

It might also be noted that under Article 12 of the Paris Convention, as incorporated into the TRIPS Agreement, each member must maintain a special industrial property service and a central office for the communication to the public of, *inter alia*, patents.

Non-discrimination Article 27.1 also lays down certain rules of non-discrimination with respect to the availability and enjoyment of patent rights. Article 27.1 requires that patents be available and patent rights enjoyable without discrimination as to (a) the place of invention, (b) the field of technology and (c) whether products are imported or locally produced.⁶⁰

Below are three examples to illustrate the three types of non-discrimination required with respect to the grant of patents:

(a) The place of invention: A member cannot impose a different practice with respect to the relevant date for determining prior art based on whether the invention was developed in that or another country.

(b) The field of technology: Members cannot grant less favourable treatment according to class of technology.

(c) Whether products are imported or locally produced: Members cannot exclude an invention from patent grant on the ground that the patented product is produced in another member country and imported.

(iii) What are the permissible exclusions from patentable subject matter? The TRIPS Agreement permits members to exclude inventions from being granted a patent even where they would meet the substantive and formal conditions outlined above. This can be done on three grounds, explained below.

Ordre public or morality Article 27.2 permits members the option of excluding from patent availability inventions that are considered to be contrary to *ordre public* or morality. '*Ordre public*' is a French term. It is literally translated into English as 'public order' but the French term was preferred because it was felt by some to have a more precise meaning; even so this term is not defined in the TRIPS Agreement. However, it

⁶⁰ The principal obligations on non-discrimination with respect to all IPRs, namely national treatment and MFN treatment, are found in Articles 3 and 4, as was discussed in Module I. These provisions relate to the nationalities of the persons involved, unlike the non-discrimination clause in Article 27.1, which prevents discrimination on other bases.

has been understood to represent ideas such as the general security and core values of society.

Article 27.2 specifically mentions inventions contrary to human, animal or plant life or health or seriously prejudicial to the environment. The use of the exception is subject to the condition that the commercial exploitation of the invention must be prevented and this prevention must be necessary for the protection of *ordre public* or morality. This provision prohibits members from excluding from patentability product or process inventions merely because their exploitation is prohibited by law. This makes it clear that inventions cannot be excluded from patentability merely because, for example, they have not yet received marketing approval from health regulatory authorities under the law. Article 4^{quater} of the Paris Convention, as incorporated into the TRIPS Agreement, also prevents a member from refusing the grant of a patent or invalidating a patent 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 domestic law.

An example of an invention contrary to *ordre public* could be a device which meets the conditions for patent grant, and whose explicit and only use is to ensure that radars that control speed limits on highways are de-activated. A member may be able to justify its exclusion on the grounds that this invention is intended to disrupt *ordre public*. However, a member cannot exclude the invention from patentability on this ground and then allow the sale or other commercial exploitation of this device. An example of inventions contrary to morality could be processes for the cloning of human beings or for modifying the germ line identity of humans.

Methods of treatment Under Article 27.3(a) of the TRIPS Agreement a second optional exclusion to a patent grant allows members to exclude from patentability (1) diagnostic, (2) therapeutic and (3) surgical methods for the treatment of humans or animals. In some members' jurisdictions that follow the patentability criterion of industrial applicability, these methods are, in any event, not considered to be susceptible of industrial application.

In their legislation, members have generally understood that this permissible exclusion from patentability applies to methods for the treatment of humans or animals, not to medical or veterinary products, including devices, substances and compositions, for use in any of these methods. Under this approach, while a new and inventive way of removing a cataract from the eye may be excluded from patent protection, an instrument invented to perform this new surgical method would not be so excluded.

Plants and animals The third optional exclusion from patentability allowed under the TRIPS Agreement is given under Article 27.3(b). Members are not required to provide patent protection for inventions of (1) plants and animals and (2) essentially biological processes for their production. They are, however, required to provide patent protection for (a) micro-organisms and (b) non-biological and microbiological processes

for the production of plants and animals. Where members do not provide patent protection for new plant varieties, they are required to protect plant varieties through an effective *sui generis* system (i.e. a system created specially for this purpose). Members also have the option of using a combination of both systems of protection, namely patents and a *sui generis* system. There is no further explicit guidance in the TRIPS Agreement as to what is to be considered an effective *sui generis* system.

The main *sui generis* system for the protection of plant varieties at the international level is that contained in the convention establishing the International Union for the Protection of New Varieties of Plants (UPOV, www.upov.int), initially adopted in 1961, and revised in 1978 and 1991. The UPOV system of plant variety protection has been specifically adapted for the process of plant breeding and has been developed with the aim of encouraging breeders to develop new varieties of plants. Many WTO members have chosen to meet their TRIPS obligations in this area by joining the UPOV upon adopting systems based on it. However, it is generally understood that there are other ways in which the TRIPS option of an 'effective *sui generis* system' can be met, and there is no presumption that members must join the UPOV to comply with this provision.

(iv) Review of Article 27.3(b) Article 27.3(b) provides for the provision to be reviewed four years after the entry into force of the WTO Agreement.

The TRIPS Council accordingly began a review of Article 27.3(b) in 1999. The Council initiated the review through an information gathering exercise. It invited members that were already under an obligation to apply this provision to respond to questions prepared by the WTO Secretariat and several members in order to provide information on how the matters addressed in this provision were treated in their national laws. Up to the end of 2002, the Council had received information from twenty-four members, and compiled all the information in the form of a structured summary in document [IP/C/W/369/Rev.1](#). This document contains tables that illustrate how these members had implemented the obligations in Article 27.3(b).

Other members have since responded to the questions. Responses are circulated in [IP/C/W/125](#) and addenda, and may be easily retrieved from the e-TRIPS Gateway, e-trips.wto.org. In the review, members have discussed two general issues relating to the provisions of Article 27.3(b): (1) the extent to which patent protection should be available for plant and animal inventions; and (2) the nature of an effective *sui generis* system for plant varieties.

(v) Relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the protection of traditional knowledge and folklore The work on these matters was formalized in the 2001 Doha Ministerial Declaration,⁶¹ which mandated the TRIPS Council to work on them.

⁶¹ [WT/MIN\(01\)/DEC/1](#).

Work in the WTO on these issues, especially on the relationship between the TRIPS Agreement and the CBD, has also been undertaken pursuant to the provisions of the Doha Ministerial Declaration on the so-called ‘outstanding implementation issues’ identified by developing countries.

The WTO Secretariat has prepared two summary notes of the points made and issues discussed: (1) on the relationship between the TRIPS Agreement and the CBD, available in [IP/C/W/368/Rev.1](#) and Corr.1, and (2) on the protection of traditional knowledge and folklore, in [IP/C/W/370/Rev.1](#). These subjects are further discussed in Module XI.

2 What are the rights to be conferred?

The TRIPS Agreement recognizes two types of patents: product patents and process patents.

(a) What are the rights to be conferred on owners of product patents?

Article 28.1(a) says that, where the subject matter of a patent is a product, the patent owner shall have the right to prevent others from the acts of: making, using, offering for sale, selling, or importing⁶² for these purposes that product. It should be noted that a patent holder’s rights are essentially rights to exclude others from doing certain acts. A patent, by itself, does not give its owner the right to make, use, sell, or import the patented invention, as such acts could be governed by other laws. For example, the patent owner of an invention that is a pesticide has the right to exclude others from exploiting his invention without his authorization in a territory where he has a patent, but may still not be able to make or sell his invention in that jurisdiction without marketing approval from the relevant regulatory authority.

(b) What are the rights to be conferred on owners of process patents?

(i) Rights of process patent owners Article 28.1(b) states that where the subject matter of a patent is a process, the patent owner must be conferred the exclusive rights to prevent others 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 directly⁶³ by that process. For example, a patented process is being used outside member A’s jurisdiction where the patent was obtained, and the resulting product is being imported into this territory. The patent owner has the right to prevent the importation from member B’s jurisdiction and the sale of the product in member A if it was directly obtained by using the patented process.

⁶² The word ‘importing’ in Article 28.1(a) has a footnote cross-referencing Article 6 of the TRIPS Agreement on exhaustion, making it clear that the extent to which this right can be exercised against parallel imports is subject to Article 6. (See the discussion in Module I, section B5.)

⁶³ ‘Directly’ in this context has been generally understood to mean ‘immediately’ or ‘without further transformation or modification’. The term ‘at least’ is used to denote that this is a minimum standard and members are free to go beyond this.

(ii) Burden of proof There is a specific provision in the TRIPS Section 5 on patents that deals with civil proceedings in respect of infringement of process patent rights, such as when a patent holder takes a court action against a competitor with the claim that their patent is being infringed. Generally, it is up to the patent holder to show that the defending party is infringing their patent. However, Article 34 states that, if the subject matter of a patent is a process for obtaining a product, courts shall have the authority, in at least one of the two circumstances (given below), to reverse the burden of proof, i.e. to order the defendant to prove that he did not use the patented process. That is, in either or both of these specified circumstances, the court must be able to find that the patent was infringed unless the defendant proves that the product was obtained by some other process and not by the patented process.

Members must provide in their legislation that this reversal of the burden of proof applies in at least one of the following circumstances:

- Option (a): the product obtained by the patented process is new; or
- Option (b): there is substantial likelihood that the identical product was made by the patented process and the patent owner has been unable to determine what process is in fact being used.

For example, suppose a member follows option (a) in Article 34.1 and its courts have the authority to reverse the burden of proof only if the product obtained by the patented process is new. This provision would assume significance if a patent has been granted for an invention of a more efficient process for producing a chemical that is already on the market (so the product itself is not new). If a court was hearing an infringement case concerning this patent, it would not be required to reverse the burden of proof: in other words, the procedure would hinge on whether the defendant (the alleged infringer) could demonstrate that they had not infringed the patent, since in this case the product obtained by that process is not 'new' in the patent law sense.

If, however, the legislation gives courts the authority to reverse the burden of proof in the circumstance identified in option (b) of Article 34.1, then the court would still have the authority to put the burden on the alleged infringer to prove that a different process was used. This would arise if the court considers that there is a substantial likelihood that the product was made by the patented process and also considers that the patent owner has been unable through reasonable efforts to determine the process actually used.

(c) Non-discrimination with respect to enjoyment of patent rights

Under Article 27.1, members are not to discriminate with respect to the enjoyment of patent rights on the basis of (a) the place of invention, (b) field of technology and (c) whether products are imported or locally produced. Here are some examples to illustrate what this may mean:

(i) **The place of invention** For example, members are not to discriminate by circumscribing the rights conferred for inventions developed outside their jurisdiction.

(ii) **The field of technology** For example, members are not to discriminate by providing special rights only for inventions in certain technological classes. In *Canada – Pharmaceutical Patents* (DS114), the Panel considered whether there had been discrimination with respect to a field of technology, specifically pharmaceutical products, as discussed in Box V.1, below.

(iii) **Whether products are imported or locally produced** This last provision was a compromise outcome in the TRIPS negotiations to a debate on whether exploitation of a patent through importing the patented product rather than through local production should be admissible as a ground for compulsory licences. The interpretation of the provision has not been addressed in any written report delivered in WTO dispute settlement. It was, however, at issue in a complaint the United States lodged against, *inter alia*, a provision in Brazil's patent law stating that a patent shall be subject to compulsory licensing if the patented product is not fully manufactured or the patented process not fully used in Brazil. A mutually agreed settlement was reached between Brazil and the United States, (but this did not settle the substance of their differences on this point).⁶⁴

(d) What other rights do patent owners have?

Under Article 28.2, both product and process patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

Thus, the owner of a patented invention can assign, i.e. transfer his ownership of the patent (for example, through a sale) or transfer it by succession (for example, by inheritance) or license the right to use the patented invention to any other person. Such other person may then, depending on the terms of the assignment (transfer or licence), have the same rights as the original patent owner.

3 What exceptions are permissible?

Other than the question of exhaustion of IPRs dealt with in Module I, there are two types of permissible exceptions to the exclusive rights conferred on patent owners: (1) limited exceptions and (2) compulsory licences. These are explained in detail below.

(a) Limited exceptions

Article 30 recognizes that members may allow 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

⁶⁴ *Brazil – Measures Affecting Patent Protection* (DS199). See Table IX.1 below.

interests of the patent owner, taking account of the legitimate interests of third parties. The exception is thus subject to three conditions:

- be limited;
- not unreasonably conflict with a normal exploitation of the patent; and
- not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Usually referred to as a 'three-step test', as with the Article 13 exception for copyrights discussed in Module II, each separate and independent requirement applies cumulatively.

TRIPS negotiators adopted the approach of establishing general principles rather than an exhaustive list of exceptions. Many members rely upon this provision to provide that certain uses shall not infringe patent rights. Members' laws have in some instances provided that third parties can make limited use of the patented invention for:

- private, non-commercial purposes;
- research or experimental purposes (to varying degrees according to national legislation and jurisprudence);
- use of patented pharmaceuticals solely for the purpose of obtaining regulatory approval (the so-called regulatory use or 'Bolar' exception);⁶⁵
- prior use, i.e. continuing use of the invention initiated secretly prior to the priority date/filing date; or
- temporary use on vessels, aircraft or land vehicles temporarily or accidentally entering the waters, airspace or land. This exception is expressed as an explicit obligation in Article 5ter of the Paris Convention.

In a number of jurisdictions, such uses have not been considered to be unreasonably prejudicial to the interests of patent owners, taking into account the interests of society and third parties. WTO dispute settlement practice has addressed the regulatory use or Bolar exception, finding such an exception compatible with the TRIPS Agreement (see Box V.1).

⁶⁵ The regulatory use or 'Bolar' exception allows manufacturers of generic drugs to use the patented invention without the patent owner's permission and before the patent protection expires for the purpose of obtaining marketing approval from health regulatory authorities. The generic producers can then be in a position to market their versions as soon as the patent expires. This exception has been upheld as conforming to the TRIPS Agreement in a WTO dispute ruling (*Canada - Pharmaceutical Patents* (DS114), Box V.1 below). The term 'Bolar' is derived from a US patent law case which considered this issue.

BOX V.1 CANADA – PHARMACEUTICAL PATENTS⁶⁶ (DS114)

PARTIES	TRIPS PROVISIONS	KEY DATES
Complainants European Communities	Arts. 27, 28, 30 and 33	Establishment of Panel 1 February 1999
Respondent Canada		Adoption of Panel report 7 April 2000

Measure and product at issue

- **Measure at issue:** Certain provisions under Canada’s Patent Act: (i) ‘regulatory review provision (Sec. 55.2(1))’; and (ii) ‘stockpiling provision (Sec. 55.2(2))’ that allowed generic drug manufacturers to override, in certain situations, the rights conferred on a patent owner. The regulatory review provision permitted generic manufacturers of pharmaceuticals to produce samples of the patented product for use during the regulatory review process. The stockpiling provision allowed producers of generic drugs to make the drugs and begin stockpiling them six months prior to the expiration of the patent.
- **Product at issue:** Patented pharmaceuticals from the European Communities.

Summary of key Panel findings

(a) Stockpiling provision

- **TRIPS Arts. 28.1 (patent owner's rights) and 30 (exceptions):** (Canada practically conceded that the stockpiling provision violated Art. 28.1, which sets out exclusive rights granted to patent owners.) Concerning Canada’s defence under Art. 30, the Panel found that the measure was not justified under Art. 30 because there were no limitations on the quantity of production for stockpiling which resulted in a substantial curtailment of extended market exclusivity, and, thus, was not ‘limited’ as required by the first of Art. 30's three cumulative conditions.

(b) Regulatory review provision

- **TRIPS Arts. 28.1 (patent owner's rights) and 30 (exceptions):** (Canada also practically conceded the inconsistency of the provision with Art. 28.1) The Panel found that Canada’s regulatory review provision was justified under Art. 30 by meeting all three cumulative criteria: the exceptional measure (i) must be limited (a narrow curtailment of the legal rights required by Art. 28, as measured by the extent to which the affected rights had been impaired); (ii) must not ‘unreasonably conflict with a normal exploitation of the patent’ (unreasonably conflict with a common and normative standard of entitlement to commercially extract economic value from the patent); and (iii) must not ‘unreasonably prejudice the legitimate interests of the patent owner’, taking account of the legitimate

⁶⁶ Canada – Patent Protection of Pharmaceutical Products.

BOX V.1 CANADA – PHARMACEUTICAL PATENTS⁶⁶ (DS114)

interests of third parties (legitimate interests being broader than legal interests, and justifiable as supported by relevant public policies or other social norms).

- **TRIPS Art. 27.1 (non-discrimination):** The Panel found that the European Communities failed to prove that the regulatory review provision discriminated based on the field of technology (i.e. against pharmaceutical products in this case), either *de jure* or *de facto*, under Art. 27.1. The Panel's view was that members may treat different fields of patent protection differently if they do so for a legitimate purpose. The Panel said that the 'ordinary meaning of the word "discriminate" ... 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. Discrimination may arise from explicitly different treatment, sometimes called "*de jure* discrimination", but it may also arise from ostensibly identical treatment which, due to differences in circumstances, produces differentially disadvantageous effects, sometimes called "*de facto* discrimination".'

(b) Compulsory licences

The TRIPS Agreement does not use the term 'compulsory licences' but rather 'use without authorization of the right holder'. Article 31 covers both compulsory licences granted to third parties for their own use and use by or on behalf of governments without the authorization of the right holder. A compulsory licence can be said to be a licence given by a government authority to a person other than the patent owner that authorizes the production, importation, sale or use of the patent-protected product without the consent of the patent owner.

The TRIPS Agreement builds upon the provision in Article 5A of the Paris Convention⁶⁷ and recognizes the right of members to authorize compulsory licences subject to conditions aimed at protecting the legitimate interests of the right holder that are detailed in Article 31. This was reaffirmed in the Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration)⁶⁸ (see details in Module X).

While setting out certain conditions, the TRIPS Agreement does not limit the grounds or underlying reasons that might be used to justify the grant of compulsory licences

⁶⁷ Article 5A recognizes the right of members 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. A compulsory licence may not be applied for on the ground of failure to work or insufficient working before 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. It must be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory licence must be non-exclusive and not transferable, even in the form of the grant of a sub-licence, except to that part of the enterprise or goodwill which exploits such licence.

⁶⁸ [WT/MIN\(01\)/DEC/2](#), reproduced in Annex 6 to this Guide.

(except in the case of semi-conductor technology).⁶⁹ Article 31 does mention (1) national emergencies, (2) other circumstances of extreme urgency and (3) anti-competitive practices – but only as grounds when some of the normal requirements for compulsory licensing, such as seeking a voluntary licence first, do not apply.

The main conditions to be respected in the grant of compulsory licences given in Article 31 are listed below:

- Applications to be considered on their individual merits (TRIPS Article 31(a))

Governments must not decide to automatically compulsorily license a ‘class’ of patents, for example steel making processes, without considering the application on its individual merits.

- First, an unsuccessful attempt ... (TRIPS Article 31(b))

As a general rule, an unsuccessful attempt must have been made first to obtain a voluntary licence on reasonable commercial terms and conditions within a reasonable period of time before a compulsory licence is granted. There are three circumstances in which this rule need not be applied: (1) in case of a national emergency or other circumstances of extreme urgency; (2) in cases of public non-commercial use; and (3) when a compulsory licence is granted as a remedy in an adjudicated case of anti-competitive practices. The Doha Declaration clarified that members have the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency (see Module X).

- Scope and duration to be limited to purposes for which granted (TRIPS Article 31(c))

The scope and duration of compulsory licences must be limited to the purpose for which they were authorized. For example, if a compulsory licence has been granted on a patented invention for the purpose of meeting a particular need, the scope and duration of the licence must be limited to what is necessary to achieve this purpose. Compulsory licences should be liable to termination when the circumstances that justified their creation no longer apply. However, in doing so the legitimate interests of the licensee may be protected – for example, any investment that the licensee has made to produce the product under the compulsory licence.

- Licences to be non-exclusive (TRIPS Article 31(d))

⁶⁹ In the case of semi-conductor technology, the grounds for compulsory licences are limited (1) to public non-commercial use or (2) to remedy a practice determined after judicial or administrative process to be anti-competitive (TRIPS Article 31(c)).

Compulsory licences must be non-exclusive, i.e. the licensee must not have the right to prevent the grant of other licences or the use of the invention by the patent owner.

- Predominantly for supply of domestic market (TRIPS Article 31(f))

Compulsory licences shall be authorized predominantly for the supply of the domestic market of the member authorizing such use. This condition may be relaxed when the government grants a compulsory licence to remedy anti-competitive practices (Article 31(k)). Article 31*bis*.1 of the amended TRIPS Agreement also permits members who issue a compulsory licence for the purpose of exporting generic pharmaceuticals to one or more eligible importing members which lack sufficient domestic manufacturing capacities to derogate from this condition (see Module X).

- Right holder: adequate remuneration (TRIPS Article 31(h))

The right holder must be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the licence. When the grant of a compulsory licence is to remedy anticompetitive practices, the need for such a remedy may be taken into account in determining the amount of remuneration (Article 31(k)). Article 31*bis*.2 of the amended TRIPS Agreement removes the requirement for adequate remuneration in the importing member, provided that the right holder is remunerated by the exporting member. The purpose is to avoid double remuneration when both the exporting and importing members issue compulsory licences for a generic pharmaceutical (see Module X).

- Decisions on grant and remuneration to be subject to judicial or other independent review (TRIPS Article 31(i))

The legal validity of any decision relating to the grant of compulsory licences, and any decision relating to the remuneration provided in respect of such use, must be subject to judicial review or other independent review by a distinct higher authority in that member.

- Certain conditions to be met in the case of dependent patents (TRIPS Article 31(l))

Where a later patented invention cannot be exploited without infringing an earlier patent (i.e. the case of dependent patents), a compulsory licence may only be granted on the earlier patent if the invention in the later patent involves an important technical advance and the owner of the earlier patent has a right to obtain a cross-licence for the later patent.

The special compulsory licensing system for access to medicines removes the requirement for a member to comply with the conditions in Article 31(f) and (h), provided they follow notification requirements and condition the licences as required by this system (TRIPS Article 31*bis* and the Annex to the Agreement). See Module X.

4 What is the minimum term of protection?

The last principal issue in this module is the duration of patent rights and the circumstances under which these can be terminated.

(a) Term of protection

The minimum term of protection available for patents shall be a period of twenty years from the filing date (Article 33). The filing date is the date of the application.⁷⁰

Members may make the patent term subject to the payment of renewal or maintenance fees. Procedures for this are governed by Article 62 on the acquisition and maintenance of IPRs. If these fees are not paid, the patent lapses; many patents lapse before the available full term of twenty years where there is no economic interest in maintaining them. There are some relevant provisions in the Paris Convention which provide for grace periods for fee payment and clarify the term of patents that rely on a right of priority from a patent application filed elsewhere.⁷¹

In some jurisdictions an extension of the patent term is given to certain classes of product to compensate for delays in obtaining the regulatory approvals that are needed before products can be marketed. The TRIPS Agreement does not require the grant of patent term extensions, and thus as a minimum obligatory standard the available term need only run to twenty years from the filing date.

(b) Revocation

Can members terminate a patent even before its expiry date? If 'yes', on what grounds? What does the Paris Convention say in this regard?

With respect to the duration of a patent right, Articles 4*bis* and 5A of the Paris Convention recognize that patents for the same invention in different countries are independent of each other and also that members shall not provide for forfeiture to prevent the abuse of exclusive rights, except in cases where the grant of a compulsory licence would not have been sufficient to prevent the abuse. No proceedings for the forfeiture or revocation of a patent may be instituted before the end of two years from the grant of the first compulsory licence. In addition, importation by the patentee into the member where the patent has been granted of an article manufactured in any of the members shall not entail forfeiture of the patent.

⁷⁰ The TRIPS Agreement states that members who do not have a system of original grant may provide that the term of protection shall be calculated from the date of filing the original patent application (footnote 8). This was intended to take account of the situation of members which did not have a system of original grant but had a system for re-registering patents granted elsewhere.

⁷¹ Article 5*bis* of the Paris Convention obliges members to grant a period of grace for the payment of the fees prescribed for the maintenance of a patent application. With respect to the duration of a patent right, Article 4*bis* of the Paris Convention, as incorporated into the TRIPS Agreement, says that patents applied for during the period of priority are independent as regards their normal duration and that those obtained with the benefit of priority must have a duration equal to that which they would have had, had they been applied for or granted without the benefit of priority.

Article 32 of the TRIPS Agreement adds to the relevant provisions in the Paris Convention and provides for the availability of an opportunity for judicial review of any decision to revoke or forfeit a patent.

There has been a discussion on the interpretation of Article 32 in the TRIPS Council recorded in [IP/C/M/8](#) and Corr.1 and [IP/C/M/9](#). Some members considered that the subject of revocation of patents was dealt with in Articles 27, 29 and 33 of the TRIPS Agreement, meaning that patents could not be revoked by members except on grounds that would have justified denial of the grant of a patent on the underlying application. According to this view, the TRIPS Agreement precluded a member from revoking a patent in order to serve other general societal goals, such as promoting technology transfer for environmentally sound technologies. Some others took the view that revocation was dealt with in Article 32 only and that this provision did not restrict the rights of members to decide on the grounds of revocation subject to the limitations prescribed under Article 5 of the Paris Convention.