

22: Patents: Rights Conferred

Article 28 Rights Conferred

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

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

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

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

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

Article 32 Revocation/Forfeiture

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

Article 33 Term of Protection

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

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

⁷³⁰ Article 6 of TRIPS stipulates that "For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."

1. Introduction: terminology, definition and scope

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

Article 28 obliges Members to ensure that patent owners enjoy exclusive rights, and details the minimum content of such rights, which may be exercised with regard to acts performed *during* manufacturing as well as to acts performed *after* manufacturing. The exclusive⁷³³ nature of the rights conferred is inherent to patent grants, though not to all forms of intellectual property.⁷³⁴ It permits the title-holder, if successful in the exploitation of the invention, to obtain significant rents during the lifetime of the patent, thus fulfilling one of the basic purposes of patent grants.

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

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

Article 32 addresses an important issue in patent law: the revocation⁷³⁷ or forfeiture⁷³⁸ of a patent. However, this provision only establishes a procedural requirement (the availability of judicial review), and does not stipulate the grounds or other substantive conditions for such acts to take place, thereby leaving considerable leeway to Members to legislate on the matter. In particular, Article 32

⁷³¹ The Concise Oxford Dictionary, p. 821.

⁷³² The Concise Oxford Dictionary, p. 820.

⁷³³ “Exclusive” means “shutting out, not admitting of”, *The Concise Oxford Dictionary*, p. 336.

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

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

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

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

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

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

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

2. History of the provisions

2.1 Situation pre-TRIPS

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

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

Such extension had been applied in some developed countries, often with considerable controversy.⁷⁴² In the case of the USA, the extension was only introduced by a legislative amendment in 1988.⁷⁴³ The extension was not provided, however, in the laws of most developing countries, where process patents only covered, in

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

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

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

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

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

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

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

2.2 Negotiating history

2.2.1 Exclusive rights

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

“2. Rights Conferred

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

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

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

- (a) The right to prevent others from making, using or selling the patented product or using the patented process for commercial or industrial purposes.
- (b) The right to assign, or transfer by succession, the patent and to conclude licence contracts.
- (c) The right to a reasonable remuneration when the competent authorities of a PARTY to the present agreement use a patent for government purpose or provide for the granting of a licence of right or a compulsory licence. Such reasonable remuneration will be determined having regard to the economic situation of the PARTY, the nature of the invention, the cost involved in developing the patent and other relevant factors.

(See also point 5A.3.9 below)”

⁷⁴⁴ See, Gervais, p. 154.

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

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

"Article 28: Rights Conferred

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

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

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

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

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

2.2.2 Revocation/Forfeiture

2.2.2.1 The Anell Draft. The Anell Draft provided:

"6. Revocation/Forfeiture

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

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

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

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

2.2.3 Term of protection

2.2.3.1 The Anell Draft. The Anell Draft provided:

"4. Term of Protection

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

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

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

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

2.2.3.2 The Brussels Draft

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

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

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

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

3. Possible interpretations

3.1 Article 28.1 (a)

Rights Conferred

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

(a) where the subject matter of a patent is a product, to prevent third parties not having the owner’s consent from the acts of: making, using, offering for sale, selling, or importing [6] for these purposes that product;

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

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

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

⁷⁴⁷ See, e.g., Gervais, p. 153.

⁷⁴⁸ The Concise Oxford Dictionary, p. 611.

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(e.g., extraction from a natural product) independently of the scale of production⁷⁴⁹ and, most importantly, of the method of production used. This signifies that whatever the process used by a third party, an infringement would occur whenever the patented product is made, even if an independently developed and inventive process were used.⁷⁵⁰ Similarly, it is immaterial for the purpose of establishing an infringement whether the product is made for domestic consumption or for export.⁷⁵¹

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

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

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

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

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

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

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

⁷⁵² See Chapter 23.

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

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

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

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

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

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

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

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

3.2 Article 28.1(b)

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

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

⁷⁵⁶ See Chapter 5.

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

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

⁷⁵⁹ See Chapter 5.

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

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

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

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

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

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

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

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

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

⁷⁶³ See Chapter 26.

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

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

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

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

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

3.3 Article 28.2

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

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

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

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

3.4 Revocation (Article 32)

Article 32 Revocation/Forfeiture

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

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

⁷⁶⁸ See Chapter 21.

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

⁷⁷⁰ See Chapter 25.

⁷⁷¹ See Chapter 29.

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

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- (a) the invention was not patentable, because it did not meet any of the patentability requirements;
- (b) the patent was granted to a person who was not entitled to that patent;
- (c) the specification of the patent did not disclose the invention clearly enough and completely enough for it to be performed by a person skilled in the art; or
- (d) the subject matter in the patent extends beyond the subject matter in the application as filed.

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

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

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

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

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

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

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

3.5 Term of protection

Article 33 Term of Protection

The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date. [Footnote 8].

[Footnote 8]: It is understood that those Members which do not have a system of original grant may provide that the term of protection shall be computed from the filing date in the system of original grant.

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

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

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

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

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

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

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

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

⁷⁷⁸ See WT/DS170/R, para. 6.103.

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

In supporting the panel’s interpretation, the Appellate Body added that “in Article 33 of TRIPS, the word ‘available’ means ‘available, as a matter of right’, that is to say, available as a matter of legal right and certainty.”⁷⁸⁰

4. WTO jurisprudence

4.1 Exclusive rights

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

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

4.2 Term of protection

As mentioned, in the *Canada – Term of patent protection* case⁷⁸² the panel and the Appellate Body addressed the interpretation of Article 33. Canada had argued that Section 45 of its Patent Act, which established a 17-year terms from the date on which the patent was issued, did not prescribe a term of protection that would end before the expiration of the 20-year period from the date of filing. Canada argued that a term of protection of at least equal to (and frequently in excess of) a period of 20 years from the date of filing was “available” under Section 45 and that this Section was, therefore, consistent with Article 33 of TRIPS. It considered that 17 years of “effective” protection for the “exclusive privilege and property rights” conferred by the Patents Act were “equivalent or superior” to the term of “exclusive privilege and property rights” provided by Article 33. Canada made such assertion based on the fact that:

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

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

⁷⁸⁰ *Ibid.*, para. 90.

⁷⁸¹ See WT/DS/114/R, para. 7.55.

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

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

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

"The key question for consideration with respect to the "availability" argument is, therefore, whether Section 45 of Canada's Patent Act, together with Canada's related regulatory procedures and practices, make available, as a matter of legal right and certainty, a term of protection of twenty years from the filing date for each and every patent. The answer is clearly in the negative, even without disputing the assertions made by Canada with respect to the many statutory and other informal means available to an applicant to control the patent process. The fact that the patent term required under Article 33 can be a by-product of possible delays in the patent-granting process does not imply that this term is available, as a matter of legal right and certainty, to each and every Old Act patent applicant in Canada" (para. 91).

"To demonstrate that the patent term in Article 33 is "available", it is not sufficient to point, as Canada does, to a combination of procedures that, when used in a particular sequence or in a particular way, may add up to twenty years. The opportunity to obtain a twenty-year patent term must not be "available" only to those who are somehow able to meander successfully through a maze of administrative procedures. The opportunity to obtain a twenty-year term must be a readily discernible and specific right, and it must be clearly seen as such by the patent applicant when a patent application is filed. The grant of the patent must be sufficient in itself to obtain the minimum term mandated by Article 33. The use of the word "available" in Article 33 does not undermine but, rather, underscores this obligation" (para. 92).

5. Relationship with other international instruments

5.1 WTO Agreements

5.2 Other international instruments

6. New developments

6.1 National laws

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

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

7. Comments, including economic and social implications

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Article 33 has had a significant impact in many developed and developing countries, which were bound to amend provisions relating to the duration of conferred rights. Thus, the USA, New Zealand, Portugal⁷⁸⁴ and Canada were among the developed countries that changed their legislation in order to conform to the 20-year term mandated by TRIPS. Numerous developing countries that previously granted a shorter term of patent protection also modified their laws accordingly.

6.2 International instruments

6.3 Regional and bilateral contexts

6.3.1 Regional

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

6.3.2 Bilateral

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

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

6.4 Proposals for review

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

7. Comments, including economic and social implications

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

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

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

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

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

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

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

Economists have extensively examined the efficiency implications of the patent system and the optimal patent life. Determining *a priori* the optimal patent life of any given invention is costly and in some cases may simply be impossible. If the patent lasts for a too long period, social costs may exceed the social benefits realized from patents. Such costs notably include a sacrifice in static efficiency⁷⁹⁰

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

⁷⁸⁶ See, e.g., Bently and Sherman, p. 494.

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

⁷⁸⁸ See, e.g., Barton, pp. 1933–1934.

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

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

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

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

23: Patents: Exceptions to Rights Conferred

Article 30 Exceptions to Rights Conferred

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

1. Introduction: terminology, definition and scope

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

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

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

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

2. History of the provision

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

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

2. History of the provision

2.1 Situation pre-TRIPS

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

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

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

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

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

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

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

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

2.2 Negotiating history

The negotiation of this provision centred on the scope of the exceptions to be allowed, as well as the way in which it would be formulated. As indicated by the Anell Draft, some of the negotiating parties (notably the European Communities,⁷⁹⁸ Brazil⁷⁹⁹ and Canada⁸⁰⁰) were inclined to develop a non-exhaustive list of specific exceptions.⁸⁰¹

2.2.1 The Anell Draft

“2.2 Exceptions to Rights Conferred”

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

2.2.1 Rights based on prior use.

2.2.2 Acts done privately and for non-commercial purposes.

2.2.3 Acts done for experimental purposes.

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

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

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

2.2.2 The Brussels Draft

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

3. Possible interpretations

3.1 The conditions of Article 30

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

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

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

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

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

⁸⁰² WT/DS114/R, 17 March 2000.

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

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

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

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

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

⁸⁰³ *Ibid.*, para. 7.20.

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

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

⁸⁰⁶ *New Shorter Oxford Dictionary*, p. 1592.

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

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

[...] The word ‘exception’ by itself connotes a limited derogation, one that does not undercut the body of rules from which it is made. When a treaty uses the term “limited exception”, the word “limited” must be given a meaning separate from the limitation implicit in the word “exception” itself. The term “limited exception” must therefore be read to connote a narrow exception – one which makes only a small diminution of the rights in question.⁸⁰⁸

[...] In the absence of other indications, the Panel concluded that it would be justified in reading the text literally, focusing on the extent to which legal rights have been curtailed, rather than the size or extent of the economic impact. In support of this conclusion, the Panel noted that the following two conditions of Article 30 ask more particularly about the economic impact of the exception, and provide two sets of standards by which such impact may be judged.[footnote omitted] The term “limited exceptions” is the only one of the three conditions in Article 30 under which the extent of the curtailment of rights as such is dealt with.”⁸⁰⁹

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

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

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

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

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

⁸⁰⁸ *EC-Canada*, para. 7.30.

⁸⁰⁹ *EC-Canada*, para. 7.31.

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

⁸¹¹ The Concise Oxford Dictionary, p. 1176.

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incompatible,⁸¹² and “normal” “conforming to standard, regular, usual, typical.”⁸¹³ Finally, “exploitation” means utilization.⁸¹⁴

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

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

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

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

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

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

⁸¹² The Concise Oxford Dictionary, p. 197.

⁸¹³ The Concise Oxford Dictionary, p. 690.

⁸¹⁴ The Concise Oxford Dictionary, p. 340.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

⁸²³ *Ibid*, para. 7.55.

3. Possible interpretations

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

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

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

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

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

3.2 Acts that may be exempted

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

3.2.1 Research and experimentation

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

⁸²⁴ The Concise Oxford Dictionary, p. 810.

⁸²⁵ The Concise Oxford Dictionary, p. 574.

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

⁸²⁷ *Ibid*, para 7.71.

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

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

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

3.2.2 Early working

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

3.2.3 Individual prescriptions

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

3.2.4 Prior use

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

⁸²⁹ *EC-Canada*, para. 7.69.

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

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

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

4. WTO jurisprudence

3.2.5 Parallel imports

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

4. WTO jurisprudence

4.1 EC-Canada

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

“(1) It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.

(2) It is not an infringement of a patent for any person who makes, constructs, uses or sells a patented invention in accordance with subsection (1) to make, construct or use the invention, during the applicable period provided for by the regulations, for the manufacture and storage of Articles intended for sale after the date on which the term of the patent expires.”

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

The panel noted that, in the framework of TRIPS,

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

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

⁸³³ Article 6 of the TRIPS Agreement states that: “For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.” For details, see Chapter 5.

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

⁸³⁵ *EC-Canada*, para. 7.14.

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Patents: exceptions to rights conferred

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

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

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

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

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

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

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

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

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

⁸³⁶ Ibid.

⁸³⁷ Ibid, para. 7.15.

⁸³⁸ Ibid, para. 7.26.

⁸³⁹ Ibid, para. 7.45.

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

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

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

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

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

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

⁸⁴⁰ Ibid, para. 7.82.

⁸⁴¹ Ibid, para. 7.34.

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

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

Finally, it is important to note that, in the panel's view, both Articles 30 and 31 are subject to the non-discrimination clause contained in Article 27.1.⁸⁴³ This interpretation has been contested, however, by a number of developing countries.⁸⁴⁴

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

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

⁸⁴² Ibid, para. 7.35.

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

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

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

⁸⁴⁶ This provision stipulates that: "Members shall confine limitations or exceptions to exclusive rights to certain special cases which do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the right holder."

6. New developments

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5. Relationship with other international instruments

5.1 WTO Agreements

5.2 Other international instruments

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

6. New developments

6.1 National laws

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

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

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

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

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

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

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

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

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

⁸⁵¹ Law of 1996, Article 75.b.

⁸⁵² Act No. 21 of 1996, Article 42.b.

⁸⁵³ The Industrial Property Regulations, 1997, Article 4.a.iii.

⁸⁵⁴ Law No. 35, 1996, Article 19.2.

⁸⁵⁵ Patents Act, 1994, as amended in 1995, Article 66.2.b.

⁸⁵⁶ The U.S. Drug Price Competition and Patent Term Restoration Act of 1984, which adopted the "Bolar exception", permitted the extension of the patent term so as to compensate pharmaceutical patent owners for the time consumed by the marketing approval of a drug, up to five years.

of materials in small quantities to initiate approval procedures before the expiry of the patent in the countries that allow it. It also grants an extension of the life of the patent for up to five years (or for 14 years from first registration worldwide or upon expiration of an extension granted elsewhere, whichever terminates the earliest). Australia also adopted an exception of this kind, linked to the extension of the patent term.

The “Bolar exception” was also incorporated into Article 43 of the Brazilian Industrial Property Code by Law 10.196 of 14 February 2001.

Though in Europe this exception has not been formally introduced yet,⁸⁵⁷ the German Federal Supreme Court accepted a “Bolar” type exception in *Boehringer Ingelheim Int. GmbH v. Dr. Rentschler Arzneimittel GmbH and others* (11.7.95). The Court stated that “... it is not contrary to the permissibility of clinical tests that the defendants are carrying out or supporting these with the further aim of licensing under the laws relating to pharmaceuticals”. In another decision (*Wellcome Foundation Ltd. vs. Parxel International and others* (1.1.98)), the Paris Court of Appeal held that undertaking tests for obtaining marketing approval did not constitute infringement as such.

Explicit derogations to the exclusive right to import have been provided for in some laws under the principle of “exhaustion of rights”. This is the case, for instance, of Argentina,⁸⁵⁸ the Andean Group countries (Decision 486), South Africa (for medicines),⁸⁵⁹ and Kenya.

6.2 International instruments

6.3 Regional and bilateral contexts

6.3.1 Regional

6.3.2 Bilateral

The USA-Jordan agreement explicitly permits the parties to adopt a “Bolar” type exception, including for exports when made to meet regulatory requirements in a foreign country. Article 19 of the agreement states that

“If a Party permits the use by a third party of a subsisting patent to support an application for marketing approval of a product, the Party shall provide that any product produced under this authority shall not be made, used or sold in the territory of the Party other than for purposes related to meeting requirements

⁸⁵⁷ The European Parliament has expressed its opinion in favour of the admission of a “Bolar” type exception. In its resolution of 16 April 1996, paragraph 17, it stated that: “Measures should be introduced which enable pharmaceutical companies to begin, in advance of patent or supplementary protection certificate (SPC) expiry, such laboratory experiments and regulatory preparations as may be required only for the registration of generic pharmaceuticals developed in the EU, to be available on the market immediately, but only after the expiry of a patent or SPC for a proprietary product”.

⁸⁵⁸ The implementing regulation (Decree 260/96), however, significantly reduces the scope of such exception.

⁸⁵⁹ The permission to parallel import is incorporated in the Medicines Act, which was challenged before the South African Supreme Court on this and other grounds by the pharmaceutical industry. The complaint, nevertheless, was withdrawn in April 2001.

7. Comments, including economic and social implications

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for marketing approval, and if export is permitted, the product shall only be exported outside the territory of the Party for purposes of meeting requirements for marketing approval in the Party or in another country that permits the use by a third party of a subsisting patent to support an application for marketing approval of a product”.

The same type of exception is permitted under Article 17.9.4 of the USA-Chile FTA.

6.4 Proposals for review

There have been no proposals for review of Article 30.

7. Comments, including economic and social implications

The economic and social implications of the exceptions allowed under Article 30 are significant. The exceptions mitigate the potential anti-competitive effects of the exclusive rights and may thereby increase static or dynamic efficiency.

Thus, the experimental use exception, particularly if permitted for *commercial* purposes, may speed up follow-on innovation and further technological progress. It may clearly enhance dynamic efficiency, without reducing static efficiency.

The “Bolar exception”, as indicated above, permits an early introduction of competitive products, normally pharmaceuticals, as soon as the patent expires and thereby allows consumers to gain access to medicines at lower prices. In the absence of such exception, the introduction of generic copies may be delayed for several months or years, during which the patent owner might charge high prices despite the expiry of the patent. This exception increases static efficiency; since the patent holder will be able to keep its monopoly till the expiry of the patent, it is unlikely to reduce dynamic efficiency. An analysis of the welfare implications of the Act that introduced this exception in the USA indicated that

“... from the perspective of economic welfare, the Act is the source of large potential positive gains of two types. First, it eliminated costly scientific testing which served no valid purpose. Second, the Act lowered prices to consumers with some elimination of deadweight losses and large transfers from producers to consumers.”⁸⁶⁰

The exception of prior use is based on reasons of justice (it is not fair to prevent the use of an invention to those who possessed it and did not apply for a patent) as well as static efficiency. The existence of an alternative supply to the patent owner may drive prices down and benefit consumers.⁸⁶¹

⁸⁶⁰ See, e.g., W. Viscusi; John Vernon and Joseph Harrington, *Economics of regulation and antitrust*, Second Edition, The MIT Press, Cambridge 1997, p. 857.

⁸⁶¹ Note that several of the above exceptions were also referred to by the IPR Commission report (p. 119). In addition to those exceptions, the Commission also proposed an exception for *teaching purposes* (ibid.) and highlights the importance of such exemption, due to the increasing encroachment of patent rights into traditional copyright areas such as computer programs.

Finally, parallel imports as an exception to exclusive patent rights may be a powerful tool to increase allocative efficiency.⁸⁶² If consumers can acquire from a foreign country legitimate products at lower prices than those locally charged by the patent holder, there is an increase in static efficiency without necessarily reducing dynamic efficiency: the patent holder has been remunerated (in the foreign market) for the intellectual contribution he has made. Of course, the levels of profit obtained by the patent holder may be lower than those obtainable if he/she were able to fragment markets and charge a higher price in the importing country, but this does not mean that the owner would not be able to recover R&D expenditures.

The pharmaceutical industry has claimed that the admission of parallel imports may endanger future R&D. It has argued that the exports of drugs sold at low cost in developing countries to higher-priced markets would affect the industry's ability to fund future R&D.⁸⁶³ It has been argued, however, that trade in medicines is subject to quite stringent national regulations that erect effective barriers to market access. Moreover, parallel imports would only take place where significant price differentials exist. Pharmaceutical firms may reduce such differentials or sell the patented products under different trademarks or packaging in major markets, in order to make parallel importation difficult or unattractive.⁸⁶⁴ Developed countries that consider their industries to be jeopardized by "parallel exports" from low price countries may adopt measures to prevent parallel imports under their national legislation. Thus, the IPR Commission in its Report recommended that

"Developed countries should maintain and strengthen their legislative regimes to prevent imports of low priced pharmaceutical products originating from developing countries."⁸⁶⁵

At the same time, it has been suggested that in order to keep a system of tier pricing and prevent low-priced medicines in developing countries from flowing to developed countries, the former should adopt measures to prevent their exportation.⁸⁶⁶

⁸⁶² For a general analysis of the exhaustion doctrine under the TRIPS Agreement, see Chapter 5. For a discussion of parallel imports in the trademark context, see Chapter 14.

⁸⁶³ Arguments against parallel trade also include the objection that it will increase opportunities for "counterfeit and substandard products to enter the market" (Harvey Bale, *TRIPS, Pharmaceuticals and Developing Countries: Implications for Drug Access and Drug Development*, paper presented at the WHO Workshop on the TRIPS Agreement and its Impact on Pharmaceuticals, IFPMA, Jakarta 2000, p. 18), but this is essentially a problem of law enforcement that can be addressed under normal procedures.

⁸⁶⁴ See, e.g., Jayashree Watal, *Pharmaceutical patents, prices and welfare losses: a simulation study of policy options for India under the WTO TRIPS Agreement*, Washington DC 2000 (mimeo).

⁸⁶⁵ See IPR Commission report, p. 41. This could be done by the adoption or maintenance in developed countries of a system of national or regional exhaustion of intellectual property rights. For more details on the principle of exhaustion, see Chapter 5.

⁸⁶⁶ Thus, the U.S. delegation held at the Council for TRIPS Special Session of June 21, 2001, that "In our view, advocates of parallel importation overlook the fact that permitting such imports discourages patent owners from pricing their products differently in different markets based upon the level of economic development because of the likelihood that, for example, products sold for low prices in a poor country will be bought up by middle men and sent to wealthiest country markets and sold at higher prices, for the benefit primarily of the middle men. The lack of parallel

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Finally, as far as the situation in developing countries is concerned, the IPR Commission recommended that:

“Developing countries should not eliminate potential sources of low cost imports, from other developing or developed countries. In order to be an effective pro-competitive measure in a scenario of full compliance with TRIPS, parallel imports should be allowed whenever the patentee’s rights have been exhausted in the foreign country. Since TRIPS allows countries to design their own exhaustion of rights regimes (a point restated at Doha), developing countries should aim to facilitate parallel imports in their legislation.”⁸⁶⁷

import protection can also have significant health and safety implications. Our law enforcement and regulatory agencies, especially FDA, have commented on how very difficult it is for them to keep counterfeit and unapproved drugs out of our country even with the strong parallel import protection provided in the United States. Advocating parallel imports, therefore, could work to the disadvantage of the very people on behalf of whom the advocates purport to be speaking.” As Dr. Brundtland in Oslo noted, “For differential pricing to work on a large scale, I think we can all agree that there must be watertight ways of preventing lower priced drugs from finding their way back into rich country markets.”

⁸⁶⁷ IPR Commission report, p. 42. A possible means to realize this objective would be the adoption in developing countries of an international regime of exhaustion, contrary to the national/regional exhaustion regimes recommended for developed countries, see above.