II. CHAPTER. THE FRAMEWORK OF TRIPS

A. Brazilian context prior to TRIPS

Patents were first introduced into the Brazilian legal system through the Charter of April 28, 1809, enacted by the Portuguese Regent Prince D. João VI, which granted temporary privileges for exclusive exploitation of new machines and inventions useful in industry to their creators.[14] Far from being a totally new field of law, Patent Law is one of the oldest in the Brazilian legal system. The first Constitution of 1824 already safeguarded the property of inventions to their inventors, and the Law of August 28, 1830 was enacted to regulate this right.[15] From the end of the nineteenth century until the Second World War, it is possible to argue that Brazil maintained a level of patent protection (and other intellectual property rights) that was compatible with which was established in international agreements.[16] Brazil was a founding Contracting State of the Paris Union for the protection of industrial property, which entered in force on March 20, 1883.[17]

During the period following the Second World War until the beginning of the 1990s, the Brazilian government adopted economic policies that protected national industry against competition from imports. These policies discredited the country's patent system and led to the erosion of legal work, scarce scholarly production and few judicial decisions regarding patents.[18] The country sought to profit from technology created in developed countries (in the public domain or not), to the benefit of national industry, which drew hostility against the idea of patents as an important component of industrial development.[19]

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14 See *Cerqueira*, Industrial Property Treaty, p. 1-48.
15 *Id.*
16 *Id.*
17 See *WIPO*, Contracting Parties, table 2.
18 See *Licks*, Patent Law, p. 9-10.
19 *Id.*

The exclusions from patentable subject matter, such as chemical and pharmaceutical products[20], were introduced into the Brazilian legislation in 1945[21] and remained in succeeding statutes.[22] Law 5772/1971, the Brazilian statute that was in force prior to the enactment of TRIPS, stated in Article 9 (a) and (b) that products obtained by chemical processes or means, as well as foodstuff, chemical-pharmaceutical products, medicines and the processes for obtaining or modifying them were not patentable. It excluded peremptorily pharmaceutical products and processes from patentable subject matter.

The Pharmaceutical Manufacturers Association or the PMA (currently the Pharmaceutical Research and Manufacturers of America – PhRMA) filed a complaint on June 11, 1987, at the Office of the United States Trade Representative (USTR), regarding the lack of patent protection for inventions in the pharmaceutical field, either for products or processes.[23] The industry association considered Brazilian policies and activities unreasonable as they would harm the American pharmaceutical industry in around US$160 million during the period between 1979 and 1986.[24] Brazilian manufacturers were accused of copying American inventions without paying licensing fees.[25] The USTR started investigating immediately.[26]

The PMA pointed out that there were several other countries that did not adequately protect pharmaceutical products. However, Brazil was a unique case since neither products nor processes for pharmaceuticals were protected and trade sanctions would serve as an example to others.[27] The complaint against the Brazilian law took into account that the country was considered to be the seventh biggest market for the pharmaceutical industry.[28]

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20 Pharmaceutical products and processes were excluded from patentable subject matter under the Law 5772/1971.
21 DL 7903/1945, Article 8.
22 DL 254/1967, DL 1005/1969 and Law 5772/1971.
23 Article 9, item c of Law 5772/1971 prohibited the granting of patents for pharmaceutical products and processes.
24 See *PMA*, Petition for Relief, p. 53.
25 *Id.*
26 See *Cepaluni*, Patent Regime: Brazil x USA, p. 54.
27 See *PMA*, Petition for Relief.
28 See *Tachinardi*, The Patent War: The Conflict Brazil x USA, p. 112.

In the same year, the Uruguay Round of Negotiations began. Brazil, along with India, strongly opposed the American proposal for introducing new topics in the GATT Agenda, such as intellectual property rights, believing that they should remain under the structure of the World Intellectual Property Organization (WIPO).[29] Brazil explicitly opposed granting patent protections for pharmaceutical products because the country considered them to be harmful to economic development.[30]

In June 1988, the Brazilian government announced that it would be prepared to protect pharmaceutical processes, but postponed the granting of product patents.[31] This decision was deemed insufficient by the US because Brazilian manufacturers would be able to easily circumvent patents by using alternative production processes. The Reagan administration accused Brazilian policies of being unreasonable and implemented trade sanctions of 100% *ad valorem* import tax on certain products, including paper, chemicals and electronic devices.[32] As a response, Brazil filed a claim to hold a panel before the GATT against the trade sanctions imposed by the US.[33]

The American punitive measures came to an end, however, only with the election of the Brazilian President Fernando Collor de Mello in November 1989. The newly elected president's political platform centered around Brazil becoming an open market and inserting itself into the globalized economy.[34] On June 26, 1990, after six months in the government, in order to keep his campaign promises, the new president announced intentions to provide protection for pharmaceutical products and their manufacturing processes.[35] The USTR, then, immediately suspended the trade sanctions and the Brazilian government withdrew the claim to hold a panel before the GATT.[36] Bill of Law 824/1991 was sent to Congress in the following year, on May 8, 1991, with the aim of modifying the Brazilian industrial property regime and providing patents for pharmaceutical processes and products.[37]

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29 See *Arslanian, Lyrio*, The Patent Statute Reform in Brazil, p. 4.
30 *Id.*
31 See *Tachinardi*, The Patent War: The Conflict Brazil x USA, p. 110.
32 *Id.*, p. 111.
33 See *Heringer*, Pharmaceutical Patents: International Context, p. 41.
34 See *Tachinardi*, The Patent War: The Conflict Brazil x USA, p. 111.
35 *Id.*
36 *Id,* p. 117-119.
37 See *Curzel*, Access to Medicines: the Brazilian Case, p. 29.

In the international sphere, the Uruguay Round was coming to a conclusion. Brazil changed its initial position towards the exclusion of intellectual property rights from international trade law and no longer opposed the patentability of pharmaceutical inventions.[38] The country opted to accede to the WTO and, consequently, to accept TRIPS in order to benefit from international trade in other sectors such as agriculture and textiles.[39] On December 15, 1993, the negotiations on market access for goods and services came to a conclusion.[40] The Final Act with the agreement was signed by ministers from most of the 123 participating governments at a meeting in Marrakesh, Morocco on April 15, 1994.[41]

The Brazilian Congress ratified the Agreements of the Final Act of the Uruguay Round on December 15, 1994, when it approved DLG 30/1994, and the TRIPS Agreement was incorporated into Brazilian law on December 31, 1995, when the Presidential Decree 1355/1995 was published in the Official Gazette. Law 9279/1996, which was published soon after on May 15, 1996, regulated industrial property rights and revoked the previous statute (Law 5772/1971). The new law did not exclude pharmaceutical inventions from patent protection and sought to harmonize with provisions in TRIPS.[42]

The following is an assessment of TRIPS provisions on patents that will allow for an analysis of their implementation within the Brazilian law.

B. TRIPS Agreement

1. General Principles

As Annex 1C of the Marrakesh Agreement, TRIPS is the result of recognition by the WTO Member States that different standards of protection and enforcement of IP rights were leading to problems in the international economy, resulting in non-tariff barriers to international trade.[43] The Agreement seeks to harmonize – rather than make uniform – protection

38 See *Arslanian, Lyrio*, The Patent Statute Reform in Brazil, p. 4.
39 *Id.*
40 See *WTO*, The Uruguay Round, para. 9.
41 *Id.*
42 See *Cepaluni*, Patent Regime: Brazil x USA, p. 61-62.
43 Preambles of TRIPS.

and enforcement of IP in Member States by establishing minimum international standards. The Preambles establish the need to promote effective and adequate protection of IP rights and to ensure enforcement as the driving goals of the Agreement,[44] taking into account the areas of IP that Member States perceived as leading to trade distortions.[45]

TRIPS determines that the basic principles of GATT 1994 and other international IP agreements are applicable, in addition to providing for multilateral prevention and settlement of disputes between parties.[46] Member States acknowledge the need for an international framework to regulate international trade in counterfeit goods and recognize that IP rights are private rights and that public policies, including those relating to development and technology, lie at the foundation of the IP system.[47] TRIPS also establishes that the needs of least-developed countries must be taken into account when implementing national legislation so as to maintain a maximum level of flexibility.[48]

The TRIPS Preamble already makes explicit reference to the bond between the protection of IP rights and the GATT rules on international trade. TRIPS provisions are not to be interpreted in isolation, but rather as an integral part of the WTO system as found in the case of *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*.[49]

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44 Preambles of TRIPS.

45 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 30.

46 Preambles of TRIPS.

47 Preambles of TRIPS.

48 Preambles of TRIPS.

49 See *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products.* Complaint filed by the United States. Report of the Panel, September 5, 1997 (WT/DS50/R). Para. 5.19. In this case, the US alleged that India's patent law violated Articles 27, 65 and 70 of TRIPS. The DSB found that India was not complying with Article 70.8(a) and Article 63(1) and (2) of the TRIPS Agreement by failing to establish a mechanism that adequately preserved novelty and priority in respect of applications for product patents covering pharmaceutical and agricultural chemical inventions. India was also not in compliance with Article 70.9 of the TRIPS Agreement by failing to establish a system for granting exclusive marketing rights. See *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, Summary of key findings, February 24, 2010 (WT/DS50). The European Communities filed a similar complaint against India in which they alleged that the Indian legal regime – India's "mailbox rule" – according to which patent application for pharmaceutical and agricultural chemical products could be filed was insufficient, and the lack of a mechanism for granting exclusive marketing rights to such products. In this case, the DSB also decided that the Indian leg-

Although the Preamble should not be used in an attempt to modify and renegotiate the obligations assumed in the agreement, they should be taken into consideration and be interpreted together with articles 7 and 8, which establish the objectives and governing principles of the Agreement. Article 7 of TRIPS defines the objectives of protection and enforcement of IP rights as promoting technological innovation. As a result of a proposal by developing countries in the context of patents,[50] Article 7 evidences the importance of balancing the protection of IP rights with the promotion of social and economic welfare and technological innovation through the due transfer of technology.[51] This provision reflects the equilibrium that IP policies should set, aiming both at rewarding creators for innovation and securing access to science, technology and culture.[52] It provides for a policy foundation within the structure of the Agreement for the protection and enforcement of IP rights.

Article 8 of TRIPS establishes the policy making principles that govern the Agreement,[53] which must be taken into consideration by Member

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islation was inconsistent with articles 70.8 and 70.9 of TRIPS. See *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, Complaint filed by the European Communities. Summary of key findings, February 24, 2010 (WT/DS79).

50 Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, India, Nigeria, Peru, Tanzania and Uruguay presented a proposal to the Uruguay Round Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, reflecting their concern on the possibility of using patents for advancing their technological and economic development. See *WTO*, Uruguay Round – Group of Negotiations on Goods – Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods; and *Carvalho*, The TRIPS Regime of Patent Rights, p. 122-123.

51 "Article 7. Objectives. The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations".

52 See *Gervais*, The TRIPS Agreement: Drafting History and Analysis, p. 117.

53 "Article 8. Principles.

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

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights

States in the implementation of any provisions therein.[54] It clearly safeguards the possibility for Member States to adopt the actions and procedures needed to protect public health and nutrition. It also fosters the public interest in areas that are important to socioeconomic and technological development and prevents the abuse of IP rights, as long as they are consistent with TRIPS. This provision was based on the same proposal submitted by developing countries that influenced Article 7.[55]

Under Article 8.1, Member States may have rules on government control of quality and safety of drugs and food, price control systems on pharmaceutical products, as well as financial incentives and tax credits in areas of the national economy that are deemed essential, for example small and medium enterprises, in order to preserve competition.[56] To balance this, the provision allows for measures which may impact patentee rights, such as price control, as long as they are necessary and consistent with the other provisions in the Agreement.[57]

Article 8.2 establishes the conditions under which Member States can issue preventive measures against the misuse of IP rights (such as abuse of patent rights), practices that unreasonably restrain trade (anti-competitive practices) and practices that adversely affect the international transfer of technology.[58] Such measures must be: (i) appropriate, i.e. adequate and proportionate to the seriousness of the practice to be inhibited; (ii) consistent with other TRIPS provisions, specifically articles 3, 4, 27 and 40; and (iii) necessary.[59] According to this provision, Member States are allowed to issue regulations and guidelines forbidding the inclusion of abusive clauses, such as exclusive and non-reciprocal grant-back to the licensor of

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by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology".

54 Article 8 explains the rationale to be taken into consideration when assessing and implementing articles 30, 31 and 40 of TRIPS. See *Gervais*, The TRIPS Agreement: Drafting History and Analysis, p. 121-122.

55 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 137.

56 *Id.*, p. 139-140.

57 *Id.*

58 Acts that adversely affect the international transfer of technology are to be hindered only in case they are considerd abusive or anti-competitive. See *Carvalho*, The TRIPS Regime of Patent Rights, p. 154.

59 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 154.

improvements introduced by the licensee as well as prohibition of challenging the validity of a licensed IP right.[60]

It is possible to conclude that Articles 7 and 8 make it clear that the freedom of Member States to legislate depends on these policy making guidelines and countries are no longer completely free to pursue their own national interests.[61] On the other hand, these same provisions have served as the foundation for discussions concerning TRIPS and public health, as well as the possibility for both developing and least developed countries to make use of TRIPS flexibilities when legislating.[62]

Apart from Articles 7 and 8, which provide general policy making guidelines, the essential principles of TRIPS that relate to IP rights are territoriality, national treatment (or non-discrimination) and most-favored nation.

TRIPS does not expressly provide for the territoriality principle (according to which intellectual property rights are to be enjoyed within the territory of one country and their effects should not extend beyond its boundaries), but rather recognizes the sovereignty of each Member State to choose the adequate method of implementing the provisions of the Agreement (see Article 1.1 of TRIPS). Accordingly, intellectual property rights are subject to the laws in force within the territory of each Member State. Within the scope of the patent holder's rights, Member States must provide for the right to prevent unauthorized parties to import a patented product or a product obtained by a patented process, as stated in Article 28.1 of TRIPS. Importation shows that patent rights should be comprised within a country's boundaries. The Agreement also indirectly refers to this principle when Article 2 determines that Articles 1 through 12 and 19 of the Paris Convention should be complied with regarding Parts II, III and IV of TRIPS, which include most of the substantive provisions on patents. It is Article 4 *bis* of the Paris Convention that establishes that a patent granted in one country is independent of patents obtained for the same invention in other countries. This independence relates primarily to causes of nullity, forfeiture and duration, but also to the scope of rights, as well as to exhaustion and compulsory licenses – invalidity of a patent in one

60 *Id.,* p. 155.

61 See *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 161.

62 The discussions on the relationship between TRIPS and public health resulted in the Doha Declaration, which will be dealt on further in this chapter.

country does not automatically lead to invalidation of a patent covering the same invention in another country.

The TRIPS Agreement seeks to provide minimum standards in the patent field and create a balance between different laws; thus, it restricts the sovereignty of Member States.[63] It still confines, however, the legal effects of a patent to the boundaries of each country. It is important to note that exactly because of the territorial effects of patent rights, different standards on patentability and scope of protection were becoming non-tariff barriers to international trade. Minimum standards provided by TRIPS are aimed at diminishing the adverse effects of IP rights in international commerce without abolishing the territoriality principle – such abolition would, then, indeed imply removing the sovereignty of Member States on the matter.

Article 3 of TRIPS establishes that each Member State must treat the nationals of other Member States in a no less favorable way than its own nationals. Exceptions to the national treatment principle are those already provided for by international treaties and in paragraph 2 concerning the appointment of an attorney in the jurisdiction of a Member State in order to secure enforcement of laws and regulations. TRIPS follows the logic of the Paris Convention, according to which the national treatment principle would apply to persons – as opposed to goods as in the national treatment principle of GATT Article III.4.[64] However, different from the language adopted by the Paris Convention and more similar to GATT, TRIPS suggests that even in case the WTO Member State does not protect the rights of its own nationals, the rights of the nationals of other Member States are to be protected up to the minimum threshold required by the Agreement.[65]

In the case of *Indonesia – Certain Measures Affecting the Automobile Industry*, a panel was established by request of the European Communities, Japan and the US, alleging that the Indonesian National Car Programmes, which established benefits including luxury tax and import duty exemptions on motor vehicles and their components, would violate provisions of the GATT.[66] A subsidiary argument claimed that the provisions

63 See *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 161-162, footnote 4.

64 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 84-86.

65 *Id.*

66 See *Indonesia — Certain Measures Affecting the Automobile Industry*. Request for Consultations by the European Communities, October 3, 1996 (WT/DS54). Re-

of the Indonesian programmes discriminate against nationals of other WTO Member States regarding the acquisition and maintenance of trademarks.[67] The panel found that the fact that only certain signs can be used as trademarks for meeting the relevant qualifications under the Indonesian National Car Programmes is not discriminatory treatment towards nationals of other countries.[68] Furthermore, the panel made a special recommendation regarding the interpretation of Article 3 of TRIPS. Taxes and other benefits to which an Indonesian company is entitled to under the program may give it a competitive advantage in relation to foreign companies.[69] However, it would not be reasonable to construe the national treatment principle "in relation to the maintenance of trademark rights as preventing the grant of tariff, subsidy or other measures of support to national companies on the grounds that this would render the maintenance of trademark rights by foreign companies wishing to export to that market relatively more difficult".[70] The scope of the national treatment principle should be cautiously interpreted and not unreasonably enhanced, at the risk of extending it far beyond the objectives of the Agreement.

The relationship between the national treatment principle in TRIPS, GATT and the Paris Convention has been addressed in *United States – Section 211 Appropriations Act*. In this case, the European Communities requested the establishment of a panel against the US, alleging that Section 211 of the US Omnibus Appropriations Act would not conform to Article 3 of TRIPS. Section 211 prohibited the registration or renewal of a trademark in the US concerning business and assets confiscated by the Cuban Government without the original owner's consent.[71] No US court should recognize or enforce any trademark rights either. Pursuant to the Appellate Body's findings, the national treatment principle is a corner-

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quest for Consultations by Japan, October 4, 1996 (WT/DS55). Request for Consultations by Japan, November 29, 1996 (WT/DS64). Request for Consultations by the United States, October 8, 1996 (WT/DS59).

67 *Id*.

68 See *Indonesia — Certain Measures Affecting the Automobile Industry*. Report of the Panel, July 2, 1998 (WT/DS55/R, WT/DS56/R, WT/DS59/R WT/DS64/R), para 14.268.

69 *Id*., para 14.273.

70 *Id*.

71 See *United States — Section 211 Omnibus Appropriations Act of 1998*, Summary of key findings, February 24, 2010 (WT/DS176).

stone of the Paris Convention and the WTO trading system,[72] and, as Article 3.1 of TRIPS adopts similar language to Article III.4 of the GATT regarding the expression "treatment no less favorable," jurisprudence in the GATT could be helpful in interpreting this principle under TRIPS.[73] In this case, the Appellate Body established non-compliance with the national treatment obligation because Section 211 imposed an extra procedural hurdle on "original owners" of Cuban nationality, but not "original owners" who were US nationals.[74] Accordingly, there would be a violation of the principle if a multiphase procedure were imposed on non-nationals and a single-phase procedure on nationals, putting the nationals of other Member States in an inherently less favorable situation.[75]

The most favored nation treatment foreseen in Article 4 of TRIPS provides that any advantage, favor, privilege or immunity given to the nationals of one country must be immediately and unconditionally granted to nationals of all other Member States. There are four possible exceptions: i) in case this beneficial treatment derives from international agreements on judicial assistance or law enforcement, ii) if they are granted according to the provisions of the Berne Convention or the Rome Convention authorizing that the treatment accorded be a function of the treatment accorded in another country, iii) if they relate to the rights of performers, producers of phonograms or broadcasting organizations not provided for in the agreement, and iv) if they derive from agreements which entered into force prior to the WTO as long as they do not constitute an arbitrary or unjustifiable discrimination against nationals of other Member States.

In *United States – Section 211 Appropriations Act*, the Appellate Body understood not only that there was a violation of the national treatment principle, as stated above, but also of the most favored nation treatment obligation. Cuban nationals residing in an authorized trade territory, such the Member States of the European Communities, would face an additional administrative procedure not applicable to non-Cuban foreign nationals.[76]

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72 See *United States — Section 211 Omnibus Appropriations Act of 1998.* Report of the Appellate Body, January 2, 2002 (WT/DS176/AB/R), para. 241.
73 See *United States — Section 211 Omnibus Appropriations Act of 1998.* Report of the Appellate Body, January 2, 2002 (WT/DS176/AB/R), para. 242.
74 *Id*., para. 256.
75 *Id*., para. 265-269.
76 *Id*., para. 314.

The TRIPS Preamble and the provisions defining the goals and general principles of the Agreement should drive the implementing legislation of the Member States, especially considering the flexibilities therein provided for. It is most important to remember that TRIPS provisions must be interpreted within the WTO system as part of the framework governing international trade among countries. Globalization made GATT 1994 and TRIPS practically inseparable[77] and any attempts either to enhance or hinder IP standards of protection should be balanced with their respective impacts in the context of international trade.

2. TRIPS Provisions on Patent Law

Provisions pertaining specifically to patents were considered to be the most difficult to negotiate.[78] They comprise Articles 27 through 34 in Section 5 of TRIPS, Articles 65 and 66 concerning transitional provisions, as well as Article 70 concerning the protection of existing subject matter.

2.1. Patentable Subject Matter and Conditions on Patent Applicants

The TRIPS Agreement provides for the enjoyment of patent rights and patent eligibility of product- and process-inventions in all fields of technology, without discrimination as to the place of the invention, importation or local production of the goods (as per Article 27.1). Thus, Member States are obligated to provide for patents covering pharmaceutical products.

Article 27 may be considered one of the core provisions of the Agreement in relationship with patent rights, since it provides for substantive harmonization criteria for the granting of patents – novelty, inventive step and industrial application – and the non-discriminatory treatment towards patentable subject matter. Its importance relies on the fact that many countries had not previously afforded patent protection in the chemical and

77 See *Straus*, The Impact of the New World Order on Economic Development, p. 14-15.

78 See *Gervais*, The TRIPS Agreement: Drafting History and Analysis, p. 220. For a brief summary of the draft proposals and negotiations results, see *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 178-179.

pharmaceutical fields. Article 27.1, however, does not define the concepts of inventions, novelty, inventive step and industrial application capability. A delimitation between invention and discoveries is also not provided in the Agreement.[79] Thus, countries have preserved the ability to determine substantive requirements, such as how novelty, inventive step and industrial application capability requirements are fulfilled under Article 1.1 of TRIPS.[80] It is important to note that the language adopted in Article 27.1 does not allow Member States to adopt other substantive requirements that either reject or invalidate a patent.[81]

In the case of *Canada – Patent Protection of Pharmaceutical Products*, the DSB panel analyzed the scope of the non-discrimination principle of Article 27.1 of TRIPS.[82] The European Communities requested a panel against Canada in 1998, alleging that there would be insufficient protection in the area of pharmaceuticals. Section 55.2(1) of the Canadian Patent Act allowed the so-called regulatory review exception, which would be inconsistent with Article 27.1, as per the arguments by the European Communities. This provision allowed potential competitors of a patent holder to use the patented subject matter for obtaining government marketing approval in order to be able to enter the market on the date the patent expires[83] The DSB ruled that the Canadian legislation providing for such

79 Accordingly, scientific principles, business methods, algorithms, as well as biological material of natural origin could be excluded from patentability. Compliance with TRIPS in this case is determined by the way such exclusions are provided in the implementing legislations. See *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 187-188.

80 See *Carvalho*, The TRIPS Regime of Patent Rights, p.63-65, 192-193.

81 *Id.*, p. 193. Under this issue, *Carvalho* refers to a further requirement of "unity of invention" (according to which a patent must concern a single general inventive concept) foreseen in patent statutes of many Member States as a substantive requirement for granting a patent, since it relates to the nature of the claimed invention. Nevertheless, the author points out that the lack of unity of invention may not be a ground for patent invalidity in such Member States.

82 See *Canada – Patent Protection of Pharmaceutical Products*, Summary of key findings, February 24, 2010 (WTO/DS114).

83 In addition to Section 55.2(1) of Canada's Patent Act, this panel also handled with the so-called stockpiling exception, provided for in Section 55.2(2) of Canada's Patent Act. According to the EC challenges, this provision would be inconsistent with Article 28.1 of TRIPS, and not covered by Article 30 of TRIPS. Canada's stockpiling exception, which allowed the manufacturing and stockpiling of patented inventions for a period of 6 months before patents expire, is going to be analyzed in this work together with Articles 28 and 30 of TRIPS.

early working for regulatory review purposes was consistent with Article 27.1, i.e. not discriminatory towards pharmaceutical patents.[84] It stated that there had not been evidence that the legal scope of Section 55.2(1) of the Canadian Patent Act was limited to pharmaceutical products, finding no discriminatory treatment towards a certain field of technology.[85]

Article 27.1 also refers to non-discrimination towards the local production of goods. Accordingly, this provision does not prohibit Member States to require that patents be worked as already foreseen in Article 5.A. 2 of the Paris Convention, but it prevents the establishment of a *local* working requirement as a condition for enjoying patent rights.[86] If a patent holder imports the patented products or the products manufactured by the patented processes, this case would be in compliance with the obligation of working a patent to avoid compulsory license or forfeiture.[87]

On May 30, 2000, the US requested consultations with Brazil under Article 4 of the Understanding on Rules and Procedures Governing the Settlement Disputes at the WTO and Article 64 of TRIPS, complaining that Article 68 of the Brazilian industrial property law, which establishes the grounds for compulsory licenses, provided a local working requirement that violates the non-discrimination principle of Article 27.1 of TRIPS.[88] In a cross dispute, Brazil filed on January 31, 2001, a request for consulta-

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84 The panel analyzed whether the non-discrimination principle would apply to article 30 of TRIPS that provides for exceptions to patent rights. Accordingly, the regulatory review exception in the Canadian legislation would fall under the scope of article 30 of TRIPS and, as the panel understood, its applicability was not restricted to the pharmaceutical field and, thus, would respect the non-discrimination principle. See *Canada – Patent Protection of Pharmaceutical Products*. Complaint by the European Communities and their Member States. Report of the Panel, March 17, 2000 (WT/DS114/R), para. 7.105.

85 See *Canada – Patent Protection of Pharmaceutical Products*. Complaint by the European Communities and their Member States. Report of the Panel, March 17, 2000 (WT/DS114/R), para. 7.93.

86 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 196-198.

87 This concept of working of a patent differs from the notion established by Bodenhausen. According to this author, "working" a patent means "manufacturing" the patented product or "industrially using" the patented process, and the acts of "importing" or "selling" would not be regarded as "working". See *Bodenhausen*, Guide to the Application of the Paris Convention for the Protection of Industrial Property, p. 71.

88 See *Brazil – Measures Affecting Patent Protection*. Request for Consultations by the United States, June 8, 2000 (WT/DS199/1). This case will be further analyzed in the following chapter of this work.

tions with the US, alleging that the provisions of the US Patent Code, Sections 204 and 209 of Chapter 18 on "Patent Rights in Inventions Made with Federal Assistance" in special, also violated TRIPS obligations by demanding a local working of patents.[89] According to the US Patent Code, small businesses or non-profit organizations which received title to any invention (i.e. patents) could only grant a person the exclusive right to use or sell the invention in the US if such person manufactures the patented product or uses the patented process substantially in the US.[90] Furthermore, the US statute limited the right to use or sell any federal owned invention in the US to a licensee that agrees to manufacture the patented product or to use the patented process substantially in the US.[91] Both Brazilian and US statutes violated Article 27.1 of TRIPS,[92] and the two States came to a mutual understanding to amicably settle the disputes.[93]

Pursuant to paragraph 2 of Article 27 of TRIPS, Member States are allowed to exclude subject matter from patentability whenever the exploitation of such subject matter is prevented in order to protect *ordre public* or morality, including human, animal or plant life and health, and to avoid serious damage to the environment. Therefore, under article 27.2 of TRIPS, national legislations may exclude from patentability inventions which exploitation put in risk *ordre public* and morality.[94] Justifications for these exclusions revolve around economic reasons related to an unnecessary engagement of resources (concerning the activities of patent offices in prosecuting applications) for the granting of patents which enforcement is unethical or socially undesirable and around the public perception towards some inventions which are deemed repugnant to social beliefs and should not deserve any public appraisal by the State.[95] This provision precludes, however, Member States to exclude inventions from patentability on the basis that exploitation of such patented subject matter is prohibited

89 See *United States – US Patents Code.* Request for Consultations by Brazil, February 7, 2001 (WT/DS224/1).
90 *Id.*
91 *Id.*
92 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 202.
93 See *Brazil – Measures Affecting Patent Protection*. Notification of Mutually Agreed Solution, July 19, 2001 (WT/DS199/4).
94 See *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 182. Discussions on the prohibition of patents covering transgenic animals and plants when national legislation prohibits exploitation of this technology.
95 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 207.

by national legislation (but for the public order and morality cases) following article 4 *quater* of Paris Convention. TRIPS and Paris Convention aim to guarantee that patents will not be refused or invalidated because the marketing of an invention is subject to security or quality requirements, or its exploitation may only be carried out by the State.[96]

Moreover, diagnostic, therapeutic and surgical methods for the treatment of humans or animals, plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes may also be excluded from patentability under Article 27.3. The availability of protection to plant varieties is an express obligation, either through patents, adoption of a sui generis system or a combination of both.[97]

96 See *Bodenhausen*, Guide to the Application of the Paris Convention for the Protection of Industrial Property, p. 65-66.

97 This wide range of protection alternatives leaves up to each Member State to choose the one preferred. For instance, the US afford protection to plant varieties by patents or by a specific regimen of breeders rights, whereas the EC countries follow a sui generis system which basis is laid out in the Convention for the Protection of New Varieties of Plants established by the International Union for the Protection of New Varieties of Plants (UPOV). See *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 185-186. Nevertheless, it is important to note that TRIPS does not obligate UPOV protection and Member States may develop their own protection system. See *Gervais*, The TRIPS Agreement: Drafting History and Analysis, p. 225.

Both paragraphs 2 and 3 of Article 27 of TRIPS were inspired by the European Patent Convention of 1973 (Articles 52.4 and 53[98]).[99] The expressions *ordre public* and morality represent a clear and direct influence by the language used in Article 53(a) of the EPC 1973. It is important to note that the text in TRIPS – as well as the EPC – adopts the French term "ordre public" instead of public order.[100] Under the EPC, the Board of Appeals of the European Patent Office has already established that the concept of public order encompasses the protection of public security and the physical integrity of individuals as part of society, in addition to the protection of the environment.[101] TRIPS also refers to the same notion of se-

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98 The European Patent Convention of October 5, 1973 was subject to a revising act of November 29, 2000. The 1973 text is now referred as EPC 1973.
EPC 1973:
"Article 52. Patentable Inventions.
(4) Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods."
"Article 53. Exceptions to patentability.
European patents shall not be granted in respect of:
(a) inventions the publication or exploitation of which would be contrary to "ordre public" or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;
(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.".

99 The European Communities supported by the developing countries put forward proposals for the exclusion of certain matters from patentability. See *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 181-183, referencing the document compiled by the GATT secretariat, "Synoptic Tables Setting Out Existing Standards and Proposed Standards and Principles", of February 2, 1990 (GATT Doc. MTN.GNG/NG11/W/32/Rev. 2) and the Guidelines and Objectives Proposed by the European Community for the Negotiations on Trade Related Aspects of Substantive Standards of Intellectual Property Rights of July 7, 1988 (MTN.GNG/NG11/26/III,3(ii)).

100 "Ordre public" is a concept linked to the notion of public policy and principles which derrogation could endanger the institutions of a society; public order, on the other hand, would be limited to the maintenance of public safety concept. See *Gervais*, The TRIPS Agreement: Drafting History and Analysis, p. 222-223.

101 See *EPO*, Case Law of the Board of Appeal: 2. Breaches of "ordre public" or morality.

curity, both collective or individually, containing the conception of protection against physical damage and not a general and abstract idea of general or collective interest.[102] Morality, in turn, concerns the beliefs serving as the foundation for a society, representing its cultural perceptions and values.[103] Protection of human, animal or plant life and health as well as the environment are of the concern of *ordre public* and morality.

Both Article 52.4 of the EPC 1973 and Article 27.3(a) of TRIPS refer to therapeutic methods as subject matter that is excluded from patentability (in the case of the former) or possibly excluded (in the latter case). Doctors and surgeons making use of a patented therapeutic method would have their medical activities severely restricted through enforcement of patents on therapeutic methods, which would not be well regarded by society – additionally there is the discussion of whether the success of medical treatment results from a patented method of treatment or from the skills of the doctor or surgeon.[104] Unlike the European provision, TRIPS does not expressly state that products, substances and compositions are not part of the exclusion. Despite this, Article 27.1 of TRIPS that allows for patents in all fields of technology (in addition to the explicit reference made by Article 70.8 of TRIPS) mandates Member States to grant patent protection for pharmaceutical products.[105]

Under Article 27.3 b) of TRIPS, animals and plants as higher life forms may be excluded from patentability, but Member States are obliged to afford patent protection for microorganisms, microbiological processes and non-biological processes for the production of plants and animals. In contrast to the EPC, TRIPS adopts broader options for exceptions from patentability, allowing Members States to exclude plants and animals in general, whereas Article 53(b) of the EPC limits the exception to plant and

102 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 208-209.

103 See *EPO*, Case Law of the Board of Appeal: 2. Breaches of "ordre public" or morality; and *Carvalho*, The TRIPS Regime of Patent Rights, p. 209.

104 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 214-215. This exclusion from patentable subject matter is not fully justifiable because including doctors' and surgeons' activities as a mandatory exemption to infringement could solve any lack of freedom-to-operate.

105 See *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 182.

animal races.[106] According to G1/98, the Enlarged Board of Appeal of the EPO established that claims towards plants (or animals) would be permissible when the teaching of the invention is not restricted to a single variety.[107] TRIPS leaves to the national legislators the option to exclude patentability of higher life forms in general, not only to varieties.

In G2/07, the Enlarged Board of Appeals of the EPO found that the exclusion from patentability of essentially biological processes for the production of plants under the EPC seeks to preserve the freedom to operate of traditional breeding processes consisting of sexual crossing of plants (whole genomes) and the selection of those with the desired traits.[108] However, the board also found that addition technical steps, irrespective of their inventiveness, technical character or contribution to the invention, would not change the character of the invention. The steps of sexually crossing the whole genomes of plants and subsequently selecting the plants with the desired characteristics are deemed essentially biological.[109] A step of technical nature, which would assist biological steps, would also be excluded under Article 53(b).[110] In order to be patentable, the claimed process needs to contain, within the steps of sexually crossing and selecting, a further technical step, which by itself introduces a trait into the genome or modifies a trait in the genome.[111] Virtually all breeding processes have become exempted from patentability as a result of this threshold, which is a consequence that was unlikely intended by legislators.

The harmonization of patent standards through TRIPS aimed to favor international trade and minimize distortions deriving from very different laws in Member States regarding patentable inventions and the enjoyment of patent rights. Article 27, in addition to the framework established by

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106 See *Gervais*, The TRIPS Agreement: Drafting History and Analysis, p. 224-225; *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 184-185.

107 See *EPO*, Transgenic plant/NOVARTIS II, case G1/98, Decision of the Enlarged Boards of Appeal December 20, 1999, para. 3.10, p. 25.

108 See *EPO*, Broccoli/PLANT BIOSCIENCE, case G2/07, Decision of the Enlarged Boards of Appeal consolidating proceedings of cases G2/07 and G1/08, of December 9, 2010, p. 65-66.

109 Pursuant to Rule 26 (5) EPC, declared invalid by the Enlarged Board of Appeals, an essentially biological process would consist entirely of natural phenomena, such as crossing and selection.

110 *Id.*, p. 69-70.

111 *Id.*, p. 70-71.

Articles 28, 30 and 31, essentially means that immaterial objects should receive the same extraterritorial treatment as other goods in international trade.[112] Patents and IP rights, in general, are now part of the world trade system.

As a condition for the patent granting, Article 29.1 of TRIPS requires disclosure of the invention in a clear and complete way so as to enable persons skilled in the art to reproduce it.[113] This mandatory requirement relates to the role of the patent system in the dissemination of technology.[114] It ensures that a patented invention may serve as basis for further development of technology and that it may be exploited without any cumbersome effort after patent expiration.[115] The text in the Agreement has been left open regarding the issue of microorganisms and biological material, such as cell lines, viruses and plasmids. In such cases, Member States – which are obligated to afford protection to those kinds of inventions under Article 27.3 of TRIPS – should establish that the deposit of such microorganisms and biological material fulfills the disclosure requirement.[116] However, TRIPS does not obligate Member States be party to the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, which accredits International Depositary Authorities.

In addition, requiring disclosure of best mode as per Article 29.1 of TRIPS is an option that Member States may adopt. According to this provision, national legislation may require inventors to specify the best manner to carry out the invention known to him/her at the time of the filing or

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112 See *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 180.

113 "Article 29. Conditions on Patent Applicants
1. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.
2. Members may require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants".

114 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 254.

115 See *Gervais*, The TRIPS Agreement: Drafting History and Analysis, p. 239.

116 See *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 196.

priority. This was an initiative by the US with the support of developing countries.[117]

Another option left open to Member States is to require that an applicant provide information on foreign applications and grants corresponding to the same invention pursuant to Article 29.2 of TRIPS. As stated earlier, Article 4 *bis* of the Paris Convention regarding the principle of independence of patents is to be respected by Member States, leading to the conclusion that submitting such information before national patent offices and courts serves to provide subsidies, for instance regarding searches.[118]

2.2. Rights Conferred and Term of Protection

The rights conferred by a patent and its term are of paramount importance, considering that the goal of TRIPS is to minimize the differences among national systems and prevent different standards of patent protection from becoming non-tariff barriers to international trade. Developed and developing countries not only afforded different standards regarding patentable subject matter, but also the scope and duration of patents. Preventing imports and extending protection to products obtained by a patented process were often not included among the patent holder's rights and the term of protection could be of five or seven years.[119]

Article 28.1 of TRIPS lists the rights of patent owners, which essentially consist of the right to exclude others from exploiting an invention (and not the right to use the invention).[120] Making, using, offering for sale, selling or importing for these purposes are the acts of exploitation that may be prevented and according to the DSB they are not subject to any hierarchy;

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117 The US legislation, namely Section 112(1) USC 35, provides for best mode requirement. See *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 197; and Section 112 USC 35. As seen in the following chapter of this work, the Brazilian law mandates in article 24 indication of best mode whenever applicable. See Lei N. 9279, of May 14, 1996, on industrial property rights, published in the Official Gazette on May 15, 1996, as amended by Law N. 10196, of February 14, 2001, published in the Official Gazette on February 16, 2001.

118 See *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 197.

119 *Id*., p. 198.

120 "Article 28. Rights Conferred.

"making" and "using" are not secondary in relation to "selling."[121] The footnote of Article 28.1 of TRIPS refers to "other distribution of goods" and extends those rights to the prevention of exporting, sampling and stockpiling.

In *Canada – Patent Protection of Pharmaceutical Products*, Section 55.2(2) of the Canadian Patent Act was found be inconsistent with Article 28.1 of TRIPS. This allowed for manufacture and storage of articles covered by a patent intended for sale after the patent expiration date during a six month period before the patent expiration. [122] The act of stockpiling while a patent was still valid was deemed to be in violation of TRIPS. Allowing third parties to make or use the invention without the patent holder's authorization during the patent term must be excused under Article 30 of TRIPS, which addresses limitations to the rights conferred.[123] This pro-

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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;
(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
(6) 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".
Among the patentee's rights is the right to prevent importation by third parties of the patented product, which relates to the issue of international exhaustion which is dealt later in this chapter.

121 See *Canada – Patent Protection of Pharmaceutical Products*. Complaint by the European Communities and their Member States. Report of the Panel, March 17, 2000 (WT/DS114/R), para. 7.33.

122 *Id.*, para. 7.38.

123 The DSB ruled in *Canada – Patent Protection of Pharmaceutical Products* that violation of article 28.1 of TRIPS would occur in case Section 55.2(2) of the Canada's Patent Act were non-compliant with the conditions of article 30 of TRIPS. See *Canada – Patent Protection of Pharmaceutical Products*. Complaint by the European Communities and their Member States. Report of the Panel, March 17, 2000 (WT/DS114/R), para. 7.18.

vision, however, does not deal with contributory and indirect infringement issues.[124].

In case of patents covering processes, protection extends to the product obtained by such patented process. This derives from enforcement difficulties raised in case of unauthorized use of a patented process in country with products shipped to and marketed only in a second country.[125]

Article 28.2 of TRIPS, which allows the patentee to assign, transfer by succession and license patents, may be regarded as a means to minimize government interference in the freedom of patent owners regarding their property title. It is important to note that if, on one hand, limitation of maximum limits to royalties is considered to be allowed under Article 8.1, on the other hand, government approval of contracts based on criteria of mere convenience, for example towards the nature of the technology transferred, should be considered an undue limitation of patent rights.[126]

Article 33 of TRIPS establishes that patent terms shall not end before a twenty-year period as of the filing date. During negotiations, proposals considered term from the date of filing and from the date the patent is granted, and there were attempts to extend protection for certain products which marketing is delayed by regulatory approval processes.[127] The patent term was also subject to discussions by the DSB in *Canada – Patent Protection of Pharmaceutical Products*.[128] The panel rejected the Canadian defense alleging that not allowing a third party to manufacture and stockpile patented goods in a short period prior to expiry would result in an additional period of market exclusivity.[129] According to the decision,

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124 See *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 199.

125 See *Gervais*, The TRIPS Agreement: Drafting History and Analysis, p. 236.

126 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 248.

127 For more, see *Gervais*, The TRIPS Agreement: Drafting History and Analysis, p. 255-256; *Carvalho*, The TRIPS Regime of Patent Rights, p. 378-379.

128 Despite dealing with term of protection, because of its findings of inconsistency of Section 55.2(2) of Canada's Patent Act with article 28.1 of TRIPS, the DSB decided not to examine the EC claims that article 33 would be also violated. See *Canada – Patent Protection of Pharmaceutical Products*. Complaint by the European Communities and their Member States. Report of the Panel, March 17, 2000 (WT/DS114/R), para. 7.38.

129 See *Canada – Patent Protection of Pharmaceutical Products*. Complaint by the European Communities and their Member States. Report of the Panel, March 17, 2000 (WT/DS114/R), para. 7.35.

such a brief period of exclusivity should be regarded as normal.[130] From this understanding it is possible to conclude that the twenty-year term provided by Article 33 is a minimum period of protection in which the patentee has the exclusive right to extract economic value from the patent and, therefore, a patent may lawfully generate effects which extend beyond its expiration.[131]

In another case filed against Canada, *Canada – Term of Protection*,[132] the DSB ruled that Article 33 of TRIPS provides the forthright obligation that Member States make a term of protection available which should not end before twenty years as of the filing date.[133] In this case, the US requested that a panel be established against Canada on July 15, 1999, in which it alleged that Section 45 of the Canadian Patent Act would be inconsistent with Article 33 of TRIPS.[134] The Canadian provision established that patents granted for applications filed before October 1, 1989, were valid for seventeen years from the date the patent was issued, which could result in a protection period shorter than the twenty-year term as of the filing date set by TRIPS.[135] The DSB found that Section 45 violated TRIPS obligations, refusing the argument that under Canadian regulatory practices and procedures applicants could control and delay the patent-granting procedure, which would give them the chance to have a the twenty-year term set by TRIPS patent term.[136] The term of protection must be

130 *Id.*, para. 7.56.

131 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 381.

132 In this case, the DSB analyzed how the 20-year term of protection would apply to existing patents. The decision clarifies that patents already granted and not yeat expired by the time TRIPS entered in force in Canada are to be considered existing subject matter under article 70.2 of TRIPS and given the term of protection provided in article 33 of TRIPS. This does not represent a retroactive application of TRIPS obligations foreseen in article 70.1 of TRIPS. See *Canada – Term of Patent Protection*. Report of the Appellate Body, September 18, 2000 (WT/DS170/AB/R), para. 79. Article 70 of TRIPS will be discussed further in this chapter.

133 See *Canada – Term of Patent Protection*. Report of the Appellate Body, September 18, 2000 (WT/DS170/AB/R), para. 95.

134 See *Canada – Term of Patent Protection*, Summary of key findings, February 24, 2010 (WTO/DS170).

135 *Id.*

136 See *Canada – Term of Patent Protection*. Report of the Appellate Body, September 18, 2000 (WT/DS170/AB/R), para. 90-92.

set as a clear right when the application is filed, being "available as a matter of legal right and certainty".[137]

This case also dealt with the relationship between Articles 33 and 62.2 of TRIPS. Accordingly, as Article 33 of TRIPS foresees a minimum date of expiration, Article 62.2 establishes the further obligation that procedures for patent granting are not excessively time consuming and the term of protection is not unreasonably curtailed. Some reduction may be allowed under Article 1.1 of TRIPS (which mandates Member States to implement TRIPS obligations, but allowing them to choose an appropriate method of implementation). However, Article 33 and 62.2 must be implemented into national law without patent applicants being forced to take extra measures in prosecution proceedings to comply with them.[138] This means that applicants should not be obliged to request for abandonment or reinstatement, not to pay fees or avoid replying to office actions to delay prosecution and reach a twenty-year term.[139]

The footnote of Article 33 of TRIPS clarifies that Member States, which simply re-register patents granted in other territories without conducting their own examination, may count the term of protection as of the date of a patent's first filing abroad.[140]

It is important to note that TRIPS does not provide for any provisional protection for patent applications.[141] Member States are not obligated to secure any right until the patent is granted.

2.3. Flexibilities within TRIPS concerning Patents

In order to mitigate the possible negative effects of exclusivity deriving from patents, TRIPS provides flexibilities for patent rights. The main instruments for these flexibilities are a) rules on implementation allowing transition periods for developing and least developed countries as well as

137 *Id.*

138 See *Canada – Term of Patent Protection*. Report of the Panel, May 5, 2000 (WT/DS170/R), para. 6.94.

139 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 381.

140 Footnote 8 of article 33 of TRIPS makes clear that member states are not obligated to carry out their own substantive examination, allowing patents of revalidation. This is the case of the Brazilian pipeline patents addressed in the following chapter of this work.

141 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 381-382.

transitory arrangements concerning protection of existing subject matter, b) exceptions to patentable subject matter, c) exclusion of the international exhaustion issue from dispute settlement proceedings, d) general exception rules to exclusive rights, and e) compulsory licenses.

2.3.1. Rules on Implementation and Protection of Existing Subject Matter

The rules allowing transition periods for accession to the Agreement grant all Members States one year to apply TRIPS standards on protection of intellectual property pursuant to Article 65.1 of TRIPS. This provision establishes that no Member State is obligated to apply TRIPS provisions for one year as of January 1, 1996, the date the Agreement entered into force. However, TRIPS recognizes that not all Member States are equally prepared to implement TRIPS provisions at the same pace. Developing countries and countries transforming from a centrally-planned economy to a market economy system were entitled to an additional four years to apply TRIPS provisions (see Articles 65.2 and 65.3 of TRIPS), with the exception of Articles 3, 4 and 5 of the Agreement.[142]

A further five-year period was given for countries to provide for product patents in previously unprotected areas of technology (see Article 65.4 of TRIPS). The transition period included in Article 65.4 of TRIPS was important for many Member States that did not provide for patents in the chemical and pharmaceutical fields. These countries were given the possibility to delay the granting of patents in such previously unprotected areas of technology until January 1, 2005. The DSB confirmed this date of applicability in *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, complaint filed by the US.[143]

Nevertheless, not all developing countries have used the full term provided to them. Brazil passed a new law in 1996, which conformed national

142 In *Indonesia – Certain Measures Affecting the Automobile Industry*, the the DSB confirmed that article 3 of TRIPS should be applied as of January 1, 1996, not being subject to the additional four years of article 64.2 of TRIPS. See *Indonesia — Certain Measures Affecting the Automobile Industry.* Report of the Panel, July 2, 1998 (WT/DS55/R, WT/DS56/R, WT/DS59/R WT/DS64/R), para. 14.266.

143 See *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products.* Complaint filed by the United States. Report of the Panel, September 5, 1997 (WT/DS50/R), para. 8.27.

legislation to TRIPS obligations.[144] India, on the other hand, was one of the few developing countries that made use of the ten-year term to fully implement TRIPS.[145] In addition to India, in 2003, there were five other Member States that were still making use of the transition periods including Egypt, Pakistan, Qatar and United Arab Emirates.[146]

Article 65.5 of TRIPS prohibits Member States benefiting of the transition periods from reducing the level of protections in national laws and practices; this is referred to as the "standstill clause." It derives from ethical commitments made during negotiations, since changing protection conditions when trade concessions are in place leads to uncertainty.[147] In the case of *Indonesia – Certain Measures Affecting the Automobile Industry*, the US complained that the Indonesian National Car Programme was introduced during the transition period and lowered the existing IP standards of protection. Nevertheless, the DSB did not find any inconsistency of the Indonesian Programme with the obligations provided in Article 20 of TRIPS (on requirements related to the use of trademarks) and, thus, concluded that there was no violation of Article 65.5[148]

Least developed countries had an eleven-year implementation period according to Article 66.1 of TRIPS, which only required the application of Articles 3, 4 and 5 – regarding national treatment and most-favored-nation treatment principles – as of the entry in force of the Agreement. The TRIPS Council Decision of 2002 following the Doha Declaration on the

144 Lei N. 9279, of May 14, 1996, on industrial property rights, published in the Official Gazette on May 15, 1996.

145 Patent Act as amended by Act No. 15 of April 4, 2005 published in The Gazette of India on April 5, 2005.

146 See *Musungu*, *Oh*, The Use of Flexibilities in TRIPS by Developing Countries, p. 7. Egyptian Law # 82, of June 3, 2002, Law on the Protection of Intellectual Property Rights, published in Egypt Official Gazette of June 2, 2002; Ordinance no. LXI, of December 2, 2000, Patents Ordinance, published in the Gazette of Pakistan of December 2, 2000; Qatari Law-Decree No. 30, of August 6, 2006, To Issue Patents Law, published in the Qatar Official Gazette of December 12, 2006; Federal Law No. 31 for the Year of 2006, of July 24, 2002, Pertaining to the Industrial Regulation and Protection of Patents, Industrial Drawings, and Designs, published in the United Arab Emirates Official Gazette of July 24, 2002.

147 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 426-427.

148 See *Indonesia — Certain Measures Affecting the Automobile Industry*. Report of the Panel, July 2, 1998 (WT/DS55/R, WT/DS56/R, WT/DS59/R WT/DS64/R), para. 14.282.

TRIPS Agreement and Public Health[149] granted an additional ten-year term, until January 1, 2016, for least developed countries to implement TRIPS provisions on patents and protection of undisclosed information regarding pharmaceutical products.[150] Without prejudice to this extension pertaining to pharmaceutical products, the TRIPS Council decided on November 29, 2005, to extend the transition period until July 1, 2013 or until the date a country ceases to be considered least developed, whichever is earlier.[151] The TRIPS Council granted a second extension of eight years on June 11, 2013, and the least developed countries will have until July 1, 2021, to fully apply the provisions of TRIPS, unless they leave their status of least developed earlier.[152] Those extensions should not alter the least developed countries rights to make full use of the flexibilities in the Agreement and to seek further extension periods.[153] Although the standstill clause was not specifically mentioned in Article 66 of TRIPS, least developed countries are also bound by it and are not allowed to reduce current standards of protection.[154] This is clearly established in the non-rollback clause of the TRIPS Council's Decision of November 29, 2005, which states "any changes in their laws, regulations and practice made during the additional transitional period do not result in a lesser degree of consistency with the provisions of the TRIPS Agreement".[155] Accordingly, if a least developed country already complies with some protection of

149 The Doha Declaration on the TRIPS Agreement and Public Health will be further analyzed in this work.

150 See *WTO*, Doha Declaration; and *WTO*, Decision on the Extension of the Transition Period for Least-Developed Members with Respect to Pharmaceutical Products. The Doha Declaration on the TRIPS Agreement and Public Health was passed by the WTO's Ministerial Conference in 2001. It deals with the interpretation of TRIPS provisions in light of public health issues faced by many developing and least developed countries. The document will be further analyzed in this chapter.

151 See *WTO*, Decision on the Extension of the Transition Period for Least-Developed Members of November 29, 2005, item I.1.

152 See *WTO*, Decision on the Extension of the Transition Period for Least-Developed Members of June 11, 2013, item 1.

153 See *WTO*, Decision on the Extension of the Transition Period for Least-Developed Members of June 11, 2013, item 2; and *WTO*, Responding to Least Developed Countries' Special Needs in Intellectual Property, para. 8.

154 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 422-427, 432.

155 See *WTO*, Decision on the Extension of the Transition Period for Least-Developed Members of November 29, 2005, item III.5.

IP rights, it may not reduce its level of compliance. The TRIPS Council's Decision of June 11, 2013, still reflects this commitment of the least developed Member States "to preserve and continue the progress towards the implementation of the TRIPS Agreement".[156] The longer transition period afforded to least developed countries is not intended to foster the creation of a technological base, but rather to provide more time to craft new legal measures to implement TRIPS obligations.[157]

Article 66.2 of TRIPS establishes that developed countries should create incentives for promoting the transfer of technology to least developed countries. The aim is to assist least developed countries accede to the international market by assisting them in creating a technological base.[158] This would be achieved by encouraging private companies – owners of IP rights – to participate in enterprises with companies based in the least developed countries.[159]

The transitional arrangements in TRIPS are interlinked with the provisions of Article 70. As Member States enjoy extended terms for implementing TRIPS obligations, in counterpart, they are subject to the determinations of Article 70 that address the protection of existing subject matter.

Article 70.1 of TRIPS establishes that the Agreement does not include obligations towards past acts, generally excluding retroactive application of TRIPS. However, pursuant to Article 70.2 of TRIPS, it does include obligations concerning subject matter existing at the date of application of TRIPS for that country. Subject matter which is either protected in that country on that date or meets or comes to meet the criteria for protection under the Agreement, except as otherwise provided in the agreement itself, is included in TRIPS. Under Article 70.2 of TRIPS, obligations refer to all WTO obligations to which Member States are bound, including those in Section 5, Part II of TRIPS.[160] In the context of patents, subject matter means patentable or patented inventions.[161]

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156 See *WTO*, Decision on the Extension of the Transition Period for Least-Developed Members of June 11, 2013, item 2.

157 *Id.*, p. 433.

158 *Id.*, p. 434.

159 *Id.*, p. 435-436.

160 See *Canada – Term of Patent Protection*. Report of the Panel, May 5, 2000 (WT/DS170/R), para. 6.53 and 6.54.

161 See *Canada – Term of Patent Protection*. Report of the Appellate Body, September 18, 2000 (WT/DS170/AB/R), para 65-66.

In *Canada – Patent Term*, the DSB panel defined that the term 'acts,' as referred to in Article 70.1 of TRIPS, comprises acts of public authorities including examination of patent applications, the granting or rejection of a patent, the revocation or forfeiture of a patent, the granting of a compulsory license, and the confiscation by customs authorities of goods alleged to infringe IP rights. Additionally it comprises the acts of private and third parties including filing of a patent application, infringement or other unauthorized use of a patent, unfair competition or abuse of patent rights.[162] Article 70.1 of TRIPS does not exclude existing rights, such as patent rights, even if such rights derive from acts which occurred before the application of TRIPS in the Member State. As a result, the DSB panel established that Canadian patents that were already granted would be within the scope of the Agreement.[163]

Addressing the relationship between Articles 70.1 and 70.2 of TRIPS, the panel further stated that existing patent rights are not finalized acts; rather, they are existing subject matter.[164] The DSB panel clarified that Article 70.1 excludes obligations only to acts that occurred prior to the date of application of TRIPS, not continuing situations; whereas Article 70.2 applies to existing subject matter that should be deemed a continuing situation and, thus, be excluded from the scope of Article 70.1. In this case, application of Article 33 of TRIPS to inventions protected under the Canadian Patent Act would be justified under Article 70.2 and not 70.1 of TRIPS.[165]

Article 70.3 of TRIPS establishes that Member States are not obligated to restore protection to subject matter that is in the public domain on the date the Agreement is applied. This applies to subject matter previously protected, but whose term of protection has lapsed, has fallen into public domain for failure to pay maintenance fees, or has been revoked. In spite of its reference to subject matter that has already been protected, the rationale of Article 70.3 is also applicable to subject matter contained in a patent application that has been published and is later rejected by the patent office.[166]

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162 *Id*., para. 54.
163 *Id.*, para. 60.
164 *Id.*, para. 58-59.
165 *Id*., para. 69-70.
166 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 441.

Article 70.4 of TRIPS determines that Member States may limit remedies available to the patentee, excluding the availability of injunctions, but guaranteeing at least equitable remuneration. The Article refers to the continuation of initially non-infringing activities that started prior to the application of TRIPS or in which significant investments were made and that become infringing under the laws implementing the Agreement. Article 70.4 aims to secure that Member States are free to allow the continuance of infringing acts provided that equitable remuneration is paid to the patentee. It is important to note that the equitable remuneration seeking to compensate losses of patent holders has a time restriction, since the activity would not be deemed an infringement until the date that laws implementing TRIPS entered in force.[167]

Article 70.6 of TRIPS is a further limitation to the rights of patent holders, determining that Member States may exclude from Article 31 and paragraph 1 of Article 27 of TRIPS the use of patented subject matter without the patent holder's authorization when such use had been permitted by the government before TRIPS' text became known. The language adopted in this Article assumes that the text of the Agreement was known to all governments at the date of its conclusion on April 15, 1994.[168] This provision protects compulsory licenses granted under existing national laws that were inconsistent with TRIPS because discriminated a certain field of technology, but it is not applicable to compulsory licenses granted based on lack of local working[169] Despite being considered "existing subject matter," Article 70.6 is an exception to Article 70.2 and compulsory licenses may continue under the condition that payment of equitable remuneration is made in accordance with Article 70.4.[170]

Amendments to IP rights that are subject to registration (which clearly include patents) should be allowed in order to enhance protections in accordance with which is provided in the Agreement as long as no new subject matter is included (see Article 70.7 of TRIPS). This provision establishes that Member States may allow applicants in pharmaceutical and chemical areas to claim products in addition to already claimed processes when such products have already been disclosed in the application, but

167 *Id.*, p. 442.
168 See *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 212.
169 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 442-443.
170 *Id.*

which have not been claimed due to legislative restrictions in Member States.[171] Nevertheless, Article 70.7 must be reconciled with Article 65.4 of TRIPS and, therefore, developing countries may wait until January 1, 2005, to let the enhancement of the scope of pending applications in order to encompass product patent protection in fields of technology not protected prior to the date of application of TRIPS.[172]

Article 70.8 of TRIPS establishes the mailbox, where Member States that do not provide for patents covering pharmaceutical and agricultural chemical products when TRIPS entered in force were obligated to a) provide a means by which applications for such subject matter may be filed, b) apply TRIPS patentability criteria to such applications, and c) provide for protection according to TRIPS standards for the remainder of the term as of the filing date pursuant to Article 33 of TRIPS. *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, complaint filed by the United States, established that the term "means" referred to a mechanism entitling the filing of mailbox applications and the allocation of filing and priority dates so as "to provide a sound legal basis to preserve novelty and priority as of those dates."[173] However, it was not within the scope of obligations deriving from Article 70.8 to provide legal certainty towards the future granting of the patent in question.[174]

Exclusive marketing rights are provided for in Article 70.9 of TRIPS and must be granted by Member States for a five-year period after marketing approval is granted in that country or until a patent covering the product is either granted or rejected. For the enjoyment of such exclusivity rights, a patent application for such subject matter must have been filed after the Marrakesh Agreement entered in force and another Member State must have granted a patent for that product, as well as marketing approval. Article 70.9 expressly establishes that it will be applicable only in situations where a product patent application is filed under Article 70.8 of TRIPS.

In *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, complaint filed by the United States, the DSB made it

171 *Id.*, p. 443.
172 *Id.*, p. 444.
173 See *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products.* Complaint filed by the United States. Report of the Appellate Body, December 19, 1997 (WT/DS50/AB/R). para. 54 and 57.
174 *Id.*, para. 58.

clear that the transition period in Article 65 is not applicable to Article 70.8 of the Agreement. Accordingly, if product patents were not available for pharmaceutical and agricultural chemical products, a means must be in place as of January 1, 1995 allowing the filing of patents for such inventions, in order to secure novelty and priority dates.[175] Exclusive marketing rights in Article 70.9 are also mandatory in case a Member State makes use of the transition periods in Articles 65 and 66.[176] For least developed countries, obligations under Article 70.9 of TRIPS regarding pharmaceutical products were waived until January 1, 2016 by means of the General Council Decision of July 8, 2002.[177]

2.3.2. Exclusions from Patentable Subject Matter

Article 27.1 of TRIPS established that patents must be granted for inventions in all fields of technology, provided that they are new, inventive and applicable to industry. Exceptions to patentable subject matter are only allowed in the cases set forth in Articles 27.2 and 27.3, as discussed previously in this text.[178]

The Agreement does not define novelty, inventive step, industrial application or invention. National legislatures are left to provide such definitions, which may differ from country to country. For instance, the patentability of second medical uses[179] is handled differently among

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175 See *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products.* Complaint filed by the United States. Report of the Panel, September 5, 1997 (WT/DS50/R). para. 7.27.

176 *Id.*, para. 7.59.

177 See *WTO*, General Council Decision of July 8, 2002, Obligations Under Article 70.9 of the TRIPS for Least Developed Countries.

178 Member States may consider certain subject matter unpatentable in order to protect public order or morality, which includes protecting human, animal or plant life or health or avoiding serious prejudice to the environment. Diagnostic, therapeutic and surgical methods for the treatment of humans or animals, plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes may also be excluded from patentability.

179 The expression "second medical use inventions" generally refer to a new use, as medication, of a known product with use outside the medical field (which actually corresponds to the first medical use of this product) or to a new medical use of a product already known as medication.

Member States regarding the concept of novelty. Such inventions are deemed to fulfill the novelty requirement in Europe, while they are not deemed so in India, Chile and Uruguay.[180] Some bilateral or regional free trade agreements have been negotiated as TRIPS-plus, such as the bilateral free trade agreement signed between Chile and the US, obligating their signatories to provide for the patentability of second uses.[181] Whether the requirement of novelty is fulfilled by the new use of a known compound represents a policy making debate. The patentability of new polymorphs also follows the same line of discussion.

2.3.3. Exhaustion and Parallel Importation

The patent holder may decide to produce, market, license or import a patented product into a country and has the right to exclude third parties from exploiting patented subject matter. However, after the product is legally put into the market, the rights of the patentee are deemed exhausted and the products may circulate, independent of the patent holder's authorization. For this to occur, the placement of the product in the market must have been made directly by the patentee or with his/her consent by means of a licensee. The exhaustion rules may be restricted to a country's national market or be international. In the first case, there is national exhaustion, the rights of the patentee are only exhausted within the territory of the country where the product was first marketed. A first sale in another country – from where the patented product was imported – does not lead to exhaustion of patent rights, and the patent holder must authorize such importation into the country. On the other hand, international exhaustion occurs when a patented product is legally put into the market in any coun-

180 European Patent Convention, of October 5, 1973, 14th edition of August, 2010, published by the European Patent Office. Indian Patent Act as amended by Act No. 15 of April 4, 2005 published in The Gazette of India on April 5, 2005. Ley n. 19.039, estableciendo normas aplicables a los privilegios industriales y proteccion de los derechos de propiedad industrial, of January 24, 1991, published in the Chile's Republic Official Diary of January 25, 1991. Ley n. 10.089, of December 12, 1941, published in the Official Gazette of December 23, 1941. For more see *Musungu, Oh*, The Use of Flexibilities in TRIPS by Developing Countries, p. 70-96.

181 See United States – Chile Free Trade Agreement (FTA), of June 6, 2003.

try in the world. In this case, the first sale abroad will lead to the exhaustion of the patent holder's rights.

Exhaustion has been considered one of the problem topics during the negotiations on TRIPS. The final text of Article 6 of TRIPS reflects the agreement reached, excluding the issue from dispute settlement proceedings.[182] Article 6 establishes that nothing in the Agreement must be used to address exhaustion in dispute settlement cases subject to the national treatment and most-favored nation principles of Articles 3 and 4 of TRIPS. This means that the adoption of international exhaustion by a certain country may not be invoked as a direct violation of the TRIPS Agreement.[183] Considering the wording of the provision, it is not possible to conclude that TRIPS leaves the matter completely open to its Member States.[184] Article 27.1 combined with Article 28.1 of TRIPS establishes that national laws in Member States must afford patent holders the right to prevent sale and importation irrespective of the manufacturing location, which is an impediment to the general adoption of international exhaustion.[185] Despite this, the interpretation that TRIPS does not handle with the question of exhaustion of intellectual property rights and that applicability of international exhaustion is left to each Member State has prevailed, at least in areas pertaining to the protection of public health.[186] In paragraph 5(d) of the Doha Declaration, the WTO Member States affirmed the understanding that exhaustion of IP rights are to be freely determined by each country.[187]

The expression parallel importation refers to importation of a patented product without the patent holder's authorization, usually being sold abroad at lower prices.[188] Whether parallel importation is prohibited or not is a question of the exhaustion rules adopted by each country. In the case

182 See *Gervais*, The TRIPS Agreement: Drafting History and Analysis, p. 112-115.
183 *Id.*, p. 112.
184 See *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 192-193.
185 *Id.* See also *Carvalho*, The TRIPS Regime of Patent Rights, p. 105.
186 See *Correa*, Integrating Public Health Concerns Into Patent Legislation In Developing Countries, p. 76; *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 191; *Carvalho*, The TRIPS Regime of Patent Rights, p. 106.
187 See *WTO*, Doha Declaration (paragraph 5(d)).
188 The price differentiation practice is not only governed by the patentee's own charging policies in the different countries but may be also influenced by factors such as government regulation of price.

of international exhaustion, the patentee may not prevent third parties from importing patented goods, which have been put into the market abroad directly by the patent holder or when consent is given. On the other hand, according to the national exhaustion principle, the patentee may prohibit such parallel importation. As a consequence of the interpretation of Article 6 of TRIPS in light of paragraph 5(d) of the Doha Declaration, by providing national or international exhaustion rules, allowing parallel importation, at least in the pharmaceutical field, is a faculty given to each national legislator by TRIPS.

The national exhaustion rule over patent rights has been adopted by the United States[189] and Brazil,[190] whereas Argentina[191] and India[192] have adopted international exhaustion.[193] The Japanese Supreme Court decided that a Japanese patent could not be enforced and, consequently, parallel importation should be allowed whenever a patented product is sold outside Japan with the consent of the patent holder. In order to prevent parallel

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189 In Quanta v. LGE, the US Supreme Court clearly established that the first sale leads to patent exhaustion; however, the court did not deal with the issue of foreign sales. See *United States Supreme Court,* Quanta Computer Inc. v. LG Electronics Inc., case 06-937, Decision of June 9, 2008, p. 17-9. Following Quanta v. LGE, the US Court of Appeals for the Federal Circuit, confirmed its previous understanding that the first sale must occurr within the US territory to result in patent exhaustion, and parallel importation is not allowed. See *United States Court of Appeals for the Federal Circuit*, Jazz Photo Corporation v. International Trade Comission, case 264 F.3d 1094, Decision of August 21, 2001, p. 16; *United States Court of Appeals for the Federal Circuit,* Fujifilm Corporation v. Benun, Jazz and Polytech, case 605 F.3d 1366, Decision of May 17, 2010, p. 7; *United States Court of Appeals for the Federal Circuit,* Ninestar Technology v. International Trade Commission, case 09-1549, Decision of February 8, 2012, p. 7. See also *Moore*, Parallel Trade, Unparallel Laws, p. 84-86.

190 The Brazilian patent statute, Law 9276/1996, refers to national exhaustion when limiting the patentee's rights in article 43, IV. The provision excludes from the scope of patent rights products which have been placed into the *internal* market directly by the patent holder or with his consent. There is an express reference to the internal market, leading to the interpretation that products placed in the *international* market are not encompassed by the provision. This provision will be also analyzed in the following chapter.

191 Law n. 24.481, of March 30, 1995, on Patents and Utility Models**,** published in the Argentinian Republic Official Bulletin on September 20, 1995.

192 Patent Act as amended by Act No. 15 of April 4, 2005 published in The Gazette of India on April 5, 2005.

193 For an analysis of the legislation of more countries, see *Musungu*, *Oh*, The Use of Flexibilities in TRIPS by Developing Countries, p. 70-96.

importation into Japan, there should be an agreement between the purchaser and the patent holder establishing that Japan be excluded from the allowed territory of sale or use. Also, resales would be prevented only if it is noted clearly on the product itself that importation into Japan is prohibited (on the label or packaging for example).[194]

In 1974, under the principle of free movement of goods, one of the pillars of the Treaty Establishing the European Communities,[195] the European Court of Justice (ECJ) decided in C-15/74 that the exercise of patent rights should not prohibit the importation into the Netherlands of products that were put into markets in other Member States with the patent holder's consent.[196] The patentee should not be able to partition off the national markets and, thus, jeopardize the free flow of goods within the Common Market.[197] The ECJ adopted the exhaustion rule for importation of patented products from countries belonging to the economic block and referred to it as European exhaustion. The ECJ reiterated its understanding in later cases,[198] having observed in one judgment issued in 1985 case C-19/84 that the patentee may prevent importation to a Member State whenever the product has been marketed in the exporting country under a compulsory license.[199] In this case, the court understood that an essential element for exhaustion was missing, which is the consent of the patentee to the product's marketing.[200] The national exhaustion rule had been applicable in

194 See *Supreme Court of Japan*, BBS Kraftfahrzeug Technik AG, BBS Japan Kabushiki Kaisha, Washimayor Kabushiki Kaisha v. Kabushiki Kaisha Racimex Japan, The Third Petty Bench of the Supreme Court, judgment of July 1, 1997.

195 Article 30 of the Treaty Establishing the European Communities, amended and renumbered to article 28 in the Amsterdam version of the treaty.

196 See *European Court of Justice,* Centrafarm BV and Adriaan de Peijper v Sterling Drug Inc., Case C 15/74, judgment of October 31, 1994, para. 10-15.

197 See *European Court of Justice,* Centrafarm BV and Adriaan de Peijper v Sterling Drug Inc., Case C 15/74, judgment of October 31, 1994, para. 10-15.

198 See *European Court of Justice*, Merck & Co. Inc. v Stephar BV and Petrus Stephanus Exler, Case C 187/80, judgment of July 14, 1981, para. 11-14, *European Court of Justice*, Merck & Co. Inc., Merck Sharp & Dohme Ltd and Merck Sharp & Dohme International Services BV v Primecrown Ltd, Ketan Himatlal Mehta, Bharat Himatlal Mehta and Necessity Supplies Ltd and Beecham Group plc v Europharm of Worthing Ltd, Joined Cases C 267/95 and C 268-95, judgment of December 5, 1996, para. 54.

199 See *European Court of Justice*, Pharmon BV v Hoechst AG., Case C 19/84, judgment of July 9, 1985, para. 27.

200 *Id.*, para. 25-26.

Germany and the German Supreme Court expressly recognized that only products placed into the market by the patentee (or with his/her consent), in States belonging to the European Communities or to the European Economic Area, could be imported into the country without infringing the German patent or the German part of a European patent.[201] The adoption of European exhaustion conformed to the case law established by the ECJ to avoid partitioning of the Common Market and should not mean that the principle of international exhaustion was adopted.[202]

Regarding medicines, the pharmaceutical industry practices price differentiation among the countries,[203] which may lead to considerable economy through the practice of parallel importation. At the end of the 1990s, South Africa based its anti-AIDS program on parallel importation in order to be able to acquire cheap antiretroviral drugs. The South African government purchased patented anti-AIDS medications in neighboring countries where they were cheaper and a group of pharmaceutical companies supported by the US government sued the South African government in a South African court on February 18, 1998. In the lawsuit, the companies claimed that South African parallel importation rules – as well as compulsory license provisions – were not compliant with TRIPS.[204] Only after worldwide protests did the pharmaceutical companies withdraw the lawsuit in 2001.[205]

Adopting the international exhaustion rule allows for a product that is legally introduced into a market to be imported and sold by a third party for a lower price in a different country. Countries would be free to purchase medications or pharmaceutical ingredients wherever it is sold cheaper. International exhaustion would then stimulate international trade and competition, forcing local distributors to lower their prices according to cheaper prices in other markets. On the other hand, when considering the implementation of international exhaustion, one should also consider that this might serve as a disincentive to establishing local industry. In light of

201 See *German Supreme Court*, "Karate", case X ZR 61/98, of Dec. 14, 1999, p. 686.

202 *Id.*, p. 687-688.

203 It is important to consider that the different prices found may also result from government regulation of price.

204 See *Consumer Project on Technology*, Pharmaceutical Firms against the South African Government, para. 1.

205 *Id.*, para. 3.

the perspective of competing with cheaper prices through importation, national or transnational corporations would not be encouraged to build local facilities and industrialization policies would be jeopardized. Furthermore, a general and uniform adoption of international exhaustion would hinder the practice of price differentiation by patent holders, which discriminates prices in accordance with the income of each country's population. If price discrimination ceases, international exhaustion would result in the opposite outcome and access to cheaper products would be more difficult.

2.3.4. General Exception Rules

Article 30 of TRIPS allows Member States to provide general exceptions to the exclusive rights conferred by a patent, if they do not unreasonably conflict with normal exploitation and do not unreasonably damage the legitimate interests of patent owners and third parties. This is a general provision that is applicable whenever there is no specific rule, for instance Article 31 of TRIPS governing compulsory licenses.[206] Accordingly, TRIPS allows Members States to limit patent holder's rights and adjust them to the principles and purposes established in Articles 7 and 8 of the Agreement. As in any limitation to rights, the exceptions provided must be interpreted in a restrictive manner. Examples of exceptions to patent rights covered by Article 30 are found in the early drafts of the provision, such as prior user rights, experimental research and compounding pharmacy activities and products.[207]

The exception rules in Article 30 played an important role in *Canada – Patent Protection of Pharmaceutical Products,* the dispute settlement between Canada and the European Communities in 2001 that was discussed earlier. Section 55.2(1) provided for an "early working" exception for regulatory review and Section 55.2(2) allowed the generic company to manufacture the generic drug six months before the end of the patent term and store the production in order to market it without delay as soon as the patent would lapse.[208]

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206 See *Gervais*, The TRIPS Agreement: Drafting History and Analysis, p. 241-242.

207 See *Canada – Patent Protection of Pharmaceutical Products*, Report of the Panel, March 17, 2000 (WT/DS114/R), para. 4.30.

208 *Canada – Patent Protection of Pharmaceutical Products*. Summary of key findings, February 24, 2010 (WTO/DS114).

Addressing the structure of Article 30, the DSB made it clear that exceptions must fulfill three conditions in order to be compliant with TRIPS: 1) they must be limited, 2) they must not unreasonably conflict with normal exploitation of the patent and 3) they must not unreasonably damage the legitimate interests of the patent owner and take into account the legitimate interests of third parties.[209] If one of these conditions is not present, it constitutes a violation of the Agreement. The limitation of exceptions to exclusive rights conferred to patent holders addresses the extent that these rights are curtailed, rather than the extent of the possible economic impact.[210] However, limitations are unrelated to the number of exclusive rights foreseen in Article 28.1 – to make, use, offer for sale, sell and import – that have been prejudiced by an exception.[211] The extent to which such legal rights have been shortened is what should be limited.[212] It is irrelevant if only one right is ultimately preserved by the exception and not all rights are affected, e.g. the acts of making and using are exempted from infringement while the acts of sale are not).[213]

The expression "normal exploitation" contained in the second condition of Article 30 should be understood as the exclusion of "all forms of competition that could detract significantly from the economic returns anticipated from a patent's grant market exclusivity." Accordingly, Section 55.2(2) of Canada's Patent Act that allows manufacture and storage was inconsistent with Article 30 of TRIPS because the benefits obtained by the patentee, in the period between the legal end of the patent term and the actual end of the patent, refer to the normal exploitation of a patent.[214] The enjoyment of the right to exclude third parties to "make" the patented product during the patent term would naturally result in the prevention of such party from immediately entering the market after expiration.[215] On the other hand, carrying out tests for regulatory review is not considered normal exploitation of a patent; therefore, Section 55.2(1) of the Canadian

209 See *Canada – Patent Protection of Pharmaceutical Products*. Complaint by the European Communities and their Member States. Report of the Panel, March 17, 2000 (WT/DS114/R), para. 7.20-7.21.
210 *Id.,* para. 7.49.
211 *Id*., para. 7.32-7.33.
212 *Id.*, para. 7.31.
213 *Id*., para. 7.32-7.33.
214 *Id.,* para. 7.56-7.57.
215 *Id.*

Patent Act providing for the "early working" exception was not in violation of TRIPS.[216]

Pursuant to the third condition established by Article 30 of TRIPS, the assessment of Canada's legislation should verify if patent holders would have a "legitimate interest" in the economic benefits deriving from *de facto* market exclusivity and if their "legitimate interest" would be "unreasonably prejudiced" by the regulatory review exception.[217] According to the DSB, "legitimate interests" are not a synonym for "legal interests" pursuant to Article 28.1 of TRIPS.[218] Rather, they should be regarded as interests that are "justifiable" to be supported by public policies and social norms, such as the use of patented subject matter for scientific research, which would take into consideration dissemination of technology, a public policy concern at the foundation of the patent system. (The "legitimate interest" of society to use the information contained in the patent specification for advancing science and technology would be justified).[219] Furthermore, the "legitimate interests" of the patentee, which would have been affected by the Canadian legislation, relate to the effective term of exclusivity enjoyed by the patentee, which is actually shortened due to the extensive trials needed to support the regulatory approval of the innovative product, the patented subject matter.[220] The panel concluded that the concept of "legitimate interest" should not be used to encompass the need of compensation for losses, since this would amount to an area of policy making that is still unresolved among countries.[221] As a result, Section 55.2(1) of Canada's Patent Act would not prejudice the "legitimate interest" of patent holders.

Article 30 of TRIPS does not specify the activities that should be exempt, but rather establishes general conditions to be fulfilled by national legislatures when regulating the matter. According to this rationale, international exhaustion should not be regarded as a general exception under Article 30 because it would conflict with the normal exploitation of a

216 *Id.*, para. 7.58.
217 *Id.*, para. Para. 7.61.
218 *Id.*, para. 7.68.
219 *Id.*, para. 7.69.
220 *Id.*, para. 7.74-7.76.
221 *Id.*, para. 7.77-7.83.

patent and may impair the legitimate interests of a patent holder.[222] In *Canada – Patent Protection of Pharmaceutical Products* decision, the DSB wisely concluded that Article 30 recognizes that the rights given to a patent owner under Article 28 of the Agreement must be balanced in order to achieve what Articles 7 and 8.1 establish.[223] Nevertheless, the three conditions set in Article 30 make it clear that the exceptions to patent rights, which may be implemented by each Member State, should be narrowly interpreted and are not to be considered a renegotiation of the Agreement.

2.3.5. Compulsory Licenses

Compulsory licensing is the most important flexibility instrument provided in TRIPS (see Article 31 of TRIPS). It is a license granted under certain conditions by a government to a third party in order to allow the production or marketing of a patented product or the use of a patented process, regardless of the consent of the patent owner.

Compulsory licenses have always been the subject of controversial debates relating to effects on a country's economy and especially on investments in research and development (R&D). For a long time, many studies have sought to evaluate and quantify such effects.[224] Though inconclusive, studies have indicated that in the long run, granting of compulsory licenses has minimal effects on investments by companies in developing countries.[225] The discussions are mostly theoretical and revolve around the balance between private interests and social welfare. On the one hand, stronger patent rights would provide better incentives for the international transfer of technology because it depends on high investments in R&D by

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222 See *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 202.

223 See *Canada – Patent Protection of Pharmaceutical Products*. Complaint by the European Communities and their Member States. Report of the Panel, March 17, 2000 (WT/DS114/R), para. 7.26.

224 See *Scherer*, The Economic Effects of Compulsory Patent Licensing; *Jewkes, Sawers, Stillerman*, The Sources of Invention; and *Chien*, Cheap Drugs at What Price to Innovation.

225 See *Rosenberg*, Patents on Medicines and International Trade, p. 172-173; and *Primo Braga, Fink*, The Economic Justification for the Grant of Intellectual Property Rights, p. 108.

transnational companies in developing and developed countries.[226] On the other hand, flexible rights would introduce competitors in an otherwise monopolized market, leading to a decrease in prices.[227]

Compulsory licenses have arisen as an alternative to prevent voiding of patents as a result of violating restrictions. Until the Paris Convention, the failure to work a patent would have resulted in loss of patent rights, i.e. forfeiture.[228] At that time, compulsory licenses represented a less cumbersome measure than forfeiture for patent owners. According to the 1883 text of the Paris Convention, the patentee was obligated to work a patent according to national laws.[229] The Convention did not define the expression "working," leaving it up to Member States to establish meaning at their own discretion.[230] In some countries, working implied local manufacture of the patented subject matter, whereas in others it would be enough if the patented product were simply being marketed.[231]

The idea of compulsory licenses as a legitimate mechanism to hinder abuses became widespread during the Paris Convention Hague Revision of 1925.[232] This concept was further elaborated in the London Revision of 1934, when Member States agreed that a waiver of patent rights would only be possible in cases where the effects of abusive conduct were still occurring two years after the first compulsory license.[233] The use of compulsory licenses was originally linked to the concept of abuse and, afterward, the mechanism was conceived as a way to restrict the rights of patent holders in the case of public interest even if abusive conduct had not occurred. The granting of compulsory licenses in the case of public interest was not expressly foreseen in the text of the Convention, but it was not prohibited. The Lisbon Revision of 1958 established that compulsory li-

226 See *Tang*, The International Trade Policy for Technology Transfers, p. 193.
227 See *Rosenberg*, Patents on Medicines and International Trade, p. 157.
228 The original text of the Paris Convention of 1883 and the subsequent acts amending it have been received by the candidate from the IP Laws and Treaties Section of the WIPO as files attached in electronic correspondance. See also *Reichman*, *Hasenzahl*, Non-voluntary Licensing of Patented Inventions, p. 10.
229 *Id*., p. 29.
230 See *Ladas*, Patents, Trademarks, and Related Rights, p. 524.
231 See *Ladas*, Patents, Trademarks, and Related Rights, p. 523.
232 See *Reichman*, *Hasenzahl*, Non-voluntary Licensing of Patented Inventions p. 10, 28. See also *Bodenhausen*, Guide to the Application of the Paris Convention for the Protection of Industrial Property, p. 68.
233 *Id.*, p. 11, 28.

censes could be granted non-exclusively and determined time limits for granting.[234]

The latest Revision of Stockholm of 1967 with an amendment in 1979, establishes that importation of goods would not result in forfeiture when such goods are manufactured in another member country.[235] National legislation may provide for the granting of compulsory licenses seeking to prevent abuses resulting from exclusive rights, such as the failure to work.[236] Only if compulsory licenses have not been able to prevent abuse, forfeiture may occur; in this case, proceedings for forfeiture or revocation may be established only after a two year period following the date of granting of the first compulsory license.[237] In addition, lack of or insufficient working may only trigger a compulsory license after a four year period following the filing date of the patent application or after a three year period following the date the patent is granted – whichever occurs last. The patentee is entitled to present legitimate reasons to prevent the granting of a compulsory license.[238] The compulsory license will be non-exclusive and non-transferable. Sub-licensing is also prohibited, except with that part of the enterprise or goodwill which exploits such license.[239]

It is important to note that the provisions of the Paris Convention on compulsory licenses are still applicable within the context of TRIPS by virtue of Article 2.1 of TRIPS. Accordingly, compulsory licenses should be granted in compliance with article 5A(2) of the Paris Convention and Article 31 of TRIPS. In case their granting was grounded on failure to work or insufficient working of the patent, the requirements of Article 5A(4) of the Paris Convention must also be fulfilled.[240]

During the GATT negotiations, developed countries sought to restrict the Paris Convention's interpretation, which allowed each Member State to adopt its own criteria of abuse, so as to inhibit developing countries from continuing to embrace local production requirements.[241] Evidence of

234 *Id*., p. 27.
235 Article 5A(1) of Paris Convention.
236 Article 5A(2) of Paris Convention.
237 Article 5A(3) of Paris Convention.
238 Article 5A(4) of Paris Convention.
239 Article 5A(4) of Paris Convention.
240 See *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 205.
241 See *Reichman*, *Hasenzahl*, Non-voluntary Licensing of Patented Inventions, p. 13-14.

this is present in the wording of Article 27 of TRIPS, which prohibits discrimination based on local production or importation. This discussion resulted in a panel requested by the US against Brazil and will be discussed later on in this text.[242]

Public interest, which includes cases of national emergency, other circumstances of extreme urgency or public non-commercial use, is one of the major grounds for granting compulsory licenses. Patent laws in most countries, if not all, allow the use of patents for public interest. Abusive conduct and cases of dependent patents are also cited expressly in Article 31 of TRIPS, yet the provision does not provide an exhaustive list of all situations where compulsory licenses are granted except for one hypothesis. According to Article 31(c) of TRIPS, in the field of semi-conductor technology, compulsory licenses are only for public non-commercial use or a remedy for practices deemed judicially or administratively anti-competitive.

Under Article 31, TRIPS establishes the conditions upon which compulsory licenses may be granted. Among the necessary requirements are: 1) the request for the license has been analyzed on its individual merits and on a case by case basis,[243] 2) the interested party has previously sought to obtain the patent holder's authorization in reasonable commercial standards and that those efforts have not been successful within a reasonable period of time (this is exempted in case of urgency or national emergency),[244] 3) the scope and duration of the license is proportional, limited to the purpose for which it was granted,[245] 4) the license is non-exclusive and non-assignable except with the part of the enterprise or goodwill which enjoys such license,[246] and 5) the products manufactured under the compulsory license serve predominantly to supply the domestic market.[247]

In cases of anti-competitive practices, prior negotiations with the patentee and the need for supplying the domestic market are not required. It is

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242 See *Brazil – Measures Affecting Patent Protection*. Request for Consultations by the United States, June 8, 2000 (WT/DS199/1). Request for Establishment of a Panel by the United States, January 9, 2001 (WT/DS199/3). Notification of Mutually Agreed Solution, July 19, 2001 (WT/DS199/4).

243 Article 31 a) of TRIPS.

244 Article 31 b) of TRIPS.

245 Article 31 c) of TRIPS.

246 Article 31 d) and e) of TRIPS.

247 Article 31 f) of TRIPS.

important to note that a controversial issue among scholars has been whether compulsory licenses for anti-competitive practices should be granted with the goal of increasing access to medicines by poor populations in developing countries.[248] Even assuming that there is a violation of competition laws, for the majority of developing countries, the compulsory licenses for anti-competitive practices are not actually available either because there is not a system of competition law or their system is not mature enough.[249] Brazil, for instance, provides this tool in Article 68 of Law 9279/1996, but there is no record that it has ever been used.

The provision in Article 31(f) of TRIPS that addresses a *de facto* limitation for the least developed countries was especially disputed. The problem was that generic products manufactured under a compulsory license could not be exported to these poor countries. As a result of this limitation, least developed countries and many developing countries were barred from the benefits of compulsory licenses, since they do not have the capacity to manufacture drugs themselves. This debate resulted in the Doha Ministerial Declaration on the TRIPS Agreement and Public Health of November 14, 2001 (Doha Declaration), and the General Council Decision of August 30, 2003 (Doha Decision), as a compromise to elucidate this issue.[250] The Doha Declaration and Decision in theory would solve the problem of the countries that lack sufficient manufacturing facilities.

Adequate compensation should be paid to the patent owner in exchange for the withdrawal of exclusive production and marketing rights in favor of the general welfare. However, payment is not calculated strictly according to losses. The patent owner must receive reasonable compensation in the concrete case taking into consideration the economic value of the license, as per Article 31(h) of TRIPS. The Agreement does not contain any criteria for determining suitable compensation, but the Guidelines of the World Health Organization (WHO) provide examples in which royalties are between 1% and 6% of the market price.[251] Payment of reasonable

248 See *Godt*, The so-called "Waiver Compromise" of Doha and Hong Kong. *Hoen*, TRIPS, Pharmaceutical Patents and Access to Essential Medicines, p. 52. *Amaral Júnior*, Compulsory Licensing and Access to Medicine in Developing Countries, p. 11-2.

249 *Id*., footnote 67 (until 2002 only 20 developing countries have passed legislation regulating competition law).

250 See *WTO*, Doha Declaration (paragraph 6); *WTO*, Doha Decision. The Doha Declaration and Decision will be dealt further on this chapter.

251 See *Correa*, A Commentary on the TRIPS Agreement, p. 323.

royalties could serve as a means for reducing the negative effects of granting compulsory licenses for technological development.[252] In the case of anti-competitive practices, Article 31(k) of TRIPS allows Member States to grant compulsory licenses with reduced payment of royalties or even for free.

TRIPS also establishes that judicial review must be available to assess both the legal validity of the granting of the compulsory license and the remuneration to be paid to the patentee as adequate compensation.[253]

In the case of dependent patents, Article 31(l) of TRIPS authorizes compulsory license of the original patent whenever the second patent concerns an important technical advance and it has considerable economic significance, which is to be evaluated in relative terms regardless of its absolute economic value.[254] The owner of the first patent is also entitled to a cross license to be able to use the second patent on reasonable terms. The license issued in this case is only assignable upon assignment of the patent that enjoys such use.

Although the issue of compulsory license has received a lot of attention in discussions regarding access to medicines in developing and least developed countries. Developed countries like the US have long provided for compulsory licenses in their national laws.[255] Several cases of compulsory licenses can be found for correcting anti-competitive practices in the US.[256] In 2001, under the menace of an anthrax epidemic, the US Depart-

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252 See *Scherer*, The Economic Effects of Compulsory Patent Licensing, p. 86.

253 Article 31 i) and j) of TRIPS.

254 Patents covering new use of an orphan drugs are cited as an example of patents which would be of small absolute value but of big economic significance. See *Carvalho*, The TRIPS Regime of Patent Rights, p. 370.

255 See in this regard the following provisions of the US legislation foreseeing compulsory licenses cases: US Clean Air Act 1988 (42 USC Sec. 7608) on products that become mandatory technical standards in consequence of environmental legislation; Atomic Energy Act 1988 (42 USC Sec. 2183) on patents of public interest regarding atomic energy; 7 USC Sec. 2402 (1988) on plant varieties; 28 USC Sec. 1498 on governmental use. See also *Love*, Don't interfere with the Thai government's decision, p. 1-2; and *Correa*, IP Rights and the Use of Compulsory Licenses, p. 1.

256 See, for example, Federal Trade Commission, Merger Ciba-Geigy and Sandoz in 1997 (compulsory license of the patent portfolio covering HSV-tk, hemophilia genes and other genetic engineering related products). Federal Trade Commission, Merger Baxtel International/Immuno International AG in 1997 (compulsory license granted for fibrin sealant, of which the merging company would be one of

ment of Health threatened to grant a compulsory license under 28 USC Section 1498 for Bayer's patent covering the drug Cipro in order to obtain a discount in its price.[257]

TRIPS does not adopt any criteria that limits the notion of public interest or define "circumstances of extreme urgency," "national emergency," "public use," and "anti-competitive practices." Nevertheless, when interpreting and implementing Article 31 of TRIPS, Member States should do it in harmony with other provisions of the Agreement in light of the balance between intellectual property and the welfare of nations, as per Article 8.1 of TRIPS.[258] Furthermore, it is important to keep in mind that the flexible interpretation of TRIPS is not unlimited – neither to raise nor decrease protection levels. In the panel *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, complaint filed by the United States, the DSB decided that TRIPS patent terms should be interpreted following the common meaning deriving from its context and in light of the Agreement's subject matter and purpose (pursuant to Article 31 of the Vienna Convention on the Law of Treaties).[259] The DSB disapproved interpretations that would elevate or diminish the rights and obligations provided in the Agreement.[260]

Although there might be homogeneity among the hypotheses for granting compulsory licenses in different Member States, legislation should vary according to the desired level of patent protection, the importance of promoting R&D, the need to have lower priced medicines and the degree of competition policies – the latter plays an important role in the pharmaceutical sector and the marketing of generic products. Despite these policy making considerations, compulsory licenses are exceptions to the rights

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the few to request the FDA approval). Federal Trade Commission, Merger Upjohn/Pharmacia Aktiebolag in 1995 (compulsory license granted for the patent covering 9-AC on cancer treatment). Federal Trade Commission, Eli Lilly in 1979 (compulsory license of the patents and know-how for the production of insulin).

257 See *Fleischer-Black*, The Cipro Dilemma, para. 14-15.

258 See *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 204.

259 See *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products.* Complaint filed by the United States. Report of the Appellate Body, December 19, 1997 (WT/DS50/AB/R), p. 16.

260 *Id.*

conferred by a patent and should be treated accordingly as exceptional; that is, measures to be taken only in certain cases that are duly justified.

2.4. Other Provisions

Article 32 of TRIPS determines that any decision revoking or declaring the forfeiture of a patent is subject to judicial review. Within the WTO system it establishes a principle specifically directed at patents based on the general guarantee that exists in most democratic states where judicial power is entitled to review measures that restrict rights. Accordingly, decisions revoking and forfeiting patents may be submitted to independent judicial assessment. In the EPC context, the Boards of Appeal of the EPO issues final decisions regarding the revocation of European patents in opposition proceedings (see Articles 106, 111 and 112 of the EPC). As its members are deemed independent and enjoy stability prerogatives similar to those granted to judges, the Boards of Appeal and the Enlarged Board of Appeal are to be considered quasi-judicial bodies following procedures similar to those of courts.[261] Therefore, review by the Boards of Appeal of decisions issued by the Opposition Division should be considered the judicial review of Article 32 of TRIPS.[262]

One could consider that the grounds on which a patent may be revoked or declared forfeited is left open by this TRIPS provision. Nevertheless, in spite of a lack of an explicit list of grounds, revocation and forfeiture of a patent may not occur based on convenience criteria under the penalty of nullifying the main objective of TRIPS to provide a sound system of protection of intellectual property. Any security deriving from the patent system would be compromised because there would always be the chance of forfeiture or revocation based on generally alleged public interest.[263] Cancellation of a patent is a consequence that is too severe even for cases of public interest; therefore, to balance this, the remedy lies with compulsory licenses.[264]

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261 See *Gervais*, The TRIPS Agreement: Drafting History and Analysis, p. 254.
262 See *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 208-209.
263 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 375-376.
264 *Id.*

Forfeiture may only occur under Article 5.A.3 of the Paris Convention, which must be complied with by Member States according to Article 2.1 of TRIPS.[265] This provision establishes that forfeiture be conditioned to the cases in which compulsory licenses have not inhibited abuses resulting from exclusivity rights such as failure to work a patent.[266] Failure to pay maintenance fees may also justify the lapse of a patent.[267] Member States may be able to revoke patents on the following grounds: 1) the grounds included in the Paris Convention such as insufficiency of compulsory license as a measure to prevent abuses and failure to pay maintenance fees (Article 5.A.3 of the Paris Convention), 2) failure to meet substantive conditions of patentability or to qualify as an invention pursuant to Article 27.1 of TRIPS, 3) the invention consists of subject matter falling under the admitted patentability exclusions of Article 27.2 of TRIPS, and 4) failure to comply with full disclosure requirement of Article 29 of TRIPS.[268] Limitations on grounds for forfeiture and revocation are necessary in order to make TRIPS effective as an agreement establishing minimum standards for IP rights. Otherwise, any harmonization of patentable subject matter and rights conferred to patent holders would be void if a patent could be invalidated or declared forfeited based on a mere convenience criteria within each country legal system and the result would be different standards of protection that create barriers to international trade.

Article 34 of TRIPS establishes the reversal of the burden of proof in civil proceedings related to the enforcement of patents for processes for obtaining new products. It aims to facilitate patent enforcement in cases where there is no direct evidence of the use of patented processes.[269] Pursuant to this provision, judicial authorities should be authorized to order the defendant to prove that the process used to obtain the product is different than the process which is patented. Member States should provide for such reversal (i) either in the case that the product obtained by the patented process is new, (ii) or there is a high likelihood that the product was

265 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 376.

266 Article 5.A.3 of Paris Convention also determines that forfeiture or revocation proceedings may only start after two years from the granting of the first compulsory license.

267 Article 5*bis*.2 of Paris Convention foresees a loss of rights resulting from the lack of payment of maintenance fees.

268 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 376.

269 See *Gervais*, The TRIPS Agreement: Drafting History and Analysis, p. 260.

obtained by the patented process and this could not be proved by the patentee through reasonable efforts. It is important to note that Member States must provide for reversal of the burden of proof in case of patents covering processes for obtaining a product, but not for other kinds of processes including methods and uses.[270] When alleged offenders submit evidence opposing the infringement allegation, their legitimate interests in protecting manufacturing and business secrets must be taken into account and, thus, the burden rests on the plaintiff as in regular civil lawsuits.[271]

If national laws provide for the reversal of the burden of proof either in one of the cases – (i) or (ii) – discussed above, then they are in compliance with TRIPS. For reversal to occur (as per the second possibility), it is not necessary for the product obtained by the patented process to be new. This is considered helpful for the enforcement of patents covering modern biotechnology processes that use rDNA technology for producing already know proteins.[272]

3. The Pharmaceutical Industry Context

Patent provisions in TRIPS have been the subject of heated debate among Member States, especially concerning the pharmaceutical context. In the past, the exclusion of certain areas of technology from patentable subject matter had been regarded as decisive for a country's development. This was the position adopted in the 1970s towards pharmaceuticals by India and Brazil; Switzerland allowed patents for pharmaceuticals only in 1977; whereas Spain, Italy and Portugal only introduced them in 1992.[273] Before

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270 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 384.

271 See *Gervais*, The TRIPS Agreement: Drafting History and Analysis, p. 260.

272 See *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 210.

273 Brazilian Federal Law 5772, of December 21, 1971, The Industrial Property Code, published in the Official Gazette on December 31, 1971. Indian Patent Act, of September 19, 1970, published in The Gazette of India on April 20, 1972. Swiss Ordinance 232.141, of October 19, 1977, on Patents for Inventions, published in the Official Gazette on October 19, 1977. Portuguese Decree N. 52/91, of August 30, 1991, ratifying the European Patent Convention, published in the Republic Diary on August 30, 1991. Spanish Law N. 11/1986, of March 20, 1986, Patent Law, published in the Official Bulletin of Spain on March 26, 1986. Italian Law N. 349/1991, of October 19, 1991, on provisions for the issue of a

the Uruguay Round in 1995 there were thirteen GATT Member States that did not provide patents for pharmaceuticals.[274] The WTO system along with TRIPS has been criticized for creating barriers to the access of essential medicines in developing countries. The introduction of patent rights in countries that did not provide this exclusivity rights would lead to a price increase. In many developing countries, the problem is considered to be quite large since medicine is purchased directly by patients without health insurance or governmental aid due to inadequate public health systems or infrastructure.

The pharmaceutical sector is highly dependent on patents to reduce competition in the marketplace. According to an early study in 1986, the pharmaceutical industry depends on the patent system twice as much as the chemical sector.[275] The research based industry defends itself by alleging that the process of developing new drugs is costly and time consuming. According to an estimate made in 2010, only one out of 10,000 potential drugs reaches the market after a fifteen year period of research and trials, costing over US$800 million.[276] Patents are considered necessary in the pharmaceutical industry to be able to recuperate investments and fuel the R&D cycle,[277] since the cost of drug development is high compared to the marginal cost for manufacturing. As settled during TRIPS negotiations and the discussions surrounding the Doha Declaration, the issue is not about protecting incentives to innovate, but how much protection is justified.

Public policies such as price control, reimbursement of expenses for medications, governmental subsides for pharmaceutical R&D activities, acquisition of patents by governments, introduction of policies regarding generic drugs, price differentiation among countries, and the use of flexibilities within TRIPS (especially the granting of compulsory licenses) may be used as tools to minimize market distortions and negative social effects

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certificate of additional protection for medicines or its members, subject to patent, published in the Official Gazette on November 4, 1991.

274 Argentina, Brazil, Cuba, Egypt, India, Kuwait, Morocco, Pakistan, Paraguay, Tunisia, Turkey, United Arab Emirates and Uruguay. See *WTO,* Pharmaceutical patents and the TRIPS Agreement, footnote 2.

275 See *Mansfield*, Patents and innovation, p. 175.

276 See *PhRMA*, Chart Pack, p. 19.

277 PhRMA points out that R&D investments by the research based pharmaceutical industry were of USD 50,7 billion in 2010. See *PhRMA*, *PhRMA*, Chart Pack, p. 21.

of patents in this field.[278] The proposed combination of compulsory licenses and price control should be carefully considered by policymakers in order to enhance access to medicines through price reduction.[279] Governments would impose a decision on patent holders: either they accept price control on patented products or agree to non-exclusive licenses to national industry.[280] Instead of an aggressive price control system, licensing would be the better option and would not be prevented under Article 31 of TRIPS because in the end there is consent from the patent holder.[281]

TRIPS includes a number of possible grounds for granting compulsory licenses, which are to be adopted by developing countries aiming to promote access to medicines. These include a) the refusal to license the patent under reasonable commercial terms, whenever the non-licensing affects the availability of a product or the development of a new activity; b) declared state of national emergency, resulting for instance from a natural catastrophe, war or epidemic; c) whenever there is a public health crisis, in order to assure the population has access to essential medicine, or in situations of public interest including national security; d) anti-competitive practices; e) the use of government to make medicine available on a non-commercial basis; f) when the lack or insufficient exploitation of the patent subject matter hinders access to health or prevents the development of a sector that is essential to a country's economy; g) facilitating the use of dependent patents; and h) public interest, broadly defined in order to cover other situations in which society's welfare is at stake.[282]

It is important to note that the flexibilities included in TRIPS such as compulsory licenses and parallel importation were barely used during the first years of the WTO system because developing and least developed countries were afraid of trade retaliation. In 1997, South Africa began making use of parallel importation seeking to reduce the price of medications for the treatment of AIDS. The US Congress then threatened to withhold all development aid and the South African government was sued by

278 See *Rosenberg*, Patents on Medicines and International Trade, p. 86-102.
279 See *Weissman*, A Long, Strange TRIPs, p. 1115-1116.
280 The granting of compulsory licenses and price control should take due care so as to not violate article 31 TRIPS, especially considering that compulsory licenses must be granted on an individual basis and not provided by national laws as a general measure.
281 *Id.*
282 See *Correa*, IP Rights and the Use of Compulsory Licenses, p. 10-22.

39 international pharmaceutical companies.[283] In addition, in 2009, the US government requested a panel against Brazil before the WTO Dispute Settlement Body alleging that the Brazilian industrial property law provided for a local working requirement on its Article 68 compulsory licenses, which would be inconsistent with the non-discrimination principle of Article 27.1 of TRIPS.[284]

Due to the need to clarify issues surrounding the controversy between patent rights and public health concerns, Member States held a Ministerial Conference in Doha in 2001 that resulted in the Doha Declaration on the TRIPS Agreement and Public Health.

3.1. The Doha Declaration on the TRIPS Agreement and Public Health

Prior to the Ministerial Conference held in Doha in 2001, developing countries were afraid to make use of the flexibilities negotiated in TRIPS due to steady resistance by industrialized countries. Developing countries were afraid of economic sanctions for the granting of compulsory licenses. As mentioned earlier in this chapter, the lawsuit relating to parallel importation against the South African government served to enhance these fears.[285] The same was true when WTO panel was established following the complaint by the US government against Brazil.[286] The problematic provision in Article 31(f) that made access to medicines difficult for least developed countries was another clear reason for developing countries to want to reform TRIPS.

The US, which at the beginning of the Doha Round strongly resisted the softening of patent rights, found itself in a weakened position. This was the result of the US government's threats against the Bayer company to grant a compulsory license for the importation of a me-too drug of the

283 See *Consumer Project on Technology*, Pharmaceutical Firms against the South African Government, para. 1-3.

284 See *Brazil – Measures Affecting Patent Protection*. Request for Consultations by the United States, June 8, 2000 (WT/DS199/1). Request for Establishment of a Panel by the United States, January 9, 2001 (WT/DS199/3).

285 See *Consumer Project on Technology*, Pharmaceutical Firms against the South African Government, para. 1-3.

286 See *Brazil – Measures Affecting Patent Protection*. Request for Consultations by the United States, June 8, 2000 (WT/DS199/1). Request for Establishment of a Panel by the United States, January 9, 2001 (WT/DS199/3).

patented antibiotic Cipro from India. The drug is used for treating anthrax, which became an issue after important US politicians received letters containing the anthrax agent following the terrorist attack of September 11, 2001.[287] The German company has made an offer to the US government and the parties have reached an agreement, but at the end the acquisition of generics has not taken place.[288]

In June 2001, a group of developing countries submitted a document to the Council for TRIPS in order to discuss intellectual property and access to medicines.[289] In November of the same year, the WTO Ministerial Conference passed the Doha Declaration. All WTO Member States expressly recognized that, although the protection of intellectual property is important for the development of new medicines, there are concerns about its effect on prices. Accordingly, TRIPS neither prevents nor should prevent members from taking measures to protect public health and promote access to medicines. The Doha Declaration reaffirms the right of WTO members to make use of the provisions in TRIPS that provide flexibility for this precise purpose.

The flexibilities established by the Doha Declaration comprise the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted. Additionally, the Declaration establishes the right for countries to determine what constitutes national emergency or other circumstances of extreme urgency such as a public health crisis, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics. Regarding Article 6 of TRIPS, the Doha Declaration confirms that the Agreement leaves Member States free to establish their own regimes for exhaustion without challenge, being subject to the most favored nation and national treatment provisions in Articles 3 and 4 of TRIPS.

In paragraph 6, the Doha Declaration instructed the Council for TRIPS to find a solution before 2002 to the problem faced by WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector in order to allow them to make effective use of compulsory licensing.

The final paragraph agrees, with respect to pharmaceutical products, that least developed countries will not be obligated to implement or apply

287 See *Fleischer-Black*, The Cipro Dilemma, para. 14-15; *Moore*, Parallel Trade, Unparallel Laws, p. 91; *Herstemeyer*, Human Rights and the WTO, p. 16.
288 See *Fleischer-Black*, The Cipro Dilemma, para. 14-15.
289 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 144-145.

Sections 5 and 7 of Part II of TRIPS nor to enforce rights established under these Sections until January 1, 2016. Accordingly, the Council for TRIPS and the General Council issued decisions implementing this waiver on June 22, and July 8, 2002, respectively.[290]

Although the Doha Declaration has not modified TRIPS, it has served as a policy making tool and the granting of compulsory licenses became an undoubtful prerogative of any Member State. Moreover, interpretations of Article 6 of TRIPS, which could lead to an increase of TRIPS protection standards, should be hindered. The possibility that medicines be exported and sold in other countries at cheaper prices was confirmed, as long as laws in such countries allow for parallel importation. Additionally, least developed countries received an additional ten-year term to implement TRIPS into their national legislation.

The position assumed by developing countries towards the Doha Declaration has been criticized for the assumption that compulsory licenses would be a tool to solve the problem of access to essential medicines in poor countries. Compulsory licenses stand as an exception to established rights and should not be used to mold public health policies at the risk of undermining private rights and incentives. Lacking access to essential medicines should not be regarded simply as a problem caused by the research-based pharmaceutical industry when in most countries the solution depends on the general restructuring of social development policies. Generic drugs may be sold at cheaper prices, but, in general, the generic pharmaceutical companies are private and profit-oriented, except some government owned industries, and the supply of essential drugs would still be subject to price negotiation between governments and private industry.

One issue that was left unanswered by the Doha Declaration, with express instructions for the Council for TRIPS to solve, was the importation of products manufactured in other countries within the scope of compulsory licenses. Since those goods have not been manufactured with the consent of the patentee, in principle there would be no exhaustion of rights. Furthermore, pursuant to Article 31(f) of TRIPS, a compulsory license

290 See *WTO*, Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products, Decision of the Council for TRIPS of June 22, 2002 (IP/C/25); *WTO*, Least-Developed Country Members — Obligations Under Article 70.9 of the TRIPS Agreement with Respect to Pharmaceutical Products, Decision of the General Council of July 8, 2002 (WT/L/478).

must be granted primarily for supplying the domestic market, which poses a severe problem for developing and least developed countries that do not possess the technical capacity to manufacture drugs in general or the specific drug covered by the compulsorily licensed patent. This problem led to the General Council Decision Implementing Paragraph 6 of the Declaration, which will be discussed below. In its essence, the Doha Declaration is a reaffirmation of concepts that were already established in TRIPS with the goal of settling any misinterpretations that could lead to a distortion of the TRIPS regime.

3.2. The Decision Implementing Paragraph 6 of the Doha Declaration

After difficult negotiations between developing countries and industrialized countries regarding the implementation of paragraph 6 of the Doha Declaration and the possibility of amending TRIPS, a decision was adopted by the General Council on August 30, 2003.[291] Pursuant to the decision, in cases of compulsory licenses of medicines Article 31(f) of TRIPS is not applicable when granted for combating public health problems. This decision was deemed as a waiver of Article 31(f) through a special procedure.

On December 6, 2005, the General Council in Hong Kong approved the waiver as permanent and thereby amended the TRIPS Agreement for health issues. The parties agreed and passed a Protocol establishing that Article 31bis (whose contents reported to the Decision of 2003) be introduced in the Agreement.[292] The transition period before entering into force was until December 1, 2007. This deadline was extended to by the General Council until December 31, 2009 and again until December 31, 2011, since the quorum of two-thirds of WTO Member States had not yet been

291 For more, see *Carvalho*, The TRIPS Regime of Patent Rights, p. 329-339; *Gervais*, The TRIPS Agreement: Drafting History and Analysis, p. 48-54.

292 *WTO*, Protocol Amending TRIPS.

achieved.[293] As of today only 44 parties have ratified the Protocol[294] and, until it enters into force, the 2003 Decision is still applicable.

The Protocol does not differ much from the 2003 Decision. In summary, the mechanism foreseen in the Decision and the Protocol provides that Article 31(f) of TRIPS be waived, allowing for the exportation of pharmaceutical products under a compulsory license to an eligible importing Member State with insufficient or no manufacturing capacities. The mechanism must be used only in cases of national emergency or other circumstances of extreme urgency or public non-commercial use. A systematic interpretation of the Doha Declaration and the Decision leads to the conclusion that the waiver of Article 31(f) must be used to protect public health and concerns medicines for treating diseases that afflict many developing and least developed countries such as AIDS, tuberculosis, malaria, and other epidemics.

Both importing and exporting countries must grant a compulsory license. Only the exporting country, and not the country in need of the medicines, should pay adequate remuneration. Importing countries should notify the Council for TRIPS of the medicines they need and in what quantity. As for the exporting country, the following conditions must be fulfilled: a) only the needed quantity may be exported, b) the whole amount that the manufacturing country will produce under the license is to be exported to the importing country, and c) the medicines imported under this procedure should bear a special label.

Within a regional trade area, if half of the members are deemed to be least developed countries, it is allowed that medicines that are imported under compulsory licenses be further exported into all the other countries in the trade area. In practice, this provision most probably only applies to African countries.

Member States must take measures against undue further sales of medicines imported under this procedure so as to ensure that they are used

293 *WTO*, Members accepting amendment of the TRIPS Agreement.

294 The following member have formally accepted the Protocol Amending TRIPS: United States, Switzerland, El Salvador, Republic of Korea, Norway, India, Philippines, Israel, Japan, Australia, Singapore, Hong Kong, China, European Union, Mauritius, Egypt, Mexico, Jordan, Brazil, Morocco, Albania, Macau, Canada, Bahrain, Colombia, Zambia, Nicaragua, Pakistan, Former Yugoslav Republic of Macedonia, Uganda, Mongolia, Croatia, Senegal, Bangladesh. See *WTO*, Members accepting amendment of the TRIPS Agreement.

only for the public health purposes justifying the compulsory license. An important provision prohibits Member States from bringing cases before the WTO Dispute Settlement Body against measures taken under the Doha Decision (or article 31*bis* once it is formally incorporated into TRIPS) and its annexes.

The mechanism may not be used by every Member State for importing medicines. Industrialized countries (Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, The Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom and the United States) have consented that they will not import medicine under the provision. Importation is allowed by developing countries through the mechanism only in case of national emergency or other urgent situations.[295]

Until February 28, 2011, few Member States had adapted their national laws to the new mechanism, including Canada, Norway, India, European Union/European Communities, Hong Kong, Switzerland, Philippines, Singapore, Albania, Croatia, China, The Republic of Korea, and Japan.[296] Four years after its creation, the mechanism was used for the first time in the second semester of 2007 between Rwanda and Canada. The African country notified the WTO General Council on July 19, 2007, that it would like to use the mechanism to import 260,000 packages of the antiretroviral drug TriAvir (a pharmaceutical combination of Zidovudine, Lamivudine and Nevirapine).[297] On October 8, 2007, Canada submitted a notification to the Council for TRIPS informing that it exported 15,600,000 generic tablets to Rwanda[298]

It is important to note the WTO General Council Chairperson's Statement on the Implementation of paragraph 6 of the Doha Declaration, according to which good faith directed at protecting public health should instruct the use of the mechanism established in the Doha Decision. The

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295 Hong Kong, Israel, Korea, Kuwait, Macao, Mexico, Qatar, Singapore, Taiwan, Penghu, Kinmen and Matsu, Turkey and the United Arab Emirates. See *WTO*, General Council Meeting adopting Doha Decision, para. 29.

296 See *WTO*, Members' laws implementing Doha Decision.

297 See *WTO,* Notification by Rwanda under paragraph 2(a) of the Decision of 30 August 2003 on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, of July 19, 2007 (IP/N/9/RWA/1).

298 See *WTO*, Notification under paragraph 2(c) of the Decision of 30 August 2003 on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, of October 8, 2007 (IP/N/10/CAN/1).

mechanism should not serve as a tool to pursue industrial or commercial objectives and be used parsimoniously in circumstances of national emergency or extreme urgency.[299]

Only after the Doha Ministerial Declaration of 2001 and the Decision of 2003 – in which all Member States agreed that each country is entitled to make use of the flexibilities within TRIPS to combat public health problems – developing countries started to mold their patent systems allowing themselves to implement TRIPS flexibilities. However, due consideration must be given to the fact that problems related to the lack of access to medicines are not to be blamed exclusively on patent rights. These problems are essentially caused by poverty, and entering the WTO system serves as a tool to foster economic growth and, therefore, raise living standards of a country's population. The fact that the mechanism established in the Doha Decision has not been widely put into practice, except possibly in the unique case of Rwanda mentioned above, corroborates the fact that access to medicines is not only a matter of drug prices imposed by the pharmaceutical industry owning patents. The generic drug industry is also profit oriented and cannot simply give away its products for free, or for a minimum price without profit, to poor populations. The mechanism will probably only work in cases where there is a not-for-profit foundation or government sponsoring the manufacturing of a drug under a compulsory license. It does not solve the inherent social and economic problems of least developed and developing countries.

C. Remarks on the Applicability of TRIPS in Brazil

International agreements and treaties[300] must be approved by the Brazilian Congress and ratified by the President, as per Articles 49, I and 84, VIII of the Brazilian Federal Constitution of 1988, and are incorporated into the country's legal system through Presidential Decree.[301] The Brazilian Pres-

299 See *WTO*, General Council Meeting adopting Doha Decision, para. 29.

300 For the purposes of this work, no distinction is made between the international agreements, treaties or acts, being the terms treated as synonims.

301 This is a long established practice in the Brazilian law becoming a customary rule and has no specific provision foreseeing it in the Federal Constitution of 1988 or in the previous ones. Brazilian scholars and the Supreme Court agree that the presidential decree of promulgation is a requirement for an international treaty to be incorporated into the domestic legislation. For more see *Mello*, Public Interna-

ident is empowered to sign international treaties, conventions and acts through a referendum of Congress. Accordingly, for Brazil to be bound by international agreements that are negotiated by the President, ratification is necessary and may only occur after Congress has voted favorably and issued a legislative decree of approval. This procedure laid out in the Brazilian Constitution is the only way for international treaties to come into effect in the country and there is no way to fast track this process.

After accepting the Final Act of the Uruguay Round, the Brazilian President sent Presidential Message 498/1994 to Congress in order to seek approval of the Marrakesh Agreement that established the WTO.[302] Approving the bill for a legislative decree containing the Marrakesh Agreement and its annexes was then subject to discussions in Congress. On December 15, 1994, DLG 30/1994 was issued approving Brazilian accession to the WTO system and consenting to the Presidential ratification of the Marrakesh Agreement. On December 21, 1994, ratification of the Marrakesh Agreement was put into the Brazilian public record.[303] The Marrakesh agreement and its annexes were, then, incorporated into the Brazilian legislation upon enactment of Presidential Decree 1355/1994, on January 1, 1995.

According to Supreme Court case law dating back to 1971, upon enactment of a Presidential Decree, international agreements are immediately applicable and deemed law of the land.[304] After TRIPS was enacted in Brazil by means of Decree 1355/1994, it was recognized by the Superior Court of Justice as incorporated into the Brazilian legal system as of January 1, 1995.[305] As law of the land and directly applicable, TRIPS should have immediately revoked Law 5772/1971, the previous statute regarding

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tional Law Course, p. 180-187; *Rezek*, Public International Law, p. 69; *Rodas*, The Publicity of International Treaties, p. 200-201; and the Supreme Court decisions on HC 2.280, RE 71.154 and Rogatory Letter 8.279.

302 Presidential Message to the National Congress n. 498, of July 1, 1994.

303 See *WTO*, Status of Legal Instruments, p. 8.

304 See *Supreme Court*, RE 71.154 and RE 80.004.

305 As per article 102 of the Federal Constitution of 1988, the Supreme Court shall have jurisdiction over cases in which a violation of the Constitution may exist. Article 104 of the Federal Constitution created a second high court, the Superior Court of Justice, primarily competent for hearing cases where there may be a violation of the federal legislation (article 105 of the Federal Constitution).

patents, and should have become the applicable law until Law 9279/1996 entered into force.[306]

Despite existing precedents, the Superior Court of Justice in REsp 960.728 (known as the DuPont case) rendered an important decision on March 17, 2009. It established that TRIPS is not applicable to private parties and would only obligate States; therefore, companies and private individuals could not invoke the Agreement in order to protect their own rights. TRIPS was no longer considered the law of the land and directly applicable.[307] The decision was based on a distinction that was made regarding the nature of international treaties, according to which there is a difference between international treaties, whose provisions regulate private relationships and may be directly applicable, and other agreements with provisions which serve as parameters for statutes to be enacted by States. These national statues would in turn regulate private relationships.[308] TRIPS fell in the category of the former as its provisions are directed to legislatures in Member States and not private parties.[309]

The DuPont case also addressed the date on which TRIPS became effective in Brazil.[310] TRIPS would not be applicable in the country beginning on January 1, 1996 – one year after the Marrakesh Agreement entered into force and the date on which TRIPS became generally applicable.[311] DuPont claimed that Article 33 of TRIPS would allow for an extension of patent term from fifteen to twenty years even prior to the enactment of Law 9279/96 (which foresees a twenty-year patent term in compliance with TRIPS)[312] The court understood that at the time Congress approved TRIPS, Brazil's unique waiver concerning delayed applicability of the Agreement under Article 65 was related to the possibility of postponing the patentability of inventions in certain technological areas (i.e., areas that were excluded as patentable subject matter under the old statute, such

306 See *Superior Court of Justice*, REsp 423.240, REsp 661.536 and REsp 667.025, following the long established understanding of the Supreme Court in RE 71.154 and RE 80.004.
307 See *Superior Court of Justice*, REsp 960.728, p. 1-2.
308 See *Barbosa*, Intellectual property: TRIPS Agreement application, p. 18; *Basso*, TRIPS application date in Brazil, p. 13-22; *Sichel*, TRIPS, p. 311-322.
309 See *Superior Court of Justice*, REsp 960.728, p. 6-9.
310 See *Superior Court of Justice*, REsp 960.728, p. 3.
311 Article 65.1 of TRIPS.
312 The previous statute, Law 5772/1971, established a patent term of fifteen years.

as chemical and pharmaceutical products) for five years.[313] When Congress approved the international agreement, it rejected the option of an additional five-year term established by Article 65.4 of TRIPS and did not make reference to its use in order to delay the application of the Agreement.[314] According to the court, Article 65.4 of TRIPS is a faculty given to Member States that should decide to use it or not.[315] On the other hand, the term established in Article 65.2 of TRIPS is a right, and as such, was taken for granted by Member States and not subject to expressed discussion regarding its use, resulting in an additional four-year term for TRIPS to be applied in Brazil and other developing countries.[316]

Despite the controversy raised by this decision, it still recognizes that Brazil did not make use of the right to postpone the applicability of TRIPS provisions until January 1, 2000.[317] The enactment of Law 9279/1996 meant the right set forth in Article 65.2 of TRIPS had been renounced.[318]

It is important to consider that the Superior Court of Justice decision in the DuPont case was influenced by the argument that there was a lack of direct applicability of the treaty in countries of the European Union.[319] This position ignores the decision by the European Court of Justice in case C-431/05 and its effects on Portuguese and Spanish jurisdictions, where their respective national courts may directly apply international treaties.[320]

The Brazilian Superior Court of Justice issued other decisions according to what was established in the DuPont case.[321] Nevertheless, the Supreme Court still has to rule on the later understanding by the Superior Court of Justice regarding the indirect applicability of TRIPS and the date the Agreement entered into force in Brazil. It is up to the Supreme Court

313 See *Superior Court of Justice*, REsp 960.728, p. 9-19.
314 *Id.*
315 *Id.*
316 *Id.*
317 See *Superior Court of Justice*, REsp 960.728, p. 17.
318 *Id.*
319 This influence may be inferred in the text of the decision. See *Superior Court of Justice*, REsp 960.728, p. 9, quoting *Barbosa*, Intellectual property: TRIPS Agreement application, p. 85.
320 *European Court of Justice*, Merck Genéricos – Produtos Farmacêuticos Ltda v. Merck & Co. Inc. and Merck Sharp & Dohme Ltda, Case C 431/05, judgment of Sep 11, 2007, para. 47-48.
321 See *Superior Court of Justice*, REsp 806.147, REsp 642.213 and AgRg no REsp 1.105.155.

to give the final word on whether TRIPS will be given differentiated treatment and, unlike other international agreements, not be considered the law of the land. The appeal against REsp 960.728 filed before the Supreme Court has been withdrawn and, thus, decision on this matter by the country's highest court has been delayed.[322]

322 See status of case RE 626.368 before the Brazilian Supreme Court at <http://www.stf.jus.br/portal/processo/verProcessoAndamento.asp> (Last visited May 9, 2012).