III. CHAPTER. THE BRAZILIAN PATENT SYSTEM

A. Overview

1. The Constitutional Clause

Article 5, XXIX of the Brazilian Federal Constitution of 1988 safeguards the protection of inventions. This provision sets forth that the law shall ensure temporary privileges for the use of industrial inventions by their authors, as well as the protection of industrial creations, keeping in mind the interests of society and national technological and economic development. The constitutional clause also provides for the mandatory protection of property rights related to trademarks, company names and other distinctive signs. The clause instructs the infra-constitutional legislature to enact a statute regulating the granting and enforcement of industrial property rights.[323]

The industrial property clause is established as a fundamental right in Article 5, reflecting the commitment of the constitutional legislature to guarantee rights of inventors.[324] Because of their aspects in relationship to patrimony, intellectual property rights could be considered separate from the Bill of Rights, where individual rights are established in the Constitution, and placed among the provisions regarding economic order.[325] However, it is important to note that property rights for tangible goods are also deemed a fundamental right in Article 5, XXII of the Federal Constitution and there is no justification for intangible property to be excluded from similar protection.

---

323 In the Brazilian Law, the Federal Constitution enjoys supremacy in the hierarchy of laws. Laws and statutes enacted by Congress would follow in the hierarchical scale, together with the Provisional Measures enacted by the President (according to Article 62 of the Federal Constitution). Presidential Decrees regulating the law enacted by Congress would come after. Ordinances and Resolutions from the governmental institutions would be at last. All the legislation, which in the hierarchical scale is subordinated to the Federal Constitution, is referred as infra-constitutional legislation.

324 See *Oswald, Leonardos*, Patent Law: Constitutional Aspects, p. 8.

325 See *Silva*, Constitutional Law, p. 276-277.

https://doi.org/10.5771/9783845259628-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

The clause has been interpreted as finalistic and, accordingly, the infra-constitutional legislature should enact laws that take social, technological and economic interests into account. Industrial property law cannot aim (or have as a material effect) only to serve external government policies to the detriment of the interests of society and technological development of the country.[326] These are conditions that are inherent to the existence of industrial property rights, otherwise the law would be rendered unconstitutional.

Under a different interpretation, this clause has been regarded as the foundation for the patent system, reflecting a compromise between inventors and society. On the one hand, inventors obtain property rights and, on the other hand, society benefits from the contents of the patent either directly (having access to the new product) or indirectly (enjoying new economic activities related to the new product in the market). Also, the governments – representing the States – profit from economic activity that fosters technological development through the transfer of technology.[327] The conditions for granting of patents would be regulated in infra-constitutional legislation, which then guide public administration's activities.

Because the exercise of property rights is not unlimited, the Brazilian Federal Constitution establishes in Article 5, XXIII that property will conform to its social function. In the case of patent rights, any abuse would be inhibited or remedied by measures also foreseen in law such as granting compulsory licenses, which will be discussed later in this text.

In this context, it is also necessary to mention Article 170 of the Constitution dealing with economic order, which is founded on valuing individual work and free initiative. The regulation of Brazil's economic order should respect private property, the social function of property and freedom of competition, as foreseen in Article 170, II, III and IV respectively. However, Article 173 paragraph 4 of the Constitution establishes that the law will reprehend abuse of economic power aiming to domination of markets, elimination of competition and abusive profit increases.

Therefore, patent rights should always be analyzed in light of their objective of advancing society, technological and economic development, and the principles of free initiative and competition. The Constitution provides exclusivity rights for inventors as long as this privilege serves social

326 See *Barbosa*, Unconstitutionality of the Pipeline Patents, p 13-14.
327 See *Oswald, Leonardos*, Patent Law: Constitutional Aspects, p. 11.

https://doi.org/10.5771/9783845259828-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

interests and fosters economic and technological development. Since patent rights enable the exclusion of third parties, which affects free initiative and competition, they should not be absolute in order to prevent abuses.[328] Through a systematic analysis of Articles 5, XXIX, 170 and 173 of the Brazilian Constitution, it is possible to conclude that whenever the Constitution authorizes law to provide for patents to be granted, there will be a balance between the principles of free private initiative and free competition. Additionally, case of abuse should be combated through competition laws. [329]

Patents constitute monopoly rights by the exclusion of third parties to exploit an invention. In light of this alone, patent rights would run counter to freedom of competition. In a balancing exercise, the constitutional assembly concluded that the monopoly rights of patents are in fact beneficial to society. It is also important to consider that patent rights do not totally exclude competition. Patents foster competing activities among innovative companies who invest in the development of new types of technology that surpass existing knowledge and replace old technologies.

2. General Provisions on Patentability

Brazilian Law 9279/1996 establishes the main set of provisions regulating the constitutional rights of inventors, providing for industrial property rights and seeking to implement TRIPS obligations into Brazilian legislation. The basic requirements for patentability – novelty, inventive step and industrial application – are foreseen in Article 8 of Law 9279/1996 pursuant to Article 27.1 first sentence of TRIPS. The Brazilian statute defines that an invention will be deemed new when not included in the state of the art as per Article 11 of Law 9279/96. Everything made accessible to the public before the application filing or priority dates will be considered part of the state of the art.[330] The contents of pending applications before the INPI, but not yet published, should also be taken into consideration provided that such applications are subsequently published.[331] There is also a

328 See *Ferraz Jr.*, Industrial Property and Competition Law, p. 11.
329 See *Rosenberg*, Patents on Medicines and International Trade, p. 131-132; *Salomão Filho*, Antitrust Law, p. 132.
330 Article 11, paragraph 1, of the patent statute.
331 Article 11, paragraph 2, of the patent statute.

https://doi.org/10.5771/9783845259828-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

twelve-month grace period foreseen in Article 12 of Law 9279/96, which establishes that the disclosure of an invention within twelve months preceding the filing or priority dates will not consist in bar of novelty, as long as disclosure is carried out either by the inventor, by the INPI in an official publication without the inventor's consent, or by third parties on the basis of information obtained from the inventor.

The inventive step requirement as legally defined states that an invention will be regarded as such when not deriving from the state of the art in an evident or obvious way for a person skilled in such art, as per Article 13 of Law 9279/96. Inventive step, thus, depends on the knowledge of the person skilled in an art, which will serve as a parameter for the examination of inventive step. The person skilled in an art must possess general education in the field of technology and should dominate the general principles of analogous industries – that is to say the person is not a beginner.[332] The criteria for determining the level of knowledge and skills required should also vary according to the technology assessed. In some areas of highly advanced studies such as biotechnology, the person skilled in the art should have a high level of knowledge and education that generally includes doctoral titles.

Inventive step is a requirement that was introduced expressly in Brazilian law only through the enactment of Law 9279/1996. However, this concept has always underlined the basic notion of an invention in Brazil.[333] Novelty and inventive step combined are part of the foundation of the patent system, as the State affords exclusivity to inventors in exchange for the disclosure of their inventions. In case the invention is not new, already exists in the state of the art, or derives obviously from therein, such exclusivity would consist in an unfair monopoly.[334]

Article 15 of Law 9279/1996 broadly defines the industrial application requirement as being fulfilled when an invention can be made or used in any kind of industry. Industry comprises any branch of production activity and includes agricultural and extractive industries, as already established in Article 1(3) of the Paris Convention.[335] Article 1(3) seeks to avoid bar-

332 See *Wolff*, Written Description, p. 25-26.
333 See *Miranda*, Treatise of Private Law, p. 274.
334 See *Cerqueira*, Industrial Property Treatise, p. 305-306.
335 "Article 1(3). Industrial property shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to agricultural and extractive industries and to all manufactured or natural products, for exam-

https://doi.org/10.5771/9783845259628-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

ring patentability of activities and products, e.g. those related to agriculture, which would otherwise be at risk of not being assimilated by the industry itself, instead of obligating countries to grant patents on products such as wines, animals or fruits.[336]

Relating to more formal aspects of requirements for patentability, disclosure and written description should also be fulfilled before a patent is granted. As stated in Article 24 of Law 9279/1996, applicants are required to describe the invention clearly and sufficiently, so as to enable a person skilled in the art to carry it out and to indicate, when applicable, the best mode of execution. For the purposes of fulfilling disclosure and written description requirements of inventions involving biological material, sole paragraph of Article 24 allows for the deposit of such biological material in an institution authorized by the INPI as a means to supplement the specification.[337] In addition, Article 25 establishes that patent claims must be based on the specification, characterizing the particularities of the application and defining clearly and precisely the subject matter to be protected. The limitations of the claimed invention must be clearly set. The same figure of a person skilled in the art as foreseen in the inventive step requirement is present for examining disclosure and written description. These requirements seek to conform legislation to Article 29.1 of TRIPS.[338] That is to say, it is based on the foundation of patent system as a negotiated relationship between the State and inventors, ensuring that an invention can actually be carried out by someone skilled in the art as described in the

---

ple, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers, and flour".

336 See *Bodenhausen*, Guide for the Paris Convention, p. 26.

337 Although Brazil is not a member of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, the INPI has been recognizing the deposit with one of the international depositary authorities accredited by this international treaty for the purposes of article 24, sole paragraph, of Law 9279/1996 (see Normative Act 127/97, item 16.1.1.2). The INPI has issued Resolution 82, of November 22, 2001, which defines the requirements for accrediting a Brazilian institution as a depository authority. As of April 3, 2006, the creation of a national depository authority in the city of Xerém in the State of Rio de Janeiro in cooperation with the Instituto Nacional de Metrologia, Normalização e Qualidade Industrial (INMETRO) has been announced by the INPI, but until the present date it has not started its operations. See *Brendler*, Storage center of biological material is likely to be created in Rio until October, para. 1-4.

338 See *Dannemann*, Commentaries on the Industrial Property Law, p. 55.

https://doi.org/10.5771/9783845259828-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

specification. Written description and disclosure are complemented by Article 25, which was clearly inspired by Article 84 of the EPC, so as to ensure that exclusivity deriving from a patent does not extend beyond the actual contribution of the invention to the state of the art as described in the specification.[339]

Although patents may be granted for inventions that meet the novelty, inventive step, industrial application and disclosure requirements, set forth in Articles 8, 24 and 25 of Law 9279/1996, they should not be subject to the statutory bars established in Articles 10 and 18 of Law 9279/1996.

Article 10 of Law 9279/1996 defines ineligible subject matter for its inability to meet patentability requirements. The following are not considered inventions: a) discoveries, scientific theories and mathematical methods; b) purely abstract concepts; c) schemes, plans, principles or methods of a commercial, accounting, financial, educational, publishing, lottery or fiscal nature; d) literary, architectural, artistic and scientific works or any aesthetic creation; e) computer programs per se; f) the presentation of information; g) rules of games; h) operating or surgical techniques and therapeutic or diagnostic methods, for use on the human or animal body; and i) natural living beings, in whole or in part, and biological material, including the genome or germplasm of any natural living being, when found in nature or isolated therefrom, as well as natural biological processes.

Article 18 of Law 9279/1996, in turn, lists the following subject matter as expressly excluded, despite fulfilling patentability requirements: a) which is contrary to morals, good customs and public security, order and health; b) substances, matter, mixtures, elements or products of any kind, as well as the modification of their physical-chemical properties and the respective processes of obtaining or modifying them, when they result from the transformation of the atomic nucleus; and c) living beings, in whole or in part, except transgenic microorganisms meeting the three patentability requirements – novelty, inventive activity and industrial application – in Article 8 of Law 9279/1996 and which are not mere discoveries. In the sole paragraph of Article 18, transgenic microorganisms are defined as organisms, except the whole or part of plants or animals, which exhibit, due to direct human intervention in their genetic composition, a characteristic that cannot normally be attained by the species under natural conditions.

---

339 *Id.*, p. 56-57.

https://doi.org/10.5771/9783845259828-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

At first glance, one would say that the exclusions from patentable subject matter established in the Brazilian statute would conform to Article 27.2 and 27.3 of TRIPS (as articles 10 and 18 of Law 9279/1996 seem to have been modeled after Articles 52 and 53 of the EPC 1973).[340] Nevertheless, TRIPS mandates Member States to provide for patentability of microorganisms in general, whereas Article 18 of Law 9279/1996 establishes that only transgenic microorganisms may be afforded patent protection.

The current industrial property law in Brazil, unlike the previous statute (Law 5772/1971), does not prohibit patents for products in the chemical and pharmaceutical fields. However, Article 10, VIII of Law 9279/1996 does not recognize operating or surgical techniques and therapeutic or diagnostic methods for use on the human or animal body to be inventions. These general provisions on patentability requirements must be kept in mind when analyzing issues that specifically concern patents on pharmaceutical inventions under Brazilian law.

3. Term of Protection and Rights Conferred by Patents

In order to be in harmony with Article 33 of TRIPS, the patent term in Brazil under Article 40 of Law 9279/1996 was extended from fifteen to twenty years as of the filing date. A minimum period of ten years of protection as of the granting of the patent is safeguarded by sole paragraph of Article 40 of Law 9279/1996, in light of the extensive backlog at the INPI.

As discussed in the previous chapter, TRIPS was enacted in Brazil by means of Decree 1355/1994 and patent owners have sought term extensions from courts for their patents, alleging that patents granted after January 1, 1995 (the date in which Decree 1355/1994 entered in force in Brazil) should be subject to Article 33 of the treaty and be granted for twenty, rather than fifteen, years.[341] Arguments were based on long-established case law from the Brazilian Supreme Court that says international agreements could be applied directly as laws and statutes passed by Congress that establish rights and obligations for citizens and residents in

340 New plant varieties are protected in Brazilian law by means of rights granted to plant breeders and is regulated by Law 9456/1997.

341 The previous statute, Law 5772/1971, established a patent term of fifteen years.

https://doi.org/10.5771/9783845259828-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

the country.[342] The fact that Brazil had not made use of the transitional provisions in Article 65 of TRIPS also contributed to arguments on the immediate applicability of the Agreement. Initially, the Superior Court of Justice granted the requests for term extensions, accepting the arguments raised by the patent holders.[343] However, in 2009, the court reversed its previous ruling and decided that private parties may not invoke TRIPS in defense of their rights, since the treaty establishes obligations only towards States.[344] The court also determined that TRIPS would only be applicable in Brazil as of January 1, 2000, pursuant to Article 65.2 and, consequently, Article 33 would not apply.[345] Only when Law 9279/1996 entered in force entitlement to a twenty-year patent term began to apply.[346] The Superior Court of Justice rendered other decisions following this interpretation, which continues to prevail,[347] yet until today the Supreme Court has not been compelled to decide on the direct applicability of TRIPS.[348]

The extension of protected subject matter is defined by the claims, which will be interpreted by taking into consideration the specification and drawings as per Article 41 of Law 9279/1996. This provision should be combined with Article 25 of Law 9279/1996, which determines that claims must be based on the specification characterizing the particularities of the application and clearly and precisely defining the subject matter to be protected. The content of claims is the basis for an infringement analysis or for the validity of the patent in light of the prior art. Specification

342 See *Supreme Court*, RE 71.154, judgment of August 4, 1971 and RE 80.004, judgment of June 1, 1977.
343 See *Superior Court of Justice*, REsp 423.240, REsp 661.536 and REsp 667.025.
344 See *Superior Court of Justice*, REsp 960.728, p. 6-9.
345 See *Superior Court of Justice*, REsp 960.728, p. 9-19.
346 See *Superior Court of Justice*, REsp 960.728, p. 17.
347 See *Superior Court of Justice*, REsp 806.147, REsp 642.213 and AgRg no REsp 1.105.155.
348 Brazil is a country following civil law tradition, where decisions issued by courts are non-binding even if rendered by higher courts, the Supreme Court included. So, trial and appellate courts may decide differently and are not bound by any obligation to follow any previous established understanding, although the latter may have strong influence. Exceptions to this rule are generally reiterated cases in which the highest courts issue a common and general applicable judgment and appeals will have certiorari denied based on such judgment. See Brazilian Federal Constitution, article 103-A.

https://doi.org/10.5771/9783845259828-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

and drawings are the primary parameters for the correct interpretation of claims.[349]

Article 42 of Law 9279/1996 specifies that the patent holder has the right to prevent unauthorized third parties from manufacturing, using, offering for sale, selling or importing for such purposes a product or a process that is the subject matter of a patent, or a product directly obtained by a patented process in conformity with Article 28.1 of TRIPS. Unlike the old statute, which granted the right of exclusive use of the patented subject matter to a patentee,[350] the current law provides for the right to exclude others even if they have independently developed the invention (with due exception for the prior user provided in Article 45 of Law 9279/1996 that will be discussed later on). Paragraph 1 of Article 42 further determines that the patentee is also entitled to inhibit acts carried out by third parties that contribute to the practice of infringing acts by other parties, thus prohibiting indirect infringement. Paragraph 2 determines that the burden of proof is reversed in the case of infringement of a patented process. It will be up to the alleged violator to prove that the product was not manufactured according to the patented process. It is important to note that unlike Article 34.1(a) of TRIPS, the Brazilian statute does not require that the product obtained by the patented process be new in order to reverse the burden of proof of infringement. The Brazilian provision is based on the presumption that the patentee is unable, through reasonable efforts, to determine the process actually used and the reversal is obtained by means of a specific judicial ruling, which should analyze whether there is a substantial likelihood that the product was manufactured by means of the patented process. Despite the absence of a specific provision in the Brazilian statute safeguarding the legitimate interests of the defendant in protecting their manufacturing and business interests, Article 34.3 of TRIPS and the principles of equity and proportionality are applicable and the defendant should not be obligated to reveal more than necessary to prove that the process used differs from the patented process. Defendants are allowed to exclude some specific details of the process that was used, as long as such omission does not interfere in the defense.[351]

Article 43 of Law 9279/1996 provides for exemptions to patent rights, which should conform to the three-step-test of Article 30 of TRIPS. As ex-

349 See *Dannemann*, Commentaries on the Industrial Property Law, p. 79.
350 See article 5 of Law 5772/1971.
351 See *Dannemann*, Commentaries on the Industrial Property Law, p. 86.

https://doi.org/10.5771/9783845259828-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

ceptions to any right, they should be narrowly interpreted, especially taking into consideration that patent rights are constitutionally safeguarded; however, on behalf of the promotion of public interest and stimulation of technical and social progress, also contained in the constitutional clause, infringement defenses may be interpreted in a more permissive manner influenced by an anti-patent environment that may still prevail in Brazil. As per Law 9279/1996, the rights of patent holders will not be violated by the following: a) acts carried out privately and without commercial ends, provided they do not harm the economic interests of patent holders (Article 43, I); b) acts carried out for experimental purposes, related to studies or to scientific or technological research (Article 43, II); c) compounding drugs and their preparation following a medical prescription for an individual patient (Article 43, III); d) products manufactured according to a patented process or patented product that have been placed in the internal market directly by the patentee or with consent, leading to exhaustion (Article 43, IV); e) in the case of patents concerning living matter, the use of the patented product as the initial source of variation or propagation for obtaining other products (Article 43, V); f) to use, place in circulation or commercialize a patented product that has been legally introduced into the market by the patentee or licensee, provided that the patented product is not used for commercial multiplication or propagation of the living matter at stake (Article 43, VI); and g) acts carried out exclusively with the purposes of producing information, data and test results seeking marketing approval in Brazil or abroad so as to commercialize or exploit the patented product after the patent term has expired (Article 43, VII).

Article 43, I of Law 9279/1996 should protect acts from infringement that are carried out by unauthorized third parties solely with private non-commercial purposes and with no harm to the economic interests of the patentee. This classically refers to acts carried out directly by consumers when using goods – falling within the scope of patent protection – in a private manner as long as they do not result in harming the patent owner.[352] This protection does not apply to resale by consumers. In this case, there is

352 Although such exception was not expressly foreseen in the previous statute, Brazilian courts have already found that consumers of counterfeited goods do not infringe any patent right when using the products according to their own end. See Habeas Corpus 44.580, Impetrante: Bel. Lanir Orlando, Pacientes: Gabriel Dias Baeta e outros, publ. RT, 459/349-50, jan 1974. In: *Dannemann*, Commentaries on the Industrial Property Law, p. 87, footnote 150.

https://doi.org/10.5771/9783845259828-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

a commercial purpose, even if no large commercial scale actually occurs, and the exhaustion principle does not apply since the product was not marketed by the patentee or with consent – that is to say the product it is counterfeited.[353]

The second exception foreseen in Article 43 of Law 9279/1996 provides for what is generally referred to as the "experimental use exception." The German interpretation of this exception as the scope of the experimental acts has not been addressed by the Brazilian legislature or by courts. The provision should exempt experimental acts from infringement that are performed by researchers on the subject of the invention in order to produce scientific knowledge or investigate the patented subject matter, which could result in finding additional uses or further data on the product or process.[354] Also, this defense against infringement should not encompass the use of a patented invention in experiments relating to a different subject matter, that does not expand the knowledge concerning the invention itself, under the penalty of rendering patents covering research tools unenforceable.[355] This provision only applies to acts of non-commercial and non-profit purposes, which is based on the argument that there would be unreasonable damage to the patent holder's rights if third parties could obtain commercial advantages through the use of the patent, even if such use has an experimental character.[356] A trial court decision endorsed this position, establishing that this exemption is applicable solely for cases in which there is no commercial interest. The court stated the actions carried out by a foundation or a not-for-profit organization could be exempted, whereas a company would have essentially commercial interests and, therefore, its activity would fall outside the scope of the provision.[357] Nevertheless, it is important to consider that the wording of the provision does not contain the restriction for "non-commercial purposes," which may jeopardize research activities in specific fields of technology, in which R&D activities are sponsored by the interest of large private companies, and such interpretation may also reduce the applicability of Article 43, I of

353 See *Dannemann*, Commentaries on the Industrial Property Law, p. 88.
354 See Clinical Trials I and II, German Federal Supreme Court cases.
355 See Clinical Trials I (IIC 1997, 103), German Federal Supreme Court case.
356 See *Philipp*, Patent of invention, p. 71-74; *Dannemann*, Commentaries on the Industrial Property Law, p. 88-92.
357 See *Abbott v. Aurobindo et al*., Trial Court Judgement, para. 3. Abbott v. Aurobindo et al., 13rd State Court of Sao Paulo, Case n. 00.5.020816-0, p. 1.

https://doi.org/10.5771/9783845259828-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

Law 9279/1996 where express reference to "non-commercial ends" may be found.

Article 43, III of Law 9279/1996 applies to activities carried out by compounding pharmacies, addressing compounded medications and their preparation by qualified professionals. This defense against infringement applies to the use of a patented process or product whenever there is a medical prescription for individual cases. Accordingly, there is no exemption for infringement if medicine is prepared in large scale even if commercialization is subject to prescription. It is the act of preparing the compounding drug – and not the act of commercializing the compounding drug – that is conditioned to prescription in order to be exempted from infringement and thus stockpiling is prohibited.[358]

Pursuant to Article 43, IV of Law 9279/1996, exhaustion of patent rights is found whenever a product, either patented or obtained through a patented process, is placed in the Brazilian internal market by the patent holder or with consent. Because the wording of this provision specifically mentions placement of the product in the *national* market, it is possible to conclude that Brazil applies the national exhaustion rule. Parallel importation of a patented product purchased in a foreign market is not allowed, even through the patentee or with consent abroad. However, the Appellate Court of the State of São Paulo rendered a decision affirming that the placement of a product in the market leads to exhaustion of patent rights, and the patentee or its licensee cannot prevent importation.[359] The court understood that the patentee receives compensation with the first placement of the product in the market, even when abroad, and patent rights are consequently exhausted.[360] The decision cites a trademark case in the Superior Court of Justice[361] to ground this ruling, which appears to be in clear conflict with the wording of the law. Article 43, IV refers to products placed in the internal market "directly by the patentee or *with his consent*," implying that the party authorized to market the patented product under a

358 See *Dannemann*, Commentaries on the Industrial Property Law, p. 92-93.

359 See *Galena v Pharmaspecial*, Appeallate Court Judgement, p. 7.

360 *Id*., p. 6.

361 See Superior Court of Justice, REsp 609.047, *American Home Products Corp. v LDZ.* In this case, the Superior Court of Justice affirmed that parallel importation is allowed whenever the product was placed in the foreign market by the patentee or with consent and the trademark rights are exhausted.

https://doi.org/10.5771/9783845259828-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

compulsory license would not have the consent of the patentee and the related patent rights would not be exhausted.

Article 43, V of Law 9279/1996 establishes that the owner of a patent on living matter may not prevent use by third parties for non-economic purposes, when the patented product constitutes the initial source of variation or propagation for obtaining other products. The provision addresses a hypothesis in which a third party acquires samples of the living matter from the authorized depositary where the patentee had deposited it in order to fulfill the written description requirements.[362] In such a case, the use of living matter should have no economic purpose and should be related to scientific research to develop new products deriving from such living matter. Nevertheless, the earlier discussion on interpreting "non-commercial" purposes continues to apply for cases involving private companies.

Whenever a patented product related to living matter has been lawfully introduced into the market by the patentee or licensees,[363] third parties may circulate or commercialize the patented product as per Article 43, VI of Law 9279/1996. This is the case as long as it is not used for commercial multiplication or propagation of such living matter. Accordingly, if a third party acquires a patented microorganism from the patentee, it may resell the acquired samples themselves (such as any other case where exhaustion applies) or multiply them for generating derived products which will then be commercialized because there is no multiplication of the microorganism for marketing of the multiplied samples.[364] The provision prohibits *commercial* multiplication, relating to the act of marketing, which should be interpreted in a stricter manner than multiplication for "economic use," which, in turn, comprises any activity resulting in an economic advantage for those using the patented microorganism.[365]

---

362 If a third party produced himself the patented living matter, there may be patent infringement in light of article 42 of Law 9279/1996. Acquisition of samples put into the market by the patentee or licensee is covered by item VI of article 43 of Law 9279/1996. See *Dannemann*, Commentaries on the Industrial Property Law, p. 97-98.

363 Different than article 43, IV of Law 9279/1996, this provision employs specifically the term "licensee" (rather than the expression "with consent" of the patentee), implying that even in cases of compulsory license, the rights would be exhausted. See *Dannemann*, Commentaries on the Industrial Property Law, p. 100.

364 See *Dannemann*, Commentaries on the Industrial Property Law, p. 99.

365 *Id.*

https://doi.org/10.5771/9783845259828-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

Article 43, VII of Law 9279/1996 establishes that acts relating to the patented invention performed by unauthorized third parties do not constitute infringement when they are carried out exclusively to produce information, data and test results used to seek marketing approval domestically or abroad, in order to exploit or commercialize patented subject matter after the patent term has expired. This provision was added to Law 9279/1996 through an amendment by Provisional Measure 2.014-7, of June 26, 2000, and was approved by Congress as Amending Law 10196, of February 14, 2001. The amendment provides for regulatory review exception, which allows research activities whose results are submitted with the purposes of obtaining marketing approval of a product that is covered by a patent, such as a generic version, prior to the patent expiration, provided that the product is marketed only after the protection term ends. A trial court decision determined that regulatory trials for obtaining a marketing approval of generic products are allowed. However, the act of submitting the data package to regulatory authorities seeking the registration and the act of granting registration by authorities, which would consequently authorize marketing of the generic product, is not covered by the provision.[366] The trial court emphasized that regulatory authorities may grant registration only upon expiration of a patent[367] because once registration is granted all the conditions enabling marketing of the product have been fulfilled.[368]

Article 44 of Law 9279/1996 authorizes patent holders to receive compensation for unauthorized use of patented subject matter during the period between the publication and the granting of an application. This provision aims to protect patent holders, to a certain extent, against unfair use of their invention by competitors taking advantage of delays in the patent granting procedure. In exchange for publishing an application prior to the granting of a patent, the patent holders are given this benefit. In the patent granting procedure, inventors disclose the invention as the application is

366 See *Nippon Soda Co. Ltda. v União Federal and Agripec Química Farmacêutica S/A,* Trial Court Judgement p. 4-5. The appeal filed against this decision is pending before the Federal Court of Appeals for the 1st Circuit. See *Nippon Soda Co. Ltda. v União Federal and Agripec Química Farmacêutica S/A,* Appeallate Court Proceeding, p. 1.

367 *Id.*, p 4.

368 *Id.*, p. 5. See also *Dannemann*, Commentaries on the Industrial Property Law, p. 106.

https://doi.org/10.5771/9783845259828-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

published even before having the guarantee of a patent. Early publication allows society and competitors to have access to the invention and be aware of the latest developments in technology and the eventual proprietary rights that are to be granted. In order to balance this relationship, the provision provides the right of compensation to the patentee. Brazilian courts have already clarified that infringement may only occur upon the granting of a patent by the INPI. Prior to granting, applicants have a mere expectation and may not prevent exploitation of the invention; however, they are entitled to damages for the undue exploitation carried out between the date of publication and granting.[369] Paragraph 1 of Article 44 determines that the period of undue exploitation for the effect of compensation should start on the date in which the exploitation began, when the infringing party had access to the invention prior to the application's publication. For cases related to biological material deposited under sole paragraph of Article 24 (fulfillment of disclosure and written description requirements), compensation is possible only if the biological material has been made available to the public (see paragraph 2 of Article 44 of Law 9279/1996). Paragraph 3 of Article 44 states that the right of compensation should follow the same logic of infringement analysis and should depend on the content of the claims to determine the extent of protection pursuant to Article 41 of Law 9279/1996.

Prior user rights are also guaranteed in Article 45 of Law 9279/1996, enabling a person who exploited the patented subject matter in good faith prior to the filing or priority date to continue such use under the previous conditions without payment of royalties or further burden. Continuation of such exploitation is allowed as long as the previous conditions of use remain the same. The prior user is not allowed to increase the volume of manufactured products, for instance, or start selling goods which were initially manufactured only for personal needs.[370] Prior user rights may be transferred, but only together with the business or undertaking, or the part of the latter, directly related with the exploitation of the respective patented invention (paragraph 1 of Article 45 of Law 9279/1996). This provisions aims at safeguarding the right for those who have developed the in-

369 See *Emplal v. Mil Past*, Appellate Court Judgement; *Isaías Júnior v. Gobi Refrigeração*, Appellate Court Judgement, p. 1.

370 See *Dannemann*, Commentaries on the Industrial Property Law, p. 110, 114.

https://doi.org/10.5771/9783845259828-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

vention in an independent manner and exploited it, secretly or not,[371] prior to the patent filing, to be able to continue their activities without being considered infringement. However, paragraph 2, establishes that those with access to an invention through disclosure under the conditions foreseen in Article 12 of Law 9279/1996 which provide for a grace period (i.e. disclosure carried out by the inventor, by the INPI in an official publication without the inventor's consent, or by third parties on the basis of information obtained from him) may not enjoy prior user rights as long as a patent application is filed within one year from disclosure. Restrictions imposed by the law entitling prior user rights have compliance with Article 30 of TRIPS precisely in mind. Prior user rights are exceptions to the rights conferred by a patent. They are limited in order not to unreasonably conflict with normal use of patents and not unreasonably prejudice the legitimate interests of patent owners while still taking into account the legitimate interests of third parties.

Law 9279/1996 also establishes that patent infringement is a statutory felony. Article 183 of Law 9279/1996 criminalizes the manufacturing of a patented product or the use of a patented means or process without authorization, under the penalty of three months to one year detention or fine. Article 184 of Law 9279/1996 establishes the same penalty for those who export, sell, exhibit or offer for sale, maintain in stock, hide or receive, use for economic purposes, a product manufactured in violation of a patent or one that is obtained by a patented means or process without due authorization. Article 184 also refers to those who import patented subject matter or products obtained by a patented process, for the above purposes, that has not been placed in the external market directly by or with consent from the patent holder. Since importation of goods marketed in foreign countries by the patentee or licensees is not considered a criminal offense by Article 184, only civil remedies may be taken for parallel importation (which may

371 A public use of the patented subject matter would render the patent invalid, but the prior user may be authorized by an interlocutory decision to continue using the invention based on prior user rights before a final decision on the invalidity. On the other hand, it is unlikely that a secret use will be subject to claims of prior user rights before courts, either because the user feels himself safe from an infringement accusation due to the secret nature of his activities, or because it is hard for a patentee to become aware of secret activities carried out by non-authorized parties. See *Dannemann*, Commentaries on the Industrial Property Law, p. 110.

https://doi.org/10.5771/9783845259628-67 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

be regarded as patent infringement through the interpretation of Article 43, IV of Law 9279/1996 as discussed earlier).[372]

Not only acts of direct infringement are considered a crime under Articles 183 and 184 of Law 9279/1996, but also acts of indirect infringement can be prosecuted. Article 185 of Law 9279/1996 determines that supplying a component of a patented product, material, or equipment for executing a patented process is a crime, provided that the final application of the component, material, or equipment results in an unauthorized use of the patent.

Pursuant to Article 186 of Law 9279/1996, a crime has occurred even when the violation does not relate to all of the claims or if it is restricted to the use of means equivalent to the patented subject matter. The provision sets statutory grounds for the doctrine of equivalence in Brazilian patent law. When Article 41 of Law 9279/1996 establishes that extension of protection will be determined by the contents of the claims, it does not mean that interpretation of claims should be restricted to the literal wording used, but should also encompass any means deemed equivalent to those referred to in the claims. The concept of infringement by equivalence, although not expressly foreseen in national legislation, has underlined the system for a long time as scholars and case law have established that infringement may be found even if the manufactured product is not identical to the patented subject matter or if the employed process is not exactly the same as described in the patent.[373] However, it is important to note that infringement by equivalence usually refers to the invention concept contained in the patent without a careful consideration of the methodology that is used when examining infringement. There is no provision in the law, nor developed case law, such as in the US[374] and Germany,[375] regarding possible criteria to be used in determining equivalence.

---

372 See *Dannemann*, Commentaries on the Industrial Property Law, p. 355.

373 See *Cerqueira*, Industrial Property Treatise, p. 542. *Taurus Blindagens Ltda. v Pier Luigi Nava*, Appellate Court Judgement, p. 1. *Elter Engenharia v. Coelma Construções*, Appellate Court Judgement, p. 1. Supreme Court, AG 19621, p. 1.

374 See *US Supreme Court*, Winam v. Denmead; *US Supreme Court*,Graver Tam & Mfg. v. Linde Air Products.; *Supreme Court*,Warner-Jenkinson Company v. Hilton Davis Chemical.; *US Supreme Court,* Festo Corp., v. Shoketsu Kinzoku Kogyo Kabushiki.

375 See *German Federal Supreme Court*, Molded Curbstone; *German Federal Supreme Court*, Cutting blade I; *German Federal Supreme Court*, Cutting blade II; *German Federal Supreme Court*, Plastic pipe; *German Federal Supreme*

https://doi.org/10.5771/9783845259828-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

B. Patents on Pharmaceuticals

Law 9279/1996 was enacted on May 15, 1996, seeking to incorporate TRIPS obligations into Brazilian legislation and allowing patents for pharmaceutical products and processes. A new player was later introduced into the Brazilian patent granting system in 1999, through an amendment to this Law, namely the Agência Nacional de Vigilância Sanitária (ANVISA), whose role has been intensely debated. The discussion below will analyze the potential impact of ANVISA in light of the framework established by TRIPS.

1. The Prior Consent Requirement

1.1) Introduction of Article 229-C in the Patent Statute and Competence of the ANVISA

The Instituto Nacional da Propriedade Industrial (INPI) was founded in 1970 with the institutional purpose of implementing Brazilian industrial property legislation and is therefore the patent granting authority.[376] In 1999, when the new governmental agency, Agência Nacional de Vigilância Sanitária (ANVISA) started intervening in the patent granting procedure, Brazil's patent system experienced an unusual situation. The ANVISA is primarily the regulatory office competent for granting the marketing approval of drugs.[377] The Brazilian President enacted a provisional measure on December 15, 1999,[378] determining that patent applications in the pharmaceutical area must be submitted to *prior consent* by the ANVISA before being issued.[379] The prior consent requirement was ultimately inserted into Law 9279/1996 as Article 229-C by the amending Law

---

Court, Custodiol I; *German Federal Supreme Court*, Custodiol II. See also *Pagenberg, Cornish*, Interpretation of Patents in Europe, p. 91-95.

376 Article 2 of Law 5648/1970.

377 Article 6 of Law 9782/1999.

378 Article 62 of the Federal Constitution empowers the President to legislate in case of relevance and urgency by enacting Provisional Measures.

379 See Provisional Measure 2006/1999, succeeded by Provisional Measure 2014-1/1999 (and its several re-editions) and, ultimately, Provisional Measure 2105-14/2000.

https://doi.org/10.5771/9783845259828-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

10196 of February 14, 2001.[380] Pursuant to the statute's amendment by this provisional measure, Ordinance 593/2000 was published so as to change the internal regulations of the ANVISA to include, among the agency's competences, in addition to regulating the marketing of drugs, consent (prior consent) on the granting of patents for pharmaceutical products and processes. On May 21, 2001, the Intellectual Property Division was created within the agency, accounting for prior consent analysis, after Ordinance 239/2001 entered into force (which once again changed internal regulations of the ANVISA).

The origin of Article 229-C was a recommendation sent to the President by the Ministries of Health, Foreign Affairs, Industry and Management,[381] yet no records remain of the pursued intention of this communication. Unlike other pieces of legislation, there were not heated debates and discussions held in Congress over the approval of this provisional measure and its purposes. It was supported through a general justification that was related to the need for better technical standards when deciding on granting of pharmaceutical patents and for reflecting procedures existing in the patent and sanitary surveillance systems of other developed countries.[382] The provision was created without parameters concerning its basis and rationale. Legal criteria for prior consent or any regulatory implementation of Article 229-C has not been established, resulting in legal uncertainty regarding the role of the ANVISA.

A legal opinion issued by the Attorney's Office at the INPI first established that the ANVISA should examine the industrial application requirement or regular applications for prior consent purposes.[383] It excluded "pipeline" patent applications from the ANVISA's assessment under Article 229-C of Law 9279/1996, as this type of patent does not undergo examination of the patentability requirements set forth in Article 8 of the statute (novelty, inventive step and industrial application).[384] However, the

380 "Article 229-C. The granting of patents in connection with pharmaceutical products or processes shall be dependent on prior consent from the ANVISA".

381 EM Interministerial 92, of December 14, 1999.

382 It must be observed that the author is not aware of any other country with requisite similar to the prior consent, that conditions the granting of a patent in the pharmaceutical field to the approval of an authority equivalent to the ANVISA.

383 INPI, PROC 003/00.

384 "Pipeline" patents or patents of revalidation consist in a validation in Brazil of a patent issued abroad, ratifying the examination done by the foreign patent office, provided that the product covered by the patent application was not made com-

https://doi.org/10.5771/9783845259828-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

INPI decided that the applications finally would be sent to the ANVISA following the end of examination by the patent office, which concludes for the granting of the patent.[385] This procedure has been applied to all patent applications, regular or "pipeline" since 2001, without establishing any definition or legal criteria for "prior consent."[386]

As a result of these changes, the ANVISA began to fully re-examine the patent applications pursuant to its own understanding of what prior consent should include. The patentability requirements such as novelty, inventive step and industrial applications, which were already analyzed by the INPI, are assessed for a second time by the ANVISA.[387] Also the agency provides an analysis of public health aspects, i.e. access to medicine, and a technical evaluation of compounds which makes the granting of patents subject to policy making considerations.[388] According to the policies for drug regulation, the granting of patents demands a rigorous analysis because it is a privilege with direct impact on the final cost of a drug.[389] On June 24, 2008, the ANVISA adopted a procedure for examining applications for prior consent by means of Resolution-RDC 45/2008. The Resolution established that the ANVISA should examine the patentability legal requirements established and may issue office actions

---

mercially available (novelty, inventive step and industrial application are not examined by the INPI). They are foreseen by the statute in Articles 230 and 231, as a transitory mechanism to allow pharmaceutical patent applications to be filed between 1996 and 1997, regardless compliance with the novelty requirement (since these applications could not benefit from Paris Convention priority any longer and already belonged to the state of the art) taking into consideration that the previous legislation did not allow patents on pharmaceutical products. For more, see *Licks, Leonardos*, Article 229-C of the Industrial Property Law. The constitutionality of pipeline patents was challenged in a lawsuit currently pending before the Brazilian Supreme Court (ADIN 4234). The country's highest court must now decide *en banc* whether pipeline patents are contrary to the constitutional clause because afford exclusivity for subject matter deemed to be already in public domain. It is out of the scope of the present work to discuss in further details pipeline patents.

385 INPI, Comunicado INPI/DIRPA 02/2001.

386 The corresponding decision is published in the Official Gazette under codes 9.1, for regular applications, and 23.17, for "pipeline" applications. The issuance of these decisions means that the INPI concluded examination, and the applications meet the respective patentability requirements, be it regular or "pipeline".

387 See *ANVISA*, Current Policies for Regulating Medicines in Brazil.

388 *Id.*

389 *Id.*

https://doi.org/10.5771/9783845259828-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

demanding applicants to submit documents, clarifications and amendments.[390] Resolution-RDC 45/2008 may be regarded as having been issued with ten years of delay.[391] Since the introduction of the prior consent requirement, even without proper regulation, the ANVISA has taken crucial decisions including the granting of patents on pharmaceuticals based on policy evaluations. It is important to note that the Resolution clearly and expressly establishes that ANVISA's activities should be bound to the law, with no room for other considerations. As a consequence, the ANVISA has been increasing barriers to patentability for some applications based on the lack of novelty, inventive step, disclosure or enablement, consisting of different criteria from the INPI and reflecting evaluations based on policy, which is theoretically forbidden. This has been the case regarding inventions of second medical uses and will be discussed in the following section.

The Associação Brasileira da Propriedade Intelectual (ABPI)[392] maintains the position that prior consent should be applicable only to "pipeline" applications, because both are inserted as transitory provisions of the statute.[393] In addition, the ANVISA is the authority for approving the marketing of the drugs, and would be better entitled to assess compliance with the non-commercialization requirement for granting "pipeline" patents. The ANVISA's interference in the patent granting procedure may be regarded as a way for the Executive Branch of the Brazilian Government to implement policy control of patents covering inventions related to pharmaceuticals.[394] In implementing the minimum standards required by TRIPS, the Brazilian industrial property law created legal grounds for the development of a sound patent system. As part of this evolving process, it is possible to consider that the INPI has been moving towards a patent-

390 Until the enactment of Resolution-RDC 45/2008, communications with applicants were done through the INPI.

391 Article 1, Paragraph 1 of Resolution-RDC 45/2008 establishes that the provisions of this resolution are retroactively applicable to all patent applications for pharmaceutical products and processes which were pending on December 15, 1999 or filed afterwards, regardless if already granted in the meantime. This provision creates acquired rights problems that have not yet been dealt by the Brazilian courts.

392 The ABPI is the Brazilian group of the Association Internationale pour la Protection de la Propriété Intellectuelle (AIPPI).

393 See *ABPI*, ANVISA's Technical Information.

394 See *Souza*, Should Brazil Allow Patents on Second Medical Use?, p. 53.

https://doi.org/10.5771/9783845259828-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

friendly interpretation and application of the statute. As a result, the Brazilian government saw that it was necessary to establish political control of the granting of pharmaceutical patents by means of the ANVISA.

The ANVISA's political control of pharmaceutical patents would be justified under the government's discretionary power to act in defense of human rights, by enhancing access to medicines, through the right to health contained in Article 196 of the Federal Constitution.[395] Article 197 of the Federal Constitution entitles public administrators to act in order to safeguard public health. The supremacy of public welfare over individual rights is established in Articles 5, XXIII and 170, III of the Federal Constitution, which require that private property observes its social function.[396] Accordingly, prior consent should represent a measure that is adopted in order to guarantee social welfare and justice, as well as access to medicine by limiting intellectual property rights and specifically patent rights.[397]

On the other hand, it is often forgotten that Article 5, XXIX of the Federal Constitution also relates to the public interest, also supporting the argument that public interest should prevail over private interests. Denying patents in the pharmaceutical field, because they are considered harmful to the public interest, does not follow the principle of proportionality.[398] Without investments in R&D that result from the existence of the patent system, the development of new drugs would be at stake. Following this logic, the ANVISA's political control is unconstitutional because patents are a fundamental guarantee and must be granted upon the fulfillment of patentability requirements as set forth in the statute.[399]

The activities of public administration are subject to the principle of legality and there should be no space for the discretionary power of the ANVISA or any other public entity.[400] The constitutional clause contained in Article 5, XXIX of the Federal Constitution represents a justification giv-

---

395 See *Basso*, The Brazilian Practice of the Prior Consent, p. 60.

396 *Id.*

397 See *Rodrigues Jr., Murphy*, Brazil's Prior Consent Law, p. 437.

398 See *Oswald, Leonardos*, Patent Law: Constitutional Aspects, p. 4-5.

399 See *Barbosa*, ANVISA's Prohibition of Claims on Pharmaceutical Use, p. 733.

400 The principle of legality established in Article 37 of the Federal Constitution orders that public administrators must act strictly in accordance with the law, i.e. the statutory acts originating from Congress. The public administration is only allowed to act when the law so establishes. Any ordinance or resolution enacted by the public administrator must conform to the laws originated from Congress. In this case, the activities of both the INPI and the ANVISA – when granting or

https://doi.org/10.5771/9783845259828-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

en by the legislators to enact the patent statute and is the legal instrument to which public administrators (in this case represented by the ANVISA and the INPI) are bound. Therefore, once it is verified that the invention is new, inventive, industrially applicable, supported by the description and not prohibited subject matter (Articles 10 and 18 of Law 9279/1996), the patent must be granted upon payment of the applicable fees. Otherwise, the actions of public administrators would be *contra legem*, as per the opinion of the public attorneys from the INPI.[401] Another interesting argument made by the public attorneys from the INPI relates to the social function of patents. They argue that patents should be granted provided the legal requisites are observed, but as property rights they should respect the principle of social function of property of Article 5, XXIII and 170, III of the Federal Constitution.[402] The limitations to the use of patent rights should be determined in favor of society in order not to unduly restrict competition, also a guarantee of Article 170, IV of the Constitution, and policy evaluations should be used to avoid an abusive exercise of patent rights.[403]

Therefore, policy considerations should not be part of the patent granting procedure, which is strictly linked to law. Matters of governmental policy should be considered at the stage when patent rights are enforced, such as the example of granting compulsory licenses as per the so-called flexibilities of TRIPS. In fact, the Brazilian government has already granted a compulsory license for Merck's drug Efavirenz for the treatment of AIDS, having declared that it is of public interest in Decree 6108, of May 4, 2007.[404]

The ANVISA has been defending itself from criticism against prior consent, alleging that it has contributed to enhance the quality of patent examinations. The INPI reviewed its position following ANVISA's assessment of the patentability of some applications.[405] The agency also ar-

---

denying applications or regulating procedures – must not contravene the patent statute.

401 See *INPI*, Legal Opinion on Incremental Inventions, p. 14.

402 *Id.*, p. 16.

403 *Id.*

404 This case will be analyzed in detail in the following chapter.

405 The ANVISA states that 5.4% of the patent applications submitted to the ANVISA have been rejected or shelved by the INPI following the ANVISA's analysis identifying irregularities. See *ANVISA*, Report on ANVISA's role in the exam os pharmaceutical patent filings, p. 3. This work provides an analysis of the

https://doi.org/10.5771/9783845259828-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

gues that it should not be held responsible for increasing the country's existing backlog (only 5.9% of 1100 applications are pending examination by the agency for prior consent purposes).[406] In addition, the ANVISA presents statistics to support that it has not been assessing patentability requirements with an anti-patent bias. By December 31, 2008, the ANVISA had assessed 1047 patent applications and 89.4% were granted prior consent, while 36.6% were granted prior consent following restrictions to the claims, and only 10.6% were denied.[407]

The role of the ANVISA within the patent granting procedure has also been discussed at the political level. On July 9, 2008, Bill of Law 3709/2008 was presented in the House of Representatives to modify Article 229-C.[408] According to the proposal, prior consent by the ANVISA would be restricted to "pipeline" patent applications.[409] The Bill's justification states that "pipeline" patents consist of re-validating patents that are granted abroad, and should, therefore, be subject to more stringent analysis regarding whether the object of the patent was made available in the international market.[410] Because "pipeline" applications are allowed only for one year after the enactment of the patent statute, Article 229-C represents a transitory provision connected to the transitory nature of the existence of "pipeline" patents in the Brazilian system.[411] These restrictions to the ANVISA's activities have prompted protests from within the agency against losing the power to intervene in patent granting proceedings. The agency argues that the INPI is too lenient when examining patents and favors industry too much.[412] The INPI, on the other hand, argues that the concomitant work of the two governmental institutions extends the period of patent examinations and opens doors to conflicting interpretations, leading to legal uncertainty – such as the case of the patentability of second medical uses.[413]

---

patent applications submitted to the ANVISA's analysis for prior consent purposes from June 2001 until July 2010.

406 *Id.*, p. 7.
407 *Id.*, p. 4.
408 See Bill of Law 3709/2008, p. 1.
409 *Id.*, p. 1.
410 *Id.*, p. 2-3.
411 *Id.*
412 See *Formenti*, ANVISA Resists in Restricting their Role during Patent Examination.
413 *Id.*

https://doi.org/10.5771/9783845259828-67 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

Bill of Law 3943/2012 was proposed on May 2012 also seeking to define the scope of prior consent by the ANVISA, but it adopted a different approach.[414] The Bill establishes that prior consent must analyze the requirements of novelty, inventive step, and industrial applications for inventions and utility models in the chemical-pharmaceutical areas, for medicine of any kind, and for healthcare products, in addition to the respective obtaining and modification processes.[415] Assessment should be made in light of technical and scientific knowledge in chemistry, biochemistry and pharmacology, as well as clinical experience and public health uses. Also, patents should only be granted upon consensus between the ANVISA and the INPI.[416] The report justifying the Bill revolves around the argument that the INPI does not have the technical capacity to examine patents in the pharmaceutical area as patents for pharmaceutical arts had been prohibited for many years and due to the fact that it has granted patents which did not comply with requirements in Article 8 of Law 9279/1996.[417] It also states that patents covering second medical uses and new crystalline forms of compounds are not innovative and are artificial tools used by big pharmaceutical companies for extending the shelf life of their patent portfolio.[418] Both Bill of Law 3709/2008 and Bill of 3943/2012 have not been submitted yet to the House of Representatives' approval, pending being voted attached to each other.

The very first trial court decision addressing the scope of prior consent by the ANVISA rejected the agency's interpretation and application of Article 229-C of Law 9279/1996. The court stated that the ANVISA lacks the statutory authority to examine the requirements of inventive step, novelty, and industrial application of pharmaceutical patent applications, and any activities by the ANVISA should be free from political bias.[419] Never-

414 See Bill of Law 3943/2012, p. 1.
415 *Id.*
416 *Id.*
417 Id., p. 2.
418 *Id.*, p. 4-6.
419 See *F. Hoffmann-La Roche AG. v ANVISA and INPI*, Trial Court Judgment, p. 91-104. On November 3, 2004, the Trial Judge of the 37th Federal District Court of Rio de Janeiro rendered a judgment overruling the ANVISA's decision denying prior consent to patent application PI 9503468-4 (covering the drug Valcyte for the treatment of AIDS) owned by F. Hoffmann-La Roche A.G. Unlike the INPI's examination concluding for the patentability, the ANVISA considered that the invention was already part of the state of the art and argued that the granting

https://doi.org/10.5771/9783845259828-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

theless, after this case, the Federal Court of Appeals for the 2nd Circuit rendered a decision in which a different understanding prevailed, according to which both the INPI and the ANVISA should coordinate examination of patentability requirements. Hence, the patent granting procedure for pharmaceutical applications became a complex act, requiring two administrative bodies. The court decided that patent applications in this field should be submitted to more stringent examination in order to avoid undue patent protection for drugs which are of high importance to the public health.[420]

More recently, a shift in position within Brazilian courts may be observed. The Federal Court of Appeals for the 1st and the 2nd Circuit have rendered decisions, according to which the prevailing understanding is that ANVISA has to limit analysis to the agency's institutional duty. This is to say, it must assess the subject matter of patent applications for pharmaceutical products and process only in connection to public health issues. The agency should not examine patentability requirements (which should be under the exclusive scope of action of the BPTO) and could only indicate possible technical obstacles for granting patents related to public health matters under Article 18, I of Law 9279/1996.[421]

The discussions gained another round when the limits of prior consent by the ANVISA raised controversy within the Attorney General's Office (AGO). The legal offices of both the ANVISA and the INPI are part of the broader structure of the AGO. On October 16, 2009, the AGO issued a first legal opinion against the ANVISA's practice of analyzing patentabili-

---

of "bad patents" are harmful to the public health. This district court decision was nullified by the decision of the Court of Appeals rendered on December 11, 2007, for non-compliance with procedural requirements in the lawsuit. It was found that the trial court erred in denying the ANVISA's request for a technical expert to assist the courts in assessing if the invention was part of the state of the art. However, the appellate court decision does not address issues concerning the ANVISA's competence for intervening in the patent granting procedure and the scope of the prior consent See *F. Hoffmann-La Roche AG. v ANVISA and INPI*, Appellate Court Judgment, p. 1.

420 See *Aventis Pharma S.A. v ANVISA and INPI*, Appellate Court Judgment, p. 1778-1779.

421 See *Merck Frosst v. ANVISA*, Appellate Court Judgement, p. 197153; *Novartis v. ANVISA*, Appellate Court Judgement, p. 861-862; *Max-Planck and Zentaris AG v INPI and ANVISA*, Appellate Court Judgement. See also *Takeda v. ANIVSA,* Trial Court Judgment, p. 791-795; *Max-Planck and Zentaris AG v INPI and ANVISA*, Trial Court Judgement, p. 5.

https://doi.org/10.5771/9783845259828-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

ty requirements, stating that the agency's activities under Article 229-C should be limited to the sanitary control of production and marketing of products and services harmful to human health; it is not for the agency to examine patentability requirements.[422] A final legal opinion was issued by the AGO, on January 7, 2011, rejecting a request for reconsideration filed by the ANVISA and upholding its previous understanding that the ANVISA's analysis should be restricted to investigating potential harmful effects to human health in light of Article 18, I of Law 9279/1996 and working in collaboration with the INPI. The latter should be provided with technical information to make the final decision regarding the granting of the patents.[423]

Following the two legal opinions issued by the AGO, a working group formed by representatives of the Ministry of Health, Ministry of Development, Industry and Foreign Trade, the AGO, the ANVISA and the INPI was created in order to analyze and suggest criteria, mechanisms, procedures and obligations regarding an articulated work between the ANVISA and the INPI under Article 229-C of Law 9279/1996.[424] On May 25, 2012, the working group published a report suggesting criteria and procedures to be adopted for the analysis of patent applications in the pharmaceutical field.[425] The report proposes a new prosecution process according to which applications filed before the INPI will be formally examined and upon identification of the subject matter as a pharmaceutical product or process, they will be sent to the ANVISA. Then, the ANVISA will carry out its analysis and publish its decision in the Official Gazette and return the application to the INPI.[426] If the ANVISA grants prior consent, the INPI will proceed to technical examination of the application. In the case that prior consent is denied, said decision is also published in the Official Gazette and the INPI will receive the application for shelving.[427] The scope of ANVISA's analysis for prior consent purposes should consider the impact of a pharmaceutical product or process in light of public health,

422 See *AGO,* Opinion 210/2009, p.13.
423 See *AGO,* Opinion 337/2010, p. 5.
424 See Interministerial Ordinance 1956/2011 and Interministerial Ordinance 2584/2011.
425 See Interministerial Ordinance, 1065/2012, p. 35.
426 See *ANVISA*, Report on criteria and procedures to be adopted for the analysis of article 229-C of Law 9279/1996, p. 8-9.
427 *Id.*

https://doi.org/10.5771/9783845259828-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

taking into consideration Article 18, I of Law 9279/1996 and pursuant to the constitutional guiding principles of universal access, integrality and equity in health.[428] The proposal seeks better interaction between the INPI and the ANVISA, establishing the role of each institution in the procedure for granting patents in the pharmaceutical field.

Following the AGO report, a new resolution regulating the procedure for prior consent was opened by the ANVISA on October 17, 2012, for public consultation.[429] According to the proposed resolution, the ANVISA's prior consent would be defined as the agency's decision that a patent application is contrary to public health.[430] Patent applications deemed contrary to public health relate to a) subject matter consisting of products and processes which presents sanitary risks, comprising or resulting in a substance forbidden in the country, or b) a product or process that is of interest for policies concerning medicine or pharmaceutical assistance within the public healthcare system and do not fulfill patentability requirements.[431]

The ANVISA announced to the public on April 8, 2013, the criteria for evaluating patent applications. The agency will analyze applications only in the following two cases: 1) whenever the molecule is analogous to products already prohibited in the country, or 2) whenever the patent subject matter claims substances that may relate to drugs considered strategic to public health.[432] Any other applications will be sent back to the INPI, which will conduct the full examination.[433] The first criterion regarding substances prohibited in the country already presented during the public hearing corresponds with the AGO's and court's understanding of the ANVISA's role. The second criterion, however, evidences that political elements still permeate the ANVISA's assessment of prior consent. It does not expressly state that denial of prior consent will result from not meeting patentability requirements, rather says that applications concerning drugs deemed of strategic importance for the public health are subject to the ANVISA's assessment. This position is expressed in a statement by the

428 *Id.,* p. 6.
429 See *ANVISA*, Public Consultation 66/2012.
430 *Id*., p. 2.
431 *Id.*
432 *Estado de São Paulo*, ANVISA establishes criteria for pharmaceutical patents, para. 2.
433 *Id.*

https://doi.org/10.5771/9783845259828-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

Commissioner of the ANVISA during a public hearing held on March 20, 2013, clarifying there may be cases in which prior consent will be denied even if the application fulfills the requirements of patentability.[434]

On April 15, 2013, the ANVISA published Resolution-RDC 21/2013 in the Official Gazette, regulating the prior consent procedure by modifying Resolution-RDC 45/2008. It defines prior consent as the examination of patent applications in the pharmaceutical area carried out by the ANVISA in light of public health.[435] A patent application will be deemed contrary to public health when a) the pharmaceutical product or process contained in the application presents a risk to health, which is characterized when the product comprises of or the process results in a substance which use has been prohibited in the country, or b) the pharmaceutical product or process is of interest for policies concerning medicine or pharmaceutical assistance within the public healthcare system and do not fulfill the patentability requirements established by Law 9279/1996. (Interest concerns substances listed as strategic medicines by the government or pertaining to the same therapeutic class as those listed by the government).[436] The Resolution further determines that the parameters for analyzing risks to health and interest for policies concerning medicine or pharmaceutical assistance within the public healthcare system will be detailed in a specific act.[437]

After the first legal opinion issued by the AGO, a public lawsuit was filed by the Office of the General Solicitor seeking to halt its effects. The purpose of this action was to determine that the ANVISA's activities, when assessing patent applications submitted to prior consent under Article 229-C of Law 9279/1996, in fact examine patentability requirements. Quoting the existing case law from the Federal Court of Appeals for the 1st Circuit, the trial court Judge denied the preliminary injunction request stating that the ANVISA's job should be protecting the population's

434 The report made by the ABAPI's representative during the public hearing held at the ANVISA on March 20, 2013, transcribes Commissioner Dirceu Barbano declaration as follows: "A patent application that fall into one of the categories proposed in the new resolution will be analyzed by the agency in depth, which does not mean that prior consent will be automatically denied. Furthermore, there may be a situation in which the consent is denied even if the application fulfills all the patentability requirements." A copy of the ABAPI's report may be found in possession with the author.

435 Resolution-RDC 45/2008, article 2, I, as modified by Resolution-RDC 21/2013.

436 *Id*., article 4, para. 1-3.

437 *Id*., article 4, para. 4.

https://doi.org/10.5771/9783845259828-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

health and not examining the requirements that will be analyzed by the INPI.[438] Despite the report published establishing the new prosecution process and the scope of prior consent following the final opinion of the AGO, a final unappealable decision on the merits in the public lawsuit will have *erga omnes* effects and will solve these disputes stemming from the lack of regulation of Article 229-C of Law 9279/1996 and pertaining to the ANVISA's legal mandate for examining patentability requirements.[439]

The ANVISA's role in the patent granting procedure tends to include an analysis of all patent applications for pharmaceutical products and processes, independent of being regular or pipeline. The discussions mentioned above relate to the scope of such analysis (including examination of patentability requirements) for the granting of prior consent. With the new procedure and the scope of prior consent by the ANVISA restricted to the evaluation of public health matters, even after the agency's latest resolution, it is still not clear how the agency will carry out assessments for prior consent. It is difficult to tell how evaluating the impact of pharmaceutical products or processes in light of public health will occur without being discretionary – if this is even possible – as patentability requirements remain as one of the items to be examined by the ANVISA when assessing applications for the purposes of prior consent.

2. Second Medical Use Inventions

2.1) INPI Examination Guidelines, ANVISA Policies and Debates on New Examination Guidelines

Second use inventions, in the pharmaceutical or other fields, are deemed patentable subject matter by the INPI provided that novelty and inventive step have been ascertained for this second use. The INPI Examination Guidelines in the Biotechnology and Pharmaceutical Field currently in force define second medical use in general as new use of a product known outside the medical field as a medication (referring to *first medical use*) or new medical use of a product already applied in the medical field (refer-

438 See *Federal Prosecution Office v. Federal Union,* Preliminary injunction decision, p. 2.

439 A final decision at the trial court level is still pending.

https://doi.org/10.5771/9783845259828-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

ring to *second medical use* in strict sense).[440] The Examination Guidelines state that claims may be permitted when drafted as "use of product X characterized in that it is for the preparation of a medication to treat illness Y" or "use of product X characterized in that it is for the preparation of a medication to treat illness Y, which treatment consists of such and such."[441] These claims make use of the so-called *Swiss-type* form,[442] so as to avoid the prohibition of patenting methods of medical treatment present in Article 10, VIII of Law 9279/1996. In contrast, claims such as "product

---

440 "2.39 Second use invention 2.39.1 Inventions of this nature can be of two types: (i) a new use, as medication, of a known product with use outside the medical field (first medical use); (ii) a new medical use of a product already known as medication (second medical use)".

441 "2.39.2 Typical claims of this type of invention would be: 2.39.2.1 Claim type: a. Product X characterized by the fact that it is used as a medication. b. Product X characterized by the fact that it is used for the treatment of illness Y shall not be granted on account of the fact that its purpose does not present newness, as, per definition (i) above, it comprises a known product which, obviously, is not new in the sense of Article 11. (...) 2.39.2.2 Claims of the type: a. Pharmaceutical preparation characterized for containing product X (occasionally with other components). b. Preparation for the treatment of illness Y characterized for containing product X (occasionally with other components). c. Preparation in the form of (tablet, gel, injected solution, etc.), characterized for containing product X (occasionally with other components) for use in the treatment of illness Y, may be granted as long as the preparations encompassed be new and display inventive activity. (...) 2.39.2.4. Claims of type: a. Use of product X characterized in that it is for the preparation of a medication to treat illness Y. b. Use of product X characterized in that it is for the preparation of a medication to treat illness Y, which treatment consisting of such and such, known as "Swiss formulas", being almost always used in second medical use inventions. They are entitled to privilege, in view of the considerations contained in item 2.23 above. (...)".

442 Swiss-type claims consist of using a wording formula for claiming inventions on second medical uses. The form of a usual Swiss-type claim is "use of a substance or composition X for the manufacture of a medicine for therapeutic application Z". The purpose of this wording is to avoid that use claims for pharmaceutical products are considered therapeutic methods, falling in the statutory prohibition against patenting this subject matter, which is foreseen in several national legislations, such as the Brazilian one. It was first adopted by the Swiss Patent Office, and afterwards by the practices of the European Patent Office. It is unlikely that the decision issued on February 19, 2010 by the Enlarged Board of Appeals of European Patent Office in case *EPO*, Dosage regime/ABBOTT RESPIRATORY, case G2/08, determining that Swiss-type claims are not going to be accepted any more, will have any impact in Brazil, since it was based on an amendment of the EPC text, which now allows patents for second medical uses in an express way.

https://doi.org/10.5771/9783845259828-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

X characterized in that it is for the treatment of disease Y" would lack novelty; and claims such as "use of product X characterized in that it is for the treatment of disease Y" or "process to treat disease Y, characterized by the administration of product X" are considered to describe therapeutic methods.[443]

Despite all of the issues surrounding the use of the Swiss-type form for drafting claims, the official position of the INPI is that second medical use inventions are patentable. Nevertheless, the ANVISA holds the opposite opinion in this regard. On August 25, 2004, the ANVISA published information on its website about procedures concerning patent applications on pharmaceutical-related inventions.[444] It published the decision of the ANVISA Collegiate Board from November 23, 2003, which established that the agency will not grant prior consent to patent applications for second medical uses.[445] According to this decision, such patents are harmful to public health, to the country's scientific and technological development, and may hinder access to medicines.

The denial of prior consent to applications claiming second medical uses by the ANVISA may be in violation of TRIPS as it represents discrimination of a field of technology, which is prohibited by Article 27.1 of TRIPS,[446] since applicants in the pharmaceutical field are submitted to a second round of examination, while inventors in other fields are not. In addition, Article 27.2 of TRIPS cannot be used to justify the denial of such patents, because this provision's goal is to prevent proprietary rights only for inventions contrary to the interest of society.[447] Exclusions from

---

443 "2.39.2.3 Claim of type: a. Use of product X characterized in that it is for the treatment of illness Y. b. Process for treating illness Y characterized by administering of product X (or preparation containing product X), are not granted on account of the fact that they comprise a therapeutic method (...)".

444 See *ANVISA*, Clarifications about Patent Applications for Pharmaceutical Products and Processes, para. 2.

445 "IV – Regarding the applications which have as claim the 'new use' of substances – The Collegiate Board, at a meeting held on 23 November 2003 stated as thus: 'The Collegiate Board considers that the institute is harmful to public health, to the country's scientific and technological development, and that it may hinder access to medication by the population. In this respect, it has decided for not granting prior consent to cases of patent applications claiming second use'".

446 See *ABPI*, ANVISA's Technical Information; and *Souza*, Should Brazil Allow Patents on Second Medical Use?, p. 62-63.

447 See *Rodrigues Jr., Murphy*, Brazil's Prior Consent Law, p. 451.

https://doi.org/10.5771/9783845259828-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

patent protection could occur only if the commercial exploitation of these inventions is not allowed.

For those that support the ANVISA's interpretation, the agency's denial of patents on second medical uses would be legitimized by Articles 7 and 8 of TRIPS, as well as by the Doha Declaration.[448] These provisions entitle WTO Member States to adopt any measures they consider necessary to promote social welfare and protect public health. Specifically, Article 8.1 of TRIPS would expressly allow countries to exclude from patentable subject matter inventions like second medical uses that are needed to protect the public health.[449] Such patents would not contribute to technological innovation, since they are the result of empirical observation and not of investments in R&D, nor would they contribute to the dissemination of technology because artificially extend the exclusive rights of patent holders.[450] Moreover, Article 27 of TRIPS does not speak to inventions for second medical use when it deals with patentable subject matter and, therefore, Member States are free to decide if they are allowed or not.[451] From this perspective, intervention in the patent granting process by the ANVISA is an important tool to ensure the implementation of public health policies by adopting more stringent criteria for patentability.[452]

The conflicts between the INPI and the ANVISA prompted heated debates during the review of the INPI Examination Guidelines. The INPI organized meetings that were open to representatives of the two government institutions, associations from innovative and generic industries, as well as practitioners.[453] During the discussions, the difference in opinion between the ANVISA and the INPI was obvious. The Head of the Chemical Patent Division of the INPI believed that a second medical application for a known substance consists in an invention and the scope of the new guidelines is to define the criteria for granting patents.[454] In contrast, representatives of the ANVISA contended that such inventions mostly consist of methods for treatment by therapy.[455] Additionally, the ANVISA affirmed

448 See *Basso*, The Brazilian Practice of the Prior Consent, p. 63.
449 See *Arruda, Cerdeira*, Patents on Medicines and Public Health, p. 124.
450 See *Basso*, The Brazilian Practice of the Prior Consent, p. 63.
451 See *Correa*, Guidelines for the Examination of Pharmaceutical Patents, p. 1; and *Rodrigues Jr., Murphy*, Brazil's Prior Consent Law, p. 430.
452 See *Correa*, Pharmaceutical Inventions, p. 17.
453 See *INPI*, Second Medical Use.
454 See *INPI*, Minutes of the First Meeting about Second Medical Use.
455 *Id.*

https://doi.org/10.5771/9783845259828-67 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

that a *Swiss-type* claim per se cannot be enabled in the specification. Based on what is disclosed in the application, it is not possible to manufacture a medication only for the treatment of a certain disease. Since descriptions do not usually refer to the process of manufacturing the medicine, the written description requirements would not be fulfilled.[456] These arguments are the same as those used decades ago to challenge the patentability of second medical use inventions, as if there were no advance in the debate, revealing the political considerations behind "technical" reasons to deny patents on this matter.

The debates at the INPI concluded favorably for patents on second medical use inventions, reiterating the institute's position under the current Examination Guidelines. The first draft of the new Examination Guidelines recognizes that an invention of second medical use is based on the report of a new therapeutic activity of a known chemical compound for the production of a medicine with a different purpose from the one that is already part of the state of the art.[457] The invention would be deemed new when the already known pharmaceutical product is used to treat a different disease.[458] Inventive step would be verified when the new medical use is not obvious to a person skilled in the art, taking into account the mode of action of the chemical compound, the relationship between therapeutic activity and chemical structure and the etiology of the targeted diseases.[459] However, the first draft of the guidelines does not suggest any parameters for disclosure requirement or for the wording of admissible claims. Since the last meeting on October 9, 2007, the INPI has been working on a final proposal for the new Examination Guidelines; in the meantime, the previously discussed regulations are still in force, as the publication of the final version still pends.

Within the context of the Brazilian pharmaceutical industry, it is important to note the remarks of a representative of the Associação dos Laboratórios Farmacêuticos Nacionais (Association of the National Pharmaceutical Laboratories – ALANAC) during the meetings for reviewing the Examination Guidelines, according to which the little research that is done in Brazil mostly consists of already known substances and any developments

456 *Id.*
457 See *INPI*, Draft Examination Guidelines for Applications Claiming Second Medical Use.
458 *Id.*
459 *Id.*

https://doi.org/10.5771/9783845259828-67 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

therefrom would be new medical uses.[460] The innovation done by Brazilian companies is incremental innovation.[461] National industry does not have the means to finance R&D activities or the clinical trials needed for new drugs containing new chemical compounds. In contrast, the expenses needed for development of a drug based on new uses of known chemical compounds are comparatively lower, since the initial tests for proving the safety of the substance have already been performed. Brazilian inventors and industry would be harmed by the ANVISA's policy that blocks second medical use patents. Examples of Brazilian inventors who could be affected by such policy have also been identified.[462]

Until today, the INPI has not issued its new guidelines. It is most likely because the debate with the ANVISA on the patentability of second medical uses, and the discussion concerning the scope of prior consent, have led the INPI to refrain from publishing new guidelines so as to avoid political conflict within the government.

2.2) Discussions in Congress and Court Decisions

The conflict between the ANVISA and the INPI has also been seen in Congress during the debate on Bill of Law 2511/2007 (proposed on November 29, 2007)[463] to amend Law 9279/1996 and bar the patentability of second medical indications of pharmaceuticals in Article 18 of Law 9279/1996. Bill of Law 2511/2007 justifies the prohibition of patents on second medical uses stating that the lack of definition of therapeutic method within the law has led to the granting of patents for new medical

460 See *INPI*, Minutes of the Second Meeting about Second Medical Use.

461 *Id.*

462 See *Souza*, Should Brazil Allow Patents on Second Medical Use?, p. 67, for patent applications PI9908664-6, filed by Henrique Chvaler; PI9806330-5-8, filed by Edson Claro do Nascimento; PI9805654-9, filed by Edson Claro do Nascimento; PI9902178-1, filed by Edson Claro do Nascimento (BR/SP); PI9806331-6, filed by Edson Claro do Nascimento; PI0202647-3, filed by José Carlos Barbosa Vosgerau; PI0202539-6, filed by Marcus Keche Weber; PI0102184-2, filed by Laboratório Catarinense S/A; PI0102186-9, filed by Laboratório Catarinense S/A; PI0102185-0, filed by Laboratório Catarinense S/A; PI0004106-8, filed by Laboratório Sintofarma S/A; PI0004105-0, filed by Laboratório Sintofarma S/A; PI9702841-0, filed by Laboratório Sintofarma S/A; and PI9802893-6, filed by Eurofarma Laboratórios Ltda.

463 See Bill of Law 2511/2007, p. 1.

https://doi.org/10.5771/9783845259828-67 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

indications, which consist of mere discoveries and do not fulfill patentability requirements. It states that the unjustified extension of protection hinders access to generic drugs by the population. It is important to note that the relationship between second medical uses being mere discoveries and the lack of definition of therapeutic methods is not clear.

In the first round of debates in the House of Representatives, each institution took opposite stances on the patentability of second medical use inventions. The ANVISA reiterated that patenting second medical uses is contrary to the public health policies because it hinders the production of generics and increases the costs of purchase of medicines.[464] In the opposite camp, the INPI affirmed their patentability upon fulfillment of requirements, based on the absence of such prohibition in the current statute.[465]

Inserted together in Congress legislative proceedings with Bill of Law 2511/2007, the new Bill of Law 3995/2008 proposed on September 3, 2008 has led to further debate in the House of Representatives.[466] Bill of Law 3995/2008 intends to modify Article 10 of Law 9279/1996 and exclude from patentability new crystalline forms of substances already in the state of the art, as well as new uses of products or therapeutic substances already subject to patent protection. The reason stated is that these kinds of patents would be in the interest of foreign pharmaceutical companies because they are an extension of the term of protection for already existing patents and they would serve as a barrier to other companies from entering the market. Second medical use includes the discovery of side effects and research is only related to adapting already existing drugs to treatment of new pathologies, which, in contrast, would constitute a therapeutic method – excluded from patentability by Article 10, VIII of Law 9279/1996.

During the political debates, the Commissioner of the INPI once again affirmed the position in favor of the patentability of second medical use inventions, as they may foster national research in the pharmaceutical field, and a number of Brazilian scientists were quoted in this regard.[467] According to the Commissioner, the INPI criteria for examining such patent applications would avoid undue extension of already existing

464 See *Agência Câmara*, Government Diverges about the Granting of Patents on Second Uses.
465 *Id.*
466 See Bill of Law 3995/2008, p. 1.
467 See *INPI*, Patentability of Pharmaceutical Incremental Innovation.

https://doi.org/10.5771/9783845259628-67 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

patents by clearly delimiting the scope of protection.[468] He recognized that such patents may serve as a tool for technological development and attended to concerns of the representative of the Ministry of Industry, where the INPI is housed.[469] On the other hand, the representative of the Ministry of Health, to which the ANVISA is affiliated, advocated for the absolute ban of patents on second medical uses.[470] This debate shed light on the fact that conflicts between the ANVISA and the INPI reflect divergent positions between two different sectors of the Executive Branch, the Ministry of Industry and the Ministry of Health.

The INPI's position was legally grounded in an opinion by its public attorneys which considered that, in absence of a restriction in the statute against the patentability of second medical uses, patents on such subject matter must be granted if the requirements of novelty, inventive step and industrial application are met.[471] In not doing so, the INPI would be acting contrary to the law because policy evaluations should be reserved for the enforcement stage.[472]

Regarding the technical aspects that justify the criteria used by the INPI, an opinion prepared by examiners was presented to confirm the understanding already revealed in the first draft of the new Examination Guidelines. The new use of a known pharmaceutical product may be protected under a *Swiss-type* claim ("use of compound X characterized in that it is for the preparation of a medication to treat illness Y") because the protection would not be directed to the already known product, but to the use of the known product to manufacture medicine for a new therapeutic use.[473] In this manner, there would be no barriers to third parties to use the product or the process, in case they are already in the public domain and are not used for the new indication.[474] In addition, therapeutic methods comprise the steps necessary for the cure or prevention of a disease, or for alleviating pain and suffering, aiming at the reestablishment of normal conditions of health. *Swiss-type* claims would not cover such steps.[475] Novelty

468 *Id.*
469 *Id.*
470 *Id.*
471 See *INPI*, Legal Opinion on Incremental Inventions, p. 14.
472 *Id.*, p. 16.
473 See *INPI*, Technical Opinion on New Crystalline Forms and New Medical Uses, p. 22.
474 *Id.*
475 *Id.*

https://doi.org/10.5771/9783845259628-67 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

would be verified when the second use is different than the one already part of the state of the art, meaning the treatment or prevention of a different disease.[476] When analyzing the prior art, side effects that are duly documented may destroy novelty.[477] The inventive step requirement would be fulfilled when a person skilled in the art does not understand the new application as obvious, taking into consideration that the invention provides a different mode of action of the pharmaceutical substance than the one described for the first use, the etiology of new diseases to be treated is also not the same, and the new therapeutic effect is not evidently derived from a molecular structure analogous to compounds presenting similar activities.[478] With regard to disclosure and enablement, *in vivo* tests are required and the disease to be treated should be specifically mentioned in the description. It is not enough to include a reference to the conditions to be treated (the mode of action of the pharmaceutical substance).[479]

Bill of Law 2511/2007 and Bill of Law 3995/2008 both seek to prohibit patenting of new therapeutic uses of pharmaceutical products and new crystalline forms of substances. These bills have received support from the Ministry of Health and the ANVISA.[480] Nevertheless, in further discussions, during a public hearing held by the House of Representatives on June 27, 2012, the INPI and the ABPI explained to congressmen that all patent applications, including ones covering new medical uses, undergo a patent examination on novelty, inventive step and industrial application and that remedies against eventual abuses are already available in the current legislation.[481] Members of the House of the Representatives have issued two opposing opinions concerning the approval of a bill modifying the statute so as to prohibit patenting of second medical uses in a congressional procedure that started in 2007.

Even though it is not likely that, this debate will be resolved in the short term, Bill of Law 5402/2013 was more recently proposed on April 18, 2013 also seeking to amend Law 9279/1996. The bill consists in another attempt to exclude subject matter comprising new properties or uses of

476 *Id.*
477 *Id.*, p. 23.
478 *Id*., p. 23-24.
479 *Id*., p. 24-25.
480 See Opinion of the House of Representative's Commission for Economic Development, Industry and Trade, p. 7.
481 *Id.*, p. 6-7.

https://doi.org/10.5771/9783845259828-67 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

known substances, as well as new forms such as salts, polymorphs, metabolites and isomers from patent protection by including them in Article 10 of Law 9279/1996.[482] Bill of Law 5402/2013 is also pending examination by Congress together with the previous discussed bills.

Brazilian courts have already dealt with the issue of second medical use inventions. The trial judge of the 35th Federal District Court of Rio de Janeiro rendered a decision on December 3, 2007 in a leading case, related to the patent application PI9606903-1, covering the active ingredient tomoxetine.[483] The applicant claimed a new use for tomoxetine in the treatment of attention deficit and hyperactivity disorder; although, this compound had been known for decades, it had not been used medically for this purpose. The trial court judge affirmed that the new application of a product is patentable when the already known object is inventively used towards obtaining a new result and the novelty consists of the relationship between the means and the result.[484] The judge stated that there is no specific provision in the Brazilian patent statute prohibiting the patentability of second uses in pharmaceutical arts (second medical uses are not prohibited by Articles 10 and 18 of Law 9279/1996) and they should be patentable provided that the new use is not part of the state of the art, and inventive step and industrial application are shown.[485] Furthermore, the judge clarified that new uses of pharmaceutical products are not therapeutic methods and are not prohibited by Article 10, VIII of Law 9279/1996.[486] Finally, the judge considered *Swiss-type* claims that are used to describe second medical use inventions should not be seen as process claims; the nature of a *Swiss-type* claim relates to a product and its purpose.[487] It is important to note that this case did not address the ANVISA's peremptory prohibition on patents for second medical use. The

482 In addition, Bill of Law 5402/2013 seeks to revoke sole paragraph of article 40 (eliminating the ten year period of minimum term of protection) and to modify articles 13 (bringing a new definition of inventive step), 31 (introducing opposition proceedings before the granting of patents) and 229-C (including the criteria according to which the ANVISA must deny prior consent) among other amendments. The contents of the proposed Article 229-C are exactly the same as in the text of Resolution-RDC 21/2013 issued by the ANVISA.

483 See *Eli Lilly and Company v INPI*, Trial Court Judgment.

484 *Id.*, p. 6.

485 *Id.*

486 *Id.*, p. 7.

487 *Id*.

https://doi.org/10.5771/9783845259828-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

INPI considered that the patent application lacked novelty, whereas in the court proceedings it was deemed to be new. This same judge rendered a second decision reiterating that there is no prohibition in the Brazilian legal system for claims covering a pharmaceutical use that presents a new and inventive use.[488]

In the tomoxetine case, the Federal Court of Appeals for the 2nd Circuit decided that patents for second medical uses do not fulfill the basic requirement of novelty, as the compound already belongs to the state of art. The use of the same compound for another end does not result in patentable subject matter as it does not involve inventive step.[489] According to the decision, this case would be at most a simple discovery of a new therapeutic use, which is not considered invention pursuant to Article 10 of Law 9279/1996.[490] A minority opinion was expressed in the dissenting vote, affirming that there is no legal prohibition in the country for second medical use patents. A distinction was made between a) a new medical application for a chemical compound already used as a medicine (with no novelty or inventive step, as no significant changes are carried out for obtaining the new medical application, consisting in discovery); b) a new medical application for a chemical compound already used as medicine through changing dosage, composition or administration periods (if such changes are new and not obvious, the new medical application may be patentable upon examination of specific cases); and c) medicinal use of a compound which already exists in the state of the art but was not used as a medicine until then (there is novelty in such use as medicine and inventiveness derives from the observation of the therapeutic effects).[491] Tomoxetine falls under the latter condition and should be patentable.[492] The dissenting opinion further stated that the claim covering tomoxetine's new use was not to be deemed process claim, but rather product claim.[493] The appellate court decision was issued by a majority vote that was confirmed by the enlarged panel of the Federal Court of Appeals for the 2nd Circuit and the current case law of the Court of Appeals for the 2nd Circuit pre-

488 See *Max-Planck and Zentaris AG v INPI and ANVISA*, Trial Court Judgement, p. 25.
489 See *Eli Lilly v INPI*, Appellate Court Judgement, p. 7.
490 *Id.*
491 *Id.*, p. 10-12.
492 *Id.*, p. 25.
493 *Id*.

https://doi.org/10.5771/9783845259828-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

vails against the patentability of second medical use inventions. [494] No further appeal has been made so far to the Superior Court of Justice, compelling the higher court to decide specifically on the patentability of second medical uses in the country.

2.3) Further Remarks

Whether the ANVISA's system of prior consent is illegal under WTO law is an issue to be evaluated before the WTO Dispute Settlement Body. This would only occur after many other considerations have been made by a Member State that were to plead against Brazil and, therefore, it is likely to never occur. Despite this, it is important to consider that the right to protect public health is not totally unlimited. Patent rights are recognized by TRIPS and the Doha Declaration to be important for encouraging the development of new life-saving medicines.[495] A balance should always be struck between public health and technological development, seen as two social interests to be taken into consideration along with any related private and public interests.

For the Brazilian pharmaceutical industry, which struggles to establish itself in the national market, the prohibition of patents on second medical uses may be prejudicial. Most of the costs involved in the development of drugs occur during the stages before clinical trials, when molecules are still being studied and before human testing. Second medical uses, in contrast, relate to already known molecules so the costs are relatively lower. With this tool, national industry may have the chance to generate new technology in this area. It is crucial for the Brazilian government to reeval-

494 See *Novartis v. ANVISA*, Appellate Court Judgement, dealing with the scope of the ANVISA's prior consent; although the patentability of second medical use inventions has not been addressed in this case, the dissenting vote states clearly that new use of medicines does not fulfill the constitutional and legal patentability requirements, specifically novelty and inventive step. See also *Max-Planck and Zentaris AG v INPI and ANVISA*, Appellate Court Judgement, p. 12, reversing the trial court decision. However, the appellate court states that a second medical use patent does not necessarily lack novelty, being possible that new therapeutic effects originate from research of complete innovative character without consisting in mere discovery, which might show that a shift in the appellate court's understanding should not be disregarded.

495 See *Rodrigues Jr., Murphy*, Brazil's Prior Consent Law, p. 448.

https://doi.org/10.5771/9783845259828-67 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

uate its policies when dealing with pharmaceutical patents under the risk of jeopardizing national industry and economic progress. The argument that the Brazil's public health and technological development are hindered by patents on second medical uses may be too simplistic. The risks related to undue extension of already existing patents would be minimized by the criteria adopted in the examination of the applications. Only when presenting novelty, inventiveness, industrial applicability, and are supported by the description (within the parameters presented by the INPI), exclusivity rights would be granted. Furthermore, any errors are subject to a reassessment within the INPI structure under appeal proceedings, in addition to a judicial review.

In light of the new prosecution process established, patent holders and applicants must wait to see how the ANVISA will assess public health matters and if this agency and the INPI will coordinate their jobs without prejudice to the patent system. Interpreting what is contrary to public health, as contained in Article 18, I of Law 9279/1996, is now going to be carried out by the ANVISA and should not be done to incorporate policy making considerations, which has been the case for inventions related to second medical uses. Policy making considerations at this level should be a topic for Congress, rather than for public administrators when applying the law. In this case, compliance with TRIPS should also be assessed. Finally, any disagreement with the ANVISA's decision, or even the INPI, on the granting of patents may be brought before courts in order to establish a final word on the matter.

C. Provisions on Compulsory License

According to Article 42 of Law 9279/1996, a patent holder has the right to prevent third parties from manufacturing, using, offering for sale, or importing for such purposes, without consent, a product or process that is subject matter of a patent, or a product directly obtained by a patented process. Compulsory licenses are thus regarded as a limitation to patent rights because the patentee is obligated to license patented subject matter to third parties.

As an exception to a right, compulsory licenses are always granted on a non-exclusive basis and sub-licensing is not permitted (Article 72 of Law 9279/1996). Accordingly, there are conditions imposed on the licensee. In the absence of legitimate reasons, Article 74 of Law 9279/1996 mandates

https://doi.org/10.5771/9783845259628-67 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

that the licensee begin exploiting the patented subject matter within one year from the date the license was granted (interruption is also allowed for an equal period) under the penalty of the possibly having the license revoked upon the patent holder's request.[496]

The licensee will be vested with all powers to act in defense of the patent.[497] This is different from other cases of non-exclusive licenses, where the licensee is not usually entitled to proceed in this manner. In addition, after a compulsory license is granted, its assignment will be only permitted together with transfer or leasing of that part of the undertaking that exploits the patented subject matter under the granted license.[498]

1. Previous Law

Compulsory licenses were introduced in Brazilian legislation by DL 7903/1945. Article 53 of this law established that a patentee who has not exploited patented subject matter in the country for two years from the granting date, or has interrupted use for longer than two years, would be obligated to give licenses to third parties. Article 64 of the statute also provided for expropriation of the patent in the case of national interest, as well as for waiving of patent rights when insufficient effective local use of the invention occurred for more than three consecutive years, as per Article 77, paragraph 1 of DL 7903/1945.[499] Later legislation regulating industrial property rights (DL 254/1967, DL 1005/1969 and Law 5772/1971) had similar provisions.

Law 5772/1971 also raised the public interest as statutory grounds for the granting of compulsory licenses for the exploitation of an unused patent or of a patent whose exploitation in the country does not fulfill the market demands. Since Law 5772/1971 was in force, two compulsory licenses were granted. The first was grounded in public interest for a patent covering a vaccine.[500] The second was a landmark case granted in 1984

496 Article 74, paragraph 1 of Law 9279/1996.
497 Article 74, paragraph 2 of Law 9279/1996.
498 Article 74, paragraph 3 of Law 9279/1996.
499 It has not been found any decision or scholar work dealing with the expressions non-exploitation and lack of effective use under the previous law. To date, there is no clear definition towards the precise use of those expressions.
500 Compulsory license for patent PI 71767, published in the Industrial Property Gazette of November 29, 1977, p. 152.

https://doi.org/10.5771/9783845259828-67 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

due to the non-use of the patented subject matter that covered the manufacturing process of the Monsanto Company's agrochemical *Round-up*.[501] The license was granted to the Brazilian company Nortox Agroquímica S.A. who was interested in exploiting *Round-up* technology and understood that three years after the patent was issued, it was not being duly exploited in the country. Nortox requested the license on March 1983 and, upon Monsanto's silence, had it granted on November of the same year.[502] Monsanto later challenged the granting of compulsory license before courts, but the license was maintained in a final decision on April 25, 1984.[503] In order to avoid the effects of the compulsory license, Monsanto sought to waive its patent rights over the production process of *Round-up*. The company believed that this strategy would exempt it from the obligation to use the patent's subject matter and, thus, no compulsory license could be granted. Such strategy did not prevail.[504] It is important to note that Nortox developed its own technology in the area of agrochemicals and the company was not dependent on the patent holder's know-how, which was considered crucial in determining the efficacy of the license granted.[505]

2. Provisions of Law 9279/1996

The current patent statute removed the possiblity to expropriate patents for national interest and to waive patent rights when there is lack of local use of the invention. However, under the new law, the situations in which compulsory licenses may be conferred were broadened. According to Articles 68, 70 and 71, compulsory licenses may be granted on the following grounds: a) abusive exercise of patent rights or abuse of economic power by means of patent rights,[506] b) non-exploitation in Brazilian territory because of lack or incomplete manufacture of the product or lack of com-

501 Compulsory license for patent PI 7107076, Process DIRCO/1649/83, published in the Industrial Property Gazette of May 29, 1984.
502 *Id.* For more see *Ash*, The Nortox v. Monsanto Case on Compulsory Licensing.
503 *Id.*
504 See *Barbosa*, Notes on the Monsanto Compulsory License of 1983.
505 *Id.*
506 Article 68 of Law 9279/1996.

https://doi.org/10.5771/9783845259828-67 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

plete use of a patented process,[507] c) insufficient commercialization,[508] d) dependence of one patent on another[509] and e) national emergency or public interest.[510]

2.1) Abuse of Economic Power and Lack of Local Exploitation

2.1.1) Abusive Exercise of Rights or Abuse of Economic Power

Compulsory licenses based on abuse of economic power were introduced into Brazilian legislation by Law 8884/1994, which regulated the competitive practices of private companies in Brazil. Law 8884/1994 was revoked by Law 12529/2011, which currently establishes the framework of Competition Law in the country. The Conselho Administrativo de Defesa Econômica (CADE), the government institution responsible for controlling the competitive practices of private companies in the marketplace, can impose punitive measures to parties violating laws relating to competition. Article 38, IV(a) of Law 12529/2011 foresees the granting of compulsory licenses of patents as a possible statutory sanction against acts characterized as anti-competitive and deemed to be grave or affecting the public interest. When violation of competition law is verified, the CADE would make a recommendation to the INPI that a license be compulsorily granted, provided that the decision issued by the CADE regarding anti-competitive practices by a patentee is not subject to an appeal within that institution or to a pending lawsuit before courts.

After consultation requested by the Ministry of Health,[511] the CADE issued a legal opinion on March 31, 1999, regarding the sort of conduct that would be characterized as anti-competitive and would justify the granting of compulsory licenses.[512] The Ministry of Health wanted clarification on the type of activities that would be considered infringement of competition

507 Article 68, paragraph 1, I of Law 9279/1996.
508 Article 68, paragraph 1, II of Law 9279/1996.
509 Article 70 of Law 9279/1996.
510 Article 71 of Law 9279/1996.
511 See Consulta Prévia 031/1999, in *Dias*, Compulsory Licenses of Patents and the Antitrust Law, p. 6-7.
512 Even though the CADE's legal opinion was written under the revoked Law 8884/1994, the concepts underlying this understanding are fully applicable, since Law 12529/2011 has not modified the contents of the relevant provisions.

https://doi.org/10.5771/9783845259828-67 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

law by companies that act in markets dealing with essential products such as medicine.[513]

The CADE understood that compulsory licenses as a sanction would be granted when nexus between the use of the patent and the activity violating the competition law were verified.[514] Article 36 of Law 12529/2011 describes the situations that consist in anti-competitive practices.[515] In or-

513 *Id*.

514 See *Dias*, Compulsory Licenses of Patents and the Antitrust Law, p. 6-7.

515 "Article 36 Law 12529/2011. Acts manifested in any form consist in anti-competitive practices, independent of guilt, if they have as scope or may produce the following effects, even if not achieved: (i) to limit, distort or in any form harm free competition or free access to market; (ii) to dominate a relevant market of goods or services; (iii) to arbitrarily increase the profits; (iv) to abuse a dominant position. Paragraph 1. Domination of a market resulting from a natural process by the most efficient economic agent in relation to its competitors does not characterize the offense provided for in section II.
Paragraph 2. The dominant position is presumed whenever a company or group of companies is capable of unilaterally or coordinately alter the market conditions or when it controls 20% (twenty percent) or more of the relevant market, being this percentage changeable by the CADE for specific sectors of the economy.
Paragraph 3. The following acts, among others, as they configure the hypothesis set forth in the caput of this article and its sections, characterize anti-competitive practices: (i) to accord, combine, manipulate or adjust with competitors, under any form: a) the price of goods or services individually offered; b) the production or commercialization of a restricted or limited quantity of goods or the provision of services in a restricted or limited number, volume or frequency; c) the division in parts or segments of a current or potential market of goods or services, by, among other, the distribution of clients, suppliers, regions or periods; d) prices, conditions, advantages or abstention in public competitions; (ii) to obtain or influence the adoption of uniform business practices or concerted action by competitors; (iii) to limit or prevent access for new companies into the market; (iv) to create difficulties for the establishment, operation or development of a competitor company or supplier, purchaser or financier of goods or services; (v) to prevent competitor from accessing inputs, raw materials, equipment or technology and distribution channels; (vi) to require or grant exclusivity for the dissemination of advertising in mass media; (vii) to use deceitful means to cause price oscillation of third parties; (viii) to regulate markets of goods or services by establishing agreements to limit or control research and technological development, the production of goods or services, or to dampen investments for the production of goods or services or their distribution; (ix) to impose on trade of goods or services, distributors, retailers and representatives, wholesale price, discounts, payment terms, minimum or maximum quantities, profit margins or any other marketing conditions related to their business with third parties; (x) to discriminate against purchasers or suppliers of goods or services by establishing different

https://doi.org/10.5771/9783845259828-67 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

der to be sanctioned with a compulsory license under Article 38, IV(a) of Law 12529/2011, the patentee must have incurred one of the hypothesis described in Article 36 which is regarded in the concrete case as grave or that affects the public interest. All the cases which are an infringement of competition law are regarded as affecting the public interest.[516] Furthermore, market power will be considered abusive for this purpose when it derives directly from the exercise of patent rights.[517] This would be the case, for instance, of pricing patented products much higher than the sum of the costs of production, research investments and a reasonable margin for profit, and could amount to abusive use of patent rights in violation of Article 36, paragraph 3, XIX of Law 12529/2011.[518]

---

prices, or operating conditions of sale or provision of services; (xi) to refuse to sell goods or provide services within the standard payment conditions for trade uses and customs; (xii) to hamper or disrupt the continuity and development of business relations indefinitely because the other party refuses to abide by unjustifiable trade or anticompetitive terms and conditions; (xiii) to destroy, discard or hoard raw materials, intermediate or finished goods, as well as destroy, disable or impair the operation of equipment to produce, distribute or transport them; (xiv) to take possession or prevent the exploitation of industrial property, intellectual or technology rights; (xv) to sell goods or provide services for unjustly below the price of cost; (xvi) to retain production or consume goods, except for guaranteeing the coverage of production expenses; (xvii) to interrupt totally or partially the company activities without proven good cause; (xviii) to condition the sale of an good to the acquisition of another or the use of a service, or to condition the provision of a service to the use of another or to the acquisition of a good; (xix) to abusively exceed or explore the industrial or intellectual property rights or technology or copyright.

516 *Id.*

517 *Id.*

518 For more see *Barbosa*, Compulsory Licenses: Abuse, National Emergency and Public Interest, p. 3-22.
"Article 21. The following acts, among others, will be deemed a violation of the economic order, to the extent applicable under article 20 and items thereof: XXIV – to impose abusive prices, or unreasonably increase the price of a product or service.
Sole Paragraph. For the purpose of characterizing an imposition of abusive prices or unreasonable increase of prices, the following items shall be considered, with due regard for other relevant economic or market circumstances: I – the price of a product or service, or any increase therein, vis-à-vis any changes in the cost of their respective input or with quality improvements; II – the price of a product previously manufactured, as compared to its market replacement without substantial changes; III – the price for a similar product or service, or any improvement thereof, on like competitive markets; and IV – the existence of agreements

https://doi.org/10.5771/9783845259828-67 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

The INPI would then act in complement based on Article 68 of Law 9279/1996, which states that "a patentee will be subject to have his patent compulsorily licensed if the rights resulting therefrom are exercised in an abusive manner or by means of the patent rights he practices abuse of economic power that is proven under the terms of the law by an administrative or court decision." It must be noted that the Article 68 does not provide for a case of compulsory licenses granted *ex officio*.[519] The procedure included in Article 73, paragraph 2 of Law 9279/1996 must be applied,[520] and a third party should apply for the license before the INPI by presenting documentary proof of the patent holder's abusive conduct (resulting from abuse of patent rights or of economic power).

According to the CADE legal opinion, after it recommends granting of a compulsory license as a sanction, the INPI would have to publish such recommendation and offer licenses to third parties in order to impose the sanction as foreseen in Article 68 of Law 9279/1996.[521] Third parties would then file for an application of license in accordance with their particular interests. This would be a reasonable way to balance the application of both laws (Law 12529/2011, which imposes compulsory licenses as a sanction for anti-competitive practices by patent holders, and Law 9279/1996 which does not foresee the exercise of patent rights in abuse of economic power as a ground for granting compulsory licenses *ex officio*) and would maintain respect for the principle of legality to which every entity of public administration is bound.[522]

Moreover, in the case that a compulsory license has been granted due to abuse of economic power, Article 68, paragraph 3 of Law 9279/1996 establishes that to the licensee proposing to locally manufacture the product in question will be given up to one year to continue importation of the licensed subject matter provided it has been placed in the foreign market directly by the patentee or with consent. This presumes that importation is

---

or arrangements in any way, which cause an increase in the prices of a product or service, or in their respective costs".

519 *Id.*

520 The compulsory license procedure of Article 73 will be discussed further on in this chapter.

521 See Consulta Prévia 031/1999, in *Dias*, Compulsory Licenses of Patents and the Antitrust Law, p. 6-7.

522 See *Dias*, Compulsory Licenses of Patents and the Antitrust Law, p. 7.

https://doi.org/10.5771/9783845259828-67 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

necessary while the licensee makes the preparations for local production.[523]

Under competition law perspectives, Articles 8.2, 31(k) and 40 of TRIPS allow Member States to adopt adequate measures to restrict the rights of patent holders whenever a judicial or administrative decision determines existence of abusive use of IP rights with adverse effects on competition. Compulsory license granted under these provisions is an available tool to limit abusive conduct of patent holders, assuring a balanced and efficient patent system without creating unnecessary social costs such as price increases. In the pharmaceutical sector, patents have the potential to bring an undertaking into a dominant position and limiting abusive conducts is in conformity with TRIPS standards. Although it is seen as a measure which could be useful for reducing the price of medications, compulsory licenses based on abuse of economic power have never been granted, either for pharmaceutical patents or for other products.[524]

2.1.2) Insufficient or Non-Exploitation in Brazilian Territory

Article 68, paragraph 1 of Law 9279/1996 establishes the conditions that may also serve as grounds for a compulsory license, as follows: a) non-exploitation of the patented subject matter in Brazilian territory due to lack of or incomplete manufacturing of the product or, furthermore, due to incomplete use of a patented process (except in the case of non-exploitation due to lack of economic viability, when importation is admitted)[525] or b) commercialization that does not meet the needs of the market.[526] However, compulsory licenses will not be granted if the patentee justifies non-use for legitimate reasons,[527] proves that serious and effective preparations for exploitation have been carried out,[528] or justifies the lack of manufacture or commercialization due to legal obstacles.[529]

---

523 See *Dannemann*, Commentaries on the Industrial Property Law, p. 139.
524 See *Curzel*, Access to Medicines: the Brazilian Case, p. 43.
525 Article 68, paragraph 1, I of Law 9279/1996.
526 Article 68, paragraph 1, II of Law 9279/1996.
527 Article 69, I of Law 9279/1996.
528 Article 69, II of Law 9279/1996.
529 Article 69, III of Law 9279/1996.

https://doi.org/10.5771/9783845259828-67 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

Despite regular manufacturing of a patented product or making use of a patented process in the country, patent holders will continue to be subject to compulsory licensing when commercialization is deemed insufficient, as per Article 68, paragraph 1, II of Law 9279/1996. It is important to note that patent holders who completely manufacture a patented product or use a patented process in the national territory may import the product in order to meet the needs of the market and, thus, avoid licensing granted under this provision.

In the situations outlined in Article 68, paragraph 1 (lack of or incomplete manufacture of a patented product, incomplete use of a patented process, or insufficient commercialization), if based on lack of local exploitation of a patent, the interested third party may apply for a compulsory license only after three years from the date the patent was granted (paragraph 5, Article 68 of Law 9279/1996).[530]

One example is the request for compulsory license that was filed for patent PI 8704197-9, covering a process of vacuum packing owned by Interprise-Brussels.[531] The company Vacuum Pack Services Limited requested compulsory license of this patent based on lack of use of the patent, as per the notification published in the Industrial Property Gazette N. 1460, of December 29, 1998. There are no reports of a decision granting or not the license and patent PI 8704197-9 expired on August 13, 2002.

2.1.2.1) Analysis under TRIPS

Article 27.1 of TRIPS reads that "patents shall be available and *patent rights enjoyable without discrimination* as to the place of invention, the field of technology and *whether products are imported* or locally produced." The Agreement establishes that rights should be enjoyed without distinction towards a product's place of manufacture.

In the panel instated by the European Communities against Canada, the WTO Dispute Settlement Body determined that the word discriminate relates to the "results of the unjustified imposition of differentially disadvan-

530 The compulsory license procedure of Article 73 will be discussed further on in this chapter.

531 See *INPI*, Patent PI 8704197-9.

https://doi.org/10.5771/9783845259628-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

tageous treatment."[532] In addition, the panel found that Article 27.1 of TRIPS prohibits discrimination regarding the enjoyment of patent rights in absolute terms, being applicable to the "exceptions to the exclusive rights conferred by a patent" under Article 30 of TRIPS.[533] This latter provision does not contain any suggestions for exemption from the non-discrimination principle in Article 27.1.[534]

As described above, Article 68, paragraph 1, I of Law 9279/1996 requires that a patent be exploited within Brazilian territory under the penalty of subjection to compulsory licensing. Exploitation must be done through the complete manufacturing of the product or the complete use of a patented process, and importation is allowed only in cases that are economically non-viable. Upon reading this provision, it is clear that discrimination against importation occurs in order for patent rights to be fully exercised.

The local working requirement is justified by the Paris Convention, which establishes in Article 5A(2) the right of Member States to provide for compulsory licenses to prevent any abuse resulting from patent rights including "failure to work." Each Member State is free to define their understanding of "failure to work."[535] In this context, Article 2(1) of TRIPS establishes that the Paris Convention provisions must be complied with by Member States and, therefore, the provision of Article 5A(2) of the Paris Convention should be considered part of TRIPS.

By mandating that patented subject matter be completely manufactured or used in Brazil, the local working requirement aims to propagate transfer of technology into the country as a counter-payment for the privilege associated with granting a patent. The mere importation of patented goods would not achieve this goal. Transfer of technology as an objective can find its international foundations in Articles 7 and 8.2 of TRIPS. Article 7 of TRIPS provides that the protection and enforcement of intellectual property rights should contribute to promotion of technological innovation

---

532 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), p. 172.

533 *Id.*, p. 171.

534 This decision invalidated the argument that, under a systematic interpretation of TRIPS, the non-discrimination principle of Article 27.1 is related only to the granting of patents, and not to the maintenance – and enjoyment – of rights.

535 See *Bodenhausen*, Guide for the Paris Convention, p. 71.

https://doi.org/10.5771/9783845259828-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

and to transfer and dissemination of technology. More specifically, Article 8.2 of TRIPS states that appropriate measures should be taken by Member States to prevent abuse of intellectual property rights, which could adversely affect international transfer of technology.

Developing countries can make use of the local working requirement to promote building their industrial and technological capacity, as well as create employment and foster the general economy. Since transfer of technology is imperative for these countries, any action to hinder this objective would qualify as an abuse of patent rights. Most patents in these countries are owned by foreign companies from developed regions and mere importation could come at social costs. In this situation, non-local working should be regarded as an abuse of patent rights. Compulsory license would be a measure to prevent such an abuse, positively affecting the international transfer of technology.

As discussed previously, the former Brazilian statute (Law 5772/1971) mandated exploitation of patented subject matter within the country by patent holders under the penalty of compulsorily licensing or waiver of patent rights.[536] Through an interpretation of the old law, the INPI concluded that an invention must be used according to the description and claims, and exploitation should fall on the patented subject matter as a whole. This means that the patent holder must use all the patent claims in the country. The INPI position was also affirmed by courts.[537]

According to the wording of Article 68, paragraph 1, I of Law 9279/1996 and in light of the interpretation established under the previous law, the patent holder is obligated to manufacture the complete content of the patent, meaning each of the independent claims, within the national territory. Production, importation or distribution of most of the patented subject matter is not enough to satisfy the law and the manufacture of most of the parts of the product is also insufficient.[538] This provision puts a large burden on the patentee, but not on the licensee, who is obligated by Article 68, paragraph 2 of Law 9279/1996 to exploit the patented subject matter only in an efficient way and not to complete manufacture or make complete use of the patented product or process.[539]

536 Articles 33 and 49 of Law 5772/1971.
537 See *Levy, Licks*, The Local Working Requirement, p. 5-7.
538 *Id.*
539 *Id.*

https://doi.org/10.5771/9783845259628-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

By mandating patented subject matter to be completely manufactured or used in Brazil, the local working requirement disregards the reality of the globalized economy. Production of goods usually follows the rules of the market, which demand efficiency with minimum costs, meaning that goods are very often not completely manufactured in a single country. In this regard, the manufacture of all the elements of every independent claim of a patent would lead to an increase in costs – due to exchange rates, economy of scale or even lack of electricity.[540] The requirement of the Brazilian statute potentially jeopardizes not only the producer/patentee, but also the final consumer who will need to pay higher prices to cover higher costs.

It is important to remember that TRIPS is only a part of the WTO system, and the expansion of international trade and optimization of global resources is one of its main principles.[541] Accordingly, the WTO Agreement and its annexes (TRIPS being Annex 1C) should be understood as a harmonious and indivisible group of principles and rules; TRIPS integrates intellectual property into the rules related to free trade of goods and services.[542] Article 27.1 of TRIPS should be interpreted together with Article III, paragraph 4 of GATT 1994, which determines that imported goods should receive the same treatment as locally produced goods.[543] In consonance, the application of Article 5A(2) of the Paris Convention – giving freedom to countries to define "failure to work" when regulating compulsory licenses – is limited by Article 27.1 of TRIPS and Article III paragraph 4 of GATT 1994. Imported goods should not receive discriminatory treatment relative to locally manufactured goods; hence, the grounds for granting compulsory licenses are restricted.[544] Mandating that patented subject matter be completely manufactured or used in Brazil goes against the spirit of free trade under the WTO system and, worse, may be impossible to put into practice and may be an insurmountable obstacle for patent holders.

---

540 *Id.*

541 See *WTO*, Principles of the Trading System, para. 1-2.

542 See *Carvalho*, Controversial Issues in the Patent Field, p. 92.

543 *Id.*

544 See *Gervais*, The TRIPS Agreement: Drafting History and Analysis, p. 148; *Blakeney*, TRIPS: A Concise Guide, p. 90-91; and *Otten, Wager*, Compliance with TRIPS, p. 401.

https://doi.org/10.5771/9783845259828-67 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

Therefore, in order to reconcile Article 68, paragraph 1 of Law 9269/1996 with the logic of TRIPS and world free trade, specificity of the technology involved and Article 69 of Law 9279/1996 must be taken into account. The later provision establishes an exception to mandatory local and complete manufacturing when there is a legitimate reason. The logic of the specific business related to the patented subject matter should be considered when determining if a compulsory license should be granted or rejected. A lack of economic viability, material or technological resources for the local manufacture of a component of a patented product, for instance, may justify importation of such component.

In the case of the pharmaceutical industry, most active ingredients are manufactured and imported from China. This is not only the case for Brazil, but also many other countries. If a pharmaceutical product were required to be completely manufactured locally, it would demand that the active ingredient be manufactured locally as well. This would require infrastructure that Brazil had not been capable of building for decades even considering the prohibition of patents on pharmaceuticals. In addition, the generic industry would also be required to manufacture the active ingredient. Allowing importation would certainly harm the principles underlying the use of compulsory licenses.

2.1.2.2) The Panel filed by the USA before the WTO

On May 30, 2000, according to Article 4 of the WTO Understanding on Rules and Procedures Governing the Settlement of Disputes and Article 64 of TRIPS, the USA requested consultations with Brazil about the local working requirement. Enjoying exclusive patent rights could only be satisfied by local production, not importation, of patented subject matter.[545] According to their understanding, by stipulating that a patent is subject to compulsory licensing if not "worked" in the territory of Brazil, the local working requirement is inconsistent with Articles 27 and 28 of TRIPS and Article III of the GATT 1994.[546] The Brazilian law would be discriminatory when not recognizing importation as one of the ways to exploit

545 See *Brazil – Measures Affecting Patent Protection.* Request for Consultations by the United States, June 8, 2000 (WT/DS199/1), p. 1.

546 *Id.*

https://doi.org/10.5771/9783845259828-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

patented subject matter and the granting of compulsory licenses would violate the exclusive rights of patent holders.

According to the Brazilian government, the granting of compulsory licenses as foreseen in the patent statute is in accordance with the conditions established by Article 31 of TRIPS for the use of a patent without the authorization of the patent holder.[547] In addition, Article 5(A) of the Paris Convention would admit the possibility of granting compulsory licenses based on the lack of exploitation of the patent and each country would be allowed to define its own understanding of failure to work.[548] US law also includes a type of "local working" requirement, according to which patented inventions developed with the use of public money must be exploited in United States territory.[549]

Because no mutual understanding between the two parties was reached, on January 8, 2001, the USA requested the establishment of a panel before the WTO Dispute Settlement Body.[550] In response, the Brazilian government started a campaign affirming that the US complaint at the WTO would jeopardize the Brazilian anti-HIV/AIDS program, which was considered the best in the world by the United Nations and the World Bank.[551] Brazil's strategy was to establish its moral high ground and gather the support of the NGOs such as the Médecins sans Frontière and Oxfam.[552] For the first time the Brazilian government mobilized public opinion in developed countries by publishing articles and interviews in The New York Times, Washington Post and on CNN.[553]

On July 5, 2001, the dispute came to an end, when both the US and Brazil filed a notification before the Dispute Settlement Body informing that the two governments had reached a mutually satisfactory solution to the matter.[554] The US agreed to withdraw the WTO panel if the Brazilian government committed itself to holding prior talks with the US govern-

---

547 See *Basso et al.*, The Brazilian Patent Statute and the WTO Rules, p. 37-40.
548 See *Scholze*, Local Manufacture, Compulsory Licenses and Parallel Importation in the Industrial Property Law, p. 10.
549 See *Curzel*, Access to Medicines: the Brazilian Case, p. 42.
550 See *Brazil – Measures Affecting Patent Protection.* Request for Establishment of a Panel by the United States, January 9, 2001 (WT/DS199/3).
551 See *Cepaluni*, Patent Regime: Brazil x USA, p. 67-69.
552 *Id.*
553 *Id.*
554 See *Brazil – Measures Affecting Patent Protection.* Notification of Mutually Agreed Solution, January 9, 2001 (WT/DS199/4), p. 1.

https://doi.org/10.5771/9783845259828-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

ment before applying Article 68 to grant compulsory licenses for patents held by US companies.[555] No decision from the WTO Dispute Settlement Body on the interpretation of the local working requirement had been rendered.

2.1.3) Economic Capacity of the Licensee and the Importation Exception

In order to be entitled to a compulsory license based on the grounds mentioned above (exercise of patent rights in an abusive manner or abuse of economic power, non-exploitation in the Brazilian territory, by lack of or incomplete manufacture of the product, lack of use of a patented process, and insufficient commercialization) the licensee must have legitimate interests and the technical and economic capacity to carry out efficient exploitation of patented subject matter.[556] Such exploitation should be predominantly for the internal market.

This requirement aims to ensure that licensing results in an effective use of the patent. For this purpose, the licensee does not need to possess the complete technical and economic capacity to exploit the whole invention; it is possible to sub-license to third parties who could supply the licensee with necessary goods and services.[557] As already mentioned, the law does not require that the licensee manufacture or use the patented subject matter completely in Brazil. It only requires that its exploitation be performed efficiently.

In this context, it is important to remember that as a condition to the licensee, Article 74 paragraph 3 of Law 9279/1996 establishes that assignments of compulsory licenses are only allowed together with transfer or leasing of the associated part of the undertaking, since the characteristics of the undertaking (the technical and economic capacity) were decisive for granting the compulsory license.

Even in the case that a compulsory license is granted as a sanction for the abuse of economic power, the licensee must satisfy the requirement of technical and economic capacity. The aim of the license is to make use of

555 *Id.*
556 Article 68, paragraph 2 of Law 9279/1996.
557 See *Barbosa*, An Introduction to Intellectual Property, p. 522.

https://doi.org/10.5771/9783845259828-67 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

the patent in an adequate manner, be it to supply market demand or to maintain competition in the market.[558]

Importation by third parties of goods manufactured according to patented processes or products is allowed by Article 68, paragraph 4 of Law 9279/1996, provided that the goods have been placed in the market directly by the patentee or with consent. This provision allows for parallel importation as an exception to the rights conferred to patent holders in Article 42 of Law 9279/1996,[559] when exploitation occurs through importation by the patentee (when the local manufacture of the product or complete use of the patented process is not economic viable, as per Article 68, paragraph 1, I of Law 9279/1996) or by the licensee (of a compulsorily license that is granted based on the abuse of economic power while assuming that preparations for local manufacture of the goods are being made, as per Article 68, paragraph 3).

2.2) Dependent Patents

According to Article 70 of Law 9279/1996, the exploitation of a patent may require the use of a part or all of a subject matter already claimed in a previous patent belonging to third parties, creating a dependent relationship.[560] Dependency occurs when the use or exploitation of the second patent can occur only by infringing on the claims of the first.[561] In this case, the owner of the first patent may be obligated to allow the second patent to be exploited upon payment of royalties, which are arbitrated by the INPI. The owner of the dependent patent must file an application under Article 73 before the INPI.[562]

License will be granted when cumulatively a) one patent is dependent on another, b) the subject matter of the dependent patent constitutes a substantial technical advance in relation to the earlier patent, and c) the first

558 See *Dias*, Compulsory Licenses of Patents and the Antitrust Law, p. 7-8.
559 See *Dannemann*, Commentaries on the Industrial Property Law, p. 139-140.
560 Article 70, paragraph 1 of Law 9279/1996.
561 See *Dannemann*, Commentaries on the Industrial Property Law, p 143.
562 The compulsory license procedure of Article 73 will be discussed further on in this chapter.

https://doi.org/10.5771/9783845259828-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

patentee does not come to an agreement with the owner of the dependent patent for the exploitation of the first patent.[563]

The notion of "substantial technical advance" should not be reduced to the analysis of inventive step.[564] Inventiveness is required for granting a patent, but at this stage there should be an evaluation of public needs that could be satisfied by the dependent technology.[565] "Substantial" should not be interpreted as revolutionary, but rather as of relevance, which in turn should be assessed following needs of society.

For the purposes of the law, the dependent relationship may also occur in the case of a process patent for the respective product, or in the case of a product patent for a previous process patent.[566] Furthermore, as per Article 70, paragraph 3, the owner of the patent licensed under this provision is also entitled to a compulsory cross license. There has yet to be any compulsory license granted in Brazil on these grounds.

2.3) Procedural Aspects

Granting compulsory licenses based on the above mentioned grounds (exercise of patent rights in an abusive manner or abuse of economic power, non-exploitation in the Brazilian territory, by lack of or incomplete manufacture of the product, lack of use of a patented process, insufficient commercialization and the dependency of one patent upon another) is subject to the procedural rules established in Article 73 of Law 9279/1996, requiring administrative judgment by the INPI. The INPI cannot grant *ex officio* compulsory licenses and due process must be respected, especially in light of its character as an exception to rights.

Accordingly, an interested (private) party must file an application for a compulsory license indicating the conditions offered to the patentee,[567] who will be notified to respond within sixty days, at the end of which the proposal will be considered as accepted in the absence of manifestation by the patent holder.[568] As mentioned earlier, the allegation of abuse of patent

563 Article 70, I, II and III of Law 9279/1996.
564 See *Barbosa*, An Introduction to Intellectual Property, p. 548.
565 *Id.*
566 Article 70, paragraph 2 of Law 9279/1996.
567 Article 73 of Law 9279/1996.
568 Article 73, paragraph 1 of Law 9279/1996.

https://doi.org/10.5771/9783845259828-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

rights or abuse of economic power must be proven and documented by the applicant for a license on these grounds.[569] In case of insufficient exploitation, the burden of proof lies on the patent holder.[570]

If a patent holder contests, the INPI may take the necessary steps, including the establishment of a committee (which may include specialists that are not part of the INPI) aimed at arbitrating the remuneration that will be paid to the patent holder.[571] Public administration entities will assist the INPI in arbitrating the remuneration by providing all necessary information requested.[572] In arbitrating remuneration, the circumstances of each case will be considered and the economic value of the license granted must be taken into account.[573] Once provided with the necessary information, within sixty days the INPI will come to a decision regarding the approval and the conditions of the compulsory license.[574] Appeals from decisions granting compulsory licenses may be filed to the President of the INPI and will not suspend the effects of the first decision.[575] That is to say that the license will already produce legal effects. As any decision within public administration, the decision on approval or denial of compulsory licenses is subject to judicial review.

2.4) Cases of National Emergency or Public Interest

In the case of national emergency or public interest, the Brazilian government may grant compulsory licenses for the exploitation of a patent insofar as the patentee or the licensee cannot meet the needs raised during such a situation, based on Article 71 of Law 9279/1996. This provision embodies Article 31 of TRIPS, which provides the standards to be implemented by WTO Member States when regulating the use of patented subject matter without the authorization of the patent holder.[576] Unlike the cases of abuse of economic power or insufficient use of patented subject matter, where licenses are justified as sanctions to correct abuse or benefit the

569 Article 73, paragraph 2 of Law 9279/1996.
570 Article 73, paragraph 3 of Law 9279/1996.
571 Article 73, paragraph 4 of Law 9279/1996.
572 Article 73, paragraph 5 of Law 9279/1996.
573 Article 73, paragraph 6 of Law 9279/1996.
574 Article 73, paragraph 7 of Law 9279/1996.
575 Article 73, paragraph 8 of Law 9279/1996.
576 See *Dannemann*, Commentaries on the Industrial Property Law, p. 146.

https://doi.org/10.5771/9783845259828-67 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

market (needed goods or transfer of technology by local production), in this case justification is the mere predominance of public need over private interests.[577]

National emergency and public interest must be declared by the Executive Branch of government. The license granted is non-exclusive and temporary and will not jeopardize other normal rights held by the respective patentee. Sole paragraph of Article 71 of Law 9279/1996 further establishes that the act granting the license will establish its term of validity and the possibility of extension. Unlike the other possibilities for granting compulsory licenses, the government may grant it *ex officio*, i.e. without an interested party applying for it under Article 73 of Law 9279/1996. Article 71 of Law 9279/1996 is further regulated through Decree 3201/1999 enacted by the President on December 22, 1999, and amended by Decree 4830/2003.

It is important to note that granting compulsory licenses under Article 71 of Law 9279/1996 is a power given to public administrators. Once circumstances characterized as national emergency or public interest have emerged, the Minister charged with this power is not obligated to grant a license.[578] This issue stands as a policy judgment, with space for discretionary action by representatives of government.[579] The convenience and opportunity of the act of granting a license is not subject to judicial review, which is only possible in case of abuse or failure to accomplish procedural rules.

Nevertheless, Article 71 clearly states that the power of granting a compulsory license cannot be used if the patentee or the licensee are able to meet the demands generated by the emergency or public interest.[580] Consequently, the patent holder must be given the right of defense, a principle established in Article 5, LIV of the Federal Constitution, taking into account the specific emergency and situation that may justify a postponed exercise of this right.[581]

---

577 See *Barbosa*, Compulsory Licenses: Abuse, National Emergency and Public Interest, p. 15.
578 See *Curzel*, Access to Medicines: the Brazilian Case, p. 37.
579 See *Scudeler*, Compulsory Licenses for Lack of Local Exploitation, p. 8.
580 See *Barbosa*, Compulsory Licenses: Abuse, National Emergency and Public Interest, p. 16.
581 *Id.*

https://doi.org/10.5771/9783845259828-67 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

Decree 3201/1999 that regulates the law allows compulsory licenses for cases of national emergency or public interest and covers all kinds of patents, including pharmaceuticals. It defines national emergency as imminent public danger, even if it occurs in one part of the territory.[582] This short definition does not give examples of cases which would be considered national emergencies. Facts of public interest are, among others, related to the public health, nutrition, defense of the environment, as well as those of significant importance to technological and socioeconomic development.[583] These hypothetical situations are only exemplary and others might be found regarding the notion of public utility, as foreseen in DL 3365/1941 regulating the expropriation of private property.[584]

It is clear in Decree 3201/1999 that compulsory licenses based on public interest cannot lead to commercial use of the licensed patent and they are restricted to only non-commercial public uses. According to the wording of Articles 1 and 2 of Decree 3201/1999, this limitation does not apply in cases of national emergency. As per Article 3 of Decree 3201/1999, national emergency or public interest cases will be declared by an act from the Minister responsible for the subject matter in question and is to be published in the Official Gazette. Once it has been verified that the patentee or the licensee are unable to address the situation of national emergency or public interest, as per Article 71 of Law 9279/1996, the public administration will grant ex officio the compulsory license of non-exclusive character, and the act shall be immediately published in the Official Gazette.[585] *Ex officio* granting does not originate from the INPI, but rather from the respective ministry. The INPI will be responsible only for recording such licenses, as well as amendments and termination.[586]

Among other stipulations, the act granting the compulsory license will specify the term of validity of the license, the possibility for extension,[587] and the conditions offered by the government, i.e. remuneration for the

---

582 Article 2, paragraph 1 of Decree 3201/1999.
583 Article 2, paragraph 2 of Decree 3201/1999.
584 Article 5 of DL 3365/1941 foresees the cases of public utility justifying the expropriation of private property, such as national security, defense of the State, public help in case of calamity, public salubrity, among several others. See *Barbosa*, Compulsory Licenses: Abuse, National Emergency and Public Interest, p. 15-16.
585 Article 4 of Decree 3201/1999.
586 Article 13 of Decree 3201/1999.
587 Article 5, I of Decree 3201/1999.

https://doi.org/10.5771/9783845259828-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

patent.[588] It may also establish the obligation of the patentee to give information that is necessary and sufficient to effectively reproduce the protected subject matter, as well as other technical features applicable to the case in question.[589] The enablement requirement of Article 24 of Law 9279/1996 should be taken into consideration, according to which the specification of the patent must describe the subject matter clearly and sufficiently so as to enable a person skilled in the art to carry it out and indicate, when applicable, the best mode of execution. The patent holder's obligation to give information about other technical features might be considered compulsory licensing of know-how, which could be deemed as abusive.[590]

The relevant economic and market circumstances, the price of similar products and the economic value of the authorization will all be considered when determining the remuneration to be paid to the patent holder.[591] The respective authority may request the necessary information for other public administration entities in order to substantiate the granting of the license or to determine the suitable remuneration.[592] In cases of national emergency or public interest that are characterized by extreme urgency, a compulsory license may be implemented, and the use of the patent subject matter may be effectively exploited regardless of previous compliance with the conditions established in Articles 4 and 5 of Decree 3201/1999 (publication of the act in the Official Gazette as well as the stipulation on the conditions of the license).[593]

The Decree clearly determines that the patent holder's agreement with the conditions of the license is not a prerequisite for beginning the exploitation of a patent licensed on such grounds.[594] Exploitation may be carried out either directly by the government or by duly hired third parties.[595] The use of the patent for other purposes is deemed illegal and hired third parties must also respect principles that regulate public administra-

588 Article 5, II of Decree 3201/1999.
589 Article 5, paragraph 1 of Decree 3201/1999.
590 See *Dannemann*, Commentaries on the Industrial Property Law, p. 146.
591 Article 5, paragraph 2 of Decree 3201/1999.
592 Article 6 of Decree 3201/1999.
593 Article 7 of Decree 3201/1999.
594 Article 8 of Decree 3201/1999.
595 Article 9 of Decree 3201/1999.

https://doi.org/10.5771/9783845259828-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

tion activities, as foreseen in Article 37 of the Federal Constitution, including the principle of legality, publicity and efficiency.[596]

In cases where it is not possible to address situations of national emergency or public interest with a product placed in the internal market, or if manufacturing patented subject matter by a third party or by the government is not viable, importation of the patented product is allowed.[597] Preference should be given to the acquisition of products which have been placed in the market directly by patent holders or with their consent, whenever this procedure does not hinder the purposes of the license.[598] Once the national emergency or public interest conditions have been addressed, the respective compulsory licenses should terminate, respecting the terms of the contract executed with the licensee.[599]

Granting compulsory licenses based on public interest will be discussed in further detail in the following chapter analyzing actual cases in which the Brazilian government made use of this instrument.

596 Article 9, sole paragraph of Decree 3201/1999.
597 Article 10 of Decree 3201/1999.
598 Article 10, sole paragraph of Decree 3201/1999.
599 Article 12 of Decree 3201/1999.

https://doi.org/10.5771/9783845259828-87 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -

https://doi.org/10.5771/9783845259828-67 - am 20.01.2026, 13:56:19. https://www.inlibra.com/de/agb - Open Access -