



Chile: Plants and Pharmaceutical Patents

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CHILE

PLANTS AND PHARMACEUTICAL PATENTS

Law on Industrial Property

The Law governing patents in Chile is Law No. 19,039,¹ regulated by Decree No. 177.² Chile is also a party to the Paris Convention³ on the protection of industrial property and the TRIPS Convention on the Protection of Intellectual Property.⁴ This is the legal framework applicable to pharmaceutical patents.

The principal provisions of the law are that, as a general rule, everything new and useful as well as the methods for producing the same can be patented.⁵ The maximum term of a patent is 15 years.⁶ Foreign patents can be patented as well as improvements on already granted patents.⁷ The patent applications, not the granting of a patent, are published. Applications are open to public inspection and can be opposed within 60 working days after publication.⁸ Marking consisting of the number of patent and date of the grant is mandatory.⁹ Infringement of patent rights is considered a criminal offense.¹⁰ Granted patents are subject to compulsory licensing in certain cases and to cancellation proceedings.¹¹ All decisions by the Patent Office are subject to appeal

¹ Law No. 19,039 on Patents, Jan. 25, 1991, Diario Oficial (D.O.)

² Decree No. 177 of Sept. 30, 1991, D.O., Sept. 30, 1991.

³ Paris Convention for the Protection of Industrial Property of Mar. 20, 1883, as amended in D.O. Sept. 30, 1991.

⁴ TRIPS Trade Related Aspects of Intellectual Property Rights, at http://www.wto.org/english/docs_e/legal_e/27trips.pdf

⁵ *Supra* note 1, art. 32.

⁶ *Supra* note 1 art. 39.

⁷ *Supra* note 1 art. 46.

⁸ *Supra* note 2 arts. 71-73.

⁹ *Supra* note 1 art. 53.

¹⁰ *Supra* note 1, art. 52.

¹¹ *Supra* note 1, art. 50.

before a special arbitration court.¹²

Patents can be divided into regular patents, patents of confirmation, *i.e.*, the granting of patents on inventions already patented in other countries, and patents on improvements of already granted domestic patents.

Subject Matter

Inventions are subject to patentability when they:¹³

- are new and are not anticipated by the prior state of the art, the latter being everything disclosed to the public, anywhere in the world, by publication in a tangible form, by sale or marketing, by use or by any other means, before the filing date of the patent application. The state of the art also includes the contents of a patent application in process with a filing date prior to that of the application being examined.
- are inventive, so that for a person with average knowledge of the relevant technical matter, it does not appear as obvious or as an evident result of the state of the art.
- are susceptible of industrial use or application, that is, can be produced or used in any kind of economic activity. Pharmaceutical products or compounds can be patented *per se*, limited to those with corresponding foreign applications that were filed after the law became effective.

Non-patentable

Discoveries, scientific theories, and mathematical methods as well as plant varieties and animal breeds are not subject to patent.¹⁴ However, new plant varieties may be protected under the provisions of Decree-Law No. 19,342/1994.¹⁵ Chile is also a signatory of the UPOV Convention.¹⁶

Duration

Patents can be granted for 15 years from date of issuance, but the protection is retroactive to the filing date of the application.¹⁷ Confirmation patents may be

¹² *Supra* note 1 art. 17.

¹³ *Supra* note 1, arts. 33-36.

¹⁴ *Supra* note 1, art. 37.

¹⁵ Decree-Law No. 19,342 on the Protection of New Plant Varieties, Oct. 17, 1994, D.O. Nov. 3, 1994.

¹⁶ International Convention for the Protection of New Varieties of Plants, Dec. 2, 1961, as revised at [<http://www.upov.int/eng/convtns/1991/content.htm>]

¹⁷ *Supra* note 2, art. 56.

granted for only the maximum term of the first patent issued in any country provided it does not exceed 15 years.¹⁸ Patents on improvements can be granted for only the same term as the original patent which is improved.¹⁹

Applicant

The applicant may be an individual, a company, or an entity. Foreign applicants have the same status as Chilean applicants, but have a priority of one year to file in Chile if an application has been previously filed abroad.²⁰ A patent can belong to two or more owners. Furthermore, a patent may belong to one and its improvement to another.

Prior Use

If there has been prior use of any invention in Chile or abroad, any interested party can oppose the application or file suit for cancellation of the granted patent.²¹

Priority

Chile is a member to the Paris Convention and priority rights may be claimed. The patent law grants a priority of one year to foreign inventors to file applications in Chile.²²

Compulsory License

Compulsory licenses are provided only in cases of monopolistic abuse determined by the Antitrust Board.²³

Reinstating

Patent applications not prosecuted and left inactive for the term established under the law are considered abandoned. These may be reinstated within 120 days.

Marking

Patented objects or articles must be marked with the number of the patent, preceded by "Patente de Invencion" either in the product itself or in its packaging or wrapping. The exceptions are methods, which cannot be marked. Failure to comply with this provision

¹⁸ *Supra* note 1, art. 39, ¶ 2.

¹⁹ *Supra* note 1, art. 41.

²⁰ *Supra* note 1, art. 34.

²¹ *Supra* note 1, art. 5.

²² *Id.* 20.

²³ *Supra* note 1, art. 51.

deprives the owner of the patent or the right to pursue infringements of the patents.²⁴

Opposition

Patent applications may be opposed within 60 days of the publication by persons who have similar patents or who are manufacturing or using similar objects or methods.²⁵

Infringement

The infringement of a patent is a criminal offense subject to a fine of US\$3,800 to US\$19,000. The owner of a patent is enabled to seize and hold all objects or articles that have been manufactured as a result of the infringement. This seizure may be ordered by the judge as soon as the legal action is instituted.²⁶

Nullity

Patents may be declared null and void when:²⁷

- the patent has been granted on behalf of someone who is neither its owner nor its assignee
- the granting of the patent has been based on obviously deficient or mistaken reports of the examiners
- the granted patent infringes on the rules of patentability established by the law.

The term for filing a cancellation action is 10 years from the grant of the patent.

Procedure²⁸

The patent application must be filed on a form supplied by the Patent Office, containing the full name, address, and occupation of the applicant and of the inventor, if different. The completed form must be accompanied by (in Spanish) an abstract, specifications, claims, and, if applicable, drawings.

If the invention has been patented abroad, it is necessary to submit the expiration date and number of the first patent granted anywhere in the world, or the number of the foreign application if none has been granted. If the patent application is pending abroad, the results of the search and examination undertaken by the foreign patent office must be submitted.

²⁴ *Supra* note 9.

²⁵ *Supra* note 8.

²⁶ *Supra* note 1, art. 16.

²⁷ *Supra* note 2, arts. 77-85.

²⁸ *Supra* note 2, arts. 38-58.

Patent applications are filed in the Patent Office, a section of the Department of Industrial Property, which is part of the Bureau of Industry and Commerce of the Ministry of Economy.

The Patent Office performs a preliminary examination of the application to determine whether it complies with all legal and regulatory requirements.

A report of the preliminary examination will be issued by the experts of the patent Office, pointing out the true nature of the application, establishing a preliminary technical classification, and making the relevant observations.

If the application is considered to be lacking necessary documents and/or information, the applicant will be notified the omissions and/or necessary corrections. Failure to comply within 40 days will cause the application to be considered withdrawn.

Patent applications are published once in the Official Gazette within 60 days from the decision of acceptance for processing. The publication contains the number of the application, the name of the applicant, and a brief summary written by the Patent Office on the subject matter of the application.

Oppositions to an application must be filed within 60 days from the publication date thereof. Once the term for filing oppositions has expired, the Director of the Patent Office will refer the application to the examiner who must issue a report within 120 days from acceptance of his/her commission, on whether the subject matter is new, inventive, and capable of industrial application, with comments on the abstract, specification claims, and drawings.

The interested party has 120 days to reply to the examiner's report, a term that may be extended once for up to 120 more days. The applicant has 60 days to reply to an opposition.

If there are substantial and relevant controverted facts, a term of 60 days is provided to submit evidence.

The final decision is rendered by the Director of Industrial Property. The Department is not bound by the Examiner's report, but its recommendations are usually followed. Furthermore, the Department may raise objections of a legal nature which could not be considered in the reports since these are of a technical nature.

The cancellation may be filed within 10 years of the original registration. Once the defendant has been officially notified of the cancellation, he/she has 60 days in which to reply. Once the term for filing the reply has expired, the Director will order an Examiner's report. The parties have 120 days to reply to such report.

Plant Varieties

The obtainer of a new plant may be an individual or a company, who through a

natural or genetic work, discovers such variety.²⁹ The right of the obtainer of new plant varieties includes the exclusive authority on his/her part to:³⁰

- reproduce such variety
- sale, offer, or exhibit the plant
- market, import, and export the plant
- regularly use the new variety for the commercial production of another

This right of protection is granted by a *Comite Calificador* (qualifying committee) within the Department of Agriculture and Cattle and must be registered in the Registry of Protected Varieties.³¹ This right does not prevent others from using the new variety to create another one without its owner's authorization. However, if the use is going to be permanent, it does require such authorization.³²

The right of the obtainer is tradeable and transferable.³³ The owner of the license may grant licences for its use. No limitation on the license contract is permitted.³⁴

Compulsory patents may be applied to patent owner who use its right violating anti-monopoly regulations, as in the general patent law.³⁵

The plant variety is considered new when it has not been marketed in the country or was so done without its obtainer's consent. New plant varieties are also those which have been marketed abroad with the obtainer's consent for no more than six years if it relates to forestry, fruit, or ornamental trees and vines, and four years for the other species.³⁶

Protection is granted for 18 years for trees and vines and for 15 years for all other species from the registration date of the patent. This right is preserved by paying all fees and expenses related to the registration and maintenance of the right.

²⁹ *Supra* note 14, art. 2.a).

³⁰ *Supra* note 14, art. 3.

³¹ *Id.* art. 4.

³² *Id.* art. 5.

³³ *Id.* art. 6.

³⁴ *Id.* ¶¶ 2 and 3.

³⁵ *Id.* art. 7.

³⁶ *Id.* art. 9.

Varieties whose patent protection term expires become available for public use.³⁷

When protection of a plant variety has been previously claimed abroad, the obtainer has priority for one year from its petition abroad to request such protection in Chile.

If the new variety has already been recognized abroad, the obtainer must provide evidence of such patent duly certified and translated before the competent Chilean authorities.³⁸

Procedural rules to acknowledge and grant patent rights are also provided under this law.³⁹

Termination and nullity of the patent may be declared: when the term of protection expires; upon request of its owner; or when its owner does not comply with its obligations to keep the patent effective, including payment of pertinent fees and expenses.⁴⁰ The decision of the *Comite Calificador* may be appealed before the Patent Arbitration Tribunal with competence in patent cases.⁴¹

Violations to the provisions of the law are punished with imprisonment and/or fines as well as seizure of the species involved in the violation.⁴²

Proposed Amendment to the Law on Industrial Property

Chile became a party to the TRIPS agreement in 1995 and agreed to amend its national legislation by January 2000 to comply with the provision of this international instrument.

However, such legislation, which started its legislative process in October 1999,⁴³ is still pending in Congress. The Lower House approved the amendment in June 2002, but it is now pending in the Senate.⁴⁴

The current negotiations for a bilateral Free Trade Agreement with the United States has put some pressure on the Chilean Government to approve this amendment in order to further these negotiations.⁴⁵ It was also an issue during the negotiations

³⁷ *Id.* art. 11.

³⁸ *Id.* art. 22.

³⁹ *Id.* arts. 20-36.

⁴⁰ *Id.* arts. 37 and 38.

⁴¹ *Id.* arts. 39-43.

⁴² *Id.* arts. 44-46.

⁴³ Acuerdos de la OMC: La Protección de la Propiedad Intelectual e Industrial, at <http://www.institutolibertad.cl> (Nov. 15, 2001).

⁴⁴ [Http://www.e-legislacion.cl](http://www.e-legislacion.cl) The draft of the amendment as well as legislative debates may be found in this site.

⁴⁵ Las Ultimas Piezas del Acuerdo, at <http://www.quepasa.cl> (Aug. 30, 2002).

of the trade agreement with the EU.⁴⁶

The proposed amendment in general adopts the provisions of the TRIPS agreement into the national legislation. Its most relevant innovations are:

- It abolishes the opposition of patents process, preventing others from challenging the granting of new patents which are based on old principles, second uses, and formulas already known.
- It supersedes the intention as a requirement for a patent infractor to be considered as such, which will allow the patent owner to file a law suit against someone who might not be aware of the violation.
- It reverses the burden of proof to the alleged infractor, who will need to provide the evidence to the contrary.
- It extends the patent protection from 15 to 20 years.⁴⁷

There is strong opposition to the proposed amendment from the Asociacion Industrial de Laboratorios Farmaceuticos (ASILFA, a national association of pharmaceutical laboratories) because it exceeds what Chile had agreed to when becoming a party to the TRIPS agreement, and it will create a monopoly that will prevent others from manufacturing such products, consequently, increasing its price.⁴⁸

According to a research conducted by the Centro de Investigacion Aplicada para el Desarrollo de la Empresa (CIADE) of the University of Chile, upon the request of a group of Chilean Laboratories, the proposed legislation would increase the price of prescription drugs up to 75 percent, since the new provision will affect the competitiveness of the drugs, its price, and availability to the public.⁴⁹ This study bases its conclusion in that the new law would allow only the owner of the pharmaceutical patent to market the product, as opposed to the present situation, where other alternative medicines are also sold for the same use.⁵⁰

The passage of this law was delayed due to amendments proposed by two sectors: the private sector, who tried to protect the rights of the national laboratories and consumers, and the government, who intended to improve fiscalization and regulation

⁴⁶ Ley de Propiedad Industrial deberá aprobarse este año por pacto con UE, *at* <http://www.eldiario.cl> (Aug. 2, 2002).

⁴⁷ Proyecto de Patentes de Medicamentos excede normas de la WTO, *at* <http://www.iepe.org/econoticias> (Nov. 22, 2001).

⁴⁸ El Alza que viene: Medicamentos, *at* <http://www.puntofinal.cl/513/medicamentos.htm>.

⁴⁹ Precios de los Remedios Subirá 75%, *at* <http://www.australtemuco.cl> (Nov. 20, 2001).

⁵⁰ Estudio Revela que remedios pueden subir 75% si cambia la ley de patentes, *at* <http://www.emol.com> (Nov. 20, 2001).

mechanisms. In February 2002, there was a change in the composition of Congress and therefore, a consequent change in the integration of commissions,⁵¹ which further delayed its treatment in the Lower court, who approved it in June 2002. As of November 6, it is still pending in the Senate.

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⁵¹ *Supra* note 46, at 1.