

Compulsory Licensing sections of Brazil's Patent Law
(Translated into English by the World Intellectual Property Organization)

Law No. 9.279 of May 14, 1996, to Regulate Rights and Obligations Relating to Industrial Property

Chapter II
Patentability

Section I
Patentable Inventions and Utility Models

Art. 10. The following shall not be considered inventions or utility models:

- I. discoveries, scientific theories and mathematical methods;
- II. purely abstract concepts;
- III. schemes, plans, principles or methods of a commercial, accounting, financial, educational or advertising nature or for games of chance or surveillance;
- IV. literary, architectural, artistic and scientific works or any aesthetic creation;
- V. computer programs *per se*;
- VI. presentations of information;
- VII. rules for games;
- VIII. techniques and methods for operations or surgery and methods for therapy and diagnosis practised on the human or animal body;
- IX. all or part of natural living beings and biological materials found in nature or isolated therefrom, including the genome or the germ plasm of any natural living being, and any natural biological processes.

Section III
Non-Patentable Inventions and Utility Models

Art. 18. The following shall not be patentable:

- I. anything contrary to morality, decency or public safety, order and public health;
- II. substances, materials, compounds, elements or products of any kind, including the modification of their physical and chemical properties and the processes for obtaining or modifying them, when they result from the transformation of the atomic nucleus; and
- III. living beings, in whole or in part, except for transgenic microorganisms meeting the three requirements of patentability-novelty, inventive step and industrial application-in accordance with Article 8 and which are not mere discoveries.

Sole paragraph. For the purposes of this Law, transgenic microorganisms mean organisms, except for plants or animals in whole or in part, that due to direct human intervention in their genetic composition express a characteristic that cannot normally be achieved by the species under natural conditions.

Chapter VIII

Licenses

Section III

Compulsory Licenses

Art. 68. A patent shall be subject to compulsory licensing if the owner exercises his rights therein in an abusive manner or if he uses it to abuse economic power under the terms of an administrative or judicial decision.

(1) The following may also be grounds for compulsory licensing:

- I. failure to work the subject matter of a patent on the territory of Brazil, failure to manufacture or incomplete manufacture of the product or failure to completely use a patented process, except for failure to work due to lack of economic viability, in which case importing shall be admitted; or
- II. marketing that does not satisfy the needs of the market.

(2) A license may be requested only by a party having a legitimate interest and having the technical and economic capacity to effectively work the subject matter of the patent for the purposes predominantly of the internal market, not subject in such case to the exception contained in item I of the preceding paragraph.

(3) If a compulsory license is granted on the grounds of abuse of economic power, a period of time, limited to that laid down in Article 74, shall be secured to a licensee who proposes to manufacture locally, to import the subject matter of the license, provided it has been placed on the market directly by the patent owner or with his consent.

(4) In the event of importation in order to exploit a patent or importation as provided in the preceding paragraph, third parties shall also be allowed to import a product manufactured according to a process patent or a product patent, provided it has been placed on the market directly by the patent owner or with his consent.

(5) A compulsory license under paragraph (1) may only be requested on expiry of three years after grant of the patent.

Art. 69. A compulsory license shall not be granted if, at the date of the request, the patent owner:

- I. justifies failure to use for legitimate reasons;
- II. proves that serious and effective preparations for exploitation have been made; or
- III. justifies failure to manufacture or to market on grounds of legal obstacles.

Art. 70. A compulsory license may also be granted where the following circumstances are shown to apply in conjunction:

- I. there exists a situation of dependency of one patent on another;
- II. the subject matter of the dependent patent constitutes a substantial technical advance in relation to the earlier patent; and

III. the owner fails to reach agreement with the owner of the independent patent on the exploitation of the earlier patent.

(1) For the purposes of this Article, a dependent patent shall be a patent of which the working depends necessarily on the use of the subject matter of an earlier patent.

(2) For the purposes of this Article, a process patent may be considered dependent on a patent for the product concerned and, likewise, a product patent may be dependent upon a process patent.

(3) The owner of a patent subject to a license under this Article shall have the right to a compulsory license under the dependent patent.

Art. 71. In cases of national emergency or of public interest, declared in a decision of the Federal Executive Power, and where the patent owner or his licensee do not satisfy such need, a temporary non-exclusive compulsory license to exploit the patent may be granted *ex officio*, without prejudice to the rights of the owner of the patent.

Sole paragraph. The instrument granting the license shall set out its term of validity and any possibility of extension.

Art. 72. Compulsory licenses shall always be granted without an exclusive nature and sublicensing shall not be permitted.

Art. 73. An application for a compulsory license shall be drawn up by setting out the conditions offered to the patent owner .

(1) On filing of the license application, the patent owner shall be invited to submit his comments within a period of 60 days, on expiry of which, in the absence of a reply from the patent owner, the proposal shall be deemed accepted under the conditions offered.

(2) An applicant for a license who alleges abuse of patent rights or abuse of economic power shall be required to submit documentary proof.

(3) If a compulsory license is applied for on the grounds of failure to exploit, it shall be for the patent owner to prove that he has exploited his patent.

(4) In the event of a contestation, INPI may take the necessary measures, including the establishment of a committee, that may include independent specialists, to arbitrate on the remuneration to be paid to the patent owner.

(5) The organs and entities of direct or indirect public administration, whether federal, state or municipal, shall provide INPI with such information as is requested to assist in the arbitration of the remuneration.

(6) When arbitrating remuneration, the circumstances of each case shall be taken into consideration and shall obligatorily include the economic value of a compulsory license granted.

(7) Once the case has been examined, INPI will take a decision on grant and on the conditions of a compulsory license within a period of 60 days.

(8) Appeals from decisions to grant a compulsory license shall not have suspensive effect.

Art. 74. Unless he has legitimate reason, the licensee shall begin exploiting the subject matter of the patent within a period of one year as from the grant of the license, whereby an interruption for the same period of time shall be permitted.

(1) The owner of the patent may request cancellation of a license if the provisions of this Article are not complied with.

(2) The licensee shall have full powers to act in defense of the patent.

(3) Once a compulsory license has been granted, assignment of such license shall only be permitted together with the assignment, transfer or leasing of that part of the enterprise that exploits it.

Chapter IX

Patents of Interest to National Defense

Art. 75. A patent application originating in Brazil of which the subject matter is of interest to national defense shall be prosecuted subject to secrecy and shall not be subject to the publications provided for in this Law.

(1) INPI shall immediately transmit the application to the competent organ of the Executive Power to enable that authority to issue an opinion on secrecy within a period of 60 days. If such period expires without the competent organ giving an opinion, the application shall be prosecuted normally.

(2) Unless explicit authorization is given by the competent organ, it shall be prohibited to file abroad a patent application of which the subject matter is deemed of interest to national defense or to disclose any part thereof.

(3) The exploitation and assignment of an application or a patent of interest to national defense shall be subject to prior authorization by the competent organ; equitable compensation shall be guaranteed whenever this implies a restriction on the rights of the applicant or the patent owner.