

OFFICIAL GAZZETE OF THE FEDERAL GOVERNMENT

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Acts of the Legislative Power

Law number 14,200, of September 2, 2021

Amends Statute 9,279 of May 14, 1996 (Brazilian Patent Statute), to address the compulsory license of patents and patent applications in cases of a declaration of national or international emergency or public interest, or declaration of state of nationwide public calamity.

THE PRESIDENT OF THE REPUBLIC

I inform that the National Congress decrees and I enact the following Law:

Article 1. This Law amends Statute 9,279 of May 14, 1996 (Brazilian Patent Statute), to address the compulsory license of patents and patent applications in cases of a declaration of national or international emergency or public interest, or declaration of state of nationwide public calamity.

Article 2. Article 71 of Statute 9,279 of May 14, 1996 (Brazilian Patent Statute), is hereby amended as follows, with its sole paragraph numbered as Paragraph 1:

“Article 71. In cases of a declaration of national or international emergency or public interest, declared by law or an act of the Federal Executive Branch, or a state of nationwide public calamity declared by the National Congress, a temporary and non-exclusive compulsory license may be granted, ex officio, for the exploitation of a patent or patent application, without prejudice to the rights of the respective holder, provided that the patent or patent application holder or its licensee does not meet these needs.

Paragraph 1. The act of granting the compulsory license will establish its term and the possibility of extension.

Paragraph 2. In the cases provided in this Article’s chapeau, the Federal Executive Branch shall publish a list of patents or patent applications potentially useful for facing the situations referred to in this Article’s chapeau, with the secrecy term provided in Article 30 of this Statute not being applicable, in a term of up to 30 (thirty) days from the publication of the referred declaration of emergency or public interest, or nationwide public calamity, excluded patents and patent applications that are subject of transfer of technology agreements for its production or voluntary licensing

capable of ensuring the fulfilment of internal demand, in the terms provided by regulation.

Paragraph 3. Public entities, educational and research institutions, and other representative entities of society and the industrial sector must be consulted in the process of drafting the list of patents or patent applications that could be subject to a compulsory license, in the terms provided by regulation.

Paragraph 4. Any public or private institution may submit a request to include a patent or patente application in the list provided in Paragraph 2 of this Article.

Paragraph 5. The list provided in Paragraph 2 of this Article shall contain sufficient information and data to allow an individualized evaluation regarding the utility of each patent and patent application and shall contemplate, at least:

I – the individualized number of patents or patent applications which may be subject to compulsory license;

II – the identification of the respective holders; and

III – the specification of the objectives for which each compulsory licensing will be authorized.

Paragraph 6. From the list published pursuant to Paragraph 2 of this Article, the Federal Executive Branch shall carry out, within a term of 30 (thirty) days, extendable for an equal period, the individualized evaluation of the listed inventions and utility models and will only grant the nonexclusive compulsory license, for manufacturers with proven technical and economic capacity for the production of the subject matter of the patent or patent application, as long as it concludes that it is useful in facing the situation that underlies it.

Paragraph 7. Patents or patent applications, which have not yet been the subject of a compulsory license, may be excluded from the list defined in Paragraph 2 of this Article in cases in which the competent authority designated by the Federal Executive Branch considers that its holders have made objective commitments capable of ensuring fulfilment of domestic demand under conditions of volume, price, and time-limit compatible with the needs of the national or international emergency, of the public interest, or of the state of nationwide public calamity, through one or more of the following alternatives:

I – direct exploitation of the patent or patent application in the country;

II – voluntary licensing of the patent or patent application; or

III – transparent contracts for the sale of a product associated with the patent or patent application.

Paragraph 8 (VETOED).

Paragraph 9 (VETOED).

Paragraph 10 (VETOED).

Paragraph 11. Public institutions that have information, data, and documents related to the subject matter of the patent and patent application are obliged to share all the elements useful for the reproduction of the licensed object, in which case the rules relating to data protection are not applicable, nor the provisions of item XIV, chapeau, Article 195 of this Statute.

Paragraph 12. In defining the compensation for the patent or patent application holder, the circumstances of each case shall be considered, necessarily in light of the economic value of the license granted, the duration of the license, and the estimates of investments necessary for its exploitation, as well as the production costs and sales price in the national market of the product associated with it.

Paragraph 13. The compensation of the holder of a patent or patent application subject to compulsory license shall be fixed at 1.5% (one point five percent) on the net selling price of the product associated with it until its value is effectively established.

Paragraph 14. The compensation of the holder of a patent application subject to a compulsory license shall be due only if the patent is granted and its payment, corresponding to the entire period of the license, shall be carried out only after the patent is granted.

Paragraph 15. The competent authority will give priority to the analysis of patent applications that are subject of a compulsory license.

Paragraph 16. The products that are subject to the sanitary surveillance regime shall comply with all requirements set forth in sanitary legislation and may only be sold after the authorization has been granted by the federal sanitary surveillance authority, whether definitively or for use on an emergency basis, in the terms provided by regulation.

Paragraph 17 (VETOED).

Paragraph 18. Regardless of a compulsory license grant, the government will prioritize the execution of technical cooperation agreements and contracts with the patent holder for the acquisition of productive technology and the process for transferring it.

Article 3 (VETOED).

Article 4. The Statute n° 9,279 of May 14, 1996 (Brazilian Patent Statute), is hereby amended with the addition of Article 71-A:

“Article 71-A. For humanitarian reasons and under the terms of international treaties to which the Federal Republic of Brazil is a party, compulsory licenses of patents of products destined for exportation to countries with insufficient or no manufacturing capacity in the pharmaceutical sector for the demand of its own population may be granted.”

Article 5. The implementation of the provisions of this Law does not exempt the Executive Branch from making efforts along with other countries and international agencies for the purposes of international cooperation in order to allow for the universal access to the pharmaceutical products, vaccines, and therapies necessary for the fight against the new coronavirus (SARS-CoV-2) and other epidemics or severe public health crises.

Article 6. This Bill shall enter into force on the date of its of publication.

Brasilia, September 2, 2021; 200th of the Independency and 133rd of the Republic.

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