

Decree No. 3,201 of October 6, 1999

Establishes rules concerning the granting, *ex officio*, of compulsory licenses in cases of national emergency and public interest provided for in Article 71 of Law No. 9,279, of May 14, 1996.

The President of the Republic, using the prerogative to which he is entitled by Article 84, Item IV, of the Constitution, and in consideration of the provisions of Article 71 of Law No. 9,279, of May 14, 1996.

Decreases:

1. The granting, *ex officio*, of a compulsory license, for non-commercial public use, in cases of national emergency or public interest, provided for in Article 71 of Law No. 9,279, of May 14, 1996, shall be ruled in accordance with this Decree.

2. There may be granted, *ex officio*, a compulsory license for a patent, for non-commercial public use, in cases of national emergency or public interest, thus declared by the Government, provided that it is ascertained that the patent holder or his licensee does not fulfill those needs.

(1) A national emergency is understood to be a condition of impending danger to the public, even if existing only in a part of the national territory.

(2) There are considered to be within the public interest those facts, among others, related to the public health, nutrition, protection of the environment, as well as those of primordial importance to the technological or social and economic development of this country.

3. The act of the Federal Executive Power declaring the national emergency or the public interest shall be performed by the Minister of State responsible for the subject matter in question and shall be published in the Federal Official Gazette.

4. There having been ascertained the impossibility of the patent holder or his licensee to fulfill the national emergency or public interest situation, the Government shall grant, *ex officio*, the compulsory license, which shall not be exclusive, and the respective act shall be immediately published in the Federal Official Gazette.

5. The act of granting the compulsory license for non-commercial public use shall establish, among others, the following conditions:

I. the term of the license and the possibility of renewal;

II. those offered by the Union, particularly regarding the compensation to the titleholder;

III. the obligation of the titleholder, if needed, to transmit necessary and sufficient information to the effective reproduction of the protected object, to the supervision of assembly and further technical and commercial aspects applicable to the case in question.

Sole Paragraph. In order to determine the compensation to which the title holder is entitled, there shall be considered the relevant economic and market circumstances, the price of similar products and the economic value of the authorization.

6. The competent authority may request information as needed to support the granting of the license or to determine the compensation due to the patent holder, as well as other pertinent information, from the federal, state and municipal, direct and indirect, public administration agencies and entities.

7. In case of national emergency or public interest characterizing extreme urgency, the compulsory license provided for in this Decree may be implemented and the use of the patent may be effected, irrespective of prior compliance with the conditions established in Articles 4 and 5 of this Decree.

Sole Paragraph. If the competent authority has knowledge, without conducting a search, of the existence of a patent in force, the title holder shall be immediately informed on such use.

8. The exploitation of a compulsorily licensed patent in accordance with the provisions of this Decree may be initiated irrespective of the existence of an agreement on the conditions included in Article 5.

9. The exploitation of a patent licensed in accordance with the provisions of this Decree may be performed directly by the Union or by duly contracted third parties, and the reproduction of the object thereof for other purposes being prohibited, under penalty of being considered illicit.

10. In such cases where it might not be possible to fulfill the situations of national emergency or public interest with the product placed on the domestic market, or the manufacture of the object of the patent by third parties, or by the Union, is found to be unfeasible, the latter may proceed to import the product that is the object of the patent, provided that it was introduced onto the market directly by the patent holder or with his consent.

11. The contracting of third parties to exploit the compulsorily licensed patents shall be performed by means of bidding, and the process thereof shall be performed in compliance with the principles of Law No. 8,666, of June 21, 1993.

12. Once the national emergency or the public interest has been fulfilled, the competent authority shall extinguish the compulsory license, respecting the terms of the contract executed with the licensee.

13. The competent authority shall inform the Instituto Nacional da Propriedade Industrial—INPI (National Institute of Industrial Property), for purposes of entry, in respect of the licenses for non-commercial public use, granted on the basis of Article 71 of Law No. 9,279, of 1996, as well as concerning changes and extinguishment of such licenses.

14. This Decree enters into force on the date of its publication.

Brasília, October 6, 1999; 178th year of Independence, 111th year of the Republic.

Fernando Henrique Cardoso

José Serra

Alcides Lopes Tápias

Notice: The English version of this law is provided only as a means of reference. It is noted that the Portuguese version solely constitutes the official one, for any use the reader may intend.
