

## BRAZILIAN PRESIDENT ISSUES NEW DECREE ON COMPULSORY LICENSE OF PATENTS

The October 7, 1999, Federal Register published Presidential Decree No. 3,201 establishing rules for the granting of compulsory licenses for governmental non-commercial use in cases of national emergency and other circumstances of extreme urgency (public interest).

Decree nº 3,201 establishes procedures to be followed by the administration, in accordance to article 71 of the Brazilian Patent law.\*

The possibility of granting compulsory licenses in cases of national emergency and public interest is specifically provided for in article 71 of the Industrial Property Law (Law 9279/96). Therefore, Decree 3,201 is only establishing the rules that will be followed when the special circumstances foreseen would indicate the need of having a compulsory license of a patent granted to the Administration.

Article 2 § 2, considers of public interest 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 the Country. This definition is very broad, however, it should of course, be careful

The provision of compulsory licenses on the indicated circumstances article 31 of the WTO's TRIPS Agreement. Therefore, it does not seem that neither the Law nor the Decree are in conflict therewith.

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It should be noted that such compulsory licenses shall only be granted in case the patent holder or its licensee would not be capable of meeting the national emergency or public interest situation.

Also, the compulsory license should contain the compensation that will be paid to the patent holder taking into consideration the relevant economic and market circumstances, the price of similar products and the economic value of the license.

Only in cases of extreme urgency the compulsory license will be issued before the remuneration parameters are established.

The Federal Government may directly work the patent or effect a bid to have the products manufactured by a 3<sup>rd</sup> party on its behalf and as soon as the emergency or public interest is over, the license will expire.

We understand that the Decree as enacted, does not violate the law, the Federal Constitution and/or the TRIPS Agreement, although it may be questioned that the procedure set forth in article 73 of Brazilian Patent Law should be used for determining the compensation to be paid.

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\* Brazilian Patent Law, Article 71 - "In cases of national emergency or public interest, declared in an act of the Federal Executive Authorities, insofar as the patentee or his licensee does not meet such necessity, a temporary *ex officio* non-exclusive compulsory license for the exploitation of the patent may be granted, without prejudice to the rights of the respective patentee.

*Sole Paragraph* - The act of grant of the license will establish its term of validity and the possibility of extension."

Any abuse or violation of rights in the granting of compulsory licenses may be contested at courts under article 5, XXXV, of the Constitution and all acts of the Administration are subject to Judicial control.

Should you need further information, please contact any of our attorneys or email us at [momsen@momsen.com.br](mailto:momsen@momsen.com.br).

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**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 in Article 71 of Law No. 9,279, of May 14, 1996.*

THE PRESIDENT OF THE REPUBLIC, using the prerogatives 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,

DECREES:

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

**Article 2<sup>nd</sup>.** There may be granted, ex officio, a compulsory license for a patent, for non-commercial public use, in the cases of national emergency or public interest, thus declared by the Public Office, provided that it is ascertained that the holder of the patent or the licensee thereof does not fulfill those needs.

§ 1<sup>st</sup>. 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<sup>nd</sup>. 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 the Country.

**Article 3<sup>rd</sup>.** 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 matter in question and shall be published in the Official Gazette of the Union.

**Article 4<sup>th</sup>.** There having been ascertained the impossibility that the holder of the patent or the licensee thereof fulfill the national emergency or public interest situation, the Public Office shall grant, ex officio, the compulsory license, which shall not be exclusive, and the respective act shall be immediately published in the Official Gazette of the Union.

**Article 5<sup>th</sup>.** The act whereby there is granted a compulsory license for non-commercial public use shall establish, among others, the following conditions:

I – the term of effectiveness of the license and the possibility of renewal thereof:

II – those offered by the Union, particularly regarding the compensation to be provided to the holder in connection therewith.

III – the requirement obliging of the holder, where needed, to transmit necessary and sufficient information enabling to reproduce the object of protection, to supervise the assembly and further technical and commercial aspects applicable to the case in question.

**Sole paragraph.** In order to determine the compensation to which the 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.

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**Article 6<sup>th</sup>.** The competent authority may request information as needed to support the granting of the license or to determine the compensation due to the holder, as well as other pertinent information, from the departments and entities of federal, municipal and state direct or indirect public administration.

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

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

**Article 8<sup>th</sup>.** 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<sup>th</sup> herein.

**Article 9<sup>th</sup>.** 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, the reproduction of the object thereof for other purposes being prohibited, subject to being deemed the performance of an illegal act.

**Article 10<sup>th</sup>.** In such cases where it might not be possible to meet the situations of national emergency or public interest with the product placed in 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 the same has been placed in the market directly by the holder or authorized thereby.

**Article 11<sup>th</sup>.** The contracting of third parties to exploit the compulsorily licensed patent shall be performed by means of bidding, the process thereof being performed in compliance with the principles of Law No. 8,666, of June 21, 1993.

**Article 12<sup>th</sup>.** Upon the national emergency or the public interest having been met, the competent authority shall extinguish the compulsory license, respecting the terms of the contract executed with the licensee.

**Article 13<sup>th</sup>.** The competent authority shall inform the National Institute of Industrial Property (Instituto Nacional da Propriedade Industrial – INPI), for recording purposes, in respect of the licenses for non-commercial public use granted based on Article 71 of Law No. 9,279, of 1996, as well as concerning amendments and extinction of such licenses.

**Article 14<sup>th</sup>.** This Decree becomes effective at the date of publication hereof.

Brasília, October 6, 1999; 178<sup>th</sup> year of Independence, 111<sup>th</sup> year of the Republic.

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