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Note C. 8828

Additional inputs for the preparation of documents to the 30th Session of the Standing Committee on the Law of Patents[1]

Brazil

Draft reference document on the exception regarding compulsory licenses

In Brazil, the exception regarding compulsory license is regulated in Section III, Articles 68 to 74 of Law 9,279, of May 14, 1996 (IPL). According to Brazilian law, the compulsory license may be granted when the patent holder exercises his rights in an abusive manner, in case of proven practice of economic power abuse, lack of exploitation or insufficient exploitation of the patent in Brazil, when market needs are not met, for situations of dependence on one patent in relation to the other and in cases of national emergency or public interest declared in an act of the Federal Executive Power.

The compulsory license on the basis of non-exploitation of the patent may only be requested after 3 (three) years of the patent granting (Article 68, § 5 of IPL), unless at the date of the application the holder presents legitimate reasons for the disuse, proves the realization of serious and effective preparations for the exploration or justify the lack of manufacture or commercialization by legal obstacle (Article 69 of IPL). When the patent holder proves that the lack of exploitation of the patent is due to economic infeasibility, importation will be allowed (Article 68, § 1 - I of IPL).

[1] The answers to this Note have been provided on behalf of Brazil by Brazilian National Institute of Industrial Property (INPI).

The compulsory license shall be granted, on a non-exclusive basis, when it is established that the patent holder, directly or through his licensee, does not respond to the national emergency or public interest (Article 71 of IPL).

The act of granting the compulsory license shall establish its term, the possibility of extension and the holder remuneration, considering the relevant economic and market circumstances, the price of similar products and the economic value of the authorization.

BRAZIL'S EXPERIENCE WITH COMPULSORY LICENSING

In 1983, Brazil created the National Program to Combat Sexually Transmitted Diseases and AIDS (National STD/AIDS Program), recognized as one of the best initiatives among developing countries by the United Nations (UN). One of the pillars of this Program is the universal and free supply of antiretroviral drugs, guaranteed since 1996 by law (Law 9,313, of November 13, 1996[2]).

The challenge of the universal offer lies in the high cost of antiretroviral therapies used in the Program in the light of the budget of the Ministry of Health. In order to guarantee the maintenance of the STD/AIDS Program, the Brazilian Government started investing in the capacity building for development of National laboratories, through public-private partnerships, in order to promote the research and local manufacture of cheaper generic medicines and, finally, to reduce the cost of therapies.

Commonly, the antiretroviral drugs used in the National Program are protected by patents or have patent applications that have not yet been decided by the Brazilian National Institute of Industrial Property (INPI). Hence, in most cases, the purchase of medicines is exclusively made from the holder, which decreases the Government negotiating power to obtain a price reduction.

In 1999, the Brazilian Government issued Decree No. 3,201[3], which provides for the *ex officio* granting of compulsory license in cases of national emergency and public interest referred to

[2] http://www.planalto.gov.br/ccivil_03/leis/l9313.htm
[3] http://www.planalto.gov.br/ccivil_03/decreto/D3201.htm

in Article 71 of IPL. According to the Decree, the term "national emergency" should be understood as the imminent public danger, even if it happens only in part of the national territory (article 2, § 1 of the Decree). Public health, nutrition and environmental protection are considered to be of public interest, as well as the facts of primary importance for the technological or socioeconomic development of the country (Article 2, § 2 of the Decree). The cases of national emergency or public interest are declared by the Federal Executive Power, through the Minister of State responsible for the matter in question. The governmental act is entirely in line with the flexibilities envisaged in the TRIPS Agreement, subsequently ratified by the 2001 Doha Declaration on TRIPS and Public Health:

"*We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all*".

Subsequently, Decree No. 4,830, dated September 4, 2003[4] , which amended the previous Decree, allowed the importation of generic products in cases in which it is not possible to attend to situations of national emergency or public interest with the product placed in the internal market, or if it is not possible to manufacture the object of the patent by a third party, or by the Union (Article 10 of the Decree).

It is important to note that, despite being provided for in TRIPS Agreement and Brazilian legislation, the compulsory license has been used as the last alternative of the Brazilian Government, only in extreme cases, when attempts to negotiate price reduction were unsuccessful and it was proved that the patent holder did not respond to the national emergency or public interest. When a satisfactory price reduction agreement between the parties is reached, the issue of a compulsory license is not necessary. This was the case of the negotiations held in 2001 with Merck (Efavirenz), Hoffman-La Roche (Nelfinavir) and Abbott (Lopinavir/Ritonavir) for the purchase of anti-AIDS cocktail medicines.

[4] http://www.planalto.gov.br/ccivil_03/decreto/2003/D4830.htm#art1

In most cases, public interest declaration of a drug in itself promotes the intensification of negotiations for price reduction. This measure represents a signal from the Government of the importance of the medicine to the Brazilian health system and the possibility of granting a compulsory license if the cost of treatment exceeds the budget.

In 2005, the public interest in the Kaletra® medicine was decreed by the Government through Ordinance No. 985[5]. According to the Ministry of Health, this measure was due to the importance of this medicine for the AIDS treatment, to the sharp increase in the number of people living with HIV/AIDS and receiving the antiretroviral therapy from the Government, to the history of the prices practiced in the acquisition of the aforementioned medicine, to the need to ensure the continuity of the National STD/AIDS Program and the distribution of antiretroviral drugs (according to Law No. 9.313 of 1996[3]), to the social risks related to the AIDS pandemic for all countries and to the right to health provided for in the Federal Constitution of Brazil.

Although this Ordinance did not establish the granting of a compulsory license, it represented a clear signal from the Brazilian Government about its intention to apply the legal mechanisms if the price negotiations did not have the expected success. Finally, after two weeks of negotiations, Abbott complied with the proposal to reduce the price of Kaletra® and the granting of a compulsory license was no longer necessary. At the time, only for this product, the Brazilian Government was spending about 30% of the budget reserved for the purchase of antiretrovirals[6].

Another situation in which the public interest was declared by the Brazilian Ministry of Health occurred in 2008 for the drug Tenofovir, by the company Gilead (Viread®), incorporated to SUS in 2003. In this case, the Government's objective was not to issue a compulsory license, but rather to prioritize the technical examination of patent application PI9811045-4, not yet examined by INPI. In Brazilian law, the filing of a patent application generates an expectation of an IP right, with an impact on the product price, and compensation is provided retroactively in case the application is granted (Article 44 of IPL). This type of measure was provided in Resolution INPI/PR No. 132, of

5 http://bvsms.saude.gov.br/bvs/saudelegis/gm/2005/prt0985_24_06_2005.html
6 https://www.bbc.com/portuguese/reporterbbc/story/2005/07/050709_patentekaletracg.shtml

2006[7], which regulated the priority examination of patent applications in the scope of INPI at that time[8].

In Government Ordinance No. 681 of April 8, 2008[9], which declared the public interest of Tenofovir, the Government clarified that technical subsidies related to patent application PI9811045-4 had been submitted to INPI, through Farmanguinhos/Fiocruz, claiming the lack of inventive step of the subject matter, a pharmaceutical composition of the fumarate salt of Tenofovir. In addition, the same challenge had been raised in respect of the corresponding US patent application (US5,935,946) by the US Patent and Trademark Office (USPTO) in January 2008. The patent application was then examined as a matter of priority and rejected by the INPI due to the absence of the inventive step requirement[10]. This decision was maintained in administrative and judicial appeal.

The Government then started to stimulate local production of the Tenofovir medicine through Partnerships for Productive Development (called "PDP")[11] [12], involving technology transfer from private companies to national laboratories, later regulated by Ordinance No. 837, of 2012[13] (revoked by Ordinance No. 2,531, dated November 12, 2014[14]). This measure paved the way for competitiveness of the pharmaceutical sector, leading to a significant reduction in the cost of the Tenofovir medicine to the Ministry of Health. After the rejection of the patent application and the announcement of the PDP for the local production of Tenofovir, Gilead started to offer the product

7 https://wipolex.wipo.int/en/text/205780

8 According to Article 3 of INPI Resolution No. 132 of 2006, "*Priority shall be given,* ex officio*, to a patent application whose subject matter is encompassed by the act of the Federal Executive Power which declares national emergency or public interest, in the cases described in paragraphs 1 and 2 of Article 2 of Decree No. 3.201, of 1999*".

9 http://www.saude.mt.gov.br/upload/legislacao/0681-[2857-120110-SES-MT].pdf

10 Source: INPI.

11 The Productive Development Partnerships (PDPs) are partnerships between public institutions and private entities with the aim of accessing priority technologies, reducing the vulnerability of the Brazilian Unified Health System ("SUS") in the long term, and rationalizing and reducing product prices strategies for health, with the commitment to internalize and develop new high-value strategic and value-added technologies (Article 2 of Ordinance No. 837, of April 18, 2012).

12 http://portalms.saude.gov.br/ciencia-e-tecnologia-e-complexo-industrial/complexo-industrial/parceria-para-o-desenvolvimento-produtivo-pdp

13 http://bvsms.saude.gov.br/bvs/saudelegis/gm/2012/prt0837_18_04_2012.html

14 http://bvsms.saude.gov.br/bvs/saudelegis/gm/2014/prt2531_12_11_2014.html

at a lower price than the one practiced by the companies of PDPs. In turn, domestic producers also had to reduce the price of their products to compete with prices charged by Gilead[15], which led to a significant reduction in the cost of the drug to the Government.

The experience of Brazilian Government has shown that the local production capacity of generic medicines plays a fundamental role in the negotiations with the owners of the reference medicines. In addition to offering medicines at a lower cost, domestic producers act as a source of information on the costs of the production of medicines, which makes Government negotiations with foreign companies more efficient, in the sense of maximizing discounts, without causing too much profit reduction for the companies[16].

To date, the only time Brazil has made use of a compulsory license for a medicinal product was in the case of Efavirenz (STOCRIN®) by Merck Sharp & Dohme. The Brazilian Government had already issued two compulsory licenses in force of Law no. 5,772, of 1971[17], but never for a medicine. The first, in 1982, was granted on grounds of non-exploitation of a patent relating to a herbicide; the second, in 1967, granted for the foot-and-mouth disease (FMD) vaccine. It is important to note the historical nature of this measure, since this was the first compulsory license granted in Latin America for a medicine.

The compulsory license of patents PP1100250-6 and PI9608839-7 for Efavirenz was enacted in the public interest and for non-commercial public use, after intensive unsuccessful negotiations with the company, through Decree No. 6,108, dated May 4, 2007[18]. Merck's best offer was the 30% discount on the medicine price, which was equivalent to a price reduction of $ 1.57 to $ 1.10 at the time, a figure still far from the applied price in Thailand by the same company (US $ 0.65), to be applied in a shorter term than the patent term (until 2010, being expired in 2012)[19].

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15 G. C. Chaves, L. Hasenclever, M. A. Oliveira “Redução de preço de medicamento em situação de monopólio no Sistema Único de Saúde: o caso do Tenofovir”, Physis: Revista de Saúde Coletiva, Rio de Janeiro, v. 28(1), e280103, 2018. DOI: http://dx.doi.org/10.1590/S0103-73312018280103.

16 A. Mello e Souza. “O licenciamento compulsório como estratégia para promover o acesso a medicamentos essenciais: o caso dos antirretrovirais no Brasil”. In: “Patentes e o acesso a antirretrovirais no Brasil. O desafio do licenciamento compulsório”, Appris Editora, Curitiba-PR, 2017, pp. 107-133.

17 https://www.planalto.gov.br/ccivil_03/leis/l5772.htm

18 https://www.planalto.gov.br/ccivil_03/_ato2007-2010/2007/decreto/d6108.htm

19 https://noticias.uol.com.br/ultnot/cienciaesaude/ultnot/estado/2007/05/03/ult4513u59.jhtm

The Decree also provides for the obligation of the holder of the licensed patents to make available to the Ministry of Health all necessary and sufficient information on the effective reproduction of the protected objects, under the risk of applying Article 24 of IPL[20], (enablement requirement) and Chapter VI of Title I (patent nullity procedures). On the other hand, it is up to the Government to ensure that such information is adequately protected against unfair competition and dishonest commercial practices.

The public interest of Efavirenz was initially stated through Ordinance No. 866, of April 24, 2007[21], by the Minister of Health José Gomes Temporão, in order to guarantee the viability of the National STD/AIDS Program, ensuring the continuity of universal and free access to all medication needed for treatment of people living with HIV and AIDS. In order to justify this extraordinary act, the Minister presented a series of considerations on the need for this measure for the health of Brazilians, the sustainability of the National STD/AIDS Program, the failure of negotiations with the patent holder and the predictability of this act in the development national and international legal framework within the scope of the patent system, according to the transcript below:

> *"Considering that health is a fundamental human right, under the terms of art. 25 of the Universal Declaration of Human Rights, of December 10, 1948, and art. 12 of the International Agreement on Economic, Social and Cultural Rights of December 16, 1966, incorporated into the national legal system by Decree No. 591 of July 6, 1992, which provides for the right of every person to enjoy the highest level of health physical and mental;*
>
> *Considering that the right to the prevention and treatment of endemic, occupational and other diseases is a human right provided for in art. 10 of the Protocol of San Salvador of November 17, 1988, incorporated into the national legal system by Decree No. 3,321, of December 30, 1999;*

[20] Article 24 of Law No. 9,279 of 1996. The specification must describe the subject matter clearly and sufficiently so as to enable a person skilled in the art to carry it out and to indicate, when applicable, the best mode of execution.

[21] The public interest was declared by the Minister of Health by means of Ordinance No. 866, of April 24, 2007. Available in: http://www.aids.gov.br/pt-br/legislacao/portaria-886-de-24-de-abril-de-2007.

Considering that health is, according to Article 196 of the Constitution, a right of all and duty of the State, guaranteed by social and economic policies aimed at reducing the risk of disease and other health problems and universal and equal access to actions and services for their promotion, protection and recovery;

Considering that the property must attend to its social function and that the protection of intellectual property must take into account social interest, according to sections XXIII and XXIX of Article 5 of the Constitution;

Considering that the State must guarantee universal and free access to health actions and services, with the obligation determined by Law No. 9.313, of November 13, 1996, to ensure the continuity of distribution of medicines necessary for the treatment of people living with HIV/AIDS;

Considering that Efavirenz is indispensable in the treatment of people living with HIV/AIDS and that the National STD/AIDS Program is recognized worldwide for its quality, due to the universality, completeness and free access;

Considering that, as a result of the increase in the number of people living with HIV/AIDS in Brazil, the prices of Efavirenz currently under way compromise the viability of this Program;

Considering that the Ministry of Health has unsuccessfully endeavored to reach agreement with the manufacturer of Efavirenz on prices practiced in Brazil on reasonable terms and conditions to meet the public interest;

Considering the possibility of using the patent subject-matter without the authorization of its holder, including non-commercial public use, in accordance with Articles 7, 8, 30 and 31 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) of the World Trade Organization (WTO), incorporated into the national legal order by Decree No. 1,355 of December 30, 1994;

Considering the WTO Ministerial Declaration on the TRIPS Agreement and Public Health adopted at Doha, Qatar, on 14 November 2001, in which WTO member countries agreed, inter alia, to recognize the seriousness of many developing countries and least developed countries, especially those with HIV/AIDS; to recognize that intellectual property protection is important for the production of new medicines and to recognize concerns

about their effects on prices; and to recognize concerns about their effects on prices; to agree that the TRIPS Agreement does not prevent and should prevent Member States from taking measures to protect public health; to reaffirm their commitment to the TRIPS Agreement and to affirm that this international instrument can and should be interpreted and implemented in such a way as to support the right of WTO member countries to protect public health and, in particular, to promote access for all to medicines; to reaffirm the right of WTO member countries to make full use of the provisions of the TRIPS Agreement which provide for flexibilities for this purpose; to recognize that each WTO member country has the right to grant compulsory licenses and freedom to determine the basis on which such licenses are granted, and

Considering the possibility of compulsory licensing of patents, for public interest, for non-commercial public use, as provided in art. 71 of Law No. 9,279 of May 14, 1996, and Decree No. 3,201 of October 6, 1999".

With the compulsory license, Brazil started to produce the drug Efavirenz for non-commercial purposes, committing itself to pay a 1.5 per cent in royalties to Merck for the patent use.

WTO PANEL AGAINST BRAZIL

The obligation to manufacture the product or to use the patented process in Brazilian territory, provided for in article 68, § 1 - I of IPL, is controversial and has already been the subject of international questioning. On February 1, 2001, the United States Government requested the opening of a panel at the World Trade Organization (WTO) against Brazil on the grounds that Article 68, §1 - I of IPL violates Article 27.1 of TRIPS, which states that "*patent rights shall be enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced*".

The Brazilian Government defended itself from the TRIPS violation complaint, arguing that Brazilian legislation follows the one established in the Paris Convention, and further that Article 2.1 of TRIPS states that "*with respect to Parts II, III and IV of this Agreement, Members shall comply with Articles 1 to 12 and 19 of the Paris Convention*". In addition, Article 68 of IPL is crucial for strengthening the bargaining power of the Ministry of Health in relation to multinational pharmaceutical industries, contributing to the sustainability of the AIDS Program.

In the 2001 Special 301 *Report*[22], the United States argued that, for the supply of medicines to treat AIDS, Brazil should opt for using the provisions of Article 71 of Brazilian IPL, which authorizes compulsory licensing in case of national emergency, which would be consistent with the TRIPS Agreement and would not have the objection of the United States. In contrast, Article 68 — the provision under dispute – may require the compulsory licensing of any patented product, from bicycles to automobile components to golf clubs. Article 68 of IPL is unrelated to health or access to drugs, but instead is discriminating against all imported products in favor of locally produced products. In short, Article 68 is a protectionist measure intended to create jobs for Brazilian nationals.

Brazil argued that Article 68 of IPL is similar to Articles 204 and 209 (b) of the US Patent Act on domestic production requirements and started the consultation procedures that could lead to a panel opening against the United States. Thus, if the United States proceeded with the panel, there would be a risk that Brazil would make a formal complaint to the WTO Dispute Settlement Body against US Law.

On June 25, 2001, after consultation with the US pharmaceutical industry associations, the panel was withdrawn by the United States in exchange for assurances that the country would be notified before any products patented by or licensed to US companies are compulsorily licensed in Brazil. Brazil, in turn, agreed to hold prior talks with the US "in the event it deems necessary to apply Article 68 to grant compulsory licenses on patents held by US companies".

[22] https://ustr.gov/sites/default/files/2001%20Special%20301%20Report.pdf