



Compulsory licensing for Sars-cov-2 – Covid 19 vaccines in Brazil and legal support under the WTO TRIPS agreement

Marcos José Bomfim dos Santos

Master's Degree in International Business from Must University (Florida), Civil Engineer, Architect and Urban Planner from UNIDOMPEDRO II, Business Administrator from UNINASSAU

E-mail: marcosbomfim@hotmail.com

ABSTRACT

The debate about compulsory licensing “patent breaking” in the case of a Pandemic arose from the need to vaccinate the Brazilian population in a short space of time, however, the pharmaceutical companies holding the patents did not have the capacity to deliver the product, since their production lines, we are not prepared for such productive speed, given that the entire planet was looking for the same product, in order to save lives, immunizing their populations where the present study has as its object, to analyze the legal support, if the country come to enact the compulsory licensing of a vaccine against (Sars-Cov2) Covid 19, what will be the impacts on the Industrial Property Agreement (Trips) of the World Trade Organization (WTO), the technical feasibility, and the diplomatic considerations of the action. And to achieve these objectives, the bibliographic research methodology with a qualitative approach was used, in order to elucidate how to meet the country's demand for the acquisition of vaccines to immunize the entire population in times of pandemic.

Keywords: Compulsory Licensing, Vaccines, TRIPS Agreement, Patent.

1 INTRODUCTION

The pandemic caused by the new Coronavirus (Sars-Cov2) Covid 19, which devastated the world, and it was no different in Brazil, a disease still little known, present since February 2020 in the national territory, claiming lives and leaving social, public health and economic sequelae, difficult to predict, since at the time there were neither vaccines nor medicines available on the world market, much less approved by the regulatory body in the country, the National Health Surveillance Agency – ANVISA for the treatment. In the economic field, COVID-19 has left traces of mass destruction of formal and informal employment.

That said, and in the wake of the search for a solution, developing and underdeveloped countries started the discussion right at the appearance of the first drugs and vaccines for the treatment of COVID 19, about the need for compulsory licensing, given the high costs and inability of pharmaceutical companies to immediately meet the demand of the world population.

According to CASTRO (2018, p.113), in several countries, the current debate and jurisprudence have been based on the premise that innovators have not only the right to recover investments in R&D, but also, in order to continue innovating, the right to make "supernormal profits" at least on a temporary basis. And contrary to this premise, the first case of patent infringement arose in Israel, in March 2020, when the Ministry of Justice authorized the licensing of substances related to lopinavir/ritonavir (Kaletra trademark), from AbbVie, which despite the patents having expired in some countries, in Israel was still in force, but in



the face of repercussions and government pressures, The American pharmaceutical company later voluntarily waived the patent for the antiviral.

This instrument of temporary expropriation of intellectual property has stimulated some countries to defend the thesis openly before the WHO/WTO. However, the strategy did not prove to be effective, because it is an extremely technological product, where it involves know-how, the simple availability of some process steps, they are not able to produce something, which requires sophisticated production plants, highly trained professionals and industrial secrets in such a short time.

In Brazil, like some other less returned nations, it does not have plants for production based on RNA technology, as in the case of Pfizer and Moderna a messenger RNA technology nanotechnology, which according to the president of the Oswaldo Cruz Foundation, Nísia Trindade in an interview with CNN Brasil, in December 2020¹, stated that "The Pfizer vaccine is a drug made with a new platform, RNA vaccine, however, we don't have this technology in Brazil in terms of a production plant capable of producing on a large scale." Thus, the matter is quite complex, and simply breaking a patent does not solve the problem in the short term.

In fact, in 2007, Brazil has already gone through a compulsory patent break of the antiviral drug STD/AIDS Efavirenz, produced and patented by the American laboratory Merck Sharp & Dohme, which even the Industrial Property Agreement (TRIPS) of the World Trade Organization (WTO), already providing for exceptionality at the time, brought some formal complaints to the agency, by the U.S. Government. The laboratory was accused by the Brazilian government of not practicing fair prices for the Brazilian nation to the detriment of others, as stated by the then Minister of Health José Gomes Temporão, in a ceremony at the Planalto Palace at the time "The compulsory licensing that is decreed today is part of a policy to make medicines accessible to the Brazilian people. Access is difficult because of the high prices charged by the laboratories that hold the patents. This decision shows the government's fight for medicines at fair prices²." (G1, 2007, Online)

This attitude led the Brazilian Government to reduce the cost of acquiring the HIV drug, which in the American pharmaceutical company Efavirenz cost US\$ 1.59, and when replaced by the Indian AZT, it started to cost US\$ 0.44. On the other hand, the production of the drug in the national territory, through the Institute of Technology in Pharmaceuticals – Farmanguinhos, took 1 year and 9 months to produce the first generic drug, after the compulsory breach of patent, since the production of drugs is an eminently technical process, it requires, in addition to equipment, a very qualified workforce. Thus, from the point of view of

1 CNN. Available in <<https://www.cnnbrasil.com.br/saude/fiocruz-diz-que-brasil-nao-tem-tecnologia-para-produzir-vacina-da-pfizer/>>. Accessed on 07/24/2022

2 G1 News. Available in <<https://g1.globo.com/noticias/ciencia/0,,mul31234-5603,00-lula+quebra+patente+de+remedy+antiaids.html>> . Accessed on 07/23/2022



the health emergency, the measure would not have technical effectiveness, because in the case of the pandemic, the main factors that motivated the patent break would be the production time to serve the nations.

According to SOUZA (2011), developing countries, such as India and Brazil, were more resistant to recognizing patents for pharmaceutical products in order to limit the costs of medicines essential to public health.

2 OBJECTIVE

The present study aims to analyze the legal support, in case the Federative Republic of Brazil decrees the compulsory licensing of vaccines against the (Sars-Cov2) Covid 19, what are the impacts on the Industrial Property Agreement (TRIPS) of the World Trade Organization (WTO).

3 METHODOLOGY

This article consists of an exploratory research, with investigation of secondary sources, through bibliographic and documentary research, with articles published in the electronic databases: Portal Capes, *Scientific Electronic Library Online* - Scielo and Google Scholar, as well as news portals. The object of an analysis the possibility of compulsory licensing of vaccines against the (Sars-Cov2) Covid 19, and what are the impacts on the Industrial Property Agreement (TRIPS) of the World Trade Organization (WTO).

4 LEGAL GROUNDS

4.1 PATENTS

In its beginnings, until the seventeenth century, kings and rulers gave their own discretion exclusive rights to carry out a certain trade. Creating commercial monopolies that aimed to favor the so-called friends of the king. Thus, the Statute of Monopolies, promulgated by the British Crown in 1623, to which made official the existence and concession of these commercial monopolies, and inventions. The granting of a monopoly on the use of patents appeared in Venice in the year 1477. In Brazil, in 1830, it began to grant protection to inventions with patents. But until the end of the nineteenth century, Brazilian laws only protected national inventors, not foreign inventors. In 1883, through the multilateral agreement, called the Paris Convention for the Protection of Industrial Property, called the Paris Convention, to which Brazil is a signatory.

In the field of public health, the changes introduced by TRIPS imposed an obligation to protect all inventions, including chemical and pharmaceutical products and processes, and, qualifiedly, biotechnological inventions (plant varieties, for example, may be protected by patents, by a sui generis system, or by a (combination of both). (CASTRO, 2018, p.60)



Thus, in the light of national legislation, "it is observed that the filing of a patent application generates an expectation of the applicant's right, since article 42 of the IP Law guarantees to the applicants that third parties, without their consent, exploit their creation in any of the following modalities: produce, use, offer for sale or import for these purposes" (AMARAL and MALVEIRA, 2020, p.17)

4.2 COMPULSORY LICENSING

In Brazil, the legislation applicable to the subject is described in Law No. 9,279, of 1996 – Industrial Property Law (LPI), which provides for and regulates in which cases the mechanisms of compulsory licensing of patents can be used in circumstances such as the fight against the pandemic of SARS-CoV-2, covid-19. Whose legislation, in line with the rules of the TRIPS agreement (Agreement on Trade-Related Aspects of Intellectual Property Rights), which confers on the Federal Executive Branch of each nation, the responsibility to conduct the process.

According to AMARAL AND MALVEIRA (2020 p.10), among the various interests provided for in world rights, intellectual property is one of the most discussed topics by international society, since it impacts both economic and technological development and public/social interests.

Thus, as defined by BARBOSA (2003), the patent is a temporal right conferred by the state, which gives its holder the exclusivity of the exploitation of a technology.

In this way, the Brazilian legislation provides for the possibility of compulsory patent infringement in the following cases:

- If the holder exercises the rights arising therefrom in an abusive manner, or through it abuses economic power (art. 68);
- the non-exploitation of the object of the patent in the Brazilian territory due to lack of manufacture or incomplete manufacture of the product, or even the lack of full use of the patented process, except in cases of economic unfeasibility (art. 68, § 1, I);
- commercialization that does not meet the needs of the market (art. 68, § 1, II)
- A situation of dependence of one patent on another, or the object of the dependent patent constitutes substantial technical progress in relation to the previous patent and when the holder does not enter into an agreement with the holder of the dependent patent for the exploitation of the previous patent (article 70).

And in the specific case of the pandemic, the legislator was even more emphatic, pointing out that:

- In cases of national emergency or public interest, declared in an act of the Federal Executive Branch, provided that the patent holder or its licensee does not meet this need, a compulsory,



temporary and non-exclusive license may be granted, ex officio, for the exploitation of the patent, without prejudice to the rights of the respective holder (article 71).

- Sole paragraph. The act of granting the license will establish its term of validity and the possibility of extension.

All these articles are in perfect constitutional harmony with our Magna Carta (article 5, item XXIX), to which the law will ensure to the authors of industrial inventions the temporary privilege for their use, as well as protection to industrial creations, the ownership of trademarks, company names and other distinctive signs, "in view of the social interest" and the technological and economic development of the country; On the other hand, Decree No. 3,201, of 2009, which was instituted to regulate article 71 of the IPL, governs that the compulsory patent license may be granted ex officio in cases of national emergency or public interest. In other words, the Brazilian State, in order to protect its population in the event of a national emergency, may suspend the temporary right of the patent for non-commercial use (art. 2).

In these terms, in order for the Brazilian government to initiate the compulsory licensing process, it was enough to decree public interest in the desired patent. Whereas, there is already Decree No. 10,659, of March 25, 2021, which instituted the state of pandemic in Brazil.

Subsequently, if the Government finds that it is impossible for the patent holder or its licensees to meet the demand of the national public interest, the Government may grant ex officio the compulsory license, of a non-exclusive nature, and the act must be immediately published in the Official Gazette of the Union, as (art. 4).

According to AMARAL and MAUVEIRA, 2020, p.17), that in a context of national or international health emergency, the public interest prevails. Thus, once the Compulsory Licensing is decreed, the exhaustion of rights is automatically reversed and creates the possibility of parallel importation than the exhaustion of national law, in force in Brazil.

4.3 REGULATORY EXEMPTION: THE BOLAR EXCEPTION

The TRIPS agreement, within the framework of the World Trade Organization (WTO), met in Doha in 2001, where the member countries through the General Council of that Organization, recognizing the public health drama of some less developed countries, especially the African continent, to which they decided regulates Paragraph 6 of the Doha Ministerial Declaration on TRIPS and Public Health, through the introduction of a new article, Article 31 and an annex to the TRIPS Agreement on compulsory licensing of patents, being;

Paragraph 6 of the Doha Declaration on TRIPS and Public Health, adopted on 14 November 2001 by the WTO Ministerial Conference, recognized that WTO Members with no or insufficient manufacturing capacity in the pharmaceutical sector may face difficulties in making effective use of



compulsory licensing under the TRIPS Agreement, and instructed the TRIPS Council, the WTO body dealing with the Agreement, to find an expeditious solution to this problem. In order to comply with the provisions of the Doha Declaration and to address the concerns of developing and least developed countries, whose capacity to produce medicines under compulsory license is limited or non-existent, the Decision of 30 August 2003 defined, among others, the relaxation of Articles 31 (f) and 31 (h) of the TRIPS Agreement. Article 31 (f) states that compulsory licensing shall be "authorized predominantly to supply the domestic market," while Article 31 (h) states that, in the event of compulsory licensing, the patent holder "shall be adequately remunerated." In addition, the Decision of 30 August 2003 assigned the TRIPS Council the task of drafting an amendment to the TRIPS Agreement to replace the temporary arrangements adopted at that time, on the basis of the Decision of 30 August 2003. (LEGISLATIVE DECREE, n. 262, 2008)

Thus, according to CASTRO (2018.p.336), the conditions for the application of the Bolar Exception are limited, therefore, to the manufacture, use, and sale of the object of the patent for the purpose of obtaining marketing approval or sanitary authorization. A second hypothesis is that of the export of the product, allowing it to occur only for the purpose of obtaining marketing approval and sanitary authorization in the exporting country

5 FINAL THOUGHTS

The breaking of patents in the event of a pandemic is an important instrument, to which it has national legislative ballast, and with the WTO/TRIPS, but from a short-term technical point of view there are no benefits, because the national pharmaceutical industry does not have the technical operational capacity to put hundreds of thousands of vaccines with RNA technology on the production line, for example. It can be an instrument of pressure in the acquisition of the product at a fairer price. Since, as shown in the research, experts believe that, despite being legal, compulsory licensing can lead to diplomatic problems with producing countries, which effectively in the midst of a pandemic would greatly harm the acquisition of the valuable product in the fight against the disease, given that producing nations tend, at first, to block exports of the product, as a form of retaliation.

That said, what the country needs is to invest even more in research and development of technologies, fostering and rewarding researchers to expand the options, both in developing and incorporating new technologies.



REFERENCES

AMARAL, L.F.G e MALVEIRA, S. Acesso Às Patentes de Medicamentos de Interesse da Saúde Pública em Tempos de Pandemia, V.04, N 02(Tomo II), Revista Direito.UNB, Maio, Agosto, ISSN 2357-8009, PP 17-42,2020.

BARBOSA, D. B. Propriedade Intelectual. A aplicação do Acordo TRIPS. Rio de Janeiro: Ed. Lumen Juris, 2003.

CÂMERA FEDERAL DOS DEPUTADOS. Decreto Legislativo 262, 2018. Disponível em <<https://www2.camara.leg.br/legin/fed/decleg/2008/decretolegislativo-262-18-setembro-2008-580863-norma-pl.html>> Acesso em 20/07/2022.

CASTRO, E. M. M. de. O acordo TRIPS e a saúde pública : implicações e perspectivas Brasília: FUNAG, ISBN: 978-85-7631-781-4, 533 p. 2018. Disponível em <<http://funag.gov.br/loja/download/1252-trips-e-a-saude-publica.pdf>> Acesso em 20/07/2022.

CNN. Disponível em <<https://www.cnnbrasil.com.br/saude/fiocruz-diz-que-brasil-nao-tem-tecnologia-para-produzir-vacina-da-pfizer/>>, 2020. Acesso em 23/10/2022.

G1. Notícias. Disponível em <<https://g1.globo.com/noticias/ciencia/0,,mul31234-5603,00-lula+quebra+patente+de+remedio+antiaids.html>> , 2007. Acesso em 23/10/2022.

SOUZA, A.M. O acordo sobre aspectos dos direitos de propriedade intelectual relacionados ao comercio (TRIPS): implicações e possibilidades para a saúde publica no Brasil. Instituto de Pesquisa Eletrônica Aplicada. Rio de Janeiro. 2011.