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HEALTH IS NOT A COMMODITY

Precisely because health is not a commodity, health regulations acquire relevance in the capitalist world. The current scandal known as "implant files" is enough to demonstrate that the appetite of companies in the area is voracious, and without the appropriate regulations and careful surveillance, not only patients will be highly damaged (in the case, with sequels resulting from low quality and unsuitability of products for their needs) but also the health systems, which apart from affording with the cost of purchase of the implants, have to bear the onus both of taking care of the sequels and of eventual compensations.

This introduction is necessary to qualify the concept of patent protection as necessary to ensure that the investments in research and development of medicines and medical devices return to the inventors, promoting a virtuous cycle: higher investments generating better products. Several and relevant factors, including patients and the health systems healthiness, interfere in this cycle. Certainly, one of them is also the creation of the World Trade Organization (WTO), in 1994, with the signature of the *Agreement on Trade-related Aspects of Intellectual Property Rights* (TRIPS)[1]. The deepening of iniquities related to the access to medicines and technologies resulted in the *Doha Declaration on the TRIPS Agreement and Public Health*[2], in 2001, seeking some balance between the recalled factors. The Declaration is a multilateral attempt to reinforce the right of developing countries of using the flexibilities contained in the TRIPS. The intention was to mitigate the adverse effects of intellectual property policies, adjusting them to public health needs in developing countries.

In the area of health, the World Health Organization (WHO) tried to contribute for the optimum balance between intellectual property rights, innovation, and public health interest of. In 2003, it created the Commission on Intellectual Property Rights, Innovation and Public Health, the germ of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property approved in 2008, which has as its main objective " to promote new thinking on the mechanisms that support innovation [...] securing an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries"[3]. This important document brings eight large chapters, one of them, entirely

[1]BRASIL. *Decreto n. 1.355, de 30 de dezembro de 1994*. Promulgo a Ata Final que Incorpora os Resultados da Rodada Uruguai de Negociações Comerciais Multilaterais do GATT. Available at: <http://www.inpi.gov.br/legislacao-1/27-trips-portugues1.pdf>.

[2]WORLD TRADE ORGANIZATION - WTO. *Declaration on the TRIPS agreement and public health*. Available at: <https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm>.

[3]WORLD TRADE ORGANIZATION - WTO. WHA59.24 - Public health, innovation, esse ntial health research and intellectual property rights: toward s a global strategy and plan of action. Available at: <https://www.who.int/phi/Res59_R24-en.pdf>.

dedicated to the **application and administration of the intellectual property regime to contribute to innovation and foster public health**. Therefore, it can be asserted that there is an international consensus regarding health that recognizes the need to explore alternatives to mitigate the deleterious effects of intellectual property on the access of developing countries to medicines.

The increase of the capacity of using all the instruments provided by the TRIPS Agreement, reinforced by the Doha Declaration, is sought to adjust its application having in mind the protection of public health. In this way (i) the compulsory license, or permission of a country's government, for the medicine to be manufactured by a third party, without the permission of the patent holder; (ii) parallel import, as an arbitration mechanism, is fundamental to limit the ability of the patents holders to exercise their market power obtaining a monopoly price for their products; and (iii) the Bolar exception, which is the right granted to a company to develop all the necessary procedures to request from the health authorities of a country, approval for their own version of the registered medicine before the patent expiration, with the purpose of introducing the medicine in the market upon the actual expiration, aim at obtaining medicines at more reasonable prices, either through the entry of their generic versions, or the import of products that are being commercialized internationally at prices lower than those practiced in the country. These are measures capable of producing immediate effects. Other instruments seek to stimulate technological development of less developed states, as experimental use and the interference of the health sector in the process of applications for pharmaceutical patents. Improving the ability of using these instruments is indispensable in face of the potentially damaging modus operandi of large pharmaceutical industries, which are given extensions of their exclusive rights over the products through patent protection, as is the case of informal categories known as "sham litigation" (fraudulent access to justice, without any prospect of being successful, only to cause damage to a third party), of "evergreening" (obtain secondary patents covering different uses, formulations, polymorphs of a basic ingredient) and "forum shifting" (search for a forum that better serve their interests in the judicial dispute).

The fact of medicine manufacturers being able to define as high a price as they can speculate people are ready to pay; and the incorporation of new technologies, accentuated by the advent of biological medicines; the technological deficit in developing countries, and the lack of biosimilar drugs in the market, are today's global concerns.

Brazil has revealed itself hesitant on this field: it started by not using the time of transition provided by the TRIPS Agreement for the conceding of pharmaceutical patents, allowing the so-called "pipeline" or retroactive recognition for the remaining time of the protection (Law No. 9.279/1996, articles 230 and 231), and adopted the national regime of exhaustion of rights, a regulation directly linked

to the possibility – or not – of the parallel import of medicines. In this case, after the product incorporating the patented invention is introduced in the market, the patent holder is no longer able to obstruct its free circulation. This means that by acquiring the product, a third party may use it freely, and the patent holder looses the right to prohibit the product's import. There is a doctrinal trend that understands that if the requirement of local exploitation is applicable by national legislation, importation cannot be considered as an act of exploitation; and that it will be legal to import any patented product, even if it is not placed on the national market by the holder of the patent, when national legislation opts for the international exhaustion of the right.

Soon after, the country used the compulsory licensing mechanism just once, turning ineffective the constant threats to use it, and has been resorting to voluntary licensing, a trade-based instrument, through Productive Development Partnerships (PDP). Note that the essence of the business of such partnerships fuses the transference of technology to the product supply, failing to support the national production of the active pharmaceutical ingredient.

An emblematic example of Brazilian conduct in this area is the current conflict, widely published on mainstream communication media, about the drug against hepatitis C. In June 2018, a plan was announced that had been agreed between the Ministry of Health, State units and Municipalities to treat all cases of hepatitis C until 2030, in accordance with the WHO goals. At the time, the director of the STD, HIV/ Aids and Viral Hepatitis Department of the Ministry of Health affirmed that to diagnose and treat the virus carriers was "essential for the quality of life of those individuals as well as for public health"[4]. Hence, uniting the technology transfer to the product supply, the PDP, which includes the Drug Technology Institute – Farmanguinhos/Fiocruz (Instituto de Tecnologia em Fármacos –Farmanguinhos/Fiocruz) and the local laboratories Blanver Farmoquímica, Farmacêutica S.A. and Microbiológica Química e Farmacêutica LTDA allowed the Institute to register the main drug for hepatitis C, sofosbuvir 400 mg. Based on this registration (2nd July 2018) the government started the distribution of the product in the Brazilian Unified Health System[5]. On the other hand, in April 2004, Gilead Pharmasset LLC submitted an application for an invention patent to the National Institute of Industrial Property (Instituto Nacional de Propriedade Industrial – INPI) and previous approval by the Brazilian Health Regulatory Agency (Agência Nacional de Vigilância Sanitária – Anvisa) was largely questioned. In February 2017, Farmanguinhos/Fiocruz also submitted grounds for technical

[4]SAÚDE lança plano para eliminar hepatite C. *Ministério da Saúde*, 05 de Julho de 2018. Available at: <http://portalms.saude.gov.br/noticias/agencia-saude/43763-ministerio-da-saude-lanca-plano-para-eliminar-hepatite-c-ate-2030>.

[5]RELATO Reunião para Reavaliação do PCDT de Hepatite C. Available at: <http://www.aids.gov.br/sites/default/files/noticia/2018/65918/relato_da_reuniao_para_reavaliacao_do_pcdt_de_hepatite_c_003.pdf>.

examination to the Gileads's patent submission, alleging that it was unqualified for patenting because it did not show innovation or inventive activity, both necessary requisites for the concession of a patent[6]. In May 2017 Anvisa agreed and in September 2018, the INPI granted the patent to the American pharmaceutical company, preventing Farmanguinhos from producing generic sofosbuvir, despite of Anvisa having already granted them the registration.

An immediate outcry against INPI's decision resulted in, for instance, a statement from the humanitarian organization known as *Médecins Sans Frontières* affirming that "the position of the Brazilian agency responsible for patent analysis occurred in spite of strong arguments against the concession"[7]. Two days later, a request for the annulment of the administrative act conceding the patent for the antiviral drug was filed, and it was immediately granted[8]. Also, the Brazilian Association of Public Health (Associação Brasileira de Saúde Coletiva – Abrasco) and the Working Group on Intellectual Property (Grupo de Trabalho sobre Propriedade Intelectual) of the Brazilian Network for the Integration of the People (Rede Brasileira pela Integração dos Povos) requested to the Health Minister that the drug be immediately declared of public interest, essential for its eventual compulsory licensing[9].

Today, the injunction to the patent of sofosbuvir, conceded to Gilead, is still maintained, and so is the imbroglio, because it remains to be seen "whether the government purchased the best medicine at the lowest price"[10]. And the issue will remain unfinished for as long as humanity be not capable of introjecting the understanding that health is not a commodity, and cannot be treated as such. Not changing this comprehension is like assuming the role of Sisyphus, always trying to keep away the damages caused – to patients and health systems – by low quality products and treatments, inappropriate or unaffordable and irreversibly linked to these damages.

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[6]BRASIL. Ministério da Saúde. Fundação Oswaldo Cruz - Fiocruz. *Compostos, composições e usos para o tratamento de uma infecção por flaviviridae*. Available at: <http://www.far.fiocruz.br/wp-content/uploads/2017/02/Subsidio-pedidoPatenteSofosbuvir.pdf>.

[7]MELLO, Patrícia Campos. Governo libera patente de remédio para hepatite C de americana e trava genérico mais barato. *Folha de S. Paulo*, São Paulo, 18 set. 2018. Available at: <https://www1.folha.uol.com.br/cotidiano/2018/09/governo-libera-remedio-para-hepatite-c-de-americana-e-trava-generico-mais-barato.shtml>.

[8]BRASIL. Tribunal Federal Regional da 1ª Região. Patente, ato lesivo ao patrimônio artístico, estético, histórico ou turístico, dano ao erário. *Consultor Jurídico*. Available at: <https://www.conjur.com.br/dl/acao-popular-hepatite.pdf>.

[9]ASSOCIAÇÃO BRASILEIRA DE SAÚDE COLETIVA - ABRASCO. Grupo de Trabalho sobre Propriedade Intelectual. Rio de Janeiro, 28 set. 2018. Available at: <https://www.abrasco.org.br/site/wp-content/uploads/2018/09/Abrasco_GTPI_MS_sofosbuvir.pdf>.

[10]LEITE, Marcelo. Confusão sem fim na hepatite C. *Folha de S. Paulo*, São Paulo, 09 dez. 2018. Available at: <https://www1.folha.uol.com.br/colunas/marceloleite/2018/12/confusao-sem-fim-na-hepatite-c.shtml>.