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PHARMACEUTICAL PATENTS AND THE RIGHT TO HEALTH - PORTUGAL AND BRAZIL

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Abstract

The defence of the patent system's legitimacy, namely in the pharmaceutical field, is consolidated, although it is not exempt from criticism. Historically, when the patent law, a legal monopoly right, is confronted with the right of access to health, which includes the right to the medicines necessary for its care, the mechanisms that have been established are scarce and weak. Nonetheless, one must recognize due merit in the search for a balance between the exclusive right of the holder of the legal monopoly and the right of the community to generalized access to medicines necessary to fulfil the right to health. In the current context of the covid-19 disease, where access to health care for all countries, rich and poor, is at stake, it seems that there is a greater will to make the right to health prevail over the property right of the holder of a pharmaceutical patent.

Keywords

Pharmaceutical patents; right to health; access to essential medicines

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PHARMACEUTICAL PATENTS AND THE RIGHT TO HEALTH - PORTUGAL AND BRAZIL[1]

RUBEN BAHAMONDE DELGADO

Introduction

The problem resulting from the confrontation between the right to health and industrial property rights is not new, nor exclusive to the Portuguese-Brazilian reality. However, the new challenges, namely those resulting from covid-19, require a greater and better clarification of this confrontation[2]. Indeed, the traditional paradigm of the interaction between the right to health and industrial property that has as its object medicines has focused on the confrontation of interests between rich or developed countries, where there are several companies holding pharmaceutical patents, and poor or less developed countries, where there are few economic and financial means to guarantee access to such medicines and where there are serious and widespread health problems. In the current context, one can say that covid-19 has levelled state economies, as many countries traditionally considered rich or developed do not have the industrial property necessary to produce a drug/vaccine to treat covid-19, thus becoming dependent on the solutions that appear on the market, obviously protected by industrial property, in order to be able to provide timely and adequate access to healthcare for its citizens. In these cases, although the countries concerned have the means to acquire the medicines protected by patents, they may not be available in the desired quantities, prices and dates. This situation reveals a scenario of high selling prices of the solutions found, protected by pharmaceutical patents, assuming that the normal and free functioning of the market will allow access to such solutions to those countries that are in the best conditions to pay a higher price, thus relegating to the background countries that have fewer economic resources. Covid-19 is not HIV/AIDS, nor bronchitis, nor tuberculosis. It affects all layers of society in all societies in all countries of the world in very worrying numbers and without there being a standard of very clear prevention/protection in terms of effectiveness. The problem is not new, but the fact that in the current context a significant number of human beings belonging to rich or more developed countries are

1 Article translated by Carolina Peralta.
2 Covid-19 is the official name of the disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), first identified in 2019, and which in this work we will refer only as covid-19. https://www.volp-acl.pt/index.php/item/covid-19

affected, should generate greater pressure/availability to face this situation from another perspective.

Patents in the international context

Patents have as their object inventions and consist of an exclusive right or legal monopolies conferred by the corresponding entities to those who apply for them, provided that the enabling legal requirements for that purpose are met (Bahamonde, 2016, pp. 163-167). In order for an invention to be granted this protection, it will be necessary that the requirements of novelty, inventive capacity and industrial use are cumulatively met[3]. Inventions for which patent protection can be claimed may concern objects, a particular substance or a device, or they may concern procedures, where what is protected is not the result, but the sequence of steps taken to achieve this particular result. In this context, inventions regarding medicines or specific procedures to obtain substances useful for the treatment of diseases are also likely to benefit from the protection conferred by the patent system.

The patent system is characterized by being nationally based, i.e. the patent is granted by the competent authority of a state and is valid for that state. However, due to the important role that patents play in economic legal traffic, and specifically for the development of markets tending to be characterized by the need to promote their growth through internationalization and globalization, the need to homogenize this matter arose. Thus, it can be said that the first positive interest in creating a system that would allow homogenizing the patent system was at the Paris Union Convention for the protection of Industrial Property of 1883[4]. Without intending to refer exhaustively to the aforementioned legislation, it is worth highlighting its main characteristics related to our topic. In this sense, the unionist priority was established (Article 4/C-1). It was the possibility of granting compulsory licences in the face of abusive exercise of the exclusive right granted by the patent (5A-2) and the possible introduction of patent expiry as a subsidiary measure to the system of compulsory licences (5A-3)[5].

Much more recently, in the Final Act of Marrakech of 1994, which contained the results of the Uruguay Round negotiations, within the scope of the World Trade Organization (WTO), and had its precedents in the General Agreement on Customs and Trade (GATT)[6], the Agreement on Trade-Related Industrial Property Rights (TRIPS) was adopted. Since the main scope of the aforementioned agreement is the adoption of measures and procedures that allow the reduction of distortions to international trade related to the

[3] In Portugal, see Article 1 of Decree-Law no. 110/2018, of 10 December, which approved the new Industrial Property Code. In Brazil, see Article 1 of Law No. 9.297, of 14 May 1996, diploma that regulates rights and obligations related to industrial property

[4] Paris Convention for the Protection of Industrial Property of 20 March 1883, last amended on 2 October 1979, available at https://www.wipo.int/edocs/pubdocs/pt/wipo_pub_201.pdf.

[5] The expiry action can only be activated two years after the granting of the first compulsory licence. With regard to compulsory licences, based on speech or insufficient use, they cannot be requested before the expiry of the period of four years from the filing of the patent application, or three years from the granting of the patent. The longest term will be applicable (5A-4).

[6] General Agreement on Tariffs and Trade established in 1947, which, through the Uruguay Round, gave rise to the World Trade Organization in 1994 (Marrakech Declaration of 15 April 1994). For additional information, see https://www.wto.org.

effective protection of intellectual property rights, the special needs of the least advanced signatory countries are expressly recognized, requiring, in these cases, a more flexible application of the rules in question so that a viable technological base can be created. In this context, the agreement establishes the possibility for the signatory countries to exclude the patentability of inventions whose commercial use in their territory must be prevented in order to protect the health or life of people and animals. It also provides for the possibility of using the patent granted without the holder's consent in national emergency situations[7].

Despite the aforementioned mechanisms, the relationship between the pharmaceutical industry and the signatory States, namely those less evolved in terms of ownership of industrial property rights in the pharmaceutical field, increased the tension between the protection of property and the right to health that the States must guarantee to their citizens. In this context, the DOHA Declaration on the TRIPS Agreement and public health was made on 14 November 2001[8]. This declaration was based on the seriousness of the public health problems that affected many developing countries, with particular relevance to HIV/AIDS, tuberculosis, malaria and other epidemics, namely in Brazil, South Africa and India (Orsi, 2007: 1997-2003; Polônio, 2006: 68; Cullet, 2003: 147-154). Despite the recognition of the fundamental importance of intellectual property protection for the development of new medicines, the legitimacy of the Member States to adopt measures aimed at protecting public health is also underlined, imposing the obligation that the TRIPS agreement be interpreted in the sense of supporting the right of WTO Members to protect health. The document reiterates the possibility for States to grant compulsory licences and their right to determine what constitutes, in each case, a national emergency or other circumstances of extreme urgency. To avoid further confusion, it is specifically recognized that public health crises, including those related to HIV/AIDS, tuberculosis, malaria and other epidemics, may represent a national emergency or other circumstances of extreme urgency[9]. Finally, the most relevant aspect of this document is the recognition of the inefficiency of the compulsory licensing system when it comes to countries whose manufacturing capacities in the pharmaceutical sector are insufficient or non-existent, which will necessarily lead to more creative solutions in this type of situation (Pontes, 2017: 49). To try to overcome this difficulty, after the DOHA Declaration, several decisions were adopted in order to allow cheaper generic medicines manufactured under compulsory licences in case the importing countries are not able to

[7] Article 27(2) of the TRIPS requires that this deviation from the rule, in addition to being supported by the corresponding legislation, must be based on the reasons provided for the protection, among others, of health. In addition, and without prejudice to the protection of the invention through a patent, article 31 establishes several situations in which the right in question can be used by third parties without the authorization of the holder. Namely, paragraph b) refers to national emergency situations or situations of extreme urgency or cases of public non-commercial use.
Article 27(2) of the TRIPS requires that this deviation from the rule, in addition to being supported by the corresponding legislation, must be based on the reasons provided for the protection, among others, of said health. In addition, and without prejudice to the protection of the invention through a patent, article 31 establishes several situations in which the right in question can be used by third parties without the authorization of the holder. Namely, paragraph b) refers to national emergency situations or situations of extreme urgency or cases of public non-commercial use.

[8] WTO Ministerial Conference (DOHA, 2001): TRIPS, WT/MIN/(01)DEC/2, 20 November 2001, available at https://www.wto.org/spanish/thewto_s/minist_s/min01_s/mindecl_trips_s.htm

[9] See point 5(c) of the Declaration on the TRIPS Agreement and public health.

manufacture them themselves. Thus, exporting countries were exempted from the obligations arising from subparagraph f) of article 31 of the TRIPS, allowing any Member country to export generic pharmaceutical products manufactured under compulsory licences to satisfy the needs of importing countries, provided that certain conditions are met[10]. In 2017, it was decided to add article 31bis to the Agreement, thus allowing importing countries to distribute the imported medicinal product under licence in countries belonging to the same economic area and facing the same health emergency situation[11].

Following this path, the European Union has also sought to clarify the problem of the supply of generic medicines manufactured using compulsory licences when its Members are States experiencing public health problems (Fernández-Nóvoa, 2017: 201-206)[12].

It is also important to mention that the problems resulting from the exercise of rights arising from pharmaceutical patents are not limited exclusively to the least developed countries. Indeed, as far as the most advanced countries are concerned, and with the means to produce the drugs in question, the question arises in terms of assessing from which moment the knowledge protected by a pharmaceutical patent can be used, to give initiation to the necessary legalization procedures, aimed at the production and subsequent commercialization of a generic drug. This issue gave rise to the well-known "Bolar provision", which relates to the interpretation of Article 30 TRIPS and the possibility, widely contemplated in legal systems, of allowing the use of knowledge protected by a patent for experimental or research purposes[13]. The Bolar provision goes beyond this situation, establishing an exception that allows the experimental use of a product protected by patent to carry out the necessary administrative procedures aimed at authorizing the marketing of the generic product in question, essentially based on the requirement to respond to social needs , namely the rapid introduction of affordable medicines (Tudor, 2018: 300-308)[14].

Alongside these instruments, and collaborating in the search for solutions to the exposed problems, there are other important international organizations such as the World Intellectual Property Organization (WIPO)[15] or the World Health Organization (WHO), namely through the Commission on Intellectual Property Rights, Innovation and Public

[10] Decision of 6 December 2005 — Amendment of the TRIPS Agreement; Decision to extend the deadline for accepting the amendment to the TRIPS Agreement, 2015; Decision on application by least developed member countries — Obligations under Article 70(8) and (9) of the TRIPS Agreement relating to pharmaceuticals, 2015 and Decision on the extension of the transition period under Article 66(1) of the TRIPS Agreement for least developed member countries in relation to certain obligations relating to pharmaceuticals, 2015.

[11] See Article 31bisd in full, updated in March 2020 https://www.wto.org/english/res_e/publications_e/ai17_e/trips_art31_bis_oth.pdf

[12] Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on the granting of compulsory licences for patents relating to the manufacture of pharmaceutical products intended for export to countries with public health problems.

[13] See. subparagraph c) of no. 1 of article 103 of the Portuguese Industrial Property Code and item II, article 43, of Law no. 9.297, of 14 May 1996, which regulates rights and obligations related to industrial property in Brazil.

[14] In any case, the aforementioned clause does not preclude the need for the basic patent or the complementary protection certificate to be expired in order to start marketing the generic product.

[15] See https://www.wipo.int/patent-law/en/developments/publichealth.html

Health[16], which, with their studies and recommendations, have greatly contributed to the evolution of the treatment given to pharmaceutical patents when related to access to the right to health in developing or less developed countries. Industrial property, as a property right or as a protection for the authorship of creations, finds a legal basis in the Universal Declaration of Human Rights of 1948, namely in article 17 on the right to property and in paragraph 2 of article 27 on moral and material interests of authors[17], and in the International Covenant on Economic, Social and Cultural Rights, (1966/1976) which recognizes, in paragraph c) of point 1 of article 15, the protection of authors' interests[18].

In the latter case, it should be noted that the Committee on Economic, Social and Cultural Rights, in the general observation of Article 17, specifies in its introduction the need to differentiate between human rights as such and intellectual property regimes, making it clear that intellectual property rights should not be equated with the human right recognized in paragraph c) of point 1 of article 15 of the Covenant[19]. To justify this position, among other arguments, the Committee specifies that human rights are fundamental because they are inherent to the human person as such, whereas intellectual property rights are mainly means used by States to stimulate creativity and inventiveness, protecting itself through intellectual property regimes, namely commercial and business investments. The Charter of Fundamental Rights of the European Union of 2000 (Article 17) also protects the right to property in the terms that were already provided for in the European Convention on Human Rights of 1950[20].

It should also be noted that the treatment of patents at international level has been given wide prominence, namely through the Patent Cooperation Treaty (PCT), whose objective is to simplify the procedures for obtaining protection of inventions through patents in the various signatory States. In the current context of covid-19, the WIPO International Secretariat has made some rules more flexible, namely interpreting the current pandemic situation as being covered by the tolerance of delays in meeting the PCT deadlines[21]. At supranational level, we have in the European context the Munich Convention on the European Patent Organization (EPO) of 1973, whose objective is also to simplify the procedures for obtaining protection for inventions in the signatory States and the much more ambitious project of the European Patent with Unitary effect, where the ultimate

16 See https://www.who.int/intellectualproperty/en/

17 Everyone has the right to the protection of the moral and material interests linked to any scientific, literary or artistic production of their authorship.

18 The States Parties to this Covenant recognize the right of every person to (…) benefit from the protection of the moral and material interests that correspond to them by virtue of scientific, literary or artistic productions of which they are the author.

19 UN Committee on Economic, Social and Cultural Rights (CESCR), General Comment No. 17: The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from any Scientific, Literary or Artistic Production of Which He or She is the Author (Art. 15, Para. 1 (c) of the Covenant), 12 January 2006, E/C.12/GC/17. https://www.refworld.org/docid/441543594.html

20 The European Convention on Human Rights and Fundamental Freedoms (Rome, 04.11.1950) introduced, through its additional protocol in 1952, article 1 on the protection of property, which states: "*No one may be deprived of his or her possessions except in the public interest and in the cases and under the conditions provided for by law*".

21 Patent Cooperation Treaty made in Washington on 19.06.1970, last modified on 30.10.2001. See PCT Rule 82Q.

objective would be to create a single procedure for the protection in several Member States of an invention through a patent[22].

With this contextualization, it is evident that the protection of inventions through patents has achieved a significant homogenization at international level, promoted mainly by commercial interests (Bahamonde, 2016: 167-171). However, as a counterpoint to commercial interests, the analysed rules also state a clear concern with the protection of social interests, namely in the field of health, with several mechanisms being foreseen to achieve the desired balance between all the interests at stake.

Patents in the Portuguese-Brazilian national context

As seen above, without being exhaustive, there is a vast international treatment of the protection of inventions as one of the typologies of industrial/intellectual property[23], so the majority of national legal systems tend to be quite homogeneous, namely in the Portuguese-Brazilian case. Still, it will be interesting to analyse the mechanisms specifically provided for in each of the legal systems in question, to ensure a certain balance with regard to patents and other interests.

The Portuguese Industrial Property Code (CPI) establishes, in line with other codes on the matter, that patents can be obtained for any inventions, whether products or processes, in all fields of technology, as long as they are new inventions, imply an inventive step and are susceptible of industrial use[24]. Article 50(5) of the CPI also provides for the possibility of protecting the same invention either through a patent application or through a utility model application. However, with regard to the specific field of protection of pharmaceutical products or procedures, it is established that inventions that affect pharmaceutical substances or compositions and pharmaceutical processes cannot be object of a utility model[25]. Thus, inventions that relate to pharmaceutical products or procedures can only be protected through a patent, thus guaranteeing a more rigorous system for the protection of these inventions (Sousa e Silva, 2011: 87-90)[26].

The legal monopoly right granted to the patent holder is not absolute, and, in this line, the Portuguese legislator has established several mechanisms to limit it in situations of justified interest. As seen above, the right conferred by the patent does not allow its holder to prohibit acts for testing or experimental purposes (103/1/c), thus allowing the

[22] Decision 2011/167/EU of the European Council, of 10 March 2011, authorizing enhanced cooperation in the field of the creation of unitary patent protection. Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012, which regulates enhanced cooperation in the field of the creation of unitary patent protection and Regulation (EU) No 1260/2012 of the Council of 17 December 2012, which regulates enhanced cooperation in the field of the creation of unitary patent protection with regard to the applicable translation regime and the Agreement on the Unified Patent Court of 19 February 2013.

[23] Intellectual property generically refers to copyright and industrial property itself, so when dealing with the matter of patents we believe it is more appropriate to use the term industrial property.

[24] See Article 1 of Decree-Law No. 110/2018, of 10 December, which approved the new Industrial Property Code.

[25] Subparagraph d) of no. 1 of article 121 of the CPI.

[26] In fact, inventions protected through the utility model have a lower requirement for inventive step, which translates into faster protection, but at the same time more tenuous and precarious.

protected and published knowledge to immediately contribute to the scientific development of the respective area of application. Subparagraph b) of the same norm also excludes from the patent holder's powers the possibility of preventing the preparation of medicines made at the time and for individual cases or preparatory procedures. Article 108 of the CPI also provides for the possibility of granting compulsory licences in the event of lack of or insufficient use of the patented invention (109th), in the event of dependence between patents (110) and for reasons of public interest (111). In the latter case, the licence will be granted by order of the member of the Government responsible for the matter, considering that there is a reason for public interest when the increase or generalization of the use of the invention, or the improvement of the conditions under which such utilisation takes place, are of paramount importance to public health. The possibility of loss or expropriation of the patent is also foreseen in the case of having to answer for obligations contracted with others or for public utility, situation in which the rules of the Code of Expropriations will apply[27].

All these limitations result from the balance between the nature of the law in question and that of other areas of law where friction can occur. It is true that the qualification of the industrial property right as a property right, i.e., within the scope of article 62 of the Constitution of the Portuguese Republic (CRP), is not pacific in terms of doctrine, as it consists, at the limit, of a *sui generis* property right. However, even with specificities, what is undeniable is that our legal system recognizes its nature, hence, it can be expropriated, which corresponds to one of the possible limitations of the property right. On the other hand, this right could also find protection within the scope of paragraph 2 of article 42 CRP (Freedom of cultural creation)[28]. In this sense, regarding the nature of the industrial property right in Portugal, when confronted with the right to health, the Constitutional Court ruled in judgment no. 216/2015 that *despite the evident constitutional protection of patents and the rights arising from them, it is unequivocal that they yield to the fundamental right of health protection*"[29].

[27] See Article 107 CPI

[28] On the one hand, paragraph 2 of article 42 CRP is a fundamental right that enjoys the enhanced protection of article 18, and the property right established in article 62 CRP is a fundamental right of a similar nature. In this sense, see the ruling of the Southern Central Administrative Court (TCAS) of 05.06.2010 in the scope of case No. 06154/10, where the Rapporteur was Dr Teresa de Sousa, establishing that "*The property right enshrined in art. 62 of the CRP, which covers industrial property rights, including rights based on drug patents, has been considered a fundamental right similar in nature to the rights, freedoms and guarantees for the purposes of applying the contents of articles 17 and 18 of the CRP".* This decision is very relevant as it was pronounced with the losing vote of Dr Benjamin Barbosa, whose reasoning was later confirmed by the Constitutional Court ruling below.

[29] Decision No. 216/2015 of the Constitutional Court, 2nd section, delivered within the scope of case 207/2013. The decision in question assessed the constitutionality of Law no. 62/2011 of 12 December with regard to the procedure for the Marketing Authorization (MA) and the Retail Price (RRP) of generic drugs that could infringe a patent. In this procedure, INFARMED could not assess the violation of a previous patent, so the marketing of a generic drug could be approved, although it could later be demonstrated that it violated a previous right. Quoting Professor Paulo Otero, he echoes the point that "*the proximity and essentiality of guaranteeing health with the dignity of the human person, in a State model where people are worth more than things or property, and the understanding that the limitation or restriction of exclusive rights arising from patents translates into an expansion of freedom, in a State model that privileges freedom over property, lead to an abstract constitutional solution that gives preference to the position that defends the introduction of generic medicines into the market, in view of the patrimonial content position defended by patent holders on reference medicines*."

In turn, the Brazilian Industrial Property Law also establishes several limitations to the patent holder's right in the same way as the Portuguese legal system. In fact, the patent holder cannot prevent acts performed by unauthorized third parties, with experimental purposes, related to scientific or technological studies or research (43/II), nor prevent the preparation of medicines according to medical prescription for individual cases performed by a qualified professional, as well as the drug thus prepared (43/II). A central role in this set of limitations is the compulsory licence that may be imposed when the object of the patent is not used in Brazilian territory, due to lack of manufacture or incomplete manufacture of the product (68 §1/I) and when the commercialization of the protected object or process does not satisfy the needs of the national market (68 §1/I) and, likewise, in the event of dependence between patents (70). Finally, in situations of national emergency or public interest, declared in an act of the Federal Executive branch, as long as the patent holder or its licence holder do not meet this need, a compulsory licence may be granted[30].

With regard to the constitutional protection of patents in Brazil, it is worth noting the greater clarity with which the Brazilian constituent expressed it when specifically enshrining in Title II of the Constitution of the Federative Republic of Brazil (CRFB), on fundamental rights and guarantees, the guarantee that "*the law will grant the authors of industrial inventions a temporary privilege for their use, as well as protection of industrial creations, the ownership of trademarks, company names and other distinctive signs, with a view to social and technological interest and the country's economic and technological development*"[31]. In other words, the Brazilian Magna Carta directly views patents not as a property right, but as a temporary privilege, subjecting their attribution and exercise to the technological and economic social interest.

At first glance, we can point out the following relevant differences between the Portuguese and the Brazilian legal systems. In the Portuguese one, the possibility of expropriation of the patent right was expressly foreseen when based on reasons of public utility, which is not provided for in Law n. 9.279 of 14 May 1999 (LPI) in Brazil. This is evaluated positively, as it recognizes a preventive function, allowing patent holders to be aware of the serious consequences that can arise from a deficient use of their right, also making it easier to justify drastic decisions in extreme situations, such as during the current pandemic, within its corresponding regulatory framework[32].

In Brazil, the legislator specifically provided for the possibility of granting compulsory licences if the patent holder abusively exercises the rights arising therefrom, or through it practices abuse of economic power, proven under the law, by administrative or judicial decision (68). In this case, we do not find a similar principle in the Portuguese CPI, perhaps because if this behaviour were to occur, we would be faced with a possible

[30] This issue was developed by Decree No. 3.201, of 6 October 1999, which provides for the granting, *ex officio*, of a compulsory licence in cases of national emergency and public interest, as provided for in art. 71 of Law No. 9.279 of 14 May.
[31] See item XXIX of article 5 of the CRFB.
[32] Despite the goodness of the rule, at present, it is not known any situation when the Portuguese State has applied it in practice.

situation of abuse of a dominant position within the scope of article 11 of the Competition Law or article 102 of the Treaty on the Functioning of the European Union[33].

However, as there is a wide interaction and/or complementarity (Pérez, 2018: 372-393; Bahamonde, 2016: 166-167) between industrial property law and competition law, this provision in the Brazilian legal system seems to us to be systematically relevant, as it reinforces legal certainty in the application of this mechanism, unlike what happens in Portugal[34].

Both legal systems focus their reaction mechanism in the face of lack of use or insufficient use by the patent holder in the field of compulsory licences (Palmela, 2016). Regarding them, it is necessary not to be too encouraging with the prospects for the future, because in fact, it has never been used in Portugal, and in Brazil (EFAVIRENZ) it was only used once[35]. However, we believe that the mere affirmation of the possibility of compulsory licencing will allow any negotiations between the parties involved to be more compromised.

The central role of compulsory licences

From the above, it follows that compulsory licences are the most common mechanism to offset possible imbalances arising from the exclusivity right conferred by a pharmaceutical patent[36].

The compulsory licencing regime in Brazil and Portugal basically provides for two modalities with regard to patents related to medicines. Firstly, a compulsory licence, which requires confirmation of insufficient use of the invention to supply the national market. In these circumstances, the Portuguese rule requires, prior to its granting, that the applicant has made efforts to obtain from the patent holder a contractual licence under acceptable commercial conditions, and that such efforts are not successful within a reasonable period (108/3). In turn, the Brazilian rule requires that the applicant has a legitimate interest and technical and economic capacity to carry out the efficient use of the object of the patent (68/§2). In fact, these two rules coincide in the need to confirm that the applicant is a serious candidate and that he has the conditions and commitment to use the licence to supply the market. In both systems, this licence is expected to be non-exclusive, non-sublicensable, revocable, and remunerated[37].

Secondly, we have compulsory licences justified by national emergency situations or public interest, in which case pre-requisites for granting them are waived. In these

[33] Law No. 19/2012, of 8 May, which established the new legal system for competition.
[34] This was also the option of the Spanish legislator provided for in article 94 of Law 24/2015, of 24 July, on Patents.
[35] Through the publication in the Official Gazette of the Union of Decree no. 6.108, of 4 May 2007, which granted the compulsory licencing, in the public interest, of the patents related to EFAVIRENZ, for the purpose of non-commercial public use.
[36] See articles 30 and 31 of the TRIPS agreement, article 109 of the CPI and article 68 and following of Law No. 9.279, of 14 May 1996. However, its use is very scarce, so it is common to say that it fell far short of the expectations placed in it (Fernández-Nóvoa, 2017: 197-206).
[37] This similarity of the norms under analysis results from the imposition that arises for the States of the TRIPS agreement, specifically from article 30.

situations, the Brazilian legislator allows the granting of a compulsory licence when it is shown that, in the face of a national emergency or public interest, the patent holder does not meet this need (Remédio, 2011: 399-400; Couto, 2005: 116-119). For its part, the Portuguese legislator also requires a public interest reason for the use of this measure. However, it differs from its Brazilian counterpart in that it is not required that the owner improperly uses the invention, i.e., the owner of the invention may be making every effort to satisfactorily use the invention, and even to be succeeding, but even then, for reasons of public health, he may be obliged to grant a compulsory licence. Apparently, the Portuguese norm is a little more restrictive than the Brazilian norm, although an extensive interpretation of this norm allows reaching the same understanding in Brazil.

The Portuguese-Brazilian compulsory licencing system is clearly the result of a "transposition" of article 31 TRIPS, resulting from both countries' membership of the World Trade Organization. In practical terms in Portugal, compulsory licences have not gone beyond paper, insofar as they are only the subject of academic study, as none have been enforced to date.

In turn, in Brazil there is only one specific situation when a compulsory licence (EFAVIRENZ) was granted. However, in the global context, the reality is more encouraging, as it appears that compulsory licences are used more than what is generally thought or known.

In fact, in a study carried out on the subject, 81 compulsory licences were identified between 2001 and 2016, which also include developed countries, as a result of the high price of certain medicines (Hoen, 2016: 186-187).

We can thus conclude that compulsory licences have been used in a very timid way, having the potential to constitute an adequate response to overcome the barriers that pharmaceutical patents may pose to the realization of the right to access medicines and, in turn, to the right to health. Additionally, it can always be argued that its legal provision gives it a preventive and dissuasive use of deviant behaviour on the part of the patent holder, which undoubtedly has encouraged the granting of voluntary licences.

The "recent" possibility of drug protection through patents

It is important to point out that both Brazil and Portugal joined the WTO on 01.01.1995, and that, until that date, protection of medicines through patents was not allowed in Brazil (Nunes, 2009, pp. 13-18). Indeed, as a result of its accession to the WTO, the LPI, in the sole paragraph of article 229 of Title VIII, of the transitional and final provisions, states[38]:

> *"To the requests relating to pharmaceuticals and agricultural chemicals, which were filed between 1 January 1995 and 14 May 1997, the patentability criteria of this Law apply on the effective date of filing of the application in Brazil or of priority, if any, ensuring protection from the date of granting the*

[38] Law No. 9.279, of 14 May 1996, whose content was inserted by Law No. 10.196, of 2001.

> *patent for the remaining period from the day of filing in Brazil, limited to the period provided for in art. 40".*

In Portugal, Decree 30679 of 24 August, which approved the Industrial Property Code of 1940, provided that the following could not be subject to patents (Article 5, no. 3:

> *"food, as well as pharmaceutical products and preparations, intended for humans or animals, although the devices or systems for their manufacture may be patented".*

However, with the accession to the European Patent Convention (EPC) in 01/01/1992, Portugal became the recipient country of a pharmaceutical product patent application. Indeed, Articles 52 and 53 of the Convention allow for patent protection of a pharmaceutical invention, with no specific exclusion preventing it.

Paradoxically in this period, in Portuguese territory it is possible to apply through the European Patent for the protection of a medicine, although its patent protection through the national route is not allowed.

Although Portugal is obliged to implement the TRIPS Agreement only as of 01/01/1996, as provided for in article 65, no. 1, its compliance was anticipated with the approval of the Industrial Property Code, through Decree-Law no. 16/95, of 24 January, which came into force on 01/06/1995 (art. 9) and adjusted national legislation to the TRIPS Agreement, allowing the patenting of pharmaceutical products (Articles 47 to 49).

In this analysis, it is important to remember that, prior to the TRIPS Agreement and despite the existence of rules regarding the protection granted by patents, the CUP enabled signatory countries to establish their own internal rules, namely, establishing what could or could not be the subject of patent. In other words, the signatory countries could choose to protect in their national territories the drug inventions through patents or, on the contrary, they could prohibit the protection through patents of drug inventions. In practice, this implied that the fact that an inventor could patent a drug in a given national territory did not prevent third parties from using the knowledge underlying that patent in another territory where the invention was not patentable.

From the above, it is clear that there is a national and international regulatory framework for the protection of inventions of medicines through patents. However, it should not be forgotten that the inclusion of drug inventions in the protection of patents is very recent, and that the aforementioned protection was achieved, not so much by virtue of the patent system to promote the right to health and innovation, but rather as a condition for benefiting from the economic prerogatives deriving from accession to the WTO.

The Right to Health

Health in the international context

The Charter of the United Nations signed in San Francisco on 26 June 1945, at the end of the United Nations Conference on the International Organization, entered into force on 24 October 1945, and established the need to promote the solution of international economic, social, health and related problems, as well as international cooperation, of a cultural and educational nature as a means of maintaining and preserving peace between peoples (55/a). The Economic and Social Council was also established, whose function is, among others, to prepare studies and reports on international matters of an economic, social, cultural, educational, health and related nature, being able to make recommendations on such matters to the General Assembly[39], members of the United Nations and interested special organizations.

In turn, the Universal Declaration of Human Rights (1948), in its article 25/1, establishes that everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, especially food, clothing, housing, medical care and the necessary social services[40].

The World Health Organization emerged as a specialized body, under the terms of article 57 of the United Nations Charter. Health is seen as a state of complete physical, mental and social well-being, not merely the absence of disease or infirmity. It is also stated that enjoying the best possible state of health is one of the fundamental rights of every human being, without distinction of race, religion, political creed or economic or social condition[41].

It is also underlined that the health of all peoples is essential for achieving peace and security and depends on the closest cooperation of individuals and States. The results achieved by each State in the promotion and protection of health are of value to all. The uneven development in different countries in terms of promoting health and combating diseases, especially contagious ones, constitutes a common danger[42].

Also within the scope of the United Nations, the International Covenant on Economic, Social and Cultural Rights is highlighted. Its article 12 clearly shows the commitment between the signatories to widely protect the right to health, recognizing all people the right to enjoy the highest level of physical and mental health and imposing concrete measures for their protection (Helfer, 2015: 317-318; Sellin, 2015: 445-473).

In turn, the Treaty on the Functioning of the European Union, in its Article 9, sets out as an objective the promotion of a high level of employment, the guarantee of adequate social protection, the fight against social exclusion and a high level of education, training and protection of human health. In the same regulation, article 168 provides that in the definition and implementation of all Union policies and actions, a high level of health protection will be ensured. Union action, which will complement national policies, will

[39] Constituted by all members of the United Nations (9/1)
[40] Adopted by the United Nations on 10 December 1948.
[41] Preamble to the Constitution of the World Health Organization.
[42] Accordingly, the primary objective of the World Health Organization is the acquisition, by all peoples, of the highest possible level of health (Article 1).

focus on improving public health and preventing human illness and disease and reducing causes of danger to physical and mental health. This action will cover the fight against major scourges, encouraging research into their causes, forms of transmission and prevention, as well as health information and education and surveillance of serious threats to health with a cross-border dimension, alerting in the event of such threats and the fight against them.

The Charter of Fundamental Rights of the European Union, in article 35 on the protection of health, establishes that everyone has the right to access prevention in health matters and to benefit from medical care, in accordance with national laws and practices. In the definition and implementation of all Union policies and actions, a high level of human health protection is ensured.

In other words, there is no doubt that the protection of the right to health occupies a pre-eminent position in the various international instruments, not only as an end, but also as a means of ensuring peace between peoples and the dignity of the human person. This right should supersede others of a more materialistic nature.

Health in the Portuguese-Brazilian context

In the Portuguese context, the right to health is enshrined in Article 64 of the CRP, which establishes that everyone has the right to health protection and the duty to defend and promote it[43]. Paragraph 2 of the same document prescribes that the protection of the right to health will take place through a universal and general national health service, which tends to be free of charge. It establishes the achievement of economic, social, cultural and environmental conditions that guarantee the protection of childhood, youth and old age. Subparagraphs c) and e) of paragraph 3 of article 64 CRP deserve special interest in the matter that concerns us. They imposes on the State the priority task of guiding action towards the socialization of the costs of medical and drug care and also disciplining and controlling the production, distribution, marketing and use of chemical, biological and pharmaceutical products and other means of treatment and diagnosis.

In line with the above in the international context, it is clear in the Portuguese national domain that the right to health allows the realization of other constitutionally enshrined fundamental rights, such as the right to life and the right to moral and physical integrity, as well as the realization of the principle of human dignity (Monge, 2019: 78; Miranda, 2010: 1309).

In the Brazilian context, health is enshrined in article 196 of the CRFB, as a right of all and a duty of the State, guaranteed through social and economic policies aimed at reducing the risk of disease and other aggravations and at universal and equal access to actions and services for their promotion, protection and recovery. Within the competences attributed to the unified health system, it is worth mentioning the one that

[43] As stated by the doctrine "The right to health protection comprises two aspects: one, of a negative nature, which consists of the right to demand from the State (or third parties) that it refrain from any act that harms health, the other, of a positive nature, which means the right to state measures and benefits aimed at disease prevention and treatment. … in the second case, it is a social right itself, with the corresponding constitutional configuration" (Canotilho, 2014: 825).

refers to controlling and inspecting procedures, products and substances of interest to health and participating in the production of medicines, equipment, immunobiological products, blood products and others[44]. This right fits within the social rights provided for in article 6 of the Brazilian Constitution, which guarantees individuals' autonomy, enabling them to exercise other rights freely through access to educational training, work, housing, and heath care (Carvalho, 2019: 25-28).

Without having the opportunity to delve further into the legal treatment given to this right and the consequent obligation imposed on the State, this paper shows that we are dealing with a right that goes beyond its own borders as an end and is also essential for the realization of many other rights. Accordingly, when compared with the property right, it seems evident that the latter must yield to the former, and this superiority does not imply the elimination or annulment of the property right.

Final considerations

As a result of the analysis carried out in this work, it would be logical to conclude on the relevant role of compulsory licences as a means to allow greater and broader access to health when used in a situation where pharmaceutical patents exist. However, if this has already proven not to be very effective when targeting access to medicines by less developed countries, in the current context, in which the problem of access to a medicine or treatment protected by patent that can treat covid-19, extends to most advanced countries, the role to be played by compulsory licences is manifestly null (Hoen, 2016: 185-193)[45].

Indeed, the recent context of covid-19 has shown that the main tool to promote the rapid and effective gaining of a pharmaceutical solution to fight the pandemic has been based on voluntary collaboration between economic agents, in an increase in permissiveness on the part of pharmaceutical patent holders so that the object of their protection can be freely used in the production of more effective medicines or vaccines and solidarity initiatives to finance the acquisition and donation of vaccines (Bartels, 2020: 11-12). There are several strategies to democratize access to patent-protected medicines in a "normal " context, i.e., non-pandemic conditions. Indeed, within the scope of the mechanisms to boost this access, and as mentioned above, TRIPS enables the possibility of compulsory licences based on the lack of sufficient use by the holder, and also compulsory licences based on a situation of national urgency or public interest and non-commercial purposes. There is also provision for flexibilization of exports from producing countries, albeit with compulsory licences, to less developed countries without production capacity and the possibility of exporting these medicines between a country that receives this aid and another country in the same economic area.

In most countries, there are expropriation regimes that can be brought against the patent right holder when faced with situations of public utility and interest. Voluntary licences

[44] See. Title I of Article 200 CRFB.
[45] These authors advocate that a wider use of compulsory licences would be essential to guarantee better and broader access to health, both in poor and rich countries.

also play an important role, as does the currently very limited ability of non-WTO member countries to exclude vaccines from patentability. We also have altruistic initiatives, such as the COVAX programme, whose objective is to raise funds to acquire vaccines and equipment and distribute them to countries with greater difficulties in dealing with the pandemic situation[46].

Despite all these mechanisms, it has been found that the solution to the pandemic situation based on the goodwill of patent holders is not enough to build an effective, rapid and global response, with very "embarrassing" situations occurring with regard to the vaccination levels of the population[47]. As a result of this situation, several proposals were presented to the WTO to suspend the WTO TRIPS agreement on vaccines, treatment and equipment related to covid-19 and increase production and manufacturing capacity in developing countries[48].

These proposals were evaluated in the Proposal for a Resolution presented by the European Parliament of 2 June 2021 on how to face the global challenge of covid-19[49]. Roughly speaking, this document opposes a possible suspension of patents related to the treatment of covid-19, stating that the patent system is essential to fostering innovation and safety in the invention ecosystem and that this safety is essential to be able to invest in finding solutions for new variants of covid-19[50]. Alternatively, the aforementioned document recommends that the emphasis should be on encouraging the donation of vaccines and on permitting the export of vaccines from producing countries to countries in need of vaccines, among other measures.

This stance is to be regretted, since there are several reasons that would impose a decision to the contrary[51]. All existing mechanisms contribute to overcome the pandemic situation at a global level, but all of them have proved to be insufficient and far from real needs. Extraordinary situations require extraordinary approaches that lead to extraordinary solutions.

The protection of medicines through patents is relatively recent and the acceptance of this protection by several States was based not so much on the conviction of its advantages, but because it is a necessary requirement to benefit from other advantages

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46 https://www.gavi.org/covax-facility

47 In fact, the vaccination rate is very high in rich countries, and non-existent or low in less developed countries. Rich countries "monopolize" vaccines to satisfy their national needs first, and there is a race between rich countries to that end. Many unnecessary doses were withheld by rich countries. In the free market, solutions could be sold to the top payer with priority, as was the case of Israel, which paid almost twice as much for the vaccine as the European Union. https://www.elindependiente.com/vida-sana/salud/2021/01/21/el-precio-del-milagro-israeli-con-la-vacuna-pagar-mas-y-dar-datos-a-pfizer/. The WHO has asked rich countries to delay the administration of a third dose of the vaccine and allow for an increase in vaccination in countries where the first doses have not yet been administered https://elpais.com/sociedad/2021-08-04/la-oms-pide-una-moratoria-mundial-para-la-tercera-dosis-de-las-vacunas-contra-la-covid-19.html. Furthermore, pharmaceutical companies did not have any problems in increasing vaccine prices in contracts signed with the European Union, which is certainly justified by commercial opportunism. https://www.lavozdegalicia.es/noticia/sociedad/2021/08/01/pfizer-moderna-suben-precio-vacunas-contra-covid/00031627826051265125579.htm

48 See https://www.wto.org/english/news_e/news21_e/trip_23feb21_e.htm

49 See https://www.europarl.europa.eu/doceo/document/B-9-2021-0311_PT.pdf

50 See Recital L.

51 See the Human Rights Watch article of 03.06.2021 entitled Seven Reasons the EU is Wrong to Oppose the TRIPS Waiver. https://www.hrw.org/news/2021/06/03/seven-reasons-eu-wrong-oppose-trips-waiver

arising from membership of the WTO. In addition, the ability of the patent system in the pharmaceutical sector to stimulate innovation is far from being peaceful, with studies showing precisely the opposite effect (Gold, 2010). Another factor to consider is the fact that many medicines protected through patents are also the result of public investment, in its various forms, which questions the democratization of investment and the monopolization of eventual profits (Cross et al., 2021)[52].

In our understanding, the provisional suspension of patents that protect vaccines is the extraordinary measure that this extraordinary situation requires to build a solid and rapid response to the global emergency. We disagree with the understanding advocated by the Chairman of the Board of GAVI – Global Alliance for Vaccines and Immunization, José Manuel Durão Barroso, in maintaining that this measure would have a negative impact on research and innovation. Another argument given is the absence of knowledge or secret know-how to put into practice the use of suspended patents, which is also difficult to understand (Barroso, 2021: 66). Firstly, as we have seen, there are situations when a large part of the funding needed to obtain vaccines is public, so an eventual suspension of patents obtained with that funding would allow for adequate economic compensation that would reward the public effort made. Secondly, an essential pillar of the patent system is the publicity of the invention to be protected in such a way that the owner of the patent right will have to reveal all the necessary procedures for any expert in the field to reproduce the protected invention. In this context, it is not clear how it can be argued that there will be an "important know-how" that would prevent verifying the quality of vaccines produced with the knowledge of suspended patents.

Indeed, if the vaccine is protected by patent, any expert in the field will be able to reproduce the vaccine following the instructions made public with the patent application. If, on the contrary, the reproduction of the procedure protected by the patent does not result in exactly the same vaccine whose protection was requested, due to the lack of important know-how, then the vaccine could not be protected by patent, and would be freely used.

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[52] See also the Human Rights Watch article entitled "Seven Reasons the EU is Wrong to Oppose the TRIPS Waiver". https://www.hrw.org/news/2021/06/03/seven-reasons-eu-wrong-oppose-trips-waiver

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