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Is the Compulsory Licensing Mechanism Guaranteed by TRIPS the Best Remedy to Improve Access to Biological Therapies Worldwide?²

Abstract. A compulsory licence is an authorisation under the state administration to use intellectual property rights by third parties, subject to payment of remuneration, regardless of the patent holder's objection. In the Polish legal system, the institution of a compulsory licence is regulated by: the Paris Convention for the Protection of Industrial Property Rights (20 March 1883), the Agreement on Trade-Related Aspects of Intellectual Property Rights (15 April 1994), 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 for export to countries with public health problems and the Industrial Property Law Act (30 June 2000). The basic research thesis of my paper was based on the assumption that a compulsory licence does not meet the objective of providing access to biologics. The regulations governing this institution need to be changed, first of all towards the re-granting of a compulsory licence with the proper meaning of balancing the interests of the public (society) and private (patent holder).

Keywords: compulsory licence, obligatory licensing, patent, biologics, biosimilars, licences

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Introduction

Biologics alternatively called biological medicinal products or biopharmaceuticals revolutionised the way patients are treated (Casasempere, 2008; Kaczor et al., 2018; Świerczyński (Ed.), 2016; Świerczyński & Więckowski (Ed.), 2019). They are made from living cells and are used for treatment of serious diseases such as cancer, rheumatoid arthritis, ankylosing spondylitis, diabetes and other inflammatory diseases (Marotto et al. 2019; Chen et al. 2018). Despite the fact that biologics are a great opportunity for millions of patients worldwide, they are still not sufficiently accessible in many countries (Cohen et al., 2019; Hoen, 2016). The main barrier is price as biologics are extremely expensive (Chen et al. 2018; Lu & Jacob 2019, O’Callaghan 2019; Kawalec et al., 2017; Olszewska, Adamski & Czarnecka-Operacz, 2018). Biologics have been on the pharmaceutical market for decades. The term “biopharmaceutical” was first used in the 1980s to describe therapeutic proteins obtained by biotechnological processes (Mehta 2019). Because of the patent expiry (Yamauchi, 2018) observed recently on numerous biological medicines (reference products), a competitive version called biosimilars (not generics) (Geigert, 2019) has started to share the market (Stiff et al., 2019). Even though they are not identical as generic version of chemically derived medicines, they are similar, which is reflected in their safety and clinical features (Pawłowska et al. 2019; Shah & Crommelin, 2019).

According to the proved level of effectiveness, biologic therapies are in high demand. Unfortunately, no more than 2% of patients in Poland are treated with biologics. Rates for other Central-European countries are similar (the Czech Republic, Hungary – 3-5%). On the other hand, more than 30% of patients in Norway are regularly treated with innovative biologic therapies (Świerczyński, 2016, p. 27), which shows the large disproportion of access.

As generic versions of chemically synthesised medicines are identical copies of innovative and expensive medicines, some authors want to consider biosimilars similarly. Biologics had been treated as non-copiable for many years, mostly because of the complicated structure (Niazi, 2016). Nowadays, manufacturing similar (but still not identical) copies of reference biologics, having the same potency, purity and safety as the originator (McKoy & Giles, 2019) have become possible (Kurki & Ekman, 2018). Public and private payers look at biosimilars with hope for price reductions and savings (Smeeding, 2019; Singh, 2018). Unfortunately, the introduction of biosimilars to the market is a time-consuming and expensive solution as the whole process of obtaining the marketing authorization takes years (Edwards et al., 2019) and is expensive (Schweitzer & Lu, 2018). It should not be forgotten that apart from a patent the new medicines are usually protected by other

legal instruments like the Supplementary Protection Certificate³, data exclusivity (Blackstone & Fuhr, 2018)⁴, and market exclusivity (Blackstone & Fuhr, 2018)⁵. Therefore, biosimilars are not the perfect solution in terms of emergency response to a given disease.

Recently the compulsory licencing has more often been presented as a viable solution for medicine access improvement (Favereau, 2017; Sanchez & Saout, 2017; Boulet, 2017; Maraninchi, 2016; Linthorst, 2016; Hoen, 2017; Hirschler, 2015; Bognar, Bychkovsky & Lopes jr, 2016⁶). Furthermore, some authors find significant the latest ruling of German Federal Supreme Court (*raltegravir case*⁶), as a compulsory licence was granted in Germany for the first time since the Second World War (Slowinski, 2018; Pacud, 2018; Hohne, 2019; Pitz, 2019).

The idea of this paper is to critically evaluate the possible usage of compulsory licences for improving the access to biologics. The hypothesis of this study is that compulsory licensing should be reserved for exceptional use under limited circumstances only and access issues could be resolved by other tools i.e. reimbursement (Burich, 2018), price negotiations (Vakil & Fanikos, 2019), or voluntary licensing. The process of redefining compulsory licences into a tool for lowering the price of medicines which started with the advent of Agreement on Trade-Related Aspects of Intellectual Property Rights of 15 April 1994⁷ (hereinafter: TRIPS) must be postponed. The original and relevant function of compulsory licensing, having its roots in the Paris Convention for the Protection of Industrial Property Rights of 20 March 1883 (hereinafter: Paris Convention) was done to balance the interests of the society and the inventor.

The questions below should help in analysing the subject:

1. Why TRIPS regulations are associated with medicines and access issues?
2. Have the TRIPS regulations on “other use without the authorisation of the patent holder” have been drafted in a clear and understandable way?

3 Council regulation (EEC) no. 1768/92 concerning the creation of a supplementary protection certificate for medicinal products, Regulation (EC) no. 1610/96 of the European Parliament and of the Council concerning the creation of a supplementary protection certificate for plant protection products.

4 “The period of eight years from the initial authorisation of a medicine during which the marketing-authorisation holder benefits from the exclusive rights to the results of preclinical tests and clinical trials on the medicine. After this period, the marketing authorisation holder is obliged to release this information to companies wishing to develop generic versions of the medicine” (Hoen, Boulet & Baker, 2017).

5 “The 10-year period after the marketing authorisation of an orphan medicine when similar medicines for the same indication cannot be placed on the market” – definition from the official European Agency Medicine website.

6 Ruling from the 11th July 2017, X ZB 2/17, GRUR 2017, p. 1017 – *raltegravir case* („International Review of Intellectual Property and Competition Law”, vol. 1, 2018, p. 94-103.

7 https://www.wto.org/english/docs_e/legal_e/31bis_trips_01_e.htm (access 21.07.2019).

3. Why compulsory licensing has no potential of enhancing access to the biologics?

The paper will be divided into four sections where answers to the aforementioned questions will be given and the last part consists of closing remarks.

TRIPS and Public Health

Even though the Paris Convention was the first international act to regulate the institution of a compulsory licence (Ricketson, 2015), the real foundation of the current IP system is TRIPS (Malbon, Lawson & Davison, 2014).

Like many international agreements, TRIPS was the result of a compromise (Skees, 2007). This fact had some important consequences, which will be developed further. One of them is the general nature of the regulation, which allows a broad interpretation of the individual provisions. In addition, the compromise accompanying the adoption of TRIPS has not proved to be sustainable. Developed countries, with the USA and the European Union at the forefront, have been striving to further strengthen the system through a bilateral agreement called TRIPS-Plus (Cheng, 2019; Frankel, 2019; Matthews, 2017). At the same time, developing countries have been calling for a greater flexibility in the provisions of TRIPS.

Compulsory licensing and TRIPS are inseparably linked to the concept of public health (Kongolo, 2004, 2008) which was strongly manifested by the Declaration on the TRIPS Agreement and Public Health⁸ (hereinafter: Doha Declaration). Although the Doha Declaration is not a comprehensive document, as it contains only seven points, its importance cannot be overestimated. This is mainly because its adoption has initiated the process of amending the content of TRIPS (Beyer, 2013).

The Doha Declaration reaffirmed the importance of public health and the problems affecting developing and less developed countries, identifying HIV/AIDS, tuberculosis, malaria and other epidemics as their causes (point 1) (Outtersson, 2010; Loveridge, 2017). Additionally, the importance of TRIPS in addressing public health problems was highlighted (section 2). It pointed out that while protection of intellectual property is important for the discovery of new medicines, it also had an impact on the price of medicines (point 3) (Sun, 2003). Nothing in TRIPS prevents states from taking measures to protect public health. TRIPS should be interpreted in such a way as to promote access to medicines (point 4). The Doha Declaration reaffirms the right to use the flexibility instruments guaranteed by TRIPS (Hoen, 2018). Those are listed in the fifth point, of which two seem to be crucial from the point of view of the issue discussed: (b) each Member State has the right to grant

8 https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (access 21.07.2019).

compulsory licences and to lay down the conditions under which such licences are granted, (c) each Member State is free to define a “national emergency” or “other circumstances of extreme urgency”, which may be public health crises, including those related to HIV/AIDS, tuberculosis, malaria and other epidemics. It should be noted that allowing TRIPS signatories to determine conditions under which compulsory licences could be granted is inappropriate. Compulsory licences are a unique institution, which means that the possibility of granting them should be limited to a finite number of cases (a precise catalogue).

The purpose of compulsory licensing, which is to respond to public health problems, as indicated in the Doha Declaration was formulated too broadly. Initially compulsory licensing was identified as a need to address the HIV/AIDS, malaria and tuberculosis epidemics. Meanwhile, according to the WHO Essential Medicines List⁹ (Bashaar, Hassali & Saleem, 2017) published annually, due to the lapse of patent protection, further products started to obtain generic equivalents (Grubb et al. 2016), which meant lower prices, and thus improved access. However, tuberculosis, malaria, HIV/AIDS are not the only diseases affecting a significant part of the population of developing and underdeveloped countries. An increasing number of deaths are caused by cancer and cardiovascular disorders¹⁰. Would an effective solution, therefore, be to deprive all medicinal products used to treat every disease in the Third World of patent protection? Of course, in the light of TRIPS regulations this is not possible. What is more important, the risk of automatic compulsory licensing of any new medicinal product could be an effective obstacle to the development of new medicines (including biologics).

It is worth noting that TRIPS´ coming into effect opened a lively discussion on the impact of intellectual property law on access to medicines. The scientific dispute has not been resolved, yet. Some authors pointed out that strong patent protection strengthens innovation and thus the tendency to create new inventions, including molecules for medicinal products (Trąbski 2010; Stankiewicz, 2014; Nambisan, 2017; de Mora, 2019). Others argued that patents affect high prices of medicines, which significantly contribute to making access to them more difficult (Boldrin & Levine, 2008). At this point it is worth pointing out that numerous papers present compulsory licences as a tool for weakening the patent regime and facilitating access to essential medicines (Jain & Darrow, 2013). The above narrative has been maintained in the European Parliament resolution on EU options to improve access to medicines (2016/2057(INI))¹¹ published on 2 March 2017. The document states that “compulsory licensing ... has indeed led to lower prices” and that such flexibility

9 <https://www.who.int/medicines/publications/essentialmedicines/en/> (access 21.07.2019).

10 https://ec.europa.eu/eurostat/statistics-explained/index.php/Causes_of_death_statistics (access 20.07.2019).

11 http://www.europarl.europa.eu/doceo/document/A-8-2017-0040_EN.html (access 23.07.2019).

“can be used as an effective tool in exceptional circumstances, as defined by the law of each WTO member, to address public health concerns, so that, within the framework of national public health programmes, it can provide essential medicines at affordable prices and protect and promote public health”.

TRIPS – “Other Use Without Authorisation of the Right Holder”

It is worth mentioning that TRIPS does not at any point use the wording: “compulsory licences” (Lewis, 2014). Article 31 of TRIPS which formulates the legal basis for this type of licence is titled: “Other use without authorisation of the right holder”. The most frequently mentioned reason for the absence of “compulsory licence” in TRIPS was the fact that some signatory states simply did not use this term. Moreover, even among developed countries, which advocate strong patent protection during treaty negotiations, there was no uniform opinion on compulsory licences. Here it is worth noting that the biggest opponent of compulsory licences, from the nineteenth century, has been the US administration.

As none of the internationally recognised treaties define compulsory licences the legal definition needs to be based on doctrine and jurisprudence. Therefore, a compulsory licence is an authorisation, sanctioned by the state, for third parties to use intellectual property rights regardless of an opposition from the patent holder. It should be noted that when a compulsory licence is granted the patent owner is obliged to receive adequate payment.

TRIPS does not list conditions in which a compulsory licence may be granted, leaving this matter to the sovereign discretion of the signatory States. The provisions refer to strictly procedural matters relating to the granting of a licence and its scope (Manu, 2015). In addition, according to article 1, TRIPS sets a minimum level of protection, which means that Member States may or may not implement more extensive protection than that required by TRIPS.

The biggest problem of TRIPS regulations titled “Other Use Without Authorization of the Right Holder” is the lack of explicit definitions. The condition called “threat to national security” can be defined in many ways. Possible interpretations can be for example an outbreak of an epidemic that results in more than a thousand deaths within a single week or the lack of medicines or even their excessive prices. Article 31 of TRIPS gives the Member States the full freedom to determine the grounds for granting compulsory licences, as the Doha Declaration has also confirmed. Unfortunately, this does not serve the purpose of compulsory licensing. Compulsory licensing should be regarded as a tool to be used only in exceptional situations (Desai, 2016). This means that the provisions governing the compulsory licence should contain clear interpretative guidance. TRIPS should define a “threat to national security”, limit it, for example, to situations where the

livelihood of citizens is threatened and make the use of a compulsory licence subject to the prior use of other available tools. An 'emergency state of urgency' should be defined only where the patent holder's consent to the conclusion of a licensing agreement cannot be obtained due to significant time constraints, such as the rapid spread of a given type of virus and simultaneous limit production of a particular manufacturer. 'Public non-commercial use' could refer only to situations where the invention is used in the public interest, for non-commercial purposes, i.e. for example the supply of medicines which are not available but preventively necessary for a given group of patients, e.g. infants, women, pregnant women or children.

Disadvantages of TRIPS Regulation Concerning Compulsory Licensing

As mentioned above the rules governing the compulsory licensing mechanism are set out in article 31 TRIPS. A detailed analysis of TRIPS provisions leads to the conclusion that it is an ineffective instrument (Mellino, 2010). Below a few disadvantages of TRIPS regulation are listed:

- a) complicated procedure - importing countries, i.e. to a large extent developing and underdeveloped countries, have been subject to obligations which, due to their state of development (including the development of public administration), they are not able to meet (Rodrigues, jr, 2012, p. 214);
- b) the risk of retortions imposed by developed countries – examples of retortions may include threats of the reduction of new investments, withdrawal from the market of already available products, a lack of registration of new medicines, or limitations of trade cooperation in other areas (Halabi, 2018; Verduzco-Aguirre, 2019);
- c) a lack of definitions - TRIPS regulations are of a general nature, which causes numerous interpretation problems;
- d) an ineffective remuneration system – TRIPS does not contain any detailed guidelines, except for the general statement that the remuneration should be "appropriate". A chance to increase the effectiveness of a compulsory license would be to determine the minimum level of remuneration. An even more effective solution would be to determine the amount of remuneration as a fixed algorithm, depending, for example, on the number of products sold, costs incurred or other objective indicators;
- e) a time-consuming process - one of the objectives of the compulsory license are public health problems, including combating all kinds of epidemic diseases. The way to limit the spread of the epidemic is to act immediately, otherwise the number of patients reaches a size difficult to treat effectively. In a real threat situation, a compulsory license would be deprived of any effectiveness due to its time-consuming nature;

- f) a lack of incentives – lack of any incentives (for example tax incentives) that would induce generic producers to take the risk of obtaining a compulsory license;
- g) the negative impact on R&D (research and development) costs - in the case of biologics the cost of developing them can be extremely high and has a considerable risk of failure (Blackstone & Fuhr, 2018) – widespread use of compulsory licenses could limit any developing work on new molecules, as the risk of granting the compulsory license would be too high;
- h) the lack of obligation to provide know-how – none of the TRIPS regulations imposes transfer of know-how to compulsory licensor. A compulsory license means the possibility of industrial application of the invention is only based on a patent application. For uncomplicated processes, production without access to know-how is possible. However, it is difficult to imagine manufacturing processes, for example, for some types of biological drugs, where the level of complexity is so high (Nathan et al., 2018) that the information contained in the patent application may not always be enough (Maybarduk & Rimmington, 2009).

It should be strongly noted that compulsory licensing has no potential for increasing access to the biologics mostly because of the absence of an obligation on the patent holder to make the compulsory know-how available to the licensee (Krauspenhaar, 2015). For the industrial exploitation of inventions, particularly complex ones such as biopharmaceuticals (Scott Morton et al., 2018; Mehta, 2019; Kornyo, 2017), the patent description is not enough to start manufacturing. In case of a licence agreement, the licensee can count on cooperation with the patent holder. Undertaking compulsory licencing without the necessary technical knowledge, adequate staff and production experience, may prove to be so costly that the whole project may be unprofitable. However, it cannot be ruled out that in the future the manufacturing processes of biologics will be so common (and thus uncomplicated) that the absence of know-how will not hinder the production.

Conclusions

It should be clearly stated that despite the recent demands made in the literature and public space even more often, the aim of a compulsory license cannot replace state authorities in the implementation of health policy, including drug policy. The real purpose of compulsory licenses should be to ensure the exploitation of the invention. Therefore, the basic postulate is to return to the original assumptions of the concept of compulsory licensing. This type of license should uphold the basic principle of patent protection, which is the promise of a legal monopoly in exchange for exploiting the invention, i.e. contributing to technological progress.

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Combining the problem of access to biological medicines with compulsory licenses is harmful in the context of the long-term effects that this type of action can bring. The widespread use of this type of license may limit research work on new drugs.

The problem of access to medicines will not be solved by *ad hoc* solutions (i.e. compulsory licenses); therefore, systemic and long-term actions are necessary. Ultimately each of the ways of addressing the problem of access to medicines should precede efforts to reach an agreement with the manufacturer of a given drug. The consideration of rights and interests of both parties is better than coercion.

To sum up, it should be noted that compulsory licensing mechanism guaranteed by TRIPS is not the best remedy to improve access to biological therapies worldwide. The system developed by TRIPS is inconsistent, too general, and therefore inefficient and ineffective. It is necessary to reject the notion of identifying problems of developing and underdeveloped countries with the effects of the patent protection system. Consideration should be given to the foundation of transnational laboratories financed by a fund established for example by the developed countries or other donors (i.e. non-governmental organizations). These kinds of laboratories could support non-commercial research into new medicines, especially those concerning the most expensive ones (biologics as first).

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