

The renaissance of compulsory licenses (in the pharma sector)

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ABSTRACT This paper examines the function of compulsory licensing of the manufacture of pharmaceutical products. The COVID-19 pandemic has challenged the pharmaceutical patents and the compulsory licenses in the pharmaceutical sector. In International law the TRIPS Agreement introduced a special possibility to use the subject matter of a patent without the authorization of the right holder. The development of this license was determined by the public health problems of the least-developed countries (hereinafter referred to as the LDCs). Today the global pandemic has challenged this system. Some developing countries proposed that the World Trade Organization temporarily shall waive intellectual property rights for COVID-19 vaccines. The legislation of some countries allowed the governance to order the limitations of patents, but such a solution could harm the legitimate interests of the patent owners. The global need for rapid treatment of COVID-19 showed that patentees cannot make pharmaceutical inventions sufficiently available on the market. There are other solutions like patent pools, by which patent owners could keep control of the use of their inventions and the patents would be still available for third parties. This would serve the general public interest, but it is a money and time-consuming, long-distance cooperation. The broadened use of compulsory licensing could also expand vaccine manufacturing within the patent system. Hungary has chosen this path and the new legislation means the renaissance of compulsory licenses.

KEYWORDS *pharma law, patent, compulsory license, COVID-19 pandemic*

1. The development of compulsory licenses

Compulsory licensing provides the use of a patented product or process – based on a decision of a court or a competent authority – without the expressed consent of the patentee.¹

The history of this type of restriction of patent law dates back to the Venetian Patent Statute of 1474.² Once the right in the patent letter was granted,

¹ Levente Tattay, György Pintz, and Anett Pogácsás, *Szellemi alkotások joga*. ed. Tihamér Tóth (Budapest: Szent István Társulat, 2017), 272.

the exploitation of the patent was required, otherwise it was revoked³ by the Senate of the Venetian State.⁴ The English Statute of Monopolies of 1623 is one of the key legal instruments in which the concept of compulsory licensing was incorporated.⁵ The obligation of industrial use was a safeguard against the misuse of the monopoly granted by patents. In case of breaching this obligation, a license of exploitation could be given.⁶ The concept had influence on many national patent laws during the nineteenth century⁷ and was also recognized by the first international document about patent law,⁸ the International Convention for the Protection of Industrial Property (Paris Convention) concluded in 1883. The original text⁹ required only the exploitation of the patented invention and did not link to it any sanctions. However, the Paris Convention has been revised 6 times, in Brussels in 1900, in Washington in 1911, in The Hague in 1925, in London in 1934, in Lisbon in 1958 and in Stockholm in 1967, and was amended in 1979, during which the regulation of compulsory licence has been developed. At the first revision, the article in question was not amended, while for the second time, the aim was to restrict the patent by revoking it if the patentee did not start exploiting the invention within a reasonable time. As a result of the Hague Act, the concept of a compulsory license also appeared in the official text of the Convention.¹⁰

Subsequently, a significant milestone in the development of intellectual property rights was Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), signed in Marrakesh, Morocco on 15 April 1994, which supposed to provide stricter, more detailed rules for

² Christine MacLeod, *Inventing the Industrial Revolution: The English Patent System, 1660-1800* (Cambridge: Cambridge University Press, 1988), 11.

³ Claudia Angélica Córdova González and Mónica Guadalupe Chávez Elorza, “Review of the International Patent System: From the Venice Statute to Free Trade Agreements,” *Mexican Law Review* XIII, no. 1 (July 2020): 70.

⁴ Michael Halewood, “Regulating Patent Holders: Local Working Requirements and Compulsory Licences at International Law,” *Osgoode Hall Law Journal* 35, no. 2 (1997): 251.

⁵ Shikha Mishra, “Effects of Compulsory Licensing in International Trade” (LLM. diss., The National University of Advanced Legal Studies of Kochi, 2016), 20.

⁶ Carlos M. Correa, “Intellectual Property Rights and the Use of Compulsory Licenses: Opinions for Developing Countries” (Working paper, University of Buenos Aires, Argentina, 1999), 3.

⁷ Mishra, “Effects of Compulsory Licensing in International Trade,” 20–21.

⁸ Muhammad Zaheer Abbas and Shamreeza Riaz, “Evolution of the Concept of Compulsory Licensing: A Critical Analysis of Key Developments Before and After Trips,” *Academic Research International* 4, no. 2 (March 2013): 485.

⁹ Art. 5. of Paris Convention accessed June 30, 2022, <https://wipolex.wipo.int/en/treaties/textdetails/12995>

¹⁰ Hague Act accessed June 30, 2022 <https://wipolex.wipo.int/en/text/287779>.

the protection of intellectual property than the Paris Convention.¹¹ The patent restrictions and exceptions included in the Agreement serve the flexible application of patent law. Besides the research exception¹², and the “Bolar” provision,¹³ there are provisions for anti-competitive practice, parallel imports,¹⁴ grey imports and exhaustion of rights¹⁵ and other uses without the permission of the patentee.¹⁶

2. The need for Doha Declaration

On 14 November 2001 the Doha Declaration on the TRIPS Agreement and Public Health¹⁷ was adopted by the WTO Ministerial Conference to clarify several aspects related to the TRIPS Agreement. The purpose of the Doha Declaration was to provide easy access to medicines to all, but intended to support especially the LDCs.¹⁸ It also gives freedom to Member States to determine the grounds for compulsory licensing,¹⁹ defining what a national emergency or other circumstances of extreme urgency or cases of public non-commercial use constitute.²⁰ The use without authorization of the right holder regulated by Article 31 refers to compulsory licences and to governmental use as well. The first condition is that each case for granting a compulsory license must be decided on a case-by-case basis and there is also a precondition that the applicant made efforts to obtain authorization from the right holder on reasonable commercial terms without success within a reasonable period of time.²¹ This precondition is not compulsory in the above listed special

¹¹ Abbas and Riaz, “Evolution of the Concept of Compulsory Licensing: A Critical Analysis of Key Developments Before and After Trips,” 482.

¹² Art. 30 of the TRIPS Agreement allows Members to grant certain exceptions to the scope of exclusive rights derived from patent.

¹³ Nóra Tosics, “Gyógyszertermékek szabadalmi oltalma a csatlakozási tárgyalások tükrében. A kompromisszumhoz vezető út – a közösségi álláspont fejlődésének visszatekintő elemzése,” *Iparjogvédelmi és Szerzői Jogi Szemle* 108, (December 2003), https://www.wipo.int/wipo_magazine/en/2014/03/article_0004.html.

¹⁴ Beáta Udvari, „Mindenki ugyanannyit veszít? – A fejlődő országok és a TRIPs Megállapodás gyógyszerkereskedelemre vonatkozó szabályai,” *Fordulat* 8 (2010): 90.

¹⁵ Art. 6. of TRIPS Agreement.

¹⁶ Art. 31. of TRIPS Agreement.

¹⁷ Doha Declaration accessed June 30, 2022 https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

¹⁸ “Obligations and exceptions,” fact sheet of WTO, accessed June 30, 2022 https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm#compulsorylicensing

¹⁹ Abbas and Riaz, “Evolution of the Concept of Compulsory Licensing: A Critical Analysis of Key Developments Before and After Trips,” 484.

²⁰ TRIPS Agreement Art 31 (b).

²¹ TRIPS Agreement Art 31 (a) and (b).

circumstances: national emergency, extreme urgency or in cases of public non-commercial use. In the first special situations the patentee shall be notified as soon as reasonably possible, and in case of non-commercial use the right holder shall be informed promptly if without a patent search, it is obvious that a patent will be used. The scope and the duration of the use shall be determined in accordance with the purpose for which it was authorized and shall be authorized predominantly for the supply of the local, domestic market.²² The obtained right is never exclusive, non-assignable and the authorization shall be terminated when the circumstances which led to it cease to exist.²³ In return for a license the applicant shall pay a fee to the patentee in accordance with the economic value of the authorization.²⁴ Against the decision on the remuneration or on the authorization a proper remedy shall be provided.²⁵ The Agreement determines two special subcategories. One is permitted to remedy a practice determined to be anti-competitive and the other one is permitted to the exploitation of a dependent patent, which cannot be used without infringing another patent.²⁶ Compliance with the Agreement shall be monitored by the Council for Trade-Related Aspects of Intellectual Property Rights (hereinafter referred to as the "TRIPS Council")²⁷ established by the Marrakesh Agreement, which shall, if necessary, mediate between its members and ensure that they comply with their obligations under this Agreement.²⁸

This legal concept of compulsory licensing could not be properly applied in the least-developed Member States, because of the provision which linked the purpose of exploitation predominantly for the supply of the domestic market. Countries with limited, or without local pharmaceutical production capacity could not produce the quantities in need and could not rely on exports from countries with adequate infrastructure with regard to their emerging public health problem.²⁹ To address this issue, section 6 of the Doha Declaration called on the Council of TRIPS to urgently seek a solution and report the result to the WTO General Council within a year.³⁰ Based on the outcome of this procedure the General Council adopted a decision on the implementation of paragraph 6 of the Doha Declaration.³¹ Sec. 2 of the Decision allows the concluded members to export patented pharmaceutical products or products manufactured through a

²² TRIPS Agreement Art 31 (c) and (f).

²³ TRIPS Agreement Art 31 (d) (e) and (g).

²⁴ TRIPS Agreement Art 31 (h).

²⁵ TRIPS Agreement Art 31 (i) and (j).

²⁶ TRIPS Agreement Art 31 (k) and (l).

²⁷ Marrakesh Agreement paragraph 5 of Art IV.

²⁸ TRIPS Agreement Art 68.

²⁹ Abbas and Riaz, "Evolution of the Concept of Compulsory Licensing: A Critical Analysis of Key Developments Before and After Trips," 483.

³⁰ Marrakesh Agreement paragraph 2 and 5 of Art IV.

³¹ Decision of the General Council of 30 August 2003 accessed June 30, 2022, https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm

patented process³² and the obligations of Art. 31 (f) of the TRIPS Agreement shall be waived subject to certain conditions. In the Annex titled the Assessment of Manufacturing Capacities in the Pharmaceutical Sector, it is defined which countries could be the destinations for exports under the compulsory license. According to this, besides LDCs other members are entitled to import if they determine that there is no production capacity in the sector for the pharmaceutical product concerned or that the available production capacity is not able to meet the needs. All in all, the eligible importing member shall confirm the need of importation in accordance with the Annex, notify the TRIPS Council of the quantity of the required products, and have to grant or have to intend to grant a compulsory license to import the patented product. The exporting WTO member may produce only the quantity authorized under the compulsory license and a distinctive mark shall be signed on the thus produced products, which must be delivered in full to the destination country. The distinguishing mark may be a label, a different colouring or a shape, but it must not significantly affect the price of the product. The licensee must publish the terms of the license, the used special mark and the quantity produced on its own website, and about the availability of these data the TRIPS Council must be notified.

The content of the decision was later incorporated into Article 31a by amending the TRIPs Agreement.³³

The European Community took an active part in the preparatory negotiations and was one of the first to adopt the amendment.³⁴ Committed to implementation, a special compulsory license was drafted on October 29, 2004 within the framework set out in Articles 31 and 31a, with the aim of making a uniform compulsory license of the manufacturing and distributing of pharmaceutical products for export in the Member States.

3. Compulsory licence on public health under EU law

The Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems established a compulsory license aimed to support the fight against HIV / AIDS, malaria, tuberculosis and related diseases in developing countries.³⁵ The Regulation explicitly prohibits the use for industrial and commercial policy purposes.³⁶ Such a license may be granted for a person who

³² Decision of the General Council Sec 1.

³³ WTO: 2005 Press Releases/426, https://www.wto.org/english/news_e/pres05_e/pr426_e.htm.

³⁴ Amendment of the TRIPs Agreement, https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm.

³⁵ Regulation (EC) No 816/2006 Preamble (7).

³⁶ Regulation (EC) No 816/2006 Preamble (7).

intends to manufacture or to sale for export a product affected by a patent or supplementary protection certificate.³⁷ If the product concerned is protected in the importing country as well, a compulsory license is also required there for importation.³⁸ Licenses may be issued only for the quantity indicated in the application, for export only into the requested country and for a specified period of time.³⁹ The product produced under the license or the product produced by a patented process shall be uniquely marked and distinctively packaged and the fact of the license shall be indicated on it.⁴⁰

The licensee shall pay to the right holder an adequate remuneration set by the competent authority. In determination of the fee the economic value of use for the importing country, and the humanitarian and non-commercial nature of the issuance of the license shall be taken into account. The amount of the fee in the event of a national emergency, or other urgent emergency and in cases of public non-commercial use is limited to 4% of the total price to be paid by or on behalf of the importing country.⁴¹ If a compulsory licence is granted the TRIPS Council must be informed about the authorization and its special conditions.⁴² In Hungary, the assigned competent authority to decide on these type of compulsory license is the Hungarian Intellectual Property Office (hereinafter: HIPO) in accordance with Section (1) of Art. 33 / A. § of Act XXXIII of 1995 on the Patent Protection of Inventions (hereinafter: PPI).⁴³

4. Compulsory licenses in the Hungarian legal system

The Hungarian legislation describes four kinds of compulsory licenses. Compulsory licenses for lack of exploitation shall be granted if the patentee does not start exploiting the protected invention within a period specified by law and does not justify the lack of exploitation. This ensures that newer and newer technical solutions will be applied or the exclusive right derived from the patent will be lost.⁴⁴ Technical solutions with greater economic value are also supported by compulsory licensing due to the dependence of patents. If the application of an invention required the use of another invention which is subjected of a patent (the so-called “impeding patent”), this may be allowed if the dependent patent constitutes significant technical progress of considerable

³⁷ Regulation (EC) No 816/2006 Art 6 (1).

³⁸ Regulation (EC) No 816/2006 Art 10 (7).

³⁹ Regulation (EC) No 816/2006 Art 10 (2) to (4).

⁴⁰ Regulation (EC) No 816/2006 Art 10 (5).

⁴¹ Regulation (EC) No 816/2006 Art 10 (9).

⁴² Regulation (EC) No 816/2006 Art 12.

⁴³ See the ministerial justification of 33 / A. §.

⁴⁴ Art 31 of PPI.

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economic interest.⁴⁵ These two may be used only for the purpose to meet domestic demand.⁴⁶ The third type is implemented compulsory license governed under Regulation 816/2006/EC. With regard to the fact, that this licence can be granted only for export purposes to certain countries, with a complementary manner a new category was created in 2020 due to the corona virus pandemic.⁴⁷ The PPI regulates basically two new subtypes of licenses under the title of public health compulsory licensing. One is a domestic compulsory license, which allows the exploitation for the supply of the local, domestic market, focusing on providing the right amount of product, medicine or equipment in a public health crisis determined in Subsection (2) of Section 228 of Act CLIV of 1997 on Health Care. The other one is the foreign compulsory license which may be granted for the purpose of exportation related to a compulsory license where this is considered necessary to address public health concerns in another country.⁴⁸ However, such authorizations shall only cover the use of a healthcare product⁴⁹ or the manufacture of a patented process, equipment or device.

This kind of exploitation can never endanger the domestic supply and this shall be justified by the government body for pharmaceuticals.⁵⁰ Actually, this authority is the National Institute of Pharmacy and Nutrition (hereinafter: OGYÉI). Such permission never grants an exclusive right and based on the license the licensee may not give rights to a third party.⁵¹ Just like in the case of the license governed under Regulation 816/2006/EC, here also the HIPO is entitled to act. The HIPO determines the duration of the license. In case of domestic compulsory license this decision is based on the OGYÉI's certification on the necessary number of products for managing the public health crisis, but it cannot be less than six months. In case of foreign compulsory license the term is adjusted to the duration of the compulsory license issued abroad.⁵² The HIPO shall establish the appropriate remuneration for the public health compulsory license, which expresses its economic value and which is proportional to the fee payable by the licensee to the patentee in the case of a (fictitious) exploitation contract, taking into account the licensing conditions in the technical field to which the invention pertains.⁵³ In

⁴⁵ Art 32 (1) of PPI.

⁴⁶ Art 33 (2) of PPI.

⁴⁷ Alexandra Rudi and Dávid Ujhelyi, "A szellemi tulajdonjog területén megvalósult különleges jogrendi jogalkotás – háttér és eredmények," *Fontes Juris*, no. 2 (2020): 57.

⁴⁸ Art 33/B (1) of PPI.

⁴⁹ A health care product is a patented or supplementary protected medicinal product, active substance or investigational medicinal product.

⁵⁰ Art 33/B (2) b) of PPI.

⁵¹ Art 33/B (3) of PPI.

⁵² Art 33/C (1) and (2) of PPI.

⁵³ Art 33/C (3) of PPI.

determining the fee the typical ratio of exploitation fee to net sales in a given industry, and the overlap ratio between the generated economical advantage and the use of the patented product affected by the compulsory license shall be taken into account.⁵⁴ Healthcare products manufactured under a compulsory public health license shall bear a unique distinguishing mark from the product manufactured by the patentee. The packaging and all related documents must clearly indicate that the health product has been manufactured under such a license and intended solely for domestic exploitation or export distribution purposes to the licensed country.⁵⁵ In the event of failure to indicate the individual mark, OGYÉI may oblige the licensee to repackage the products.⁵⁶ The license may be terminated by surrender (partial surrender), expiration of the specified period, or termination of the patent or supplementary protection. The foreign compulsory license terminates upon the revocation of the foreign compulsory license on the basis of which it is issued, of which the SZTNH shall be notified within 8 days. In the event of surrender, the HIPO shall notify the patentee and OGYÉI of this legal declaration.⁵⁷ Thereafter, and in the event of the expiration of the specified time, OGYÉI shall order the destruction of the non-marketed health care products, the equipment and devices used for their production, and the termination of the manufacturing process.⁵⁸

5. Gilead Sciences vs. Richter

Due to COVID-19 this new category was a necessary opening in the light of the recognition of Article 31 (f) of the TRIPS Agreement and in the light of the limited authorization provided by Regulation (EC) No 816/2006. Protected health products can also be on a shortage of goods in developed countries, and with this license it is possible not only to satisfy domestic supplies, but other developed countries in a similar situation can be helped out as well. This brings the health system closer to the demands of the people, so that health products are distributed as evenly as possible to control and treat the pandemic. This is well illustrated by the fact that in December 2020, the HIPO granted three compulsory public health compulsory licenses for the minimum 6 months long period of time in Hungary, while there was no example of the issuance of licence under Regulation (EC) No 816/2006.⁵⁹ All three were linked to the active ingredient named remdesivir and the licensee was Richter Gedeon Nyrt.

⁵⁴ Art 33/C (4) of PPI.

⁵⁵ Art 33/C (10) of PPI.

⁵⁶ Art 33/C (11) of PPI.

⁵⁷ Art 33/C (5) and (6) of PPI.

⁵⁸ Art 33/C (7) of PPI.

⁵⁹ Gazette for Patents and Trade Marks *Hungarian Intellectual Property Office* Vol. 125. Issue 24 (December 28, 2020), 209.

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(hereinafter: Richter). The patentee, Gilead Sciences challenged the HIPO's decision granting the compulsory license with action for reversal both on procedural grounds and in view of the merits of the decision. The Gilead Sciences objected that the Office conducted a de facto ex parte procedure, without hearing the applicant, based on the relevant rules of the PPI, and considered it unlawful that as the patentee, could not participate as a client in the compulsory licensing proceedings. The company had neither the opportunity to comment nor to make a statement regarding the granting of a compulsory license. Both the Court of First Instance⁶⁰ and the Court of Appeal⁶¹ ruled that the provisions of a compulsory public health license are expressly different from the general compulsory licensing procedure. In this special procedure the Office only notifies the patentee of the action and informs them of the decision on the grant of the license. However, it is not an inter partes proceeding, the Office shall decide on the grant of the license without a hearing and the patentee shall not be entitled to any legal status or any rights deriving therefrom. In the field of compulsory public health licensing, only the applicant for a compulsory license is considered as a client. In addition, the court marked, that the action of reversal is a judicial remedy which ensures the right of appeal.

The substantive objection of the Gilead Sciences was that the HIPO failed to clarify the circumstances of the domestic need and did not provide evidence as to whether the resources of the patent holder alone would be sufficient to meet the domestic needs of the epidemic. The debate thus traced back to an assessment of the legislature's intention, as it raised the need for the issuance of a compulsory public health permit, the basic purpose of which is to provide a sufficient health product to meet domestic needs in a health crisis should in fact be a statutory requirement or the existence of a crisis situation and the fact that the patentee has not satisfied the entire domestic claim by the time the application is received is sufficient.⁶² According to the PPI, the applicant is expected to submit a certificate covering the applicant's suitability to meet domestic needs related to the health crisis and the quantity of product required.⁶³ If the applicant has sufficient capacity for this quantity, it is irrelevant for the grant of the license that the original patent also has the

⁶⁰ According to Art 86 of PPI the proceedings for the reversal of the decisions of the HIPO shall fall within the exclusive jurisdiction of the Capital Regional Court of Budapest. Decision numbers: Pk.20219/2021/16. and Pk.20224/2021/17. and Pk.20225/2021/18.

⁶¹ Decision numbers of the Budapest-Capital Regional Court of Appeal: Pkf.25536/2021/6. and Pkf.25537/2021/6. and Pkf.25538/2021/6.

⁶² Ádám György, "Jogalkotási és jogalkalmazási kérdések a közegészségügyi kényszerengedély kapcsán," *Jogászvilág*, March 21, 2022, <https://jogaszvilag.hu/szakma/jogalkotasi-es-jogalkalmazasi-kerdesek-a-kozegeszsegugyi-kenyszerengedely-kapcsan/>.

⁶³ Art 83/I (1) f)-h) of PPI.

necessary capacity. Research of these data if it is available for the HIPO at all would run counter to the purpose of the license, as it would be particularly time-consuming and goes beyond the competence of the authority. This case shed light on the difference between the regulations and the principles of the earlier (compulsory licenses for lack of exploitation and due to the dependence of patents) and the public health issue related compulsory licenses and highlighted the special function of the latest category. As a result of the 3 compulsory public health licenses, 13,000 moderately or severely covid-infected lives were saved.⁶⁴

6. What should be the solution?

With the health-related compulsory licenses, the accessibility of pharmaceutical products can be remedied within the framework of Patent law, in case of urgent need, like a pandemic meanwhile the benefits and the long-term trust in law, legal certainty is also protected.⁶⁵ The compulsory patent license protects against the abusive exercise of rights and promotes the applicability of existing knowledge. Some states allow exploitation in the public interest instead of, or in addition to a compulsory patent license. We can find such a patent limitation in German law in the Infection Protection Act.⁶⁶ The Federal Ministry of Health or its subordinate authority are entitled to order the use of a patent-protected invention or process without the authorization of the patentee for public welfare.⁶⁷ This option is limited to a specific range of patented inventions, such as drugs and medical devices, and processes used for their production.⁶⁸ In any case, the registered owner of the patent must be informed of such an order before the beginning of exploitation, which covers production and sale within the framework of public health use, excluding the purpose of making a profit.⁶⁹ As in the case of a compulsory license, there is

⁶⁴ Balázs Gabay, “Lejárt a remdesivir engedélye, nem gyárt többet a Richter,” May 10, 2021,

<https://index.hu/gazdasag/2021/05/10/richter-covid-remdesivir-tocilizumab-vakcina/>.

⁶⁵ Jenő Bobrovsky, “Az enyém, a tied, és a miénk a szellemi tulajdonjogban,” *Liber amicorum – Ünnepi dolgozatok Gyertyánfy Péter tiszteletére*, ed. Gábor Faludi (Budapest: ELTE, 2008), 25.

⁶⁶ Patent Gesetz 13. §.

⁶⁷ Christian Dekoninck, Paul England, Judith Krens, Anja Lunze, and Jan Phillip Rektorschek, “COVID-19 and public compulsory licensing of drugs in Europe,” *Taylorwessing* April 17, 2020, <https://www.taylorwessing.com/en/insights-and-events/insights/2020/04/covid-19-and-public-compulsory-licensing-of-drugs-in-europe>.

⁶⁸ Art 5 (2) 4. Infektionsschutzgesetz.

⁶⁹ Dekoninck, England, Krens, Lunze, and Rektorschek, “Public compulsory licensing of drugs in Europe”.

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also compensation for the patentee, covered by the Federal Government.⁷⁰ The English Patent law also recognizes a special possibility for the exploitation of patented inventions without the right holder's permission.⁷¹ The search for alternative solutions indicates that compulsory licenses are not a complete solution to the problem that arises.

As a result of the pandemic, the most radical possible solution has emerged, which means the temporary waving from certain provisions of the TRIPS Agreement. This was requested by India and South-Africa.⁷² According to this, the application of certain provisions in relation to the acquisition, scope, use and enforcement of intellectual property rights would be waived for the prevention, containment and treatment of COVID-19. The TRIPS Council discussed the issue several times in 2021, but these did not lead to results, and no decision was made on the suspension.⁷³ This effort also appeared in Brazil,⁷⁴ where the Senate passed a bill to suspend patent protection for pharmaceutical products that help fight against COVID-19, but the proposal failed. However, this solution draws attention to the fact that if it is not possible to meet the needs of developing countries particularly affected by COVID-19 at an adequate pace for effective action, then the patent protection system itself may be at risk and it is questionable whether the public health problem that arose due to the pandemic can be solved within the traditional legal framework. To avoid this undesirable result, we must find a delicate balance which enables the preservation and encouragement of the innovative achievements of inventors,⁷⁵ while promoting the equitable distribution of medicines, medical devices and procedures all around the world.

Based on all of this, it is in our common interest to solve the problem uniformly by the least radical, restrictive legal institution, which is according to my opinion the patent compulsory license.

⁷⁰ Art 13 (3) of Patent Gesetz.

⁷¹ Art 55 (1) a) Patents Act.

⁷² Communication from India and South Africa, <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:IP/C/W669.pdf&Open=True>.

⁷³ TRIPS Council agrees to continue discussions on IP response to COVID-19, https://www.wto.org/english/news_e/news21_e/trip_20jul21_e.htm.

⁷⁴ Brazilian senate votes to suspend patents in bid to widen access to Covid-19 vaccines, <https://www.statnews.com/pharmalot/2021/04/30/brazil-covid19-coronavirus-vaccines-wto-patent/>.

⁷⁵ Gábor Szilágyi, "Adok is kizárólagosságot, meg nem is, avagy a pandémia kezelésének lehetőségei a szabadalmi jog rendszerében, különös tekintettel a közegészségügyi kényszerengedély, valamint a Bolar kivétel hazai implementációjára," *Kúriai Döntések Bírósági Határozatok* 70, no. 4 (April 2022): 630.

