3. THE INABILITY OF COMPULSORY LICENSES TO ADDRESS THE PROBLEM OF MEDICINES AND VACCINES ACCESS IN LDCs IN THE CONTEXT OF THE COVID-19 PANDEMIC

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ABSTRACT

With the outbreak of the pandemic caused by the Coronavirus SARS-COV 2, COVID-19, research has been undertaken to find vaccines or drugs against this global scourge. This research led to the development of vaccines that were quickly made available to the populations of rich countries, the latter having undertaken to vaccinate all their populations. For developing countries, a global mechanism, COVAX, has been set up to help these countries immunize at least, the most vulnerable people. However, these efforts remain insufficient to immunize a large part of the world population.

Therefore, some have proposed, in order to provide access to these vaccines to populations in developing countries, to suppress or suspend the patents on the COVID-19 vaccines. This is neither an equitable nor a sustainable solution for the sake of research or innovation. Others argue that compulsory licensing mechanisms should be mobilized to allow low-income countries to get access to those new vaccines for their populations.

In fact, the compulsory licenses are presented as a step forward in solving the problem of access to medicines for the populations of the LDCs. Both the ancient and the new system of compulsory licensing impose, however, many administrative, legal, and policy barriers to the export of generics and involves a series of barriers to the flow of new medicines and vaccines. This unique framework provided for by the WTO Agreements makes it more complicated and complex to import or export new drugs than any other product manufactured under compulsory licenses.

Keywords*: patent, compulsory license, drugs (medicines), LDCs, TRIPS Agreement, amendment, Doha Declaration.*

1. INTRODUCTION

Known as a non-voluntary license, the compulsory license is an authorization granted by the public authorities to a third person, other than the patentee, allowing him to use or exploit an invention without the consent of the patentee. It is compulsory because it is issued by the authority when certain conditions justify it (public interest, competition objectives, health emergency, failure of the agreement of the patentee, etc.), unlike the voluntary license granted by the patentee, after a contractual assignment of rights, to a third party, the licensee. The granting of a compulsory license to exploit an invention without the authorization of the patentee may be used in all fields, including that of health[1]. The term compulsory license is not expressly included in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)[2]. It is drawn from the doctrine on Article 31 of the TRIPS Agreement, which frames the use of **other use without authorization of the right holder**.[3]

In its original version, to mean before its amendment on 30 August 2003 in the Doha Round negotiations, the TRIPS Agreement prohibited the possibility of exporting or importing products produced under the compulsory

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[1] Verschave FX, (dir.), *La santé mondiale, entre racket et bien public (*Mayer 2004) 236.

[2] The TRIPS Agreement sets the minimum rules for the protection of IP rights that Members must incorporate into their national laws. They cannot provide for protective measures that are below than these minimums. For example, Article 33 of the TRIPS Agreement states that the term of protection is at least 20 years. This implies that Members may grant more, but not less than this minimum term.

[3] TRIPS Agreement, Article 31 <https://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm> accessed 12 December 2017.

licenses. Indeed, under Article 31(f), compulsory licenses are issued **mainly for the supply of the market of the Member who has granted them**. They were, therefore, intended to solve only the internal problems of the country that issued them. Therefore, **original** compulsory licenses provided in the TRIPS Agreement could not address the health concerns of countries that do not have the capacity or infrastructure to locally produce the drugs and vaccines, which is the case for the least developed countries (LDCs) and many other developing countries. This significantly reduces the scope and effectiveness of compulsory licensing as an instrument to address the problem of access to medicines when the country is unable to provide its own production or when it needs to respond quickly to an emergency. That is why additional measures have been adopted at the WTO, in the margins of the Doha Round negotiations[4], to correct this situation, by adopting the authorization for the export and import of medicines produced under compulsory licenses. But this must follow a very strict procedure and conditions, as will be seen in the paragraph devoted to this new version of compulsory licenses. But before we get to that point, we must start with the mechanism of the general version of compulsory licenses, the new version being an exception provided for medicines only.

2. COMPULSORY LICENSES IN THE TRIPS AGREEMENT

Article 31 (**other use without authorization of the right holder**[5]) provide that the Member may authorize the use of the patented object without the authorization of the right holder, particularly in cases of national emergency[6]. Thus, compulsory licenses were presented as an answer to the problem caused by patents in access to medicines in the South countries and in the LDCs in particular[7]. In theory, the use of compulsory licenses could make medicines affordable and accessible while ensuring that the patent owner receives remuneration for the exploitation of his invention. In most developed countries, compulsory licensing is one of the mechanisms that WTO Members use to promote competition and access to medicines. However, the fact that products manufactured under compulsory licenses cannot be exported deprives them of their usefulness as an instrument for promoting access to medicines. What is the guiding principle of compulsory licenses, and what is the procedure for their use to address an emergency need?

A. THE PRINCIPLE OF COMPULSORY LICENSES AND THEIR APPLICATION

In principle, compulsory licenses are granted in the event of a national emergency in order to permit the local exploitation of a patented invention in order to solve a conjectural problem that the country is facing. The TRIPS Agreement expressly authorizes Members to grant compulsory licenses on the basis of their particular circumstances. It is the Member himself who determines the circumstances that justify the granting of these compulsory licenses, but this use must cease when the circumstances justifying them no longer exist[8].

Article 31 of the TRIPS Agreement, which allows compulsory licenses, does not specify the grounds on which such licenses may be granted[9]. It lists only, for information, some situations justifying their granting. It is referred to that a Member may derogate from the normal

[4] The Doha Round of negotiations (Qatar) began with the WTO Ministerial Conference, which was held from 9 to 13 November 2001. The Doha Round is the current round of trade negotiations between WTO Members. This round of negotiations began on 1 January 2002, initially for a maximum of three years, and continues until today! Also known as the **development round**, its goal is to fundamentally reform the international trade system through the reduction of trade barriers and the adoption of revised trade rules. The work program includes some 20 areas, including agriculture, services and IP that have already been negotiated. Negotiations between developed and developing Members, however, have yet to reach a compromise in areas such as agriculture and non-agricultural market access (WTO, The Doha Round, <https://www.wto.org/english/tratop_e/dda_e/dda_e.htm> accessed 16 January 2018).

[5] According to footnote 7 of the TRIPS Agreement, other uses mean uses other than those permitted under Article 30 of this Agreement, namely exceptions to patentee.

[6] TRIPS Agreement, Article 31(b).

[7] Guesmi A, *Le médicament à l'OMC : droit des brevets et enjeux de santé (*Larcier 2011) 182.

[8] TRIPS Agreement, Article 31(g).

[9] Remiche B, Kors J, *L'Accord sur les ADPIC : dix ans après (*Larcier 2007) 189.

rules of patent protection in situations of '**national emergency or other circumstances of extreme urgency or in the case of public use'**[10]. These situations may include reasons of public health (for example, following a natural disaster, war or epidemic)[11]. Thus, a compulsory license may include medicine, an instrument, or any other product whose use relates to health (hospital equipment and materials, diagnostic equipment, etc.)[12].

Thus, the protection of the public interest, like public health, is sufficient to justify the granting of compulsory licenses. For those reasons, epidemic or pandemic diseases, like COVID-19, can be considered as a national emergency to justify the granting of such licenses and thus meet the needs of developing countries in terms of access to medicines or vaccines[13]. It is therefore accepted that the WTO Member can exploit any patented invention for public health reasons and use compulsory licenses to produce drugs or vaccines and provide them at the cost of production, or even free of charge, to the poorest patients who need them urgently[14].

While Article 31 of the TRIPS Agreement leaves Members free to determine the grounds for granting compulsory licenses, it is very explicit in terms of the conditions that must be fulfilled for a compulsory license to be granted. In addition to the obligation to apply for the voluntary license before it can be granted *ex officio* by the public authorities, the owner of the patent must, in the event of compulsory use of his invention, receive 'adequate remuneration, taking into account of the economic value of the authorization'[15] and this condition is applied to all types of compulsory licenses.

Although a system of compulsory licensing is provided for in many national laws, the number of such licenses granted in practice remains relatively low in developing countries. However, even if their use is relatively limited, they are an effective mechanism for stimulating competition and a credible weapon that can lead the patentee to grant price reductions or a voluntary license[16]. According to Ladas, 'the advantage of the existence of provisions concerning the granting of compulsory licenses in national legislation is that the threat created by these provisions incites patent owners to grant contractual licenses on reasonable terms'[17]. Beier has developed a similar reasoning by noting that 'compulsory licensing, because of the fear that it gives rise to forced licensing procedures, makes patentees more inclined to grant voluntary licenses'[18]. In Brazil, for example, Decree No. 3201/99 provides that in cases of national emergency or for reasons of public interest recognized by the authorities, a compulsory license may be granted *ex officio* on a temporary basis if necessary[19]. In 1999, Brazil has threatened to produce generic drugs for HIV/AIDS and to grant a compulsory license to obtain from pharmaceutical companies' discounts on their patented medicines. For many years, this strategy has been successful[20]. However, one compulsory license was granted in 2007 for non-commercial public use of efavirenz for a period of five years and a rate of remuneration of the patentee of 1.5%. While the patentee was offering a 30% discount on its prices, the first batch of generic efavirenz products under compulsory license from July 2007 had a discount of 65-70%[21]. This example is presented as evidence of the effectiveness of compulsory licensing in solving the problem of access to medicines in poor countries. But if this has been possible in Brazil, this cannot be valid in

[10] TRIPS Agreement (n 5).

[11] Correa C, Velasquez G, *L'accès aux médicaments: entre le droit à la santé et les nouvelles règles du commerce international* (Harmattan 2009) 44-45.

[12] Ibid 73.

[13] This allowed, for example, Zimbabwe to declare in May 2002 a "six-month emergency", allowing the manufacture of generic drugs used in the treatment of HIV / AIDS or its opportunistic diseases (Guesmi A, (n 8)268-269.

[14] Guesmi A (n 7) 267-268.

[15] TRIPS Agreement, Article 31(h).

[16] Correa C, Velasquez G, *Comment préserver l'accès aux médicaments* (Harmattan 2010) 94.

[17] Pericles Ladas S, *Patents, trademarks and related rights national and international protection* (Vol. 1, HUP 1975) 427.

[18] Karl Beier F, 'Exclusive rights, statutory licenses and compulsory licenses in patent and utility model law' (1999) 30 International Review of Industrial Property and Copyright Law 260.

[19] Correa C, Velasquez G (n 11) 77.

[20] ibid 77.

[21] Correa C, Velasquez G (n 11) 78.

most poor countries, since besides these countries do not have the same industrial capabilities as Brazil, these drugs produced in Brazil or other emerging countries cannot be exported to other southern countries.

B. THE LIMITS OF COMPULSORY LICENSES TO ALLOW ACCESS TO MEDICINES IN THE LDCs

The text of Article 31 of the TRIPS Agreement contains an important provision regarding the scope of the use of compulsory licenses in solving the problem of accessibility of patented medicines by the populations of LDCs. Indeed, any use of compulsory license must be authorized 'mainly for the supply of the internal market of the Member who authorized this use'[22]. Thus, the TRIPS Agreement prohibits the use of compulsory licenses that are not intended to supply the domestic market of the country that issued them. However, importation is the only option that LDCs can use to buy drugs since they do not have the capacity to produce them locally. This significantly reduces the effectiveness of compulsory licensing as a tool to facilitate access to medicines, as local production may not be feasible in several LDCs and other developing countries, given that the size of their local markets does not justify such production or investment for the private sector[23]. Indeed, the problem for many LDCs is the lack of means to manufacture their own medicines, especially in case of emergency situations. They must therefore refer to imports. However, a developed Member could not, under Article 31 of the TRIPS Agreement, allow the use of a patent for the purpose of exporting a patented medicine that would be necessary for a country other than him, even in case of emergency. The latter, rich or poor, could not authorize the importation of drugs manufactured under a compulsory license in another country that authorized their production[24].

As a result, countries that do not have sufficient infrastructure, technical and financial capacity in the pharmaceutical sector to locally produce the medicines they need are not able to take advantage of the compulsory licensing system. However, they may allow the importation of medicines from countries where they are not patented, which is random in the case of more interesting drugs, inventors hastening to patent them wherever they are likely to be easily reproduced[25]. For this, seen in this aspect, the TRIPS Agreement opposes compulsory licensing to satisfy international markets through export and import. However, it should be noted that, even though the WTO Dispute Settlement Body (DSB) has not yet been seized for the interpretation of Article 31 of the TRIPS Agreement, the presence of the word 'mainly' implies, according to us, that the export of the products manufactured under compulsory licenses remains possible. In our point of view, the usual meaning of this provision is erroneous because its right interpretation is that exports are possible, even though they are not the principal activity of the licensee of the patented product. This provision simply means that the use of a compulsory license for export may be an exception[26], the rule being internal use. Something which is an exception is not illegal. It is only circumscribed or subject to conditions. The beneficiary of the compulsory license may export his products, but only in exceptional circumstances, which can be the case in an emergency. The only problem is that the TRIPS Agreement did not provide for the conditions for this eventuality.

Moreover, it is difficult to determine the criteria that would make it possible to judge the 'main' or 'subsidiary' nature of these exports (in particular with regard to amounts, volumes, frequencies, destinations, etc.). The consequence of this confusing situation is that it is the countries without technological capabilities that are in difficulty and who are most affected by the problem of

[22] TRIPS Agreement, Article 31(f).

[23] Remiche B, Kors J (n 9) 189.

[24] Remiche B, Cassiers V, Droit des brevets d'invention et du savoir-faire : Créer, protéger et partager les inventions au 21ème siècle (Larcier 2010) 143.

[25] Correa C, Intégration des considérations de santé publique dans la législation en matière de brevet des pays en développement (South center 2001) 162.

[26] This is an exception to the use of compulsory licenses, which is itself an exception to the normal patent system.

access to medicines[27]. This prompted LDCs, particularly African countries, to request a revision of this mechanism to allow the export and import of medicines produced under compulsory licenses and a new version of compulsory licenses was adopted in response to the concerns of those countries that "do not have the local capacity to produce themselves the generic drugs they need"[28].

3. THE AMENDMENT OF ARTICLE 31(f) AND PARAGRAPH 6 OF THE DOHA DECLARATION AND THEIR LIMITS

In 2001, during the Doha WTO Ministerial Conference, a declaration was adopted concerning the links between the TRIPS Agreement and public health problems. While some people attach importance to this statement, reiterating the idea that intellectual property (IP) protection remains an incentive for the development of new medicines, it explicitly mentions, in a clear manner, the harm to public health that patents represent, given their impact on the prices of medicines[29]. Following this more political than legal signal[30], the most important measure taken in the WTO framework to solve patent problems in the field of public health has been the Decision of the WTO General Council of 30 August 2003, which allows the export or import of drugs produced under compulsory licenses for countries that do not have the infrastructure or the capacity to produce them locally. This Decision, which was provisional, was made permanent by the ratification of the Protocol amending the TRIPS Agreement, open to signatures by WTO Members, in accordance with Article X of the Marrakech Agreement establishing the WTO, since 6 December 2005. Although this 2003 Decision was presented as a step forward in solving the problem of access to medicines for the populations of LDCs, it did not produce the expected effects because of several failures (paragraph b), which handicapped its effectiveness. Indeed, this new procedure for exporting medicines produced under compulsory licenses (paragraph a) is long, cumbersome, and restrictive. This means that Members, which are not directly concerned, are not ready to engage in these 'new' compulsory licenses.

C. THE 'NEW' OR 'SPECIAL' COMPULSORY LICENSING PROCEDURE FOR MEDICINAL PRODUCTS

The Doha Declaration is a compromise resulting from negotiations between WTO Members to reassure international public opinion[31] and to demonstrate the willingness of Members to settle the question of access to new drugs and vaccines. This political commitment to solve the patent problem in access to medicines (point i) has been reflected by the adoption of the 2003 Decision, which has become binding since then, pending the ratification and entry into force of the Protocol to amend Article 31 of the TRIPS Agreement (point ii).

4. THE 2001 DOHA POLITICAL CONSENSUS ON THE INEFFECTIVENESS OF 'ORIGINAL' COMPULSORY LICENSES

The Doha Declaration, which embodies this consensus, states in paragraph 6 that Members with insufficient manufacturing capacity or low technological capabilities in the pharmaceutical sector find it difficult to make effective use of compulsory licenses under the TRIPS Agreement. The Declaration recommends to the TRIPS Council to find a quick solution to this problem. This Declaration is the first relaxation of the constraints on the

[27] Remiche B, Kors J (n 9) 190.

[28] Decision of 30 August 2003 on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, (see for more details WTO, Decision of the General Council of 30 August 2003, implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, WT/L/540 and Corr.1, September 2003, <https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm>, accessed 11 December 2017).

[29] Article 3 of the Doha Declaration on TRIPS Agreement and Public Health, <https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm>, accessed 21 November 2017.

[30] It is only a declaration and not a treaty or agreement, in the sense of international, and does not reflect, as such, commitments of Members. Remiche B, Kors J (n 9) 235.

[31] Botoyltuku E, Propriété intellectuelle et droits de l'homme : l'impact des brevets pharmaceutiques sur le droit à la santé dans le contexte du VIH/SIDA en Afrique (Bruylant 2007) 387.

LDCs on the issue of access to medicines[32]. Even if a Declaration does not constitute a binding legal instrument in international law, the Doha Declaration is considered as an interpretative framework of the TRIPS Agreement, which must be interpreted in the light of this Declaration, which **'allows making righteous decisions with respect to conflicting interests'**[33] under the TRIPS Agreement'[34]. In recognizing the importance of the problem of access to medicines in the developing countries and the urgent need to find solutions quickly, the Doha Declaration recognizes that there is a problem regarding the use of compulsory licenses in developing countries that do not have local manufacturing capabilities for medicines. The Doha Declaration thus had important political and legal implications. Although it is not binding, it has a certain value in that even if Members cannot require the application of the provisions it contains, they must at least observe what has been agreed upon, and their partners cannot blame them, even if this behaviour was contrary to pre-existing rules[35]. With the adoption of this Declaration, the consensus on the patent issue and public health was formed and served as proof of the existence of the *opinio juris*[36] that has formed around this issue[37]. The Doha Declaration recognized the need to fill the gap found after the entry into force of the TRIPS Agreement and set guidelines that members have to follow. Indeed, Article 4 of the Doha Declaration states that the TRIPS Agreement does not prevent Members from taking measures to protect public health. Accordingly, the Agreement must be interpreted and implemented in a manner that supports the right of Members to protect the health of their populations and promote the access to medicines for all[38]. It, therefore, represents new provisions that can no longer be validly opposed in the DSB and affirms the right of Members to interpret and apply the TRIPS Agreement in a manner that protects health. Subsequently, the influence of the Declaration on the formation of the 2003 Decision and the 2005 Amendment was decisive.

5. THE DECISION OF 30 AUGUST 2003 AND THE PROTOCOL OF 6 DECEMBER 2005

The 2001 Declaration was clarified and made enforceable by the Decision taken on 30 August 2003, of the General Council. This Decision has the scope of a provisional derogation from Article 31(f) of the TRIPS Agreement, pending its proper revision. By this Decision, the WTO General Council intended to prescribe the abandonment of the provision of the TRIPS Agreement, which limited the import or export of pharmaceutical products produced under compulsory licenses. By this Decision, Members are now allowed to derogate, under certain conditions, from the obligations established by Article 31(f) of the TRIPS Agreement and to proceed with the export of generic drugs manufactured under compulsory licenses to 'eligible importing Members'[39]. By clarifying the content and conditions of implementation of paragraph 6 of the Doha Declaration[40] in order to promote the import and export of generic medicines, it enshrines the legality of the importation of generic drugs from countries in which they are also patented but which are not able to produce them themselves, or that they do not have the technical capabilities, or that local production would be complex or expensive to implement[41].

[32] Remiche B, Kors J (n 9) 235.

[33] This is to balance the interests of patent holders and those of patients who need to use drugs covered by these patents.

[34] Gervais D, L'Accord sur les ADPIC: propriété intellectuelle à l'OMC (Larcier 2010) 77-78.

[35] Daillier P, Forteau M, Pellet A, Droit international public (L.G.D.J Lextenso Éditions 8 éd 2009) 430.

[36] This may be considered that this is a new source of international law, not provided for in Article 38 of the ICJ Statute, or at least a new technique for the creation of international legal rules, all the more so that an international body is bound by the resolutions it adopts, even if they are not binding on Member States. This way of developing international law is particularly effective in new areas: economic law, environmental law, etc. Kiss A, Beurier JP, *Droit international de l'environnement* (3rd ed. A. Pedone 2004) 73.

[37] ibid 69.

[38] Remiche B, Kors J (n 9) 236.

[39] 'Eligible importing Member' means any LDC Member, and any other Member that has made a notification to the TRIPS Council of its intention to use the system set out in Article 31*bis* and his Annex as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example, only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use (Article 1(b) of the Annex of the TRIPS Agreement).

[40] Remiche B, Kors J (n 9) 241.

[41] Correa C, Intégration des considérations de santé publique, 90.

At the WTO Ministerial Conference in Hong Kong in December 2005, Members approved the changes that were transforming this temporary abandonment of Article 31(f), in the case of medicines, into a definitive amendment to the TRIPS Agreement only and exceptionally in the case of medicines. Indeed, Article 31*bis* incorporates in the TRIPS Agreement the provisions of the Decision of 30 August 2003, thus making it final. Article 31*bis* states that the obligations of an exporting Member under Article 31(f) shall not apply regarding granting that Member of a compulsory license to the extent necessary for the production of a pharmaceutical product and its export to an eligible importing Member[42]. This is the first amendment of the WTO Agreement. Despite this, the importation and exportation of medicines produced under compulsory licenses are subject to prior modification of national laws in relation to Article 31(f) of the TRIPS Agreement. However, the law modification is not always an easy procedure, whether in the importing or exporting countries, given the stakes that characterize the pharmaceutical field. Since 30 August 2003, only three exporting countries have amended their laws to adapt Article 31(f), namely Canada, Norway and India[43]. As for the importing countries, apart from Rwanda, no other Member has yet changed its national law to comply with the 2003 Decision or the 2005 Protocol[44]. From the foregoing, it would not be wrong to conclude that the decision of 30 August 2003 did not achieve its objectives.

THE FAILURES OF THE REVISED VERSION OF THE COMPULSORY LICENSES FOR MEDICINAL PRODUCTS

The new procedure of compulsory licenses for medicinal products has many obstacles that hinder its effectiveness in solving the problem posed by patents in the field of medicines access. Apart from the fact that the Protocol on the amendment of Article 31 of the TRIPS Agreement was not greeted with enthusiasm by the LDCs and has not yet been incorporated into the national legislation of potential exporters, it provides for a cumbersome procedure that imposes many constraints. In addition, the drug-producing countries continue to use their political and economic influence to obtain from Southern countries the abandonment of the use of these new compulsory licenses, notably by entering into bilateral or regional agreements on IP: TRIPS **plus**[45] [46]. The result is that about 15 years after its adoption, the new procedure of compulsory licenses has been used only once and with less efficiency since the medicines requested by Rwanda were produced and delivered only four years after the start of the procedure[47]. This single example to date of the export of generic drugs from Canada to Rwanda provides evidence of the inefficiency and non-operationality of this new solution contained in the 2005 Protocol amending Article 31(f) of the TRIPS Agreement.

[42] Protocol amending the TRIPS Agreement, Article 31*bis*, paragraph 1, <https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm> accessed 14 December 2017.

[43] Bouissou J, 'En Inde : la bataille pour des médicaments bon marché continue', Le Monde du 2 avril 2013, <http://www.lemonde.fr/sante/article/2013/04/02/en-inde-la-bataille-pour-des-medicaments-bon-marche-continue_3151796_1651302.html> accessed 11 January 2018.

[44] OMC, Notifications des membres importateurs de l'OMC, 2013 <http://www.wto.org/french/tratop_f/trips_f/public_health_notif_import_f.htm> accessed 26 October 2017.

[45] Morin JF, Surbeck J, (2019) Mapping the New Frontier of International IP Law: Introducing a TRIPs-plus Dataset, World Trade Review 1–14, <https://doi.org/10.1017/S1474745618000460> accessed 4 May 2022.

[46] El-Said H, El Said M, 'TRIPS Plus Implication for Access to Medicines in Developing Countries: Lessons from Jordan-United States Free Trade Agreement' 2007, J World Intellectual Property 10(6).

[47] The application began in August 2004, but was blocked by the fact that MSF, which was the payer, should transit through its warehouses in France, while the latter is not an "eligible importing Member" (Esmail L, Elliott R, Accès aux médicaments et la propriété intellectuelle: uneréuniond'expertsinternationaux sur le Régime canadien d'accès aux médicaments, les développements dans le monde et les nouvelles stratégies pour améliorer l'accès, 19-21 avril 2007: rapport sur la réunion <http://www.aidslaw.ca/publications/interfaces/downloadFile.php?ref=1253> accessed 23 December 2017. In addition, recipient countries were not well specified, which is normal for an NGO operating in more than one country. After several negotiations, Rwanda, with the support of MSF, has notified the WTO of the issuance of a compulsory license and its intention to import a triple therapy (zidovidune/lamivudine/nevirapine) from Canada. On 19 September 2007, Canada granted a compulsory license to a Canadian firm, Apotex, to produce 260,000 tablets of Apo-Triavir at cost and ship them to Rwanda. On 23 September 2008, Apotex announced that it was ready to deliver the product to Rwanda. A total of 15.6 million tablets of Apo-Triavir were exported to Rwanda at a price of CAD 0.195 per tablet. Correa C (n 41) 95-96.

6. LDCs LACK OF ENTHUSIASM FOR THE 2005 PROTOCOL AMENDING THE ARTICLE 31(F) OF THE TRIPS AGREEMENT

The Marrakesh Agreement Establishing the WTO makes the modification or clarification of WTO agreements conditional on a Decision of the Ministerial Conference ratified by a two-thirds majority of the members. Article X of the Agreement Establishing the WTO provides, in its third paragraph, that amendment takes effect once it has been ratified by two-thirds of the Members, in accordance with the internal procedures of each Member. In application of this Article, the Hong Kong Ministerial Conference of December 2005 gave Members until 1 December 2007 to 'accept'[48] this Protocol. This deadline has been postponed several times, and the required number of signatories has not been reached at the end of 2011. Thus, the WTO General Council has decided to postpone the entry into force of the Protocol indefinitely until the required ratifications are reached.

Finally, on 23 January 2017, the WTO announced the entry into force of the 2005 Protocol 'after its ratification by two-thirds of the Members'[49], as provided by Article X of the Marrakesh Agreement establishing the WTO, and replaced, from that moment, the August 2003 Decision that remained in force until that date. However, by that date indicated by the WTO as the date of entry into force of the Protocol, only 16 LDCs out of 48 have ratified.[50] A surprising number for an amendment that was supposed to solve the problem of access to medicines, a problem that affects them more than other countries. The reason for the lack of interest of most of these LDCs for this amendment is that they are aware that the provisions contained in this Protocol will not allow them to solve the problem of access to medicines, given the cumbersome nature of the mechanism it plans. Moreover, if the amendment were to improve the situation, the change would already have been noted since. Although the Protocol has not yet entered into force, the Decision of 30 August 2003, which provides for the same mechanism, was provisionally in force[51].

Nevertheless, the problem of access to medicines has remained intact, despite almost two decades that have passed since its adoption. The obstacles of the application of the 2005 Protocol remain even after its entry into force. The difficulties are to look elsewhere, especially in the cumbersome of this mechanism.

7. THE CUMBERSOME NEW PROCEDURE OF COMPULSORY LICENSES

The complexity of the new compulsory licensing mechanism has generated some scepticism about its functionality. While the Doha Declaration called for a quick and easy solution to be implemented, it is a cumbersome, lengthy, and costly mechanism provided for in the decision of 30 August 2003. Before importing medicines produced under compulsory licenses, the 'Eligible importing Member' that wishes to issue the compulsory license must demonstrate the failure of its attempt to negotiate with the patent holder[52]. This was not required in the general TRIPS flexibility regime if the license is issued in a national emergency. Thus, this new mechanism complicates the 'normal or general'[53] procedure of compulsory licenses, a system that was already particularly difficult to implement.

[48] In this context, this verb 'accept' means 'ratify'.

[49] WTO, WTO IP rules amended to ease poor countries access to affordable medicines <https://www.wto.org/french/news_f/news17_f/trip_23jan17_f.htm> accessed 27 September 2017.

[50] See the list of countries that have ratified the Protocol of the amendment of the TRIPS Agreement <https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm> accessed 15 January 2018.

[51] It should be noted that even the non-ratification of the 2005 Protocol, which would make the August 2003 Decision permanent, does not prevent it from being applied in accordance with the provisions of the Agreement Establishing the WTO (Article 10 of the 2003 Decision and Article XXIII of the GATT 1994 paras. 1(b) and (c).

[52] Implementation of the Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540 and corr. 1, 1 September 2003, <https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm> accessed 3 May 2022.

[53] It should be recalled that the compulsory licensing system provided for in the 2003 Decision and the 2005 Amendment applies only to medicinal products. Other products remaining under the general compulsory licensing regime as provided for in Article 31 of the TRIPS Agreement.

The process of using these new compulsory licenses is extremely laborious. To obtain supplies of drugs produced under compulsory licenses, the Member in need of these drugs makes the request to another Member who has the capacity to produce them. The latter makes the order and is a guarantor to the pharmaceutical firm that agrees to produce them. The obligation to issue compulsory licenses simultaneously in the producing country and the importing country, the multitude of notifications and information to be transmitted to the WTO, the proof of the needs of the importing country and its inability to produce locally[54], are factors that would make the process more cumbersome and slower. These administrative procedures complicate the mechanism to the point of rendering the decision of 30 August 2003 and 2005 Protocol ineffective. Thus, importing countries, which until then only had to declare a compulsory license to be able to obtain generic supplies of a patented medicine, are, by this device, obliged to carry out information and notification procedures to the TRIPS Council[55].

In addition, the **exporting Member**[56] has to manufacture only the product in a quantity that it has notified to the WTO. In fact, the compulsory license must specify the name and quantity of the products that the country wants to export in this context. All drugs produced under compulsory licenses must be identified by means of specific labelling or marking (colour, shape, or packaging) to distinguish them from the patented products for which they are equivalent[57]. This implies that if a company wants to produce for several different countries, it must proceed to a different marking for each country of destination[58]. It must export all the products manufactured in each eligible importing Member, which in turn must take **reasonable measures** to ensure that the exemption does not result in the diversion of the exported pharmaceutical products and to prevent their re-export or use by ineligible Members[59]. This is likely to discourage developed country firms from becoming involved in the process of exporting drugs produced under compulsory licenses, as this requirement of multiple marking constitutes an additional constraint or burden in money and time. For example, Appotex[60] did not wish to receive a new order from Rwanda, claiming that it had lost money in the first order of antiretroviral it has delivered to Rwanda[61].

The exporting country must finally vouch for remuneration and payment to the patent holder[62]. Thus, in the event the importing country fails to honour its commitments, it is the exporting country that should pay this remuneration. In addition, the conditions under which the amount of such remuneration is determined remains imprecise, as mentioned above. As far as this remuneration is concerned, the importing country is relieved of all liability to the patentee, who may directly seize the exporting country. Thus, instead of encouraging the export of drugs produced under compulsory licenses, the mechanism provides a kind of sanction to companies

[54] The country wishing to use the mechanism must establish that it does not have manufacturing capacity in the pharmaceutical sector or that it is insufficient and that it is not in a position to acquire such capabilities in the short term, unless it is a LDC in which case this does not apply, as the LDCs are presumed not to be in possession of it.

[55] Annex of the WTO TRIPS Agreement, para. 2(a), <https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm> accessed 14 December 2017.

[56] 'Exporting Member' means a member using the system to produce pharmaceutical products for, and export them to, an eligible importing member. See the Annex of the TRIPS Agreement, paragraph 1(c), <https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm> accessed 14 December 2017.

[57] Gervais D (n 34) 76.

[58] Gervais D (n 34) 79.

[59] Re-export is not even allowed for developing or LDC Members with similar health problems who have signed a regional trade agreement within the meaning of Article XXIV of the GATT 1994. Diversion (export to a third country instead of the country for which the product was manufactured) remains the main concern of rich countries. The circumstances which justify the manufacture of a medicinal product under a compulsory license for export to a country A and notifications requirements do not apply to a country B, and the latter must make the orders and notifications provided if it also wants to benefit from the system. Gervais D (n 34) 387.

[60] Appotex is the Canadian pharmaceutical firm that produced and exported the compulsory licensed antiretrovirals in Rwanda.

[61] Kohler JC, Lexchin J, Kuek V, Orbinski J, 'Canada's Access to Medicines Regime: promise or failure of humanitarian effort?' (2010) *Healthc Policy* 5(3) 40-48 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2831732/> accessed 14 May 2017.

[62] Correa C, Velasquez G (n 16) 92.

and developed countries that would be engaged in the procedure.

The most worrying is that generic manufacturers are allowed to produce only piecemeal and in quantities previously specified. It is hard to imagine how they could engage in investment by making adequate production facilities without the guarantee of a sustainable market or a sufficient volume to amortize its investment costs. This situation alone constitutes a major discouragement. Except in exceptional circumstances (many orders, production process easy to copy, etc.), it is hard to see how the mechanism would motivate firms to become involved in such a process, without forgetting, as we have seen, the pressures that these firms and their country exercise over other countries that intend to use them.

In addition, requiring a manufacturer to obtain a compulsory export license for each offer and for each recipient country is a significant obstacle. This requirement implies that the manufacturer establishes a production line to execute an order and dismantle everything after and to build or refurbish other new infrastructure for another. It is simply surreal, as long as the needs of the countries are often identical and often concomitant, especially in case of epidemics, diseases, or disasters. There is, therefore, a clear desire on the part of developed countries to defeat the mechanisms provided for by the new compulsory licensing procedure provided for in the 2003 Decision.

8. THE WEAK INVOLVEMENT OF DEVELOPED COUNTRIES

Already, several developed countries (such as Australia, Canada, United States, Japan, and the European Union) have indicated that they will not use the new system of compulsory licenses as importers[63]. This is logical because they have sufficient capacity to produce locally the drugs they need. Others (such as China, South Korea, Mexico, and Turkey) said they would only use it in emergencies[64]. Even worse, despite the lawful nature of these compulsory licenses, their use remains residual, also because, the pressure exerted by the rich countries and their firms on the governments of the developing countries which are using or planning to use them.

Some countries that have indicated their intention to use it have been threatened by some developed countries with commercial retaliation. These threats are sufficiently dissuasive for these countries of the South to give up the use of compulsory licenses[65]. Indeed, the United States brought a complaint before the WTO challenging the fact that it was possible to acquire a compulsory license in Brazil even if the patent was not of Brazilian origin[66]. In addition, Thailand was also granted a compulsory license for efavirenz in 2006 to import it from India at a price corresponding to half of its marketing price in Thailand. In retaliation, one of the pharmaceutical companies withdrew the pending applications for approval of new drugs in Thailand. Meanwhile, the United States has threatened Thailand with commercial retaliation on jewellery, wood and microprocessors and has placed it on the 'priority watch list', that of countries whose IP protection is judged inadequate[67]. Thus, political, and economic pressures remain a recurring problem even in the case of the new compulsory licensing procedure, despite the fact that these pressures have been formally denounced in the Doha Declaration and in the 2005 Protocol itself[68]. In paragraph 4, the 2001 Declaration states that the pressure to impede the use of available flexibility in the TRIPS Agreement runs counter to the spirit and purpose of the Agreement. This provision has no longer been

[63] Annex of the WTO TRIPS Agreement <https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm> accessed 14 December 2017.
[64] ibid.
[65] See the US Trade Representative's 30 April 1999, press release which lists countries that may be subject to economic trade sanctions under Special Section 301 of the US Trade Act. Correa C, Velasquez G (n 11) 47.
[66] Remiche B, Cassiers V (n 24) 144.
[67] Correa C, Velasquez G (n 11) 77.
[68] Protocol amending the TRIPS Agreement, Article 31*bis*, paragraph 4.

respected; a Declaration remains a simple declaration without any binding legal force. The answer to the problem of patents and access to medicines in the LDCs is, therefore, neither in the old version of the compulsory licenses, nor in the new one designed specifically to solve this problem, nor in any other exception provided for through the WTO Agreements.

In the context of the SARS-COV-19 pandemic, it already seems that the provision of the 2005 Protocol cannot operate, that why many countries, United States, France, the BRICS, European Union, among these, are in favour of the suspension of patents on new vaccines against COVID-19 to allow poor countries to acquire the doses necessary to vaccinate their populations at a lower cost.

If the countries are traditionally hostile to any measures aimed at calling into question the current system of patents, with regard to drugs and patents, and even want to suspend them, it is because they have observed the failure of the mechanism established by the 2005 Protocol. In addition to the suspension of patents on vaccines against COVID-19, other mechanisms have been introduced to allow the vaccination of a large part of the world population, especially in the COVAX mechanism.

Even if these measures, including that of suspending patents, do not constitute adequate answers, in my opinion, to the problem of patents and access to drugs in developing countries, they at least have the merit of showing that the system put in place within the framework of the WTO is not likely to resolve it and that we must still get to work to adopt mechanisms likely to resolve it. Proposals exist. It only remains to analyse and adopt them.

9. CONCLUSIONS

Despite the flexibility of the TRIPS Agreement and other WTO Agreements that are favourable to the LDCs and that they can be exploited to take action in favour of health, the reality is that these countries are still unable to have access to new medicines for their populations. Indeed, in addition to the fact that these flexibilities are inoperative because of technical incapacity and the fear of trade and economic retaliation by rich countries, developing countries cannot use compulsory licenses. The latter, which are the most interesting of these flexibilities and which could enable the LDCs to obtain generic medicines, has proved ineffective in most of these countries. Article 31 of the TRIPS Agreement authorizing such compulsory licenses provides in paragraph (f) that they may be granted only for the supply of the domestic market of the Member who authorized them. Thus, as this provision is interpreted as a formal ban on the export of drugs produced under compulsory licenses, the LDCs cannot exploit it to obtain the medicines they need at reasonable and affordable prices for their populations. Their pharmaceutical industries lack the technical capacity and human resource skills in drug production. The implementation of local production in the LDCs is therefore not technically or economically viable in these countries.

It is in this perspective that the 2001 Doha Ministerial Conference allowed the relaxation of the compulsory licensing rules by inviting Members to take measures favourable to health. In 2003, the TRIPS Council adopted a Decision amending Article 31(f) and making it enforceable until the entry into force of the 2005 Protocol amending the TRIPS Agreement, which made this derogation from Article 31(f) permanent. The novelty of this 2003 Decision is that for countries without technical capacity, the importation of drugs manufactured elsewhere under compulsory licenses became legally possible, thus repealing the provision that prevented their export. But the conditions to be fulfilled as well as the formalities to be done are all constraints and limits to the use of this new system of compulsory licenses. Indeed, this new system imposes many administrative, legal, and political obstacles to the export of generics. While the problem of affordable prices for patients in the LDCs may theoretically be limited by this

new system of compulsory licenses, the implementation of this new system is more restrictive than the general rules of the TRIPS, and it has become more complicated and complex to import or export drugs than any other product manufactured under compulsory licenses. Because it has multiple requirements and multiple notifications, and because it is based on country-by-country, drug-by-drug action, it creates a lot of paperwork and stretching delays that do not take into account the urgent drug needs that the countries and patients often face.

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