



Will the Amendment to the TRIPS Agreement Enhance Access to Medicines?*

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Introduction

After the entry into force of the Agreement on Trade Related Aspects of Intellectual Property Rights ('TRIPS Agreement'), all members of the World Trade Organization (WTO) were obliged to grant patents on pharmaceutical products. As a result, generic producers that in some countries were formerly able to supply low-cost generic pharmaceuticals to local and foreign markets could not continue to reverse engineer new, patented drugs and sell generic drugs. This new scenario affected not only the producing countries, but also those importing generic drugs that were left with the only option of purchasing them from the patent owner, often at unaffordable prices. While those countries could issue compulsory licenses, their grant would not provide a solution if there is no

manufacturing capacity in the country and the needed pharmaceuticals cannot be imported from low-cost producers. The TRIPS Agreement did not allow the grant of compulsory licenses for exports only, thereby preventing generic manufacturers from eventually exporting the required products to countries unable to produce them.

The problem created by the limitations imposed by the TRIPS Agreement was addressed, in the context of the WTO, through paragraph six of the Doha Declaration on the TRIPS Agreement and Public Health (hereinafter 'the Doha Declaration'), which instructed the Council for TRIPS 'to find an expeditious solution' to address this serious public health problem: if a medicine is patented in a country where there is insufficient or no manufacturing capacities in the pharmaceutical sector, and the medicine is unavailable (because of high prices or other reasons),

Abstract

An amendment to the TRIPS Agreement by incorporation of the text of the decision of the WTO General Council on 30 August 2003 (as article 31bis) has been made in response to the problem identified in paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. This paragraph sought a solution to situations where patented pharmaceuticals which are not available in a country with no or insufficient manufacturing capacity can be supplied by a foreign provider. As originally adopted, the TRIPS Agreement did not allow the grant of compulsory licenses for exports only, thereby preventing generic manufacturers from exporting the required products to countries unable to produce them. While the new article 31bis is a step forward as it reflects public health concerns, it would be necessary to streamline the procedures to effectively ensure broader access to pharmaceutical products at low cost and in a timely manner.

Le texte de la décision du Conseil général de l'Organisation mondiale du commerce (OMC) du 30 août 2003 a été ajouté (en tant qu'article 31bis) à l'Accord sur les aspects des droits de propriété intellectuelle qui touchent au commerce (ADPIC) afin de résoudre le problème soulevé au paragraphe 6 de la Déclaration de Doha sur l'Accord sur les ADPIC et la santé publique. Ce paragraphe visait à traiter les cas où des produits pharmaceutiques non disponibles dans des pays dont les capacités de fabrication sont insuffisantes ou inexistantes peuvent être obtenus auprès d'un fournisseur étranger. Tel qu'il avait été initialement adopté, l'Accord sur les ADPIC n'autorisait pas la délivrance de licences obligatoires pour l'exportation uniquement ; les fabricants de génériques ne pouvaient donc pas exporter les produits nécessaires aux pays n'ayant pas la capacité de les fabriquer. Si le nouvel article 31bis est un pas en avant car il prend en compte les préoccupations de santé publique, il est toutefois nécessaire de simplifier les procédures en vue de véritablement élargir l'accès aux produits pharmaceutiques à bas prix et en temps voulu.

El Acuerdo sobre los ADPIC ha sido modificado mediante la incorporación (como artículo 31bis) del texto de la Decisión del Consejo General de la OMC del 30 de agosto de 2003, en respuesta al problema identificado en el párrafo 6 de la Declaración de Doha sobre el Acuerdo sobre los ADPIC y la Salud Pública. Este párrafo buscaba una solución para situaciones en las que un proveedor extranjero puede suministrar productos farmacéuticos patentados que no están disponibles en un país que no tiene capacidad de fabricación o con capacidad de fabricación insuficiente. Tal como se adoptó originalmente, el Acuerdo sobre los ADPIC no permitía la concesión de licencias obligatorias sólo para exportaciones, lo que impedía a los fabricantes genéricos exportar los productos requeridos a países que no podían producirlos. Si bien el nuevo artículo 31bis es un paso adelante, ya que refleja los problemas de salud pública, sería necesario simplificar los procedimientos para garantizar un acceso más amplio a los productos farmacéuticos a bajo costo y de manera oportuna.

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granting a compulsory license (that is, authorizing a third party to produce and sell the medicine against payment of a remuneration to the patent owner) becomes ineffective, since the medicine might not be produced anyway (Thapa, 2011). It could be exported from a country where such manufacturing exists, but paragraph (f) of article 31 of the TRIPS Agreement banned the grant of a compulsory license for export only.

Hence, the country in need of a medicine would be in a trap: it will be unable to ensure the supply of the needed medicine, even if the medicine were available and could actually be sold by the patent owner (or its licensees). Importantly, this situation may arise even in countries where a medicine is not protected by any patents, such as in the case of least developed countries (LDCs), which were temporarily exempted from complying with the TRIPS Agreement under article 66.2 of said agreement. The initial transitional period of 10 years was subsequently extended; it will expire on 1 January 2033, unless renewed again.

In fact, many developing countries and LDCs cannot produce either active ingredients or formulations, due to lack of technological capacity, equipment, human resources, or simply because domestic production would not be economically viable, especially when the markets are small and economies of scale cannot be realised.

This is the problem the Council for TRIPS was instructed to deal with and solve. It took the WTO members more than one and a half years to strike an agreement: a decision was adopted by the WTO General Council on 30 August 2003 (hereinafter 'the WTO Decision').

Significantly, the problem addressed under Paragraph six of the Doha Declaration is not the unavailability of a particular medicine but the effects of the monopoly created by patents and the conduct of the patent owner. The system developed by the WTO Decision (hereinafter 'the system') is meant to apply in a scenario where the world supply of a patented product is controlled by the owner of one or more patents (often a large number of patents are obtained around a single active ingredient) and, therefore, no alternative supply of *generic* products is available (Correa, 2014). The use of that system becomes necessary because the patent owner refuses to supply a patented product in a country (with insufficient or no manufacturing capacity in pharmaceuticals) at an affordable price or under other conditions that the demanding country cannot meet.

Paragraph six addressed the described problem by adopting two 'waivers' in respect of the obligations set out in article 31 paragraph (f), regarding the ban to grant compulsory licenses exclusively to export, and paragraph (h), regarding the obligation to pay a remuneration to the patent owner in the country where the medicines are imported. A waiver under WTO rules can be granted 'in exceptional circumstances' and al-

lows a member not to comply with certain obligations; it must be reviewed annually by the WTO Conference (article 9.4 of the Agreement Establishing the WTO). The WTO Decision that adopted these waivers provided for an annual reporting on the operation of the system set out, and stipulated that the waivers would be terminated on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for a member.

An agreement to amend the TRIPS Agreement by incorporation (as article 31*bis*) of the text of the decision was reached in December 2005, subject to further approval by two thirds of the WTO members, as requested by the WTO rules (article X(3) of the Agreement Establishing the WTO). The process of approval demanded 10 years, an extremely long period as compared, for instance, to that required for the approval of the Trade Facilitation Agreement (TFA), which entered into force a little more than three years after its adoption.

The Compulsory License System

The process leading to the adoption of the Doha Declaration was highly controversial, particularly due to the initial opposition by the US government and pharmaceutical industry. Its adoption was a significant achievement for developing countries, as it recognized the 'gravity' of the public health problems afflicting many developing countries and LDCs, confirmed the 'flexibilities' allowed under the TRIPS Agreement (such as compulsory licenses and parallel imports) and, although it specifically referred to HIV/AIDS, tuberculosis and malaria, it covered all diseases, including non-communicable diseases (Correa and Matthews, 2011).

The negotiation and adoption of the WTO Decision (often called 'the paragraph six solution') were equally or, perhaps, even more controversial. In particular, the US rejection to a broad scope for the system to be established – covering all diseases and not just malaria, tuberculosis and HIV/AIDS – significantly delayed the conclusion of an agreement. A final compromise was reached upon issuance by the chair of the WTO General Council of a 'statement' intended to further expand some of the conditions established to export a pharmaceutical product under the compulsory license system (Correa, 2004).

In order to use the system, a potential importing country must send a notification to the Council for TRIPS:

(i) specifying the names and expected quantities of the pharmaceutical product(s) needed;

(ii) confirming (unless the importing country is an LDC) that has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question; and

(iii) confirming that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory license in accordance with Article 31 of the TRIPS Agreement and the provisions of the WTO Decision. Complying with this condition would mean, *inter alia*, that a prior request of a voluntary license needs to be

made to the patent owner (unless grounds of extreme urgency or anti-competitive practices were invoked or the non-commercial public use of the patent/s decided) and, only if refused or deemed to be refused, a compulsory license can be subsequently granted.’ (WTO Decision)

In addition, the potential supplier of the required product should seek a voluntary license from the patent owner on commercially reasonable terms to produce the required drug in the exporting country and, once refused or deemed to be refused, submit to the competent authorities an application for the grant of a compulsory license, which will be subject to a number of conditions:

‘(i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the license and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;

(ii) the products manufactured under the license shall be clearly identified through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, ‘provided that such distinction is feasible and does not have a significant impact on price’; and

(iii) before shipment begins, the licensee shall post on a website the following information:

- the quantities being supplied to each destination; and
- the distinguishing features of the products;

(iv) a remuneration must be paid to the patent owner in accordance with article 31(h) of the TRIPS Agreement.’

These conditions must be fulfilled over and over even if the same importing country requests an additional quantity of the same product, since only the amount necessary to meet the needs initially notified by the importing country may be manufactured under the license.

Two additional notifications to the Council for TRIPS are needed. On one hand, prior to using the system as prescribed, an interested country (unless it is an LDC) must notify of its intention to use the system as an importer. Significantly, not a single notification for this purpose has been made so far in accordance with the WTO ‘Dedicated page’ on the WTO Decision.

On the other hand, if a compulsory license has been granted, the exporting country is bound to notify of the grant of the license and the conditions attached to it, including the name and address of the licensee, the product(s) for which the license has been granted, the quantity for which it has been granted, the country to which the product is to be supplied, the duration of the license and the address of the website where the licen-

see will post the information required about the quantities and features of the products.

It is also to be noted that the implementation of the WTO Decision or article 31*bis* may require some changes in national patent laws if they only provide for the granting of compulsory licenses for the manufacture of patented subject matter, and not for importation. More importantly, since most countries introduced in their legislation the limitation imposed by Article 31 (f) of the TRIPS Agreement (that is, compulsory licenses may be granted only to supply ‘predominantly’ the domestic market), they would not be able to grant compulsory licenses exclusively for export to countries without sufficient manufacturing capacity in pharmaceuticals, unless the national law is amended accordingly. So far only Canada, the European Union (EU), the Netherlands, Norway, India, China, Switzerland, and Australia seem to have amended their legislation accordingly. Out of these countries, only India and China would have the potential to supply pharmaceutical products, including active ingredients, at low cost under the established export/import system.

The required notifications and the nature of the information required – plus the obligation to adopt measures to avoid the ‘diversion’ of the products to other countries – would seem more suitable for the export of weapons or dangerous materials than for products to address public health needs. The adoption of the WTO Decision, and later of the amendment to the TRIPS Agreement, was described by the WTO as a proof that this organisation ‘can handle humanitarian concerns’ (WTO, 2003) and as ‘an extremely important amendment...that helps the most vulnerable access the drugs that meet their needs, helping to deal with diseases such as HIV/AIDS, tuberculosis or malaria, as well as other epidemics’ (WTO, 2017).

However, the procedural burden imposed on governments and potential suppliers to deal with an essentially humanitarian issue, has raised significant criticism from academics, non-governmental organizations (NGOs) and potential suppliers, and scepticism about the effectiveness of the adopted ‘solution’.

The scholars’ prevailing view has been summarized as follows,

Among the scholars, it is a common view that the Decision will create more hurdles than solution to paragraph 6 problem of the Doha Declaration. It is saddled with many administrative pre-requisites, which will hamper the very purpose of the Para 6 System. A country in need of required drugs to meet the health emergency, and lacking manufacturing capacity will have to go through many layers of procedure...All these measures not only will delay the manufacture and supply but increase the cost of the drugs. Decision is termed to be a temporary solution which is difficult to operate. It is considered not faithful to Doha Declaration on TRIPS and Public Health.

(Verma, 2006, pp. 90-1)

The practical hurdles that, in particular, a potential supplier would have to face under the system have been highlighted in some of the academic literature. For instance, Cohen-Kohler et al. (2007) have noted the need to negotiate a voluntary license with potentially multiple patent holders (which is a lengthy, complex and expensive process), that the quantity of the license is limited to that which was originally applied for by the country, and that there is heavy front-end investment and little incentive, particularly if a company would need to adjust and/or increase their manufacturing infrastructure for products which are not normally part of their product portfolio.

The view of many NGOs is exemplified by a statement of Doctors Without Borders (MSF) – a humanitarian organisation that was awarded the Nobel Prize in 1999. It noted that,

The Decision flies in the face of the practical reality of managing a health programme, where flexibility and rapidity of response to ever-changing circumstances are vital. It also ignores the fact that economies of scale are needed to attract interest from producers: without the pull of a viable market for drugs, generic manufacturers will not seek to produce for export.

(MSF Canada, 2006, p. 3)

The opinion of generic pharmaceutical companies – the potential suppliers under the system created by the WTO Decision – was equally sceptical. The Director General of the European Generic Medicine Association (EGA), for instance, declared that the ‘WTO’s 2003 August 30 Decision concerning compulsory licenses is complicated, unworkable and unable to deliver any significant improvement in access to medicines’ (Rehman, 2011).

The same scepticism was expressed by the main potential suppliers of generic medicines, the Indian firms who are major providers of medicines to developing countries. Thus, the representative of CIPLA – one of the top global pharmaceuticals companies in India – observed that the paragraph six system is ‘a cumbersome and ineffective process and that CIPLA will not use para 6 in its current state of writing’ (Nightingale, 2016).

Since, by hypothesis, when a particular pharmaceutical product is demanded for supply under the system created by the WTO Decision – and incorporated in article 31*bis* of the TRIPS Agreement, its global production and commercialisation is controlled by the patent owner, any alternative supplier would have to take several steps to be able to sell the (limited) quantity that may be supplied under such system.

First, research and development need to be conducted on the chemical composition of the needed product. This exercise, sometimes characterised as ‘reverse engineering’, has to be made without the technical coopera-

tion of the patent owner. Patent specifications normally do not disclose the know-how necessary to develop a protected chemical compound; hence considerable experimentation may be needed to develop an efficient and reliable process to obtain the required product. Second, once this step is completed, an appropriate salt (if produced in solid form) and stable formulation (tablet, capsule, etc.) for the particular drug must be developed. In designing the formulation and its packaging, the producer would need to investigate the product’s shape, colouring, labelling and packaging of the patent-holder’s product in the importing country in order to differentiate the product for export. Finally, the producer will also need to seek marketing approval and, eventually, demonstrate bioequivalence and bioavailability, when required by national law. In some cases, such approval would be needed both in the importing and exporting country.

While these activities may take several months or more than one year for a chemical compound, in the case of biologicals the investment and time necessary to develop a ‘biosimilar’ would be much longer, so long that the use of the export/import system would become illusory. Given the costs and risks involved in the development of biosimilars, the lack of automatic substitution and need to undertake (at least some) new clinical studies (Blackstone and Fuhr, 2013), it is practically unthinkable that a producer will consider a request under the article 31*bis* system for the supply of a small quantity of a biological product. In fact, the number of potential producers of biosimilars is several times less than generic producers (of chemically synthesised drugs) and the market is still largely controlled by a few large companies (Desai, 2016).

A potential supplier must, therefore, make a considerable investment and devote a significant time to develop the limited quantity of the product demanded under the system. This is to be done, in addition, in a context of high risk: *at any time*, the patent owner may decide to lower the price or even donate the required medicines to the country in need, and thereby frustrate the whole process and deprive the investment made of any possible return.

Even worse, the patent owner may exploit the intricacies and complexities of the system, for instance, by delaying a response to a request of a voluntary license – as mentioned above, one of the conditions to put the system into operation – or exercising his rights under the relevant national laws to block the grant or execution of a compulsory license. This can be done through an appeal against a decision granting a compulsory license in the importing and/or exporting country. Although some national laws (e.g. Argentina) have stipulated that an appeal by the patent owner against the grant of a compulsory license does not suspend its immediate execution (e.g. Article 49, Argentine Patent Law No. 24.481, as amended), this is not the case in many other countries. The patent owner may file for an injunction and thereby stop exports until a final administrative or judicial decision is taken, perhaps a few years later.

In countries where test data are protected under the so-called 'data exclusivity' regime, an additional hurdle may be created by the marketing approval of the product to be imported under a granted compulsory license. Unless the national law of the importing country specifies (such as in the case, for instance, of Chile) that data exclusivity may not be invoked when a compulsory license has been granted, the needed products may not be authorised for commercialisation, or the right-holder may request a court to prevent it. It is worth noting, however, that data exclusivity could not normally be invoked in the exporting country, since that form of protection only relates to the commercialisation of a product in the territory where the protection was not acquired, and not to exports (Correa, 2017).

As noted, the basic assumption for the application of the system is a situation where a product is available and could effectively be supplied to the country in need by the patent owner. In the last instance, the system legitimises the conduct of a patent owner who refuses to sell a product under his monopolistic control. By subjecting the use of the system to a large number of stringent conditions, it seems to be designed to protect the patent owner rather than facilitating access to pharmaceutical products where needed. Whatever humanitarian reasons may underpin a country's demand of a given drug, nothing in the adopted system compels the patent owner to supply the required drugs or to grant a voluntary license to a potential exporter. The patent owner may just passively watch how the country in need and a potential supplier strive to fulfil the conditions imposed by the WTO Decision (now article 31*bis*), while people remain without treatment.

The WTO Decision was apparently built upon the assumption that a patent owner is legitimised to prevent access to products under his control, even in the presence of compelling humanitarian reasons. This is inconsistent with the Doha Declaration (particularly paragraph four) and with the states' commitments under the International Covenant on Economic, Social and Cultural Rights, especially its Article 12 (recognising the human 'right of everyone to the enjoyment of the highest attainable standard of physical and mental health' and obliging states to take steps to fully realise this right, including 'those necessary for ... the prevention, treatment and control of epidemic, endemic ... and other diseases').¹

Use of the WTO Decision

The system set out by the WTO Decision was used only once for the export by a Canadian firm, Apotex, of a combination of anti-retrovirals (Apo-TriAvir) to Rwanda. The active ingredients were protected by patents held by Boehringer Ingelheim (Canada) Ltd. and GlaxoSmithKline Inc. in Canada, to whom Apotex was bound to request voluntary licenses as the first step to comply with the WTO Decision and the national law. The case was instigated by Doctors Without Borders to test the viability of the system and the suitability of the

Canadian legislation. The Canadian Access to Medicines Regime - CAMR was adopted in 2004 as the first law in the world to implement the WTO Decision. The process took, due to various factors (including the delay in finding a candidate importing country and the tender process), nearly four years. Apotex representatives have made the following statements in relation to their experience in this case,

We've spent millions of dollars on the [research and development] we've spent lawyers' time at our cost, just because it's the right thing to do. It would be difficult to do again unless the legislation is made simpler...Imagine if ... another country, like Malawi, comes forward asking for the drugs, we'd have to start this whole process again.

(Gandhi, 2008)

Well, we might end up with a couple of orders, but at the end of the day we won't make any money out of it, and I'm going to get to a point where someone else comes along, like [NGO], and say 'we want this other compound', I'm not going to be able to develop it, because I'm in business to make money and I can only do so many products.

(Cohen-Kohler et al., 2007)

It has been reported that if Rwanda had procured the required medicine from, e.g., Indian generic manufacturers, it would not have needed to use the WTO Decision at all, since the products were not patented in India. In accordance with one estimate, Apotex lost US\$3-4 million dollars by offering a lower price to win Rwanda's tender, as it could not otherwise compete with other low-cost producers (Nightingale, 2016). Another application for a compulsory license under the system was reportedly filed in September 2007 by a company with the Indian patent office to export an anti-cancer drug (erlotinib) to Nepal. However, Nepal's government never notified that it intended to carry out the importation from India of that drug and no compulsory license was issued (WHO et al., 2012).

The way in which the system was used in the case of Canada, and the absence of other uses, certainly raises questions about its appropriateness and effectiveness to address the problem it was intended to solve. As noted by one commentator,

[I]n the light of theoretical analysis and the two cases (Rwanda and India), it is hard to construe the Waiver Decision 2003 as a positive measure which can solve the problem of access to medicine. The decision is cumbersome and rigid and beyond its textual constraints, it also restricts the economic incentive which is essential to maintaining a manufacturing base.

(Rehman, 2011, p. 13)

In addition, given the intricacies of the system as now incorporated into the TRIPS Agreement, it does not put

any pressure on patent owners to lower their prices or to negotiate voluntary licenses.

Amending the System

The numerous conditions imposed for the use of the system show how difficult it was for developing countries and notably, the African Group, to get the agreement of developed countries, notably the USA (Abbott, 2005; Abbott and Reichman, 2007). As discussed above, the system has failed to deliver the expected outcomes. No systematic study has been made so far to explain why the system has not been effectively used. A better understanding of the factors that determine its failure would be useful in order to consider, in particular, what further steps need to be given or what amendments need to be introduced. Different hypotheses can, however, be made regarding those factors.

The main hypothesis that may be advanced relates to the barriers that the system creates for potential suppliers to exploit economies of scale. Since the markets that may be supplied (in countries where there is insufficient or non-existent manufacturing capacity in pharmaceuticals) are small, generic producers are unlikely to be interested – as the evidence so far indicates – in becoming involved in complex legal procedures when there are no chances for economies of scale to recoup the investment made and generate at least a reasonable profit. As suggested in one of Apotex's comments quoted above, generic producers are not philanthropic but business organisations that respond to economic incentives.

The WTO Decision, in fact, recognised that the viability of the 'solution' largely depended on the existence of economies of scale. Paragraph 6 of the Decision allowed, 'with a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products', the export of products manufactured upon request of a country to other developing or least developed country parties who are part of a regional trade agreement, provided that at least half of its membership is made up of least developed countries. However, this latter requirement means that this possibility will only be open in the case of regional trade agreements established by African countries, whose aggregate demand for particular medicines would still be insufficient to generate a sizeable market and realise economies of scale.

It has been argued that the lack of incentives resulting from the impossibility of realising economies of scale may be overcome by '[r]egional approaches to procurement and joint notifications by countries with similar needs for accessible medicines' (WHO et al., 2012; Abbott and Reichman, 2007). In some cases, progress has been made in pooled procurement for certain medicines to obtain lower prices. The Strategic Fund of the Pan American Health Organization (PAHO), for instance, is a system for the pooled procurement of es-

sential medicines that has allowed governments to obtain significant savings (PAHO, 2017). Another initiative that has led to better bargaining for prices is PAHO's revolving fund for vaccine procurement (PAHO, 2016). However, pooling for the purposes of using the system discussed here is not a realistic approach since it is too complicated to organise given differences in planning, legal procedures, and regulatory frameworks. A well-functioning system should allow individual countries to expeditiously address their health needs.

It has also been argued that generic medicines have been available so far from non-patented sources, thereby making it unnecessary to use the WTO Decision system, and that the problem of access to patent drugs has been alleviated by voluntary licenses, particularly as a result of the operation of the Medicines Patent Pool established in 2010 (WHO et al., 2012). It has also been argued, as noted in the Report of the United Nations (UN) High Level Panel on Access to Medicines, that the availability of multilateral health financing for resource-constrained countries explains the lack of use of the system (UN High Level Panel on Access to Medicines, 2016).

In fact, the political and economic pressures felt by some countries not to use compulsory licenses – which are highlighted in the same report (UN High Level Panel on Access to Medicines, 2016) – may have played a role in discouraging the use of the system. Most probably, there has been a multiplicity of factors that determined the lack of interest in using it. They probably included 'burdensomeness and complexity, economic and political pressures, reluctance in implementation and its failure to recognize the need for economies of scale for exporting countries' (Thapa, 2011, p. 474).

In light of the failure of the WTO Decision, the High Level Panel on Access to Medicines established by the UN General Secretary in 2016 recommended that:

WTO Members should revise the paragraph 6 decision in order to find a solution that enables a swift and expeditious export of pharmaceutical products produced under compulsory license. WTO Members should, as necessary, adopt a waiver and permanent revision of the TRIPS Agreement to enable this reform.

(UN High Level Panel on Access to Medicines, 2016, p. 27)

It will be worth pursuing this recommendation, as the problem of access to medicines may aggravate in the years to come. On one hand, probably due to new humanitarian demands (such as the refugee crises) and the fiscal austerity in many countries, recent years have seen a regression of donor funding, for instance, for the HIV response in low- and middle-income countries; it declined by almost 13 per cent between 2014 and 2015 (Avert, 2017). This trend may be further aggravated by the announced budgetary cuts of the US for foreign aid, including funding for the President's Emergency Plan for AIDS Relief (Aizenman, 2017)

On the other hand, while many countries have some

manufacturing capacity (albeit in most cases for pharmaceutical formulations, not active ingredients) relating to drugs produced by chemical synthesis, the production of biologicals (such as the growth hormone, interferon, erythropoietin, monoclonal antibodies) is much more complex and only a few countries have manufacturing capacity in this field. Biologicals account for a growing share of the pharmaceutical market, which reflects their increasing importance in the arsenal of therapeutic tools available to treat diverse diseases (Blackstone and Fuhr, 2013; Desai, 2016). In fact, biologicals in some cases are the single option available to address some diseases (such as certain types of cancer), generally at a very high cost. Few countries have manufacturing capacity to produce biosimilars (that is generic versions of biologicals), and given the cost and time needed to develop them it seems unthinkable that the system, as currently designed, could contribute to facilitating access to those products.

An amendment to the system may be conceived in different ways. The most efficient one from the perspective of access to pharmaceutical products would be just to delete paragraph (f) of article 31 of the TRIPS Agreement that has created the problem addressed by the Doha Declaration.

Another possibility would be to clarify that the production for export of a patented product does not violate the patentee's exclusive rights as contemplated in article 28 of the TRIPS Agreement. An authoritative interpretation of this kind may be made by a three-fourths majority of the WTO members (article IX(2) of the Agreement Establishing the WTO). However, individual members may adopt this interpretation, albeit with the risk of facing a complaint under the WTO Dispute Settlement Understanding that would clarify whether it is consistent or not with the TRIPS Agreement. In fact, there is considerable leeway for interpreting article 30 of said Agreement² which authorises exceptions to the patent owner's exclusive rights. Producing a protected product only for export does not affect the patent owners' *ius exclusendi* in the territory where the patent has been granted. An exception that allows for such exports would be limited, would not unreasonably interfere with the normal exploitation of the patent (since patents are territorial and sales in the domestic market will not be affected), and would not unreasonably prejudice the legitimate interests of the patent owner (who may not claim interests based on rights he may have in other jurisdictions). In addition, such an exception would take into account the legitimate interests of third parties, in this case, patients in developing and least developed countries.³

The referred two options were known to the negotiators of the WTO Decision, but discarded by developed countries. They had been discussed and proposed by the UK Commission on Intellectual Property Rights, which published its final report in 2002 (Commission on Intellectual Property Rights, 2002). Interestingly, on 3 October 2002, the European Parliament adopted Amendment

196 to the European Medicines Directive, which provided that,

[M]anufacturing shall be allowed if the medicinal product is intended for export to a third country that has issued a compulsory licence for that product, or where a patent is not in force and if there is a request to that effect of the competent public health authorities of that third country.

(Eur. PARL. Doc. (AMEN. 196, 2002))

Less radical alternatives to the deletion of article 31(f) or the confirmation of an exception for exports would be to amend the system, as now incorporated into article 31*bis* of the TRIPS Agreement, to eliminate some of its problematic conditions, such as the limitation of a compulsory license to the quantity of products initially demanded by the importing country, and the need to request the patent owner for a voluntary license prior to applying and obtaining a compulsory license.

It is fair to recognise, however, that amending a provision that has just been approved by the WTO members, after 10 years of its formal adoption, seems to be a very challenging objective. Ironically, perhaps, the most feasible approach might be to resort again to a waiver, which is easier to adopt than an amendment and may enter into force immediately. In any case, the process of reform should be initiated by a WTO member or a group of members, who would face the daunting task of reaching consensus (or the required majority under the WTO rules) to move forward. This would certainly need to recreate the sentiment of urgency that underpinned the debates on access to medicines at the time the Doha Declaration and the WTO Decision were adopted. In the meantime, article 31*bis* should be interpreted, in line with the Doha Declaration, in a manner that facilitates an increase in the supply of medicines to countries eligible to use the system.

Conclusions

In order to be effective, a solution to the problem identified in Paragraph 6 of the Doha Declaration should provide the incentives necessary to attract the interest of potential suppliers of good quality pharmaceutical products at low cost. Pharmaceutical firms are unlikely to make the required investment and engage in complicated legal procedures if there is no expectation of a reasonable return, particularly through the realisation of economies of scale. This applies to drugs of chemical synthesis and, most importantly, to biosimilars that require significant investment and time to develop and get approved by regulatory authorities.

An amendment to the system has been suggested by the UN High Level Panel mentioned above. Such an amendment would be needed, indeed, to streamline the procedures and ensure access to pharmaceutical products in a timely manner. However, given the recent incorporation of the WTO Decision into the TRIPS Agreement, it would seem difficult to mobilise the needed support if the

urgency to find a better solution is not fully acknowledged by the international community.

Endnotes

¹ See also Resolution 32/L.23 of the Human Rights Council, adopted in its 32nd session (2016), which reaffirms the need for access to affordable, safe, efficacious and quality medicines for all as a primary human right and underscores that improving such access could save millions of lives every year. The resolution also calls upon Member States and other stakeholders to create favorable conditions at the national, regional and international levels to ensure the full and effective enjoyment of the right of everyone to the highest attainable standard of physical and mental health.

² See, e.g. the Declaration on Patent Protection. Regulatory Sovereignty under TRIPS elaborated under the auspices of the Max Planck Institute for Innovation and Competition, available at www.mpg.de/8132986/Patent-Declaration.pdf (accessed 18 July, 2017).

³ The EU Parliament Report on reindustrialising Europe to promote competitiveness and sustainability (2013) recognized the feasibility of an exception for exports of medicines (including 'biosimilars') at least during the additional period of exclusivity granted to patent owners (under the supplementary protection certificate - SCP) in order 'to foster job creation in the EU, as well as to create a level playing field between European companies and their competitors in third countries' (EU Parliament, 2013, p. 19). A draft regulation for this purpose is currently under consideration by the EU. See https://www.consilium.europa.eu/en/press/press-releases/2019/01/16/eu-to-help-boost-exports-of-generic-pharmaceuticals/?utm_source=dsm-s-au-to&utm_medium=email&utm_campaign=EU+to+help+boost+exports+of+generic+pharmaceuticals.

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