Waiver Solution in Public Health and Pharmaceutical Domain under TRIPS Agreement

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WTO adopted the waiver solution in compulsory licensing, beginning from the Doha Declaration to the amendment of TRIPS Agreement, to facilitate access to medicine to the countries lacking manufacturing capacity. This article examines challenges faced by countries while issuing compulsory licensing; waiver decision with regard to Article 31(f) and 31(h) of TRIPS Agreement. The article further analyses the causes as to why the waiver solution has not been as effective as it was hoped and envisages an increase in its importance in the coming days.

Keywords: Compulsory licensing, TRIPS Agreement, Doha Declaration, Article 31

Compulsory licenses are generally defined as ‘authorizations permitting a third party to make, use, or sell a patented invention without the patent owner’s consent.’ Because they limit the power conferred by patents, compulsory licenses have long been controversial. The disputes about compulsory licensing or other types of liability rules are particularly heated in the context of pharmaceutical inventions, which are often very inexpensive to copy. Although pharmaceutical companies are opposed to parallel imports and compulsory licensing, such practices are legal as per WTO provisions. Under TRIPS, promotion of the public health is socially and collectively justifiable, and it allows its members to adopt any means necessary to serve this end as long as they are consistent with the remainder of the agreement. This includes issuing compulsory licenses for pharmaceuticals.

Article 31 of TRIPS Agreement

The TRIPS Agreement does not contain the term ‘compulsory licensing’ However, Part II of TRIPS, Article 31, clearly contemplates use of a patented product without the consent of the patent holder. Article 31 of the TRIPS Agreement specifically allows compulsory licensing, albeit under a different title; ‘other use without authorization of the right holder.’ The allowance of compulsory licensing is implied when Article 31 is read in conjunction with Article 2(1) of the TRIPS Agreement and Article 5(A)(2) of the Paris Convention of 1967. Article 2(1) of the TRIPS Agreement states that WTO Members must comply with specific articles of the Paris Convention, including Article 5 which permits the use of compulsory licensing. This article sets down several conditions on a case-to-case basis, regarding when national authorities can permit a person other than the patent holder to make available the patented product, including ‘the right holder shall be paid adequate remuneration’ [Article 31(h)] and that ‘such use shall be authorized predominantly for the supply of the domestic market’ [Article 31(f)]. Except in cases of national emergency, circumstances of extreme urgency, or of government noncommercial use, the potential licensee first attempts to negotiate a voluntary license with the patentee. Furthermore, the compulsory license must be non-exclusive and spell out the terms and conditions. Additionally, the patentee be paid ‘adequate remuneration’ and when conditions justifying a compulsory licence cease, the licence must expire.

Doha Declaration, Waiver Decision and Amendment to TRIPS Agreement

Article 31(f) of TRIPS specifically states that the use of a compulsory licence shall be ‘authorized predominantly for the supply of the domestic market’ and

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of the Member authorizing such use.\textsuperscript{11} Many developing and least developing countries apparently found it difficult to obtain pharmaceuticals at an affordable price in the quantity and quality required.\textsuperscript{12} The limitation posed by Article 31(f) of the TRIPS Agreement in the form of a domestic market, was recognized by developing countries and NGOs well before the 2001 ministerial meeting, and a proposal to address it was incorporated in a draft for the Doha Declaration prepared by the developing countries.\textsuperscript{13}

The Declaration on the TRIPS Agreement and Public Health adopted on 14 November 2001 during the WTO’s Doha Ministerial Conference attempted to give a political answer to the issue as to the relationship between IP and public health by recalling to Members the existence of some so-called flexibilities that are contained in the TRIPS Agreement that Members could implement at the national level.\textsuperscript{14} The Doha Declaration Paragraph 6 ‘recognize[s] that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement’.\textsuperscript{15} The Declaration did not, however, resolve the issue of compulsory licences for countries with no or insufficient manufacturing capacity.\textsuperscript{16}

On 30 August 2003, the General Council of the WTO adopted the Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. The Decision established a mechanism under which the restriction of Article 31(f) will be waived for an exporting Member when it is requested by an eligible importing Member to supply products under compulsory licence issued in the exporting country. It also provided a waiver of Article 31(h), namely, remuneration for the importing country when remuneration is paid in the exporting country.\textsuperscript{17}

On 6 December 2005, shortly before the Hong Kong Ministerial, WTO Member States agreed to accept a protocol of amendment to the TRIPS Agreement, making permanent the interim waivers granted earlier. Embodied in the proposed Article 31bis, along with an annex and an appendix to the annex, the amendment lays out conditions under which countries can suspend Article 31(f) of the TRIPS Agreement.\textsuperscript{18} Governments around the world are currently considering whether to ratify and accept the Amendment to the TRIPS Agreement adopted by WTO Members on 6 December 2005, which would formally add a new Article 31bis to that Agreement.\textsuperscript{19} The amendment will take effect when two third of WTO members have accepted the change. The deadline for acceptance is now 31 December 2011 (ref. 20).

Constraints for Compulsory Licensing

Compulsory licences have been seen both as ‘cost-cutting’ and ‘access-assuring’ tools for developing countries to provide critical, often life-saving, medicines to their citizens.\textsuperscript{21} It is not contested that the underlying policy behind compulsory licences is positive, and under certain circumstances this powerful right granted to governments can provide unmatched relief to affected people around the globe.\textsuperscript{22} Probably the most important advantage of compulsory licensing is that it can strengthen the government’s negotiating position vis-a-vis the patent holders and influence them to lower their prices.\textsuperscript{23} For instance, the Brazilian National STD/AIDS Program (NSAP) has, among other things, established the threat of compulsory licensing as a means to negotiate with pharmaceutical companies in order to promote low-price access to AIDS drugs.\textsuperscript{24}

Since Doha, compulsory licensing has become popular among many NGOs and developing country governments that see it as the only mechanism under the TRIPS regime to improve access to essential medicines in a health crisis. Compulsory licensing, however, has key limitations.\textsuperscript{25} Article 31 of TRIPS seemingly limits compulsory licensing without prior negotiation to genuinely extreme circumstances, and even then ensures ‘adequate remuneration’ to the compulsory licensor. It is difficult to equate its text with the proposition that developing countries can unilaterally determine that they are unable to afford pharmaceuticals at current prices, declare a ‘national emergency’ and then implement policies that leave patent holders with rents near zero.\textsuperscript{26} The emerging pattern tends to show that the leveraging capacity of compulsory licensing depends on the relative political strength of the licensing country.\textsuperscript{27} Political pressure from the governments of major pharmaceutical companies discourages the use of compulsory licensing to increase affordable access to medicine in developing countries and undermines the international rule of law.\textsuperscript{28}

The importance of patents in preventing or reducing access to life-saving pharmaceuticals is however, still the subject of debate among experts.
While a compulsory licence may reduce the patent cost (royalty), it eliminates neither the production costs nor the problems associated with distribution and timely administration of the medicines.\textsuperscript{29} The danger of compulsory licensing is that it can be abused in developing countries and create a culture of disrespect for intellectual property.\textsuperscript{30} In practice, the countries that intend using compulsory licensing have always been under considerable economic pressure.\textsuperscript{31} The reality in the pharmaceutical industry shows that the medical field is as sensitive to economic factors as any other.\textsuperscript{32} It is sometimes argued that compulsory licensing reduces the amount of money invested in R&D by pharmaceutical companies. This is true since by reducing the income of pharmaceutical companies, the amount of funds available for reinvestment is reduced as well.\textsuperscript{33}

Also, WTO Members need not notify the TRIPS Council if they use compulsory licences for pharmaceuticals other than under the Paragraph 6 system. As a result there is no official record of how prevalent recourse to compulsory licensing has been since the Doha Declaration.\textsuperscript{34} Still, irrespective of these potential constraints, the accord sets an important precedent of ensuring that international trade law does not ignore the importance of public health necessities.\textsuperscript{35}

Efficacy and the Problem of Waiver Decision: Status

Various stakeholders have developed a number of well-established positions in the ongoing debate over patent law and access to medicines. Major industrialized nations, pharmaceutical companies and industry groups have argued that strong patent protection is necessary for the development for new pharmaceutical drugs to address infectious diseases. Middle tier countries – most notably India, Brazil, South Africa, Thailand and China have sought to take advantage of the flexibilities allowed for under international trade regime established by the TRIPS Agreement. Developing countries and least developed countries have sought to import essential medicines to combat infectious diseases because of a lack of local pharmaceutical manufacturing capacity. There have also been a number of alternative proposals– such as prizes, gifts and rewards – put forward to provide incentives for research and developments to address global health epidemics.\textsuperscript{36}

Many commentators and NGOs initially hailed the 2001 Public Health Declaration as a major breakthrough for access to medicines. More recent assessments of the Declaration, in particular the 2003 waiver and 2005 amendment, have been more equivocal.\textsuperscript{37} There are several reasons why the waiver has not been as successful as the WTO had hoped. First, exporting countries are expected to amend their patent legislation to produce generic drugs solely for export to countries that need them. In view of a strong pharmaceutical lobby, this may be a difficult task for exporting countries to undertake. Second,\textsuperscript{38} though the 2003 Decision allows all WTO members to waive their obligations under Article 31(f) and import generic drugs, many developed countries have announced that they will not use the waiver to undermine the patent system by importing generics.\textsuperscript{39} All WTO member countries are eligible to import under this decision, but 23 countries are listed in the decision that they will not use the system to import: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and the US. After having joined the EU, the list now includes 10 more: Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic and Slovenia. As recorded in a separate statement that is not part of the waiver, 11 other members announced voluntarily that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency: Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey, and United Arab Emirates. So far Norway, Canada, India and the EU have formally informed the TRIPS Council that they have modified their laws so that the production under compulsory licensing is primarily for the domestic market.\textsuperscript{40}

Even if countries amend their laws to permit compulsory licenses for export, there still remain some serious hurdles to overcome. For a country to import patented drugs, they must first be an ‘eligible importing member,’ which is defined as any least-developed country member, or a member that has notified the TRIPS Council of its intention to use the system as an importer.\textsuperscript{41} Although the Decision adopts a solution [waiver of Article 31(f)] as proposed by developing countries, the numerous safeguards ensuring that no abuses and trade diversions will be possible under an amended compulsory licence
mechanism make the process of acquiring a compulsory licence disproportionately burdensome for a country facing a public health crisis. The safeguards include: the specification of the expected quantities; evidence from every importing country (except a least-developed one) to establish a lack or insufficiency of manufacturing capacities, with no detailed instructions as to the kind of evidence that would satisfy this requirement; various notifications required from an exporting member; and the general instruction for members to ensure that the products imported under a compulsory licence will be used for public health purposes. It has been argued that the conditions established in both the text of the Decision and the statement for allowing exports of patented medicines are hardly compatible with the idea of an ‘expeditious’ solution: in order to qualify for importing drugs under this mechanism, 12 exacting steps must be followed. The argument continues that, in view of the multiple conditions required for its application, such a complex and burdensome system is largely symbolic and is unlikely to lead to any significant increase in the supply of medicines for the poor.

The waiver process had only been used once, partly due to the cumbersome procedures put in place by some governments, in addition to the core WTO process. On 19 July 2007, Rwanda took the first step in the Article 31bis process and informed the WTO of its intention to import compulsory-licensed pharmaceuticals for public health reasons. In September 2007, Canada became the first country to issue a compulsory export licence and granted Apotex, a Canadian generic drug manufacturer, permission to supply TriAvir, a combination AIDS drug, to Rwanda. In early 2008, Nepal became the second country to apply for an import-licence under Article 31bis. Indian drug-manufacturer Natco Pharma responded, and sought a compulsory licence to produce generic versions of two anti-cancer drugs. Natco proposed to manufacture 45,000 doses of the drugs, and, subject to Article 31(h), remunerate the patent-holders a five percent royalty. The Indian government is currently considering the matter. At the end of February 2008, the proceedings were indefinitely postponed to permit one of the patent-holders the opportunity to lobby for the right to attend the full hearing. As of early April, the hearing was still delayed. It is likely that the licence will be granted if Natco shows that Nepal lacks the local manufacturing capacity to produce generic drugs and if its order request clearly articulates that the drugs will be used for emergency need. The example of India and Nepal illustrates the hurdles created when domestic legislation is too vague and non-specific. It is clear from these two examples that there is no easy solution for drafting legislation that fully reflects the intent and functionality of the WTO General Council Decision and does not impose restrictive Decision-plus obligations.

In order to avoid double compensation, this obligation [Paragraph (h) of Article 31] is waived in the importing country provided that adequate remuneration was paid in the exporting country. The Decision specifies that the remuneration to be paid to the right holder in the country of export must take into account ‘the economic value to the importing country of the use that was authorized in the exporting country.’ No clarification was provided on the application of this standard and besides it offered little incentive for exporting countries to participate in the new compulsory licensing scheme. Furthermore, if countries are reluctant to issue compulsory licences for the benefit of their own people, it is even less likely that they will use this measure to assist another country that lacks manufacturing capacity. For example, the Canadian company that exported that drug has publicly stated it would not be willing to do so again because the procedure was so cumbersome.

**Proposed Article 31bis Amendment**

The proposed Article 31bis amendment is in three parts. The first contains five paragraphs constituting the proposed Article 31bis itself. The second part, an annex, consists of definitions, notification requirements from importing and exporting Members, requirements for Members to prevent improper diversion of pharmaceutical products produced under the system into their territories, and to prevent re-exportation of these products from their territories, provision for the transfer of technology, etc. The final part, an appendix, sets standards for assessing the lack or insufficiency of manufacturing capability for the importing Member. Article 31bis.1 and Article 31bis.3 exempt Members from their obligation under Article 31(f), whereas Article 31 bis.2 exempts Members from their obligation under Article 31(h).

Unfortunately, because Article 31bis specifically requires that least developed countries make up at least half of the membership of any beneficiary
regional trade agreement, the provision would benefit only a limited number of developing countries. While Article 31bis seeks to assist developing countries in acquiring needed medications, its concessions do not go far enough. There are a number of deficiencies within the new regulations, but none greater than the lack of ability for developing countries to realize economies of scale. So far, there is no sufficient evidence to justify enthusiasm or pessimism about this ‘solution’. But some skepticism is warranted for two reasons. The first is the low uptake so far. The second is that while the Amendment reflects a genuine attempt, albeit an imperfect one, to improve access, the intellectual property chapters of recent Free Trade Agreements seem to reflect a deliberate attempt to undermine anything that the international community can achieve multilaterally. That is an avoidable tragedy. In the meantime, as regards the actual system of compulsory licensing of pharmaceutical products solely for export, the consequences of legal uncertainty regarding the entry into force of the Amendment are alleviated by the interlocking nature of the current waiver and the Amendment until the Amendment takes effect for two-thirds of the Members.

**Way Forward**

If a government is genuinely interested in eliminating constraints on life-saving medicines, any legislation furthering that goal should be narrowly tailored to meet this goal. Instead of triggering a lawsuit, the proposal of a compulsory licence statute might encourage the government and the patent holder to negotiate a pre-specified price. A negotiated agreement would benefit both parties. The government would benefit because it would signal to potential future investors that it is willing to consider the needs of foreign rights holders before passing legislation. This would encourage companies with sensitive intellectual property interests to commence foreign direct investment in that country. The patent owner benefits due to the ability to control more closely the terms under which the drug is sold. Competition among generic drug manufacturers is the most potent force to bring drug price levels down. An in-depth study of extensive survey data in 36 countries recommended promotion of generic medicines as one of two suggested policy options to improve availability, prices, and affordability of drugs in developing countries.

It should not be forgotten that the system established by the Decision is just the first step. A much larger network of efforts is required, both at the national and international levels, to address the grave public health problems afflicting many developing countries and LDCs, and to facilitate their access to medicines. It remains to be seen whether these waivers will be effective in ensuring that countries with insufficient or no pharmaceutical manufacturing capacities can participate fully in a compulsory licensing scheme of which they were clearly the intended beneficiaries. While it may not be economically attractive for many generic drug producers to serve as a Paragraph 6 system exporter in the current market, as the sources of the generic drug are substantially depleted over time, the only method by which a country with insufficient or no manufacturing capacities may obtain certain medicines at competitive pricing is to utilize the Paragraph 6 route.

**Conclusion**

WTO Members have been slow to implement domestic legislation enshrining the provisions in Article 31bis. The Paragraph 6 system has been used only once since August 2003. This underutilization can be attributed to the system’s burdensomeness and complexity, economic and political pressure, reluctance in implementation and its failure to recognize the need for economies of scale for exporting countries. The experience of these implementing countries can be a learning opportunity for countries seeking to implement the WTO Decision in order to improve access to medicines among those countries with insufficient pharmaceutical manufacturing capacity.

Any government that adopts the compulsory licensing strategy must exercise caution in choosing the legal instruments best suited to accomplish its goals, in order to endure both the political and economic pressures it is certain to endure. More objective laws are needed to govern the practice of issuing compulsory licences so that the delicate balance between the right of access to life-saving medicines along with the humanitarian duty of countries to help improve the lives of others throughout the world and the protection of incentives of pharmaceutical companies is maintained. It cannot be denied that using the Paragraph 6 is not effortless, nevertheless, it is predicted that it will become essential to developing and least-developed countries in the coming days for the access to medicines.
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