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TRIPS and access to medicines in developing countries: is it a matter of law or a matter of corporate responsibility?

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TRIPS has historically been criticized on the grounds that it makes access to medicines in developing countries more difficult. To address this concern, on 30 August 2003 the World Trade Organization ("WTO")'s General Council approved a Decision aimed at implementing the famous paragraph 6 of the Doha Declaration of 14 November 2001. To sum up, paragraph 6 of the Doha Declaration had asked the General Council to propose a solution to the problem raised by the fact that WTO member states with insufficient manufacturing capacity in the pharmaceutical sector might have difficulties making effective use of compulsory licenses.

The Decision, building upon sections f) and h) of Article 31 of the TRIPS agreement, which establish that the Members of the WTO may issue obligatory licences when specific circumstances are complied with, provides for a system of exemptions (waivers) to the obligations deriving from section f) of Article 31 of the TRIPS agreement in favour of Member States with the capacity to export drugs, provided that the requirements summarised below are fulfilled.

The Decision provides for the exemption of exporter Member States from the above-mentioned obligations when a compulsory licence needed for the manufacture of a pharmaceutical product bound for an importer Member which meets the conditions established in the Decision for its importation is granted ("Entitled Importer Member"). In particular, the Entitled importer Member must send a notification to the TRIPS Council: (i) indicating the name and amount envisaged of the needed product; (ii) justifying that it lacks sufficient manufacturing capacity (unless it involves a less developed country), and (iii) confirming that it involves a product patented in its territory, it has granted or has the intention to grant a compulsory licence.

Additionally, the compulsory licence granted by the exporter Member must comply with the following conditions: (i) only the amount necessary to meet the needs of the Entitled Importer Member may be manufactured and the full amount of the production must be exported to it; (ii) the products must be clearly identified; (iii) prior to beginning the shipment process, the licensee must announce on a website the amounts to be supplied to each destination and the product's distinctive characteristics.

The Decision also places the obligation on the exporter Member to notify the TRIPS Council of the granting of the licence. The notification must include the conditions of the licence, the name and address of the licensee, the product that is the subject matter of the licence, the amount, the supplying country, the term and the website where the amounts to be supplied to each destination and the product's distinctive characteristics will be announced.

The requirement that the product be labelled in such a way that it highlights that it is marketed in accordance with a "licence of the system provided in paragraph 6" complies with the concern of

avoiding parallel imports: i.e., the trade diversion of drugs from the entitled importer member to other markets where the price of the drug is higher. In fact, paragraph 4 of the Decision encourages the Entitled Importer Members to adopt any measures necessary to prevent the re-exportation of the products to other markets. Additionally, paragraph 5 imposes upon the Members the obligation to ensure that there are effective legal means to prevent the importation of the products into their territories. An example of these types of measures can be found in Council Regulation (EC) No. 953/2003 of 26 May 2003, meant to avoid trade diversion to the European Union of certain essential drugs (DO L135, of 3 June 2003, pg. 5).
Regardless of the "licence based on the system established in paragraph 6", which constitutes a circumstantial measure for providing access to drugs, the Decision elaborates on the need for structural action —already established in the articles of the TRIPS agreement— tending towards the promotion of the transfer of technology and the creation of the industrial capacity in the pharmaceutical sector, in order to overcome the problem identified in paragraph 6 of the Doha Declaration.
Furthermore, the Decision (paragraph 10) "shields" the adopted measures in accordance with the exemptions granted on the basis of the Decision vis-à-vis possible claims before the WTO's Dispute Settlement Body based on sections b) and e) of paragraph 1 of Article XXIII of GATT l994]. To summarise, this means that actions cannot be brought against Members which grant compulsory licences that comply with the requirements of the Decision.

On 17 July 2007, Ruanda became the first WTO member to communicate to the General Council a notification based on paragraph 2 a) of the Decision of 30 August 2003. In particular, Ruanda notified the intention to import 260,000 packs of TriAvir®, a drug prescribed to treat AIDS. As the drug was meant to be manufactured by Apotex® in Canada, this country had to notify the grant of a compulsory export license to the TRIPS Council. In this way, Canada became the first WTO member to notify a compulsory export license under the so-called "paragraph 6 system." However, in practice, the derogation mechanism introduced by the Decision has hardly never been used.

The disappointing practical experience with the Decision of 30 August 2003 has jeopardized the expectations of those who had advocated that access to medicines in developing countries would be eased with a more flexible law. The failure of the "paragraph 6 system" seems to indicate that access to medicines in developing countries is more dependent on corporate responsibility than on the rigidity or malleability of the law.

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