European Union and a Member State — Seizure of Generic Drugs in Transit: Request for Consultations by India (DS408/1) and Brazil (DS409/1), 19 May 2010 WTO, Dispute Settlement Body

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Summary

The dispute concerns the questions whether the seizure of goods in transit as border measures for enforcement of intellectual property rights is compatible with the TRIPS Agreement and GATT rules on freedom of transit, among others. Although a request for consultation was made by two complainants, the dispute was amicably resolved between the parties.

The Facts

- In two separate trade dispute complaints at the World Trade Organization (WTO) in 2008 and 2009, India and Brazil asked the European Union (EU) and one of its member states, the Netherlands, to enter into dispute settlement consultations over the alleged violation of multilateral trade rules by illegally confiscating generic drugs exported by Indian pharmaceutical companies in transit through Europe to destinations in Latin America, Oceania and Africa. According to Brazil and India, the EU and the Netherlands through their actions were also undermining public health in developing countries.
- In each case, a batch of medicines *en route* from one developing country to another was temporarily held by border officials at European harbors or airports. The first such case concerned a shipment of a generic version of the hypertension drug Losartan potassium that was confiscated in the Netherlands in December 2008. The Dutch authorities held the shipment in Rotterdam, which was bound for Brazil, for 36 days stating that it infringed an existing Dutch patent on the original drug named Cozaar. However, the medicine Losartan is not patented either in India or in Brazil. After it had been established that the goods were not intended for the EU market, they were released by the European authorities and sent back to India, where the drugs had been manufactured.
- Similarly throughout 2009, shipments of legitimate generic drugs transiting through Europe were detained by customs authorities on allegation of intellectual property rights infringement. Around 20 ships were detained by the custom officials, 16 of which originated in India.
- The Dutch authorities applied the judicially created rule that the IP status of in-transit drugs should be judged as if they had been manufactured in the Netherlands. The customs officials sometimes acted *ex officio* to initiate temporary seizures based on suspicion of domestic patent law violation. They however continued such seizures based on applications by pharmaceutical companies, which requested delay in shipments of medicines coming from India, where they were lawfully manufactured and exported to countries in Africa, Oceania, and Latin America, where they would have been lawfully imported, marketed and consumed. After multiple seizures, the customs authorities also required the suspect medicines to be destroyed or returned to India or delayed to their destination.
- India in response requested dispute settlement consultations on 11 May 2010 at the World Trade Organization with the European Union and the Netherlands, where the

shipments were detained. Brazil, Canada and Ecuador joined the consultation on 28 May 2010, and China, Japan and Turkey on 31 May 2010.

The Legal Issues

In their Request for Consultations dated 19 May 2010, India and Brazil raised certain legal issues with regard to the seizure of drugs transiting through Europe where the measures instituted by the Netherlands and the EU were considered inconsistent with the following obligations, among others:

- Article V of GATT 1994 – as per the request for consultations, the measures taken by the EU member states were stated to be unreasonable, discriminatory and interfering with, and imposing unnecessary delays and restrictions on, the freedom of transit of generic drugs lawfully manufactured within, and exported from, India by the routes most convenient for international transit.
- Article X of the GATT 1994 – as per the request for consultations, the measures taken by the EU member states were stated to be contrary to their obligations to:
    - promptly publish laws, regulations, judicial decisions and administrative rulings pertaining to the requirements, restrictions or prohibitions of imports or exports or of the transfer of payments therefor, or affecting their sale, distribution, transportation, insurance, warehousing inspection, exhibition, processing, mixing or other use;
    - administer laws, regulations, decisions and rulings described in Article X:1 in a uniform, impartial and reasonable manner;
- Article 28 read together with Article 2 of the TRIPS Agreement, Article 4bis of the Paris Convention, 1967 and the last sentence of paragraph 6(i) of the Decision of the General Council of August 30, 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (the "August 30, 2003 Decision"). In Brazil's and India's view the rights conferred on the owner of a patent cannot be extended to interfere with the freedom of transit of generic drugs lawfully manufactured within, and exported from, India. In particular:
    - Art. 2 of the TRIPS Agreement requires WTO members to comply with certain provisions of the Paris Convention (1967) and provides that nothing in Parts I to IV of the TRIPS Agreement shall derogate from existing obligations that Members may have to each other under the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits.
    - Article 4*bis* of the Paris Convention, 1967 states that patents applied for in various countries shall be independent of patents obtained for the same invention in other countries.
    - The Decision of the General Council of August 30, 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health states that the territorial nature of patents will not be prejudiced.
- Articles 41 and 42 of the TRIPS Agreement. In Brazil's and India's view, the measures create barriers to legitimate trade, permit abuse of the rights conferred on the owner of a patent, are unfair and inequitable, unnecessarily burdensome and complicated and create unwarranted delays. In particular:
    - Article 41 stipulates that WTO members should make enforcement procedures available against infringement of intellectual property rights and must include

expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements. These procedures should be applied in a manner that avoids the creation of barriers to legitimate trade and to provide for safeguards against their abuse.

  - Article 42 stipulates that WTO members are to make available to right holders civil judicial procedures concerning the enforcement of any intellectual property right covered by the TRIPS Agreement. Defendants have the right to timely written notice containing sufficient detail, including the basis of the claims.

- Article 31 of the TRIPS Agreement read together with the provisions of the August 30, 2003 Decision. According to Brazil and India, the measures authorise interference with the freedom of transit of drugs that may be produced in, and exported from, India to Members of the World Trade Organization with insufficient or no capacity in the pharmaceutical sector that seek to obtain supplies of such products needed to address their public health problems by making effective use of compulsory licensing.

Points of Significance

- If the dispute had been brought to WTO's Dispute Settlement Body, the most significant question that would have been addressed would have been whether a regulatory authority, on the basis of a patent, could seize drugs in transit that were not being worked in the regulatory authority's jurisdiction.
- The parties amicably settled the dispute. They reached an understanding that the EU would no longer intercept generic medicines in transit unless there is adequate evidence to satisfy customs authorities that there is a substantial likelihood of diversion of such medicines to the EU market and that the EU would amend the relevant laws accordingly. The EU subsequently revised its Customs Regulations in 2013[1] and also adopted implementation guidelines.[2] In meetings of the WTO Council for TRIPS in 2017[3] and 2018,[4] India submitted a series of questions to the EU regarding the revised regulations and the guidelines.

Key words: border measures; goods in transit; seizure of goods; EU Regulation 1383/2003.

Available at: https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds408_e.htm and https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds409_e.htm

[1] European Union, Regulations 608/2013.
[2] European Union, 2016.
[3] WTO, 2017, IP/C/W/636 and WTO, 2018, IP/C/W/636/Add.1.
[4] See further Abdelgawad, H. M. (2018). "Detention of 'Non-Union Goods in Transit' at the EU customs and the right to freedom of transit: a new battle between IP and international trade?", *Journal of Intellectual Property Law & Practice*, Volume 13, Issue 6, June 2018, Pages 469–476.