

TRIPS Council
03 and 04 February 2009

Agenda item 'M' – OTHER BUSINESS – Public Health dimension of TRIPS Agreement

Statement by Brazil

Mr. Chairman,

In the last General Council meeting Brazil, together with India, brought to Member's attention what we believe to be a serious violation of WTO disciplines: the seizure of goods in transit on grounds that they might be violating IP rights conferred by a patent registered at the country of transit. More specifically, it was the seizure by the Netherlands' authorities of a consignment of the generic drug LOSARTAN POTASSIUM. Today we also bring this issue to the attention of the TRIPS Council. We do so for at least two reasons. *First*, this is the forum where the intellectual property aspects of the matter can be more fully appreciated. *Second*, because we have better analyzed the factual circumstances of that episode as well as its legal implications.

2. From the outset let me indicate that the mere seizure of goods in transit – any good: be it a medicine or not – on grounds that they may be violating IP rights registered in the country of transit is, in itself, a violation of GATT Article V and other GATT obligations. Here, however, Brazil will confine this statement to the IP aspects of the matter and to its public health dimension.

3. Let me start with a factual recollection of the episode at hand. On December 04, 2008, Dutch authorities seized a cargo of generic medicines en route from India to Brazil. The cargo consisted of 570 kilos of LOSARTAN POTASSIUM, an active pharmaceutical ingredient used in the production of medicines for arterial hypertension. It was a sale by the Indian exporter DR. REDDY's to the Brazilian importer EMS. The cargo was held back by Dutch authorities for 36 days. After this period the cargo was released and, instead of following its course to Brazil, it was directed back to India. LOSARTAN

POTASSIUM does not enjoy IP rights in India, the country of origin, nor in Brazil, the country of destination.

4. At the General Council meeting, we assumed that the seizure of the cargo was motivated by a request lodged by the company that holds patent rights on LOSARTAN POTASSIUM in the Netherlands on grounds that such rights were being violated. Since that meeting, new evidence collected strongly indicates that the Dutch authorities acted and have regularly been acting *ex officio*, following procedures required or authorized by EC Council Regulation 1383, of 22 July 2003. This regulation refers to customs actions regarding goods suspected of infringing intellectual property rights.

5. The EC delegation at the General Council provided clarifications suggesting that we were before a minor, exceptional and inconsequential incident. That could have been reassuring but Brazil is now in a position to assert that such incident was neither minor, nor exceptional, nor without consequences.

6. At the General Council, the EC pointed out that the cargo was – and I quote – “a small shipment of drugs worth 55,000 Euros”. First, let me note that the size of the shipment is in no way relevant in ascertaining the egregious nature of the action of the Dutch authorities *vis-à-vis* the WTO disciplines. Furthermore, despite its low monetary value, that shipment of 570kg was enough to treat 300,000 Brazilian patients for a full month. That’s 300,000 people who suffer of hypertension, a deadly disease if not treated properly. **It was not, as we can see, a minor incident.** Let me recall that one of the benefits of generic medicines is precisely the fact that they are less costly than those that enjoy patent protection. Therefore one should, in fact, expect lower than usual monetary values when dealing with such shipments and this in no way mitigates or justifies the action of the customs authorities.

7. I also regret to say that **the incident at issue was not exceptional.** In fact, such incidents occur rather frequently. In letters addressed to the DGs of the WTO, Pascal Lamy, and of the WHO, Dr. Margaret Chan, sixteen NGOs expressed their grave concern with public health implications of the episode and mentioned three additional cases of drugs seizure by the Dutch authorities. Two of them involved medicines headed for Peru and one, for Colombia. That was just the tip of the iceberg. Our own inquiries led to the

identification of more than a dozen other instances of consignments of generic drugs in transit on Dutch territory in 2008 alone. They were directed to at least 7 different developing countries in South America and Africa.

8. This brings me to the last argument: that the LOSARTAN incident **had no serious consequences** because the parcel was subsequently released. Also here our inquiries led to more disturbing findings. First, the shipment did not follow its original course to Brazil due to an autonomous decision of the exporter to bring it back to India. Such action by the exporter was a result of negotiations with the holder of the patent in the Netherlands, who actually threatened to request the destruction of the apprehended goods. Second, we have evidence indicating that around **half** of last year's Dutch seizures resulted in the destruction of the goods in transit.

9. The consequences of these individual acts are not limited to each specific transaction. In letters to the European Commissioners for Trade and for Taxation and Customs Union, the humanitarian organization "Médecins Sans Frontières" voiced concerns that their activities of medicine distribution to needy populations in the developing world could be severely hampered "if on key transit routes the risk exists that supplies can be regularly subject to interception based on assertion of patent infringement in the transit country". The exact same concern was articulated by the William J. Clinton Foundation, on behalf of UNITAID, regarding the apprehension of generic drugs used in AIDS fighting humanitarian programs in Africa. These are the most disquieting systemic consequences of the behavior of the Dutch authorities under the umbrella of EC Council Regulation 1383/2003.

10. Mr. Chairman, these are the facts as we were able to ascertain independently. Let me now make a few comments on the substantive implications of the repeated actions of the Dutch authorities when implementing EC Council Regulation 1383.

11. A merely perfunctory examination of the WTO disciplines will lead us to the simple and straightforward conclusion that the Dutch authorities had no right to do what they did. They could not have detained the consignment, obstructed or delayed its transit, nor prevented its arrival in Brazil based on a claim of violation of patent rights. The medicines seized did not enjoy patent protection either in the country of exportation, or in

the country of importation. Whether or not the medicines were protected by patent rights in the country of transit is utterly irrelevant for they were not headed for the Dutch market.

12. Trade in generic medicines is not only perfectly legal under international IP law, it is also desirable from a development and public health perspective. The transit of generic medicines cannot possibly be construed as a violation of patent rights in the country of transit. The TRIPS Agreement does not allow such interpretation. TRIPS Article 28 entitles a patent owner with the exclusive rights of “making, using, offering for sale, selling or importing” in/to/from the market where those rights exist. The transit of goods neither affects, nor diminishes any of the exclusive rights conferred by a patent.

13. The decision taken by the authorities of the Netherlands prevented the LOSARTAN consignment from reaching Brazil. This is a clear case of extraterritorial application of Dutch patent rights. The principle of territoriality, familiar to us all, is a keystone of the international IP system.

14. Such excessive and inappropriate interpretation of IP rights, granting extraterritorial effects, runs counter the objectives and purposes of the TRIPS Agreement. Such interpretation effectively guts the provisions granting TRIPS flexibilities to developing countries. It offends Articles 7 and 8 of the Agreement. Article 7 states that the “enforcement of intellectual property rights” must be done “in a manner conducive to social and economic welfare”. Article 8 upholds Members’ rights to “protect public health and nutrition”.

15. TRIPS flexibilities are so vital that the WTO Ministerial Conference decided to strengthen them by adopting the Doha Declaration on TRIPS and Public Health. This Ministerial Declaration also paved the way to the so-called “paragraph 6 system”, a much needed and long awaited response to the specific situation of countries with insufficient or no manufacturing capacity in the pharmaceutical sector.

16. We all know that the actions of the Dutch authorities are not in conformity with WTO disciplines in general nor with the flexibilities under the TRIPS Agreement. Nonetheless, these disciplines and flexibilities are under threat in other international *fora*, where some developed countries are attempting to adopt TRIPS-plus resolutions. The

SECURE Working Group in the World Customs Organization, and the IMPACT initiative, in the World Health Organization, are examples of this concerted effort. If these attempts succeed, the Dutch authorities' actions could then take place with the blessing of those organizations.

Mr. Chairman

17. The LOSARTAN episode and all the other incidents I mentioned earlier are a major source of concern for developing countries because they essentially imperil the public health dimension of the TRIPS Agreement. This threat is even more daunting in light of the concerted attempts to incorporate these TRIPS-plus concepts in international *fora* such as the WHO, WCO, UPU, and others.

18. Since our first statement in the last General Council meeting, our apprehensions have increased considerably due to the preliminary results of our still ongoing inquiries. I would therefore seek guidance and clarifications from the EC on:

- (a) How the Dutch authorities' actions can be reconciled with WTO disciplines;
- (b) Whether EC Council Regulation 1383/2003 requires or justifies such actions from the customs authorities of the Communities; and, above all,
- (c) How will the Communities ensure that such actions will not reoccur.

Thank you.