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EUROPEAN UNION AND A MEMBER STATE – SEIZURE OF GENERIC DRUGS IN TRANSIT

Request for Consultations by Brazil

The following communication, dated 12 May 2010, from the delegation of Brazil to the delegation of the European Union and to the Chairman of the Dispute Settlement Body, is circulated in accordance with Article 4.4 of the DSU.

Upon instructions from my authorities, pursuant to Article 4 of the Understanding on Rules and Procedures Governing the Settlement of Disputes ("DSU"), Article 64.1 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), and Article XXII:1 of the General Agreement on Tariffs and Trade 1994 ("GATT 1994"), I hereby request consultations with the European Union and with the Government of the Netherlands regarding the following matters:

(A) A shipment of the generic drug Losartan Potassium, produced in India and destined to Brazil, was seized[1] when in transit at Schipol Airport, in the Netherlands, in December 2008, and later returned to the country of origin. The Dutch authorities seized the shipment pursuant to the European Communities Council Regulation No 1383/2003 (EC Regulation No 1383/2003). Based on complaints of suspected infringement by alleged owners of patents (or supplementary protection certificates), over the last two years, customs authorities in the Netherlands have seized a substantial number of consignments of generic medicines from India in transit through the Netherlands, including the aforementioned shipment of Losartan Potassium destined to Brazil.

(B) EC Regulation No 1383/2003 sets out rules for "customs actions against goods suspected of infringing intellectual property rights and the measures to be taken against goods found to have infringed such rights", including goods in transit through the territory of the European Union, and provides, among other actions, for the seizure of goods. The applicability of EC Regulation No 1383/2003 encompasses medicines[2] in transit through the territory of the European Union that are suspected of infringing patent rights or are found to have infringed patent rights constituted

[1] For the purposes of this request for consultations, the scope of the expression "to seize" and its derivations ("seizure", "seizing", etc.) includes, but is not limited to, the expressions "to suspend the release" and "to detain" and their derivations contained in EC Regulation No 1383/2003.

[2] For the purposes of this request for consultations, the scope of the word "medicines" includes, but is not limited to, products of the pharmaceutical sector needed to address health problems, active ingredients necessary for their manufacture and diagnostic kits needed for their use.

according to the laws of the EC transit country, regardless of the patent status of such medicines in the countries of origin and destination.

(C) In Brazil's view, the seizure of the shipment of Losartan Potassium by the Dutch authorities, including legal, administrative or judicial measures of any nature which provided the basis for such measure or which were issued in connection with such measure, is inconsistent with the obligations of the European Union and of the Netherlands under the *Marrakesh Agreement Establishing the World Trade Organization* ("WTO Agreement") and the Agreements annexed thereto.

(D) Furthermore, in Brazil's view, EC Regulation No 1383/2003 – including, but not limited to, recitals (3), (4) and (8) as well as Articles 1, 2, 4, 5, 6, 7, 8, 9, 10, 11, 13, 16 and 17 thereof – is inconsistent as such with the obligations of the European Union and of the Netherlands under the *Marrakesh Agreement Establishing the World Trade Organization* ("WTO Agreement") and the Agreements annexed thereto.

(E) Brazil is also concerned that a rule of general and prospective application in force in the European Union and in the Kingdom of the Netherlands – providing that, *ex officio* or following request from right-holders, competent authorities seize, authorize the seizure, order the seizure or otherwise restrict the passage of goods in transit[3] on grounds[4] that they infringe patents (or supplementary protection certificates) under a relevant national law, or are suspected thereof – is inconsistent as such with the obligations of the European Communities and of the Netherlands under the *Marrakesh Agreement Establishing the World Trade Organization* ("WTO Agreement") and the Agreements annexed thereto. The aforementioned rule of general and prospective application seems to result from the individual or combined operation of the following instruments:

(i) Council Regulation (EC) No. 1383/2003 of 22 July 2003;

(ii) Commission Regulation (EC) No. 1891/2004 of 21 October 2004;

(iii) Council Regulation (EEC) No 2913/92 of 12 October;

(iv) Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004;

(v) Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006;

[3] For the purposes of this request for consultations, the scope of expression "goods in transit" includes, but is not limited to, medicines, and generic medicines, in transit. To the extent that the legal nature of the measures identified in this request may differ if medicines, or generic medicines, are involved, the scope of this request for consultations covers both situations: the measures as applicable to goods in transit in general *and* the measures as applicable to medicines, or generic medicines, in transit.

[4] For the purposes of this request for consultations, the grounds on which competent authorities take one the abovementioned actions include, but are not limited to, the so-called "manufacturing fiction", pursuant to which a determination as to whether goods in transit infringe, or may be suspected of infringing, patents (or supplementary protection certificates) under the law of the relevant EC Member State is made *as if* the goods had been manufactured in that EC Member State.

(vi) Relevant provisions of the Patents Act of the Kingdom of the Netherlands, 1995 (Rijksoctrooiwet 1995) (the "Patents Act"), as amended, including, but not limited to, the provisions of Chapter IV thereof, especially Articles 53 and 79, and relevant rules, regulations, guidelines and administrative practices;

(vii) Relevant provisions of the General Customs Act of the Netherlands (de Algemene douanewet (Adw)) (the "Customs Act"), as amended, including, but not limited to, Articles 5 and 11 and relevant rules, regulations, guidelines and administrative practices;

(viii) Customs Manual VGEM (30.05.00 Intellectual Property Rights, Version 3.1) (Douane Handboek VGEM, 30.05.00 Intellectuele eigendomsrechten, 6 April 2009, Versie 3.1) including, but not limited to, the provisions of Chapter 6 and of other relevant Chapters;

(ix) The Public Prosecutor's Office Guide to Intellectual Property Fraud 20005A022 of 1 February 2006 (Aanwijzing intellectueleeignendomsfraude 2005A022) and the Public Prosecutor's Office Directive (2005R013);

(x) Relevant provisions of the Criminal Code of the Netherlands (Het Nederlandse Wetboek van Strafrecht) including, but not limited to, the provisions of Article 337, and relevant rules, regulations, guidelines and administrative practices;

(xi) Relevant provisions of the Criminal Procedure Code of the Netherlands and relevant rules, regulations, guidelines and administrative practices; and,

(xii) Court decisions in the Netherlands[5] finding that goods in transit infringe patents (or supplementary protection certificates) in the Netherlands, including, but not limited to, due to the operation of a legal fiction pursuant to which the legal status of goods in transit is to be assessed *as if* they had been manufactured in the Netherlands.

(F) In Brazil's view, EC Regulation No 1383/2003 – including, but not limited to, recitals (3), (4) and (8) as well as Articles 1, 2, 4, 5, 6, 7, 8, 9, 10, 11, 13, 16 and 17 thereof – is inconsistent with the obligations of the European Union and of the Netherlands under the *Marrakesh Agreement Establishing the World Trade Organization* ("WTO Agreement") and the Agreements annexed thereto, as it was applied in the seizure of Losartan Potassium described in item (a) above.

(G) Finally, Brazil is concerned that the Patents Act of the Kingdom of the Netherlands of 13 December 1994 – including, but not limited to, the provisions of Chapter IV thereof, especially Articles 53 and 79, and relevant rules, regulations, guidelines and administrative practices – is inconsistent as such and as applied in the seizure of Losartan Potassium described in item (a) above with the obligations of the European Union and of the Netherlands under the *Marrakesh Agreement Establishing the*

[5] Such court decisions include, but are not limited to, the judgment of Sosecal v. Sisvel (Case 311378 / KG ZA 08-617) by the Court of The Hague in preliminary relief proceedings dated 18 July 2008.

World Trade Organization ("WTO Agreement") and the Agreements annexed thereto.

For the measures referred to above, this request also covers any amendments, replacements, extensions, implementing measures or other related measures.

The provisions with which the above-mentioned measures appear to be inconsistent include, but are not limited to, the following:

- Article V:1, V:2, V:3, V:4; V:5, V:7 and X:3 of the GATT 1994;
- Articles 1.1, 2, 28, 31, 41.1, 41.2, 42, 49, 50.3, 50.7, 50.8, 51, 52, 53.1, 53.2, 54, 55, 58(b), and 59 of the TRIPS Agreement, and Article 4*bis* of the Paris Convention of 1967;
- Article XVI:4 of the WTO Agreement;

Brazil reserves the right to raise additional claims and legal matters during the course of the consultations. It looks forward to receiving your reply to this request and to setting a mutually acceptable date for consultations.