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

Request for Consultations by India

The following communication, dated 11 May 2010, from the delegation of India to the delegations of the European Union and the Netherlands, and to the Chairman of the Dispute Settlement Body, is circulated in accordance with Article 4.4 of the DSU.

My authorities have instructed me to request consultations with the European Union (the "EU") and the Kingdom of the Netherlands (the "Netherlands") pursuant to Article 4 of the Understanding on Rules and Procedures Governing the Settlement of Disputes, Article XXII:1 of the General Agreement on Tariffs and Trade 1994 (the "GATT 1994") and Article 64.1 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPS Agreement"), regarding the repeated seizures of consignments of generic drugs originating in India at ports and airports in the Netherlands on the ground of alleged infringement of patents subsisting in the Netherlands while these consignments were in transit to third country destinations (the "measures at issue").

Based on complaints of alleged infringement by alleged owners of patents over the last two years, customs authorities in the Netherlands have seized a substantial number of consignments of generic drugs from India in transit through the Netherlands. India understands that these seizures were made by applying the so-called "manufacturing fiction" under which generic drugs actually manufactured in India and in transit to third countries were treated as if they had been manufactured in the Netherlands. These consignments were initially detained and later, either destroyed or returned to India. In a few cases, the consignments were permitted to proceed to the destination country after considerable delay. Available evidence confirms that the customs authorities seized at least 19 consignments of generic drugs in 2008 and 2009 while in transit through the Netherlands, 16 of which originated in India. An illustrative list setting forth relevant details of some of these seizures is provided in the Annex to this request.

The measures at issue also include the reiterated conduct and practice of seizing generic drugs in transit on the ground of alleged patent infringement and the following, among other, laws, rules, regulations, guidelines and administrative practices of the EU and of the Netherlands but only to the extent that they authorise or require the seizure or destruction of drugs in transit on the ground of alleged patent infringement:

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

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

(c) Council Regulation (EEC) No 2913/92 of 12 October 1992;

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

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

(f) Relevant provisions of the Patents Act of the Kingdom of the Netherlands, 1995 (*Rijksoctrooiwet 1995*) (the "Patents Act"), as amended, including, without limitation, the provisions of Chapter IV thereof, especially Articles 53 and 79, and relevant rules, regulations, guidelines and administrative practices;

(g) Relevant provisions of the General Customs Act of the Netherlands (*de Algemene douanewet (Adw))* (the "Customs Act"), as amended, including, without limitation, Articles 5 and 11 and relevant rules, regulations, guidelines and administrative practices;

(h) 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, without limitation, the provisions of Chapter 6 and of other relevant Chapters;

(i) 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);

(j) Relevant provisions of the Criminal Code of the Netherlands (*Het Nederlandse Wetboek van Strafrecht*) including, without limitation, the provisions of Article 337, and relevant rules, regulations, guidelines and administrative practices; and

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

This request also covers any amendments, replacements, extensions, implementing measures and any other related measures with respect to the laws, rules, regulations, guidelines and administrative practices of the EU and of the Netherlands set forth above.

India considers that the measures at issue are, in several respects, inconsistent as such and as applied, with the obligations of the EU and the Netherlands under the following provisions of the GATT 1994 and of the TRIPS Agreement:

1. Paragraphs 2, 3, 4, 5 and 7 of Article V of the GATT 1994 because the measures at issue, *inter alia*, are unreasonable, discriminatory and interfere with, and impose 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;

2. Article X of the GATT 1994, including, without limitation, Article X:3, because the measures at issue, *inter alia*, are not administered in a uniform, impartial and reasonable manner;

3. Article 28 read together with Article 2 of the TRIPS Agreement, Article 4*bis* 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") because a cumulative reading of these provisions confirms, *inter alia*, that 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;

4. Articles 41 and 42 of the TRIPS Agreement because the measures at issue, *inter alia*, 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; and

5. Article 31 of the TRIPS Agreement read together with the provisions of the August 30, 2003 Decision because the measures at issue, *inter alia*, 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.

India considers further that the measures at issue also have a serious adverse impact on the ability of developing and least-developed country members of the World Trade Organization to protect public health and to provide access to medicines for all. Accordingly, the provisions of the TRIPS Agreement referred to above must be interpreted and implemented in light of the objectives and principles set forth in Articles 7 and 8 of the TRIPS Agreement, the Doha Ministerial Declaration on the TRIPS Agreement and Public Health adopted on 14 November 2001 and in the light of Article 12(1) of the International Covenant on Economic, Social and Cultural Rights, which recognizes the right of all persons to the enjoyment of the highest attainable standard of physical and mental health.

We reserve the right to raise additional claims and legal matters regarding the measures at issue during the course of the consultations.

We look forward to receiving your reply to this request to set a mutually convenient date for these consultations.

ANNEX

Seizures by Dutch Customs of Pharmaceutical Products
Originating in India during Transit through the Netherlands

1. Seizure in October 2008 at Schiphol airport (Netherlands) of a consignment of clopidogrel from India destined for Colombia, on the ground of infringement of one or more patents[1] alleged to be valid and enforceable in the Netherlands and owned or licensed by Sanofi-Aventis.

2. Seizure in November 2008 at Schiphol airport (Netherlands) of a consignment of abacavir from India, purchased on behalf of UNITAID and destined for Nigeria, on the ground of infringement of one or more patents alleged to be valid and enforceable in the Netherlands and owned or licensed by Glaxo.

3. Seizure in November 2008 at Schiphol airport (Netherlands) of a consignment of olanzapine from India destined for Peru, on the ground of infringement of one or more patents alleged to be valid and enforceable in the Netherlands and owned or licensed by Eli Lilly & Co.

4. Seizure in November 2008 at Schiphol airport (Netherlands) of a consignment of rivastigmine from India and destined for Peru on the ground of infringement of one or more patents alleged to be valid and enforceable in the Netherlands and owned or licensed by Novartis AG.

5. Seizure in December 2008 at Schiphol airport (Netherlands) of a consignment of losartan from India and destined for Brazil on the ground of infringement of one or more patents alleged to be valid and enforceable in the Netherlands and owned or licensed by E.I. Du Pont de Nemours and Co. Inc., Merck & Co. Inc. and Merck Sharp & Dohme B.V.

[1] In this Annex, "patents" also refers to, and includes, supplementary protection certificates.