WORLD TRADE ORGANIZATION

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CANADA – PATENT PROTECTION OF PHARMACEUTICAL PRODUCTS

Request for the Establishment of a Panel by the European Communities

The following communication, dated 11 November 1998, from the Permanent Delegation of the European Commission to the Chairman of the Dispute Settlement Body, is circulated pursuant to Article 6.2 of the DSU.

My authorities have asked me to submit the following request on behalf of the Communities and their Member States for consideration at the next meeting of the Dispute Settlement Body.

The Agreement on Trade-Related Aspects of Intellectual Property Rights contained in Annex 1C to the Agreement Establishing the World Trade Organization (hereafter the "TRIPS Agreement") obliges those Members of the World Trade Organization (hereafter the "WTO"), which apply the Agreement since 1 January 1996 (Article 65.1 of the TRIPS Agreement), to grant patent protection for the subject matter specified in Article 27 of the TRIPS Agreement for a defined period of time. More precisely, the TRIPS Agreement provides in its:

- Article 27.1 that "[...] patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced";

- Article 28 that a patent shall confer on its owner the exclusive right to prevent third parties not having the owner's consent from the acts of making, using, offering for sale, selling or importing the patented product;

- Article 33 that the "term of protection available shall not end before the expiration of a period of twenty years counted from the filing date".

However, the legal regime currently in force in Canada does allow with respect to pharmaceutical patents only that a third party may, without the consent of the patent holder, use the patented invention to:

- carry out experiments and tests required (proof of safety and bio-equivalency) to obtain marketing approval of the copy of an innovative medicine before the expiration of the relevant patent in order to ensure market access immediately following the patent expiry (in particular, Section 55.2 (1) of the Patent Act);

- manufacture and stockpile patented products for a period of up to six months before patent expiry for sale after expiry (in particular, Section 55.2 (2) of the Patent Act in

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conjunction with the "manufacturing and Storage of Patented Medicines Regulation").

As a consequence of the above, Canada's legal regime appears to be inconsistent with its obligations under the TRIPS Agreement, including but not limited to Articles 27, 28, and 33 of the TRIPS Agreement.

In a communication, dated 19 December 1997 (WT/DS114/1), the European Communities and their Member States requested consultations with Canada pursuant to Article 4 of the Understanding on Rules and Procedures Governing the Settlement of Disputes (hereafter the "DSU"), contained in Annex 2 of the WTO Agreement and Article 64 of the TRIPS Agreement in conjunction with Article XXII of the General Agreement on Tariffs and Trade 1994 (GATT 1994). Consultations were held on 13 February and 12 June 1998, but did not result in a satisfactory solution of the dispute.

Accordingly, the European Communities and their Member States request the establishment of a panel to examine the matter in the light of the relevant provisions of the TRIPS Agreement and to find that Canada fails to conform to the obligations contained in Articles 27, 28, and 33 of the TRIPS Agreement and thereby nullifies or impairs benefits accruing directly or indirectly to the European Communities and their Member States under the TRIPS Agreement.

The European Communities and their Member States ask that the panel be established with the standard terms of reference as provided for in Article 7 of the DSU.