

Original: English

CANADA - PATENT PROTECTION OF
PHARMACEUTICAL PRODUCTS

Request for Consultations by the European Communities

The following communication, dated 19 December 1997, from the Permanent Delegation of the European Commission to the Permanent Mission of Canada and to the Dispute Settlement Body, is circulated in accordance with Article 4.4 of the DSU.

Pursuant to Article 4 of the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU), Article 64 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement) in conjunction with Article XXII of the General Agreement on Tariffs and Trade 1994 (GATT 1994), we request consultations on behalf of the European Communities and their Member States with the Government of Canada regarding the protection of inventions in the area of pharmaceuticals under the relevant provisions of the Canadian implementing legislation (in particular the Patent Act) in relation to its obligations under the TRIPs Agreement.

By virtue of the TRIPs Agreement, Members of the World Trade Organisation (WTO) are required to provide:

- for patent protection without discrimination as to the field of technology (Article 27.1 of the TRIPs Agreement);
- that patents confer on their owners the exclusive right to prevent third parties not having the owner's consent from, among others, the acts of making and using the patented product (Article 28 of the TRIPs Agreement);
- for a term of protection of a period of 20 years counted from the filing date (Article 33 of the TRIPs Agreement).

Under Canadian patent legislation, however, a third party may, without the consent of the patent holder, use a 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;
- manufacture and stockpile patented products for a period of up to six months before patent expiry for sale after expiry.

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In the view of the European Communities and their Member States, Canada's patent legislation is not compatible with Canada's obligations under the TRIPs Agreement, since it does not provide for the full protection of patented pharmaceutical inventions for the entire duration of the term of protection as foreseen under Articles 27.1, 28 and 33 of the TRIPs Agreement.

We look forward to receiving your reply to the present request for consultations and to agreeing on a mutually acceptable date on which these consultations can be held.
