

Standing Committee on the Law of Patents

Twenty-Fifth Session
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ADDENDUM TO DOCUMENT SCP/25/3 REGARDING PRACTICAL EXPERIENCES ON THE EFFECTIVENESS OF, AND CHALLENGES ASSOCIATED TO, EXCEPTIONS AND LIMITATIONS

Document prepared by the Secretariat

1. Based on the communication dated November 14, 2016, received from the Delegation of Canada regarding practical experiences on the effectiveness of, and challenges associated to, exceptions and limitations to patent rights, the following paragraphs should be inserted between paragraphs 2 and 3 of document SCP/25/3:

“Canada

3. Canada’s Access to Medicines Regime (CAMR) implements a World Trade Organization (WTO) decision and allows Canada to issue a compulsory license authorizing a generic manufacturer to export generic drugs to countries unable to manufacture their own. It does so by creating an authority, under the Patent Act, for the granting of compulsory licenses for the manufacture and export of patented drugs that are product, quantity and importing country specific. It contains safeguards against inappropriate or illicit use, to ensure the interests of patent holders are taken into account, and to ensure the safety of drugs exported under the regime.

4. CAMR was used successfully to authorize Apotex Inc. to export an HIV/AIDS therapy to Rwanda in 2008. From the required notification to the WTO to the first shipment of drugs, it took 14 months. Within this period, it took the government 15 days to issue the license. A second shipment was sent in 2009.”

2. Consequently, in document SCP/25/3, paragraph 3 onwards should be renumbered accordingly.

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