<u>CANADA</u>

Response to WIPO Questionnaire

Pursuant to the decision of the *Standing Committee on the Law of Patents (SCP),* at its twenty-fourth session held in Geneva from June 27 to 30, 2016 (document SCP/24/5, paragraph 17, first bullet point under "Exceptions and Limitations to Patent Rights" and "Confidentiality of Communications between Clients and Their Patent Advisors"), members and observers of the SCP are invited to provide information on:

(i) their practical experiences on the effectiveness of, and challenges associated to, exceptions and limitations to patent rights, in particular in addressing development issues; and

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 licences 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.

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 licence. A second shipment was sent in 2009.

(ii) court cases with respect to client-patent advisor privilege including limitations or difficulties encountered.

Previous Canadian case law did not recognise client-patent advisor privilege (Lumonics Research Co. v. Gould, 70 C.P.R. (2d) 11; Whirlpool Corp. v. Camco Inc., 72 C.P.R. (3d) 444; Lilly Icos LLC v. Pfizer Ireland Pharmaceuticals, 2006 FC 1465). However, that case law is no longer valid in light of recent legislative changes creating a privilege for the clients of agents.

On June 24, 2016, Canada enacted amendments to its patent legislation to recognize as privileged confidential communications between patent advisors and their clients. This privilege applies to any communication; between a registered patent agent and their client; which is intended to be confidential; and is made for the purpose of seeking or giving advice with respect to any matter relating to the protection of an invention. Canada's new patent law also recognizes as privileged in Canada communications between a client and a patent advisor from another country, provided that the law of the other country also recognizes those communications as privileged.

So far, no court decisions have been issued regarding this new legislation.

Based on the information received, the Secretariat will prepare working documents to be submitted to the twenty-fifth session of the SCP, which is tentatively scheduled to be held in Geneva from December 12 to 15, 2016.

In addition, Member States and Regional Patent Offices are invited to send updated

information concerning their applicable laws on the following subjects in order for the Secretariat to carry out the future work agreed by the Committee (document SCP/24/5, paragraph 5 and paragraph 17, second bullet point under "Quality of Patents, including Opposition Systems"):

(i) certain aspects of nationaVregional patent laws, available at: <u>http://www.wipo.int/scp/en/annex_ii.html;</u> and

No response.

 (ii) opposition systems and other administrative revocation and invalidation mechanisms, in document SCP/18/4 available at: http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=202420

Canada does not currently have a patent opposition system, but does have related mechanisms which allow third parties to intervene in the patent examination process before the grant of a patent or to challenge the grant of a patent after its grant.

Under s. 34.1 of the Patent Act, any person may file with the Commissioner prior art, consisting of patents, applications for patents open to public inspection and printed publications, that the person believes has a bearing on the patentability of any claim in an application for a patent. The person may explain the pertinence of the prior art, and the commissioner may take this prior art and explanation into consideration when deciding whether to grant the patent.

Under s. 48.1 of the Patent Act, Any person may request a re-examination of any claim of a patent by filing with the Commissioner prior art, consisting of patents, applications for patents open to public inspection and printed publications, and by paying a prescribed fee. Upon receipt of the request, the commissioner shall establish a Re-Examination Board consisting of not fewer than three persons, at least two of whom shall be employees of the Patent Office, to which the request shall be referred for determination. If the Board determines that a substantial new question of patentability affecting any claim of the patent concerned is raised by the request for re-examination, the Board will cause a re-examination to be made of the claim of the patent in respect of which the request for re-examination was submitted. The re-examination is conducted ex parte, and the third party challenger is not a party to the process. Decisions of the Re-Examination Board can only be appealed by the patentee, to the Federal Court.