

Essential Inventions, Inc.

P.O. Box 19405 Washington D.C. 20036 - <http://www.essentialinventions.org>
Voice +1.202.387.8030 - fax+1.202.234.5176

14 December 2004

Honourable Ujjal Dosanjh
Minister of Health
Health Canada
Brooke Claxton Bldg; Tunney's Pasture
P.L. 0906 C
Ottawa, Ontario, Canada
K 1A 0K9

Via fax +1.613.952.1154 and post

Honourable Ujjal Dosanjh:

We applaud Canada for being the first country to enact legislation and issue draft regulations to provide badly needed medicines and medical devices to developing countries. This farsighted leadership is critical in the global campaign for equal access to medicine and health care. The purpose of our letter is to register our intent to pursue, under your new law, the export of Imatinib Mesylate from Canada at an affordable cost to certain countries not defined as high-income countries by the World Bank.

To this end, we are asking the Canadian government to issue a non-exclusive "open" compulsory license to authorize any qualified entity to manufacture and distribute Imatinib Mesylate to any country that qualifies under the provisions of Bill C-9 (the Jean Chrétien Pledge to Africa).

Imatinib Mesylate is used to treat certain rare forms of cancer, including chronic myeloid leukemia (CML) and gastrointestinal stromal tumors (GIST). The Canadian patent owner is Novartis, which markets the product under the trade name of Gleevec. Currently the Novartis price for Gleevec in Canada is \$ 35,000 to \$ 70,000 (CAD) per year. Novartis has sought to charge similar price world wide, including in developing countries.

Essential Inventions is a non-profit organization, which is incorporated in the United States, and operates in several countries. On March 10, 2004, we asked Novartis for a voluntary license to its patents on Imatinib Mesylate, in order to provide an affordable supply of the product in countries not defined as high income by the World Bank. Novartis has yet to respond. We are now seeking a compulsory license to the Novartis patents on Imatinib Mesylate in order to become a Canadian manufacturer and exporter of Imatinib Mesylate (in cooperation with firms currently manufacturing generic products in Canada for the Canadian market).

We have reviewed the Canadian legislation, regulations and official commentary and have the following questions regarding our request.

- a) To whom (and in what format and with what justification) do we submit our request for Imatinib Mesylate to be added to the list of qualifying pharmaceutical products?

- b) Some importing countries require evidence that one can manufacture and export a product before issuing a compulsory license for import of a patented product. If Canada requires evidence that a compulsory license will be issued in the importing country, before it agrees to issue a compulsory license to manufacture and export a product, it will be difficult for the *Jean Chrétien Pledge to Africa* to serve the needs of certain countries. In such cases, is it possible to obtain a provisional authorization for the compulsory license, subject to Essential Inventions (or any other party) satisfying the requirements that it obtain the compulsory license (and TRIPS notification) in the importing country?

Please direct us to the persons in your Ministry that we should work with to pursue this request.

Thank you.

Sincerely,

Terry Gardiner
CEO
Essential Inventions, Inc.