Essential Inventions, Inc.

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December 17, 2004

Dr. Rodrigo Salinas
Director
Instituto de Salud Publica de Chile
Santiago de Chile
Via fax +56 2 3707570

Dear Dr. Salinas:

Essential Inventions, Inc., a non-profit organization that seeks to expand access to essential medical technologies, asks the Government of Chile to take certain steps that will enable the competitive supply of generic versions of Imatinib Mesylate to the Chilean market.

Imatinib Mesylate is used to treat certain forms of cancer, including chronic myeloid leukemia (CML) and gastrointestinal stromal tumors (GIST). Several patents relevant to this product are owned by Novartis, a firm that markets Imatinib Mesylate product under the trade name of Gleevec. Novartis has sought very high prices for Gleevec.

Several countries with important generic industries have signaled a willingness to exercise new flexibilities in the WHO TRIPS agreement to authorize exports of generic medicines to countries that lack the capacity to manufacture products domestically. For example, governments in Canada, France, India and Switzerland are evaluating different responses to the recent August 30, 2003 decision of the World Trade Organization to implement Paragraph Six of the Doha Declaration on the TRIPS Agreement and Public Health, which is designed to expand and enhance the export of generic medicines produced under a compulsory license.

Essential Inventions will soon ask the Chilean government to issue compulsory licenses on the Novartis patents for Imatinib Mesylate, on the grounds that (1) the Novartis price for Gleevec is excessive, particularly in countries not defined as high income by the World Bank, and (2) that Novartis has refused to license its patents to generic competitors, including Essential Inventions.

In several countries, generic manufacturers cannot export Imatinib Mesylate unless the exporting countries utilize the new WTO rules which permit the waiver of the TRIPS rules (Article 31.f) restricting exports of medicines manufactured under a compulsory license. In order for a country to obtain such a waiver to export Imatinib Mesylate to Chile, two actions must be taken.

1) The Chile National Government must make a notification to the WTO TRIPS Council, of its intention to be an eligible importer under the August 30, 2003 Decision. This is a general notification that is not related to a particular medicine. It is in the interest of every nation to notify the TRIPS council that they are eligible for this flexibility, which can be exercised at any time when it serves the public interest in Chile.

2) Second, the Chile National Government should determine that it has insufficient manufacturing capacity for Imatinib Mesylate. The clear grounds for this are that it is not practical or economically efficient to manufacture this product for the Chilean market, because of:

a. the small number of patients in Chile,
b. the high fixed cost of gearing up to manufacture small dosage levels to meet the needs of the Chilean patients,
c. the high variable costs of annually manufacturing small volume of Imatinib Mesylate to meet Chilean patient needs,
d. Trade secrets barriers and a lack of manufacturing know-how for Imatinib Mesylate.

Chile is free to make the assessment in (2) in the manner of its choosing, and there is no provision for submitting such an evaluation to the WTO, and the assessment is not subject to WTO dispute resolution.

We appreciate the fact that Chile is exploring a variety of options to import generic Imatinib Mesylat, including some options that would not require the exporting country to use the WTO August 30, 2003 decision to waive Article 31.f of the TRIPS. That said, it is clear that Chile will *expand* its options to obtain competitive supplies of all versions of Imatinib Mesylat if it exercises the flexibilities in the TRIPS.

Today prices for innovative medicines are high, escalating, and rarely in reach of populations with modest or low per capita incomes. In November 2001 in Doha, Chile and other WTO members pledged to implement intellectual property laws in a manner that promotes access to medicine for all. For this to have meaning and benefit patients, it must be connected to policies and actions. Chilean leadership in implementing TRIPS flexibilities is important for patients throughout the world.

Thank you.

Sincerely,

Terry Gardiner
CEO, Essential Inventions, Inc.