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Bogotá
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Patent of Imatinib / Glivec: Closing arguments

Dear Mrs Gómez

On behalf of the State Secretariat for Economic Affairs of Switzerland, I would like to seize the opportunity to present our views referring to an official request to declare of public interest the patent of Imatinib / Glivec. On May 18th, State Secretary and Director of the Federal Office of Public Health Pascal Strupler presented our concern to the Minister of Health and Social Protection, Alejandro Gaviria.

First, let me highlight our excellent bilateral economic relations with in particular agreements on free trade, investment protection and double taxation. Colombia is an important destination for Swiss investors with more than 16'000 jobs created locally and one out of two partners in Latin America benefitting from the Swiss Economic Development Cooperation (SECO). Switzerland and Colombia further cooperate in the fields of humanitarian aid, peace promotion and human rights.

Within the procedure of "closing arguments", I would like to present the concern of the State Secretariat for Economic Affairs of Switzerland regarding the request to the Ministry of Health and Social Protection of two Colombian NGOs and the Center for the study of Medicines of Universidad Nacional to declare of public interest the patent of Imatinib. This would be a first step to the issuance of a compulsory license by the Colombian Patent Office.

The Swiss firm Novartis has developed the beta crystal form of Imatinib Mesylate creating a breakthrough, life-saving cancer medicine. No other drug comprising Imatinib was available anywhere in the world before Glivec was launched. Scientists at Novartis developed the Me-

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sylate Salt of Imatinib and then the Beta crystal form of Imatinib Mesylate to make it suitable for patients to take in a pill form that would deliver consistent, safe and effective levels of medicine.

In Colombia, the drug is in the basic formulary and its price has been regulated by the authorities. The product has not been out of stock at any time and supply has been guaranteed to the Colombian health authorities.

Novartis requested before the Superintendency of Industry and Commerce a patent for Glivec covering the crystalline form Beta on July 9th, 1998. The Superintendency denied the patent on February 25th, 2003 on the grounds that it lacked inventive step. After a very long judicial process (9 years), the State Council issued its final decision on the case ordering the Superintendency to issue the patent on February 9th, 2012.

While compulsory licenses are permissible under the WTO TRIPS Agreement on the condition of compliance with the terms and conditions set out in its Art. 31, they are also considered a policy tool of last resort. A Compulsory license is tantamount to an expropriation of the patent owner and constitutes a deterrent to future research and development of innovative medicines and their placing on the market in Colombia. Accordingly, it is our view that all efforts should be undertaken by the Colombian authorities to find a mutually agreeable solution with the right holder and that all other options are exhausted before the issuing of a compulsory license is being contemplated.

The Glivec case raises important issues that are essential to the future of intellectual property law and the innovative pharmaceutical business in Colombia. The ability to rely on patents in Colombia benefits government, industry and patients alike because research-based organizations will know that investing in the development of better medicines for patients is a viable and sustainable long-term option.

Patents are the foundation of innovative drug discovery and essential to advancing medical science and treatment for patients. Without patents, there would be less incentive for investment in drug discovery research and clinical development, which over time would halt innovative drug discoveries for patients in need of new treatment options.

I thank you for taking duly into consideration the views of the Swiss government. We are available to discuss any point referring to this very important issue.

Best Regards,

State Secretariat for Economic Affairs SECO

Livia Leu

Ambassador, Head of Bilateral Economic Relations
Delegate of the Federal Council for Trade Agreements