FW: Novartis - CL

From:

Christine Peterson <christine.peterson@trade.gov>

To:

"O'Connor, Leslie" <leslie_oconnor@ustr.eop.gov>

Date:

Thu, 16 Jul 2015 14:31:19 -0400

Attachments:

Patent of Imatinib _ Glive_ Closing arguments.pdf (154.15 kB); 20150603PagerCLUSEmb.pdf (21.66 kB)

FYI-

From: Paola Lugari
Sent: Tuesday, June 09, 2015 9:53 AM
To: Laura Ebert; Christine Peterson; ventlingar@state.gov
Cc: Michael McGee
Subject: RE: Novartis - Hello today and the CL

Hi Laura and Christine, Novartis just sent me copy of the letter sent by the Swiss Embassy to the MOH
Regards
Paola Lugari Pezzano
Especialista Comercial/ Commercial Specialist
Departamento de Comercio / U.S. Department of Commerce
Embajada de los Estados Unidos / U.S. Embassy
Bogota, Colombia
Tel. 275-2796
Email: paola.lugari@trade.gov

Visit us at
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Remember: **It's Colombia, not Columbia.**

From: Laura Ebert
Sent: Monday, June 08, 2015 4:31 PM
To: Christine Peterson; Paola Lugari; ventlingar@state.gov
Cc: Michael McGee
Subject: RE: Novartis - Hello today and the CL

Here's the attachment.

Laura Beth Ebert
Chile, Colombia, Panama Desk
International Trade Administration
U.S. Department of Commerce
laura.ebert@trade.gov
T: (202) 482-4187 M: (b) (6)

From: Christine Peterson
Sent: Monday, June 8, 2015 3:09 PM

To: Laura Ebert; Paola Lugari; ventlingar@state.gov
Cc: Michael McGee
Subject: RE: Novartis - Hello today and the CL

Hi Laura, Thanks for looping me in. (b) (5) [redacted] Can you send the one pager attachment referenced in the initial email?

-Christine

Christine R. Peterson
International Trade Specialist
Office of Intellectual Property Rights
International Trade Administration
U.S. Department of Commerce
11500 Olympic Blvd. Suite 601
Los Angeles, CA 90064
(310) 235-7430
Christine.Peterson@trade.gov
www.STOPfakes.gov

From: Laura Ebert
Sent: Monday, June 08, 2015 11:31 AM
To: Paola Lugari; ventlingar@state.gov; Christine Peterson
Cc: Michael McGee
Subject: RE: Novartis - Hello today and the CL

Sharing with Christine Peterson, our IPR expert at HQ. This is my first time working with a compulsory licensing concern, (b) (5) [redacted] Christine, let us know what you think.

Regards,

Laura Beth Ebert
Chile, Colombia, Panama Desk
International Trade Administration
U.S. Department of Commerce
laura.ebert@trade.gov
T: (202) 482-4187 M: (b) (6) [redacted]

From: Paola Lugari
Sent: Wednesday, June 3, 2015 2:42 PM
To: ventlingar@state.gov; Laura Ebert
Cc: Michael McGee
Subject: FW: Novartis - Hello today and the CL

Hi Angel and Laura, hope everything is fine.

We received the email below from Novartis (b) (5)
(b) (5)
(b) (5) They also mention that the period for sending arguments is officially closed for non-determined third parties. Attached is a brief summary.

Best Regards

Paola Lugari Pezzano
Especialista Comercial/ Commercial Specialist
Departamento de Comercio / U.S. Department of Commerce
Embajada de los Estados Unidos / U.S. Embassy
Bogota, Colombia
Tel. 275-2796
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Visit us at
http://export.gov/colombia/index.asp

Remember: **It's Colombia, not Columbia.**

From: Hurtado, Maria [mailto:maria.hurtado@novartis.com]
Sent: Wednesday, June 03, 2015 1:13 PM
To: Michael McGee; Paola Lugari
Subject: Novartis - Hello today and the CL

Dear Michael and Paola..

I hope this e mail finds you well..

Today I am touching base with you with respect to the issue of the Compulsory License of Glivec.

We were wondering if the Embassy will be interested in sending to the Ministry of Health a communication with respect to the request of the declaration of public interest our patent on Glivec (Imatinib). From our previous conversation this item needed to be consulted with the Ambassador and discussed as well within the Commercial Office.

Although the period for sending arguments is officially closed for non-determined third parties, we think it is highly valuable to have a communication from your Embassy and count with your support on this important case taking into consideration that if granted the Compulsory License could establish a serious precedent for R & D companies doing business in Colombia..

Attached a pager describing the situation for your better reference..

Looking forward to hearing back from you.

Best,

Maria

Maria Fernanda Hurtado
Public Affairs & Social Responsibility Head
Novartis de Colombia S.A.
Bogota D.C.

COLOMBIA

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Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

Federal Department of Economic Affairs,
Education and Research EAER

State Secretariat for Economic Affairs SECO
Bilateral Economic Relations
Americas

CH-3003 Bern, BWAM / SECO/lea

Dr
Carolina Gómez
Asesora del Despacho del Minsitro
Ministerio de la Salud y Protección Social
Bogotá
Colombia

Bern, 26 May 2015

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-

State Secretariat for Economic Affairs SECO
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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

COMPULSORY LICENSE

- Novartis developed the beta crystal form of Imatinib Mesylate and in that way created 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 Mesylate 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.
- 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 of 2003 on the grounds that it lacked inventive step.
- After a very long judicial process (9 years), the State Council (the highest administrative courte in Colombia) issued its final decision on the case ordering the Superintendency the issuance of the patent on February 9th of 2012.
- Two Colombian NGOs and the Center for the study of Medicines of Universidad Nacional made an official request to the Ministry of Health (MoH) to declare of public interest the patent of Imatinib as a prior step to request the Colombian Patent Office the issuance of a compulsory license.
- The MoH has accepted this request for analysis.
- Novartis has been able to enjoy for very few months the exclusive rights of its patent. Novartis has not in any way abused of its rights and there are not reasonable grounds for issuing the compulsory license.
- Access to treatment for Colombian patients with Glivec is guaranteed: the drug is in the basic formulary and its price has been regulated. There has not been any stock outs of the products and supply has been guaranteed to the Colombian health authorities.
- There are not grounds for the declaration of Public Interest of the Imatinib patent.
- 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.
- We firmly believe that patents are the foundation of innovative drug discovery and essential to advancing medical science and treatment for patients. Without patents, there would be diminished 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.
- We request the support of US Embassy in the submission of comments during the process of the study of the license addressed to the MoH.