U.S. CHAMBER OF COMMERCE

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Washington, DC 20062-2000
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Messrs.
Ministry of Health and Social Protection
Attention: Dr. Alejandro Gaviria Uribe
Minister of Health and Social Protection
E. S. D.

Re: Request for the Declaration of Public Interest regarding access to Imatinib submitted by MISIÓN SALUD, IFARMA and CENTRO DE INFORMACION DE MEDICAMENTOS DE LA UNIVERSIDAD NACIONAL-CIMUN

Resolution No. 2475 dated 14 June 2016. Declaration of Public Interest seeking a price reduction before the National Pharmaceutical Price Commission. Docket No. 201524000237131

INTERVENTION AS AN INTERESTED THIRD PARTY

Patrick Kilbride of legal age, resident of Washington, DC, United States of America identified with the ID No. under my signature below, acting as a legal representative of U.S. Chamber of Commerce ("U.S. Chamber") pursuant to Article 38, section 3, of the Administrative Procedural Code (Law 1437/2011), respectfully address your office in order to file an INTERVENTION AS AN INTERESTED THIRD PARTY in the referenced administrative procedure.

Background

On behalf of the U.S. Chamber of Commerce the world's largest business federation, representing the interests of more than 3 million businesses of all sizes, sectors, and regions, as well as state and local chambers and industry associations, we appreciate this opportunity to comment on the Ministry of Health and Social Protection's Resolution Number 2475 of 2016.

On June 15, 2016, the Ministry of Health issued a declaration of public interest (DPI) for Novartis AG's leukemia medicine, Glivec. The U.S. Chamber believes the issuance of the DPI creates uncertainty for innovative companies seeking to serve the Colombian market, harming Colombia's innovation ecosystem and hampering the development of new, innovative medicines.

Legal Interest

The U.S. Chamber and its Global Intellectual Property Center (GIPC) are deeply committed to advancing a global innovation economy, one where all of the world's citizens are empowered both to produce and benefit from new technologies, inventions, and creative content. We believe that robust, predictable, and well-enforced intellectual property (IP) laws are essential to that goal. Strong intellectual property (IP) protections provide a stimulus to investment, including foreign direct investment, in turn driving job creation, fostering economic growth, and stimulating global competitiveness. Among Latin American nations, Colombia has been a leader in IP protections, ranking among the top regional economies in the U.S. Chamber of Commerce

International IP Index, which benchmarks the IP environment in 38 economies around the world[1]. As a complement to this policy analysis, the U.S. Chamber Index also includes a set of rigorous and empirical statistical correlations demonstrating the strong, positive relationships between strength of an IP environment and important socioeconomic indicators. Among other things, these correlations reveal a strongly positive relationship between robust life sciences IP and increased ability to attract biomedical FDI, improved access to technological developments, and greater biopharmaceutical R&D expenditure[2].

These are among the reasons the U.S. Chamber is troubled by the DPI issued with regard to the innovative Novartis medicine, Glivec. The issuance of the DPI, which is discretionary in nature, creates tremendous uncertainty for other innovators in the Colombian market. In the present case, following two price reductions in the last three years, Glivec is already priced 39% below what the Colombian government requires under its own pricing rules. The U.S. Chamber would like to use our comments on the DPI to clarify a few essential points that we believe the DPI did not fully capture.

Petition

Given that Colombian patients in need of imatinib are currently being afforded access, and for the reasons delineated below, the U.S. Chamber respectfully requests the Ministry of Health revoke resolution 2475.

Arguments

First, in the DPI, the Ministry alleges that the pure alpha form of imatinib cannot exist without some traces of beta form. However, controlling the temperature and storage of the polymorph ensures that the rate of conversion from the alpha form to the beta form will be so gradual that it is not pharmaceutically relevant. Even in the current proceedings, an affidavit submitted to the Colombian government by Michael Mutz, a senior expert in pharmaceutical chemistry, states that stable alpha forms of imatinib are commercially available. Moreover, Lafrancol, one of the generic companies which sells a non-infringing alpha form of imatinib in Colombia, agreed that a compulsory license was not necessary given the alternative forms of imatinib available in the market.

Second, the DPI states *"Novartis considers there will be a violation of its patent 29270 when the presence of trace amounts of the polymorph beta of imatinib mesylate is identified in other polymorph forms of imatinib mesylate.[3]"* Novartis currently holds a patent on the beta form of imatinib in Colombia, which is valid until July 2018. Meanwhile, generic companies are able to produce stable alpha forms of imatinib by regulating the manufacturing and storage temperature. Thus, generic manufactures can produce non-infringing forms of imatinib without violating

[1] Global Intellectual Property Center (GIPC). "Infinite Possibilities: U.S. Chamber International IP Index." U.S. Chamber of Commerce, 10 Feb. 2016. < http://www.theglobalipcenter.com/wp-content/themes/gipc/map-index/assets/pdf/2016/GIPC_Index_2016_Final.pdf>

[2] Global Intellectual Property Center (GIPC). "Infinite Possibilities, IP as a Development Tool: Supplementary Statistical Analysis to the U.S. Chamber International IP Index." U.S. Chamber of Commerce, 10 Feb. 2016. <http://www.theglobalipcenter.com/wp-content/themes/gipc/map-index/assets/pdf/2016/GIPC_IPIndex_Annex.pdf>.

[3] Ministry of Health and Social Protection Resolution Number 00002475 of 2016. 14 June 2016. Pg. 8.

the Novartis patent on the beta form. Given that stable alpha generic alternatives are available, the Ministry's assertion that Novartis maintains a "monopoly" on imatinib in Colombia is unfounded.

Third, the DPI specifically states that the intention is to stimulate competition, rather than address a public health need, noting, *"[T]he Committee's recommendation to declare the drug imatinib is one of public interest associated with the need to preserve savings in public health expenses, resulting from market competition."*[4] To our knowledge, there has been no suggestion that patients in need of imatinib have been unable to receive the medicine. Instead, the Government has explicitly stated that the DPI is intended to stimulate competition, strongly suggesting the issue is a fiscal challenge, rather than a matter of public health. Issuing the DPI on these grounds further undermines the legal certainty critical to an effectively functioning IP regime in Colombia. Importantly, the DPI fails to recognize that the respective prices of innovative and generic drugs reflect fundamentally different cost structures: The innovative price reflects the costs of researching, developing, and testing the new medicine, as well as others in the company's pipeline – including the costs associated with failed lines of research; while the generic price need only cover the cost of manufacturing a dose of medicine. When countries fail to acknowledge and respect this basic dichotomy, and benchmark innovative prices against generic prices in order to justify the expropriation of intellectual property rights, they pose an existential threat to the very innovative pipeline that makes such medicines available to patients in the first instance.

Fourth, the DPI sets a harmful global precedent that intellectual property rights will be discretionary when a government no longer wishes to pay the cost previously agreed to with the innovative company. Investors seeking to expand access to new markets require commercial certainty that their products will be protected under the government's regulatory and legal framework. Unilaterally reducing prices in the name of meeting the budgetary constraints of a universal healthcare system undermines the investor confidence necessary for the system to work to produce new cures.

Fifth and finally, while the U.S. Chamber appreciates that negotiations between the Colombian government and Novartis have not to date led to the issuance of a compulsory license, we believe the precedent set in the current circumstances is equally damaging. The Ministry of Health ultimately utilized the same rationale for unilateral price setting as the previously stated intention of issuing a compulsory license. Namely, the DPI makes the case that setting aside the patent for the innovative pharmaceutical will stimulate free market competition. No global organization is a greater advocate of the power of free markets than the U.S. Chamber. However, we believe that undermining IP principles in order to provide the appearance of price competition undermines the rule of law that is the bedrock of the free market system. The U.S. Chamber looks to Colombia as a leader in the region given its long-term commitment to a market-oriented, pro-growth economy. As a country setting the example for a stable and resilient economic model in Latin America, we urge Colombia to embrace policies which create an environment welcoming to investors in order to further Colombia's economic growth and global competitiveness.

[4] Ministry of Health and Social Protection Resolution Number 00002475 of 2016. 14 June 2016. Pg. 7.

Notification

Thank you for your consideration of these comments. If you have any questions about the U.S. Chamber's comments, please contact me electronically at pk[redacted]m or via mail at 1615 H St., NW Washington, DC 20062, United States of America. We welcome the opportunity to discuss these views at any time.

Yours sincerely,

Patrick Kilbride
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Global Intellectual Property Center
U.S. Chamber of Commerce
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