April 10, 2023

RE: U.S. International Trade Commission Investigation No. 332-596: COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities

Post-Hearing Brief of Frank Cullen

Council for Innovation Promotion (C4IP)

Dear Commissioners,

On behalf of the Council for Innovation Promotion, I appreciate the opportunity to provide supplemental information following my March 29 oral testimony. The Council for Innovation Promotion is a bipartisan coalition dedicated to promoting strong and effective intellectual property rights that drive innovation, boost economic competitiveness, and improve lives everywhere.

In this brief, I specifically would like to address two questions prompted during the March 29 hearing in connection with Inv. No. 332-596:

1) Can you provide examples of the type and number of unused treatments and diagnostics and why?

2) Can you provide examples of how compulsory licenses have proven not to have been as effective a tool as anticipated in delivering significant cost savings?

Concerning the first question, a substantial number of Covid-19 treatments and diagnostics have gone unused. According to Airfinity, by November 2022, voluntary licensing agreements asked for 67.3 million treatments, while total production reached nearly 82 million.[1] In September 2022, low- and middle-income countries had only disbursed 10 million of the more than 35 million treatments donated by governments and NGOs.[2] Overall, manufacturers have produced more than 70 million courses of Covid-19 antivirals and built stockpiles of more than 30 million, which are predicted to surpass total global demand in 2023.[3] Demand for diagnostic products has also not exceeded the supply.[4]

This surplus is due to problems with medicine distribution and administration, as well as a lack of demand. Developing countries are struggling with last-mile logistics, including providing adequate transportation and cold storage for treatments. In addition, many developing countries lack the necessary medical infrastructure and healthcare workforce. Policymakers should focus on improving these vulnerabilities rather than needlessly waiving intellectual property rights.

Regarding the second question, there is clear evidence that compulsory licenses often underperform in securing significant cost savings. For example, a HealthAffairs research study concluded that procurement prices from compulsory licenses can exceed those from voluntary agreements.[5] When analyzing the prices of thirty compulsory license cases, researchers found

[1] Airfinity Data

[2] Airfinity Data

[3] Airfinity Data

[4] https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W693.pdf&Open=True

[5] https://www.healthaffairs.org/doi/epdf/10.1377/hlthaff.2014.0658

that the median international procurement price was lower nearly two-thirds of the time, with price gaps often topping 25%.[6]

Compulsory licenses can cost more than anticipated because licensees may have insufficient specialists and lack the institutional knowledge to produce treatments safely and effectively.

Furthermore, compulsory licenses have failed in a variety of ways in practice. In 2012, for instance, India issued its first compulsory license for Bayer's anti-cancer drug Nexavar.[7][8] India's use of compulsory licenses directly impacted foreign investment into the country. Just one year after the first compulsory license was granted, foreign direct investment into the country dropped from $35.1 billion to $22.4 billion.

By contrast, voluntary licenses can lead to opportunities for companies to share technological expertise. For instance, Gilead Sciences provided technical assistance when they licensed their Covid-19 antiviral treatment Remdesivir to partners in developing countries. As noted by Gilead's Director of IP & Trade Policy, "Ultimately we share our IP in order to show our partners how to safely and effectively make the product. Onboarding manufacturers involves significant technology transfer and you need to be able to share and speak freely."[9]

Voluntary licenses are playing a significant role in fighting the pandemic. Pharmaceutical companies have signed more than 140 voluntary licensing agreements for Covid-19

[6] https://www.healthaffairs.org/doi/epdf/10.1377/hlthaff.2014.0658

[7] https://www.worldtrademarkreview.com/regionindustry-guide/india-managing-the-ip-lifecycle/2020/article/dealing-compulsory-licensing-in-india#:~:text=India's%20first%20ever%20compulsory%20licence,of%20liver%20and%20kidney%20cancer.

[8] https://www.theglobalipcenter.com/us-chamber-releases-statement-indias-issuance-its-first-compulsory-license/

[9] https://geneva-network.com/research/trade-secrecy-and-covid-19/

treatments, which cover more than half of the world population. These licenses can improve worldwide access to treatments without undermining the intellectual property rights that provide the necessary incentives for future investments.

Thank you for the opportunity to provide further comments on your investigation. We hope to serve as a continuing resource to the Commission.

Sincerely,

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