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Docket No. USTR-2020-0041
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SUBMITTED ELECTRONICALLY

Mr. Daniel Lee
Assistant U.S. Trade Representative
for Innovation and Intellectual Property (Acting)
Office of the U.S. Trade Representative
600 17th Street, N.W.
Washington, DC 20508

Re: Correction to Comments on 2021 Special 301 Review

Dear Mr. Lee,

Per the Request for Comments and Notice of a Public Hearing Regarding the 2021 Special 301 Review (85 Fed. Reg. 81263) dated December 15, 2020, the Pharmaceutical Research and Manufacturers of America (PhRMA) submitted comments in this Review on January 28, 2021. In further reviewing our comments, we have identified a typographical error in the comments concerning Malaysia (page 119 of our submission). A corrected version of that page is attached.

We apologize for the inconvenience and thank you for your review of PhRMA's comments.

Sincerely,

/s/ Ernest Kawka

Ernest Kawka
Deputy Vice President, International

unnecessary and unjustified measure was taken in a unilateral and non-transparent fashion, despite the fact that the U.S. manufacturer had decided to include Malaysia in its voluntary licensing program. The CL has sent a devastating signal to America's biopharmaceutical innovators that their patents are not safe in Malaysia.

While imposing a license is rarely, if ever, an appropriate mechanism to improve patient access, that is particularly true in this instance. Industry experience clearly demonstrates that collaborative access policies enable significantly better treatment access outcomes. Malaysia's compulsory license reportedly only treated 1,501 patients with hepatitis C over a 12-month period in 2018.[214] However, cooperative discussions and collaborative access policies like voluntary licensing treated over 15,000 patients over the same period in neighboring Vietnam.[215]

While this CL has significantly undermined investor confidence in Malaysia, industry is glad to see that the Malaysian Government elected not to renew the CL when it expired in October 2020. This promising action is undermined, however, by reports that Malaysia is considering compulsory licenses for other products, as well as the government's broad support for unsubstantiated calls by certain countries at the World Trade Organization to suspend certain IP rights during the global pandemic.

Further, in August 2019, Malaysia's intellectual property office (the Intellectual Property Corporation of Malaysia or MyIPO), released for public comment a "consultation paper" on proposed amendments to the Patents Act 1983.[216] The consultation paper and commenting period were not widely publicized. While the consultation paper lacked specific textual proposals, PhRMA members are very concerned that the proposed amendments could promote vague and ambiguous grounds for compulsory licensing, restrictions on what can be patented, and unnecessary procedures that would undermine granted patents. Considering the preliminary nature of that consultation paper and limited information, PhRMA provided MyIPO an initial response calling for the Malaysian Government to engage in a meaningful and transparent consultation process.

Recognizing that Malaysia has not renewed the CL, but that the specter of further CLs remains, we strongly encourage the U.S. Government to maintain the out-of-cycle review that it initiated in 2020 to seek stronger enforcement of IP rights in Malaysia.

[214] "Malaysia to make drug to treat Hepatitis C," *The Star* (Mar. 8, 2019), available at https://www.thestar.com.my/news/nation/2019/03/08/malaysia-to-make-drug-to-treat-hepatitis-c (last visited Jan. 27, 2021).
[215] "Five Takeaways: Bridging access and innovation in healthcare policy," Observer Research Foundation (Oct. 31, 2019), available at https://www.orfonline.org/research/five-takeaways-bridging-access-and-innovation-in-healthcare-policy-57163/ (last visited Jan. 27, 2021).
[216] Consultation Paper on Proposed Amendments to the Patents Act 1983 [Act 291] published on Aug. 30, 2019.