March 14, 2018

The Honorable Robert Lighthizer
United States Trade Representative
Executive Office of the President
600 – 17th Street, NW
Washington DC 20508

RE: Malaysia / Special 301

Dear Ambassador Lighthizer:

One of the countries that PhRMA, NAM and others have singled out to be placed in the Special 301 list is Malaysia, as a retaliation for the granting of a compulsory license on hepatitis C patents in September 2017. KEI would like to offer a few comments on this case, and explain why it does not merit sanctions by the U.S. government.

1. The Malaysia compulsory license and the Gilead voluntary licenses both permit generic production of sofosbuvir.

The Malaysia HCV compulsory license is unusual in the sense that it was issued after Gilead, a U.S. company that holds several patents on sofosbuvir based HCV treatment regimes, had announced that it would expand the geographic area for its voluntary license to include Malaysia. Gilead made that announcement on August 23, 2017 via twitter and in a blog posted to linkedin in late August.

Officials from the Ministry of Health have told several persons that they were never provided with any official notice of the voluntary license at the time. A copy of the voluntary license is now available on the Gilead web page (see attached PDF file), and appears to have been published November 20, 2017.

In between the August 23, 2017 announcement on twitter and the November 20, 2017 revised agreement, the Malaysia government issued a compulsory license. A press statement from the Minister of Health issued on the September 20, 2017[1] described the action as an authorization to acquire generic versions of sofosubuvir for "use in government facilities only (MOH and Armed Forces Hospitals), whereby at initial phase it will only be offered at 12 MOH Hospitals." (See attachment).

What the Malaysia MoH described is a narrower authorization than what Gilead has authorized in its November 20, 2017 revised voluntary license. For example, the Gilead license covers several additional drugs which are used in combination with Sofosbuvir.

According to Fifa Rahman, writing in IP-Watch, the Malaysia government had been considering a compulsory license since the first quarter of 2017, after having failed to negotiate more favorable prices or inclusion in the Gilead HCV voluntary license in 2016.[2] Gilead no doubt was aware of the progress on the compulsory licensing proposal, and this probably motivated the announcement in August that Malaysia would be included in the voluntary license.

Gilead was sufficiently distracted by its other business interests that it did not provide any significant details immediately. KEI received a letter from Gilead dated September 12, 2017, outlining some of the terms, but also explaining that some important details, such as measures on diversion, needed to be worked out.

It would be odd for the USTR to sanction Malaysia for authorizing the procurement of generic versions of sofosbuvir when this is exactly what Gilead is also authorizing. It's a no harm, no foul situation, with some trade associations worked up because a tweet from Gilead in August wasn't sufficient to delay the compulsory licensing announcement. In the big scheme of things, it is surprising that USTR has interrogated Malaysian diplomats over the details. Don't your staff have more pressing matters to worry about?

2. Everyone has been up in arms over the Gilead pricing of sofosbuvir.

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[1] Press Statement Minister of Health 20th September 2017 – Implementation of the Rights of Government for Sofosbuvir Tablet to Increase Access for Hepatitis C Treatment in Malaysia. https://kpkesihatan.com/2017/09/20/press-statement-minister-of-health-20th-september-2017-implementation-of-the-rights-of-government-for-sofosbuvir-tablet-to-increase-access-for-hepatitis-c-treatment-in-malaysia/

[2] Malaysia Inclusion In Gilead Voluntary Licence – A Product Of Compulsory Licence Pressure, August 24, 2017. IP-Watch.https://www.ip-watch.org/2017/08/24/malaysia-inclusion-gilead-voluntary-licence-product-compulsory-licence-pressure/

From the moment that Gilead announced its initial price of $1,000 per pill for sofosbuvir, a huge debate has ensured over the price of sofosbuvir itself, and drug prices in general. The U.S. Senate has conducted an investigation into the sofosbuvir pricing, as have several leading news organizations. A Google search with the terms “sovaldi excessive price” yields 400,000 hits.

Many governments have acted or considered taking actions to address the price of sofosbuvir. Switzerland announced it would liberalize the rules on personal importation of generic versions. Italy used the threat of a compulsory license to obtain price concessions. Colombia and Chile are considering issuing compulsory licenses. 18 members of the U.S House of Representatives have called upon Secretary Azar to use 28 USC 1498 to obtain affordable generic versions of the drug. A Senate Committee is considering proposals for changes in 28 USC 1498 to make it easier for the Department of Veterans Affairs use compulsory licenses in the United States. The Governors of Louisiana and New York have investigated the possibilities of compulsory licensing, as have officials in the federal prison system. Some academics have proposed the United States buy all of the shares in Gilead, in order to obtain more affordable versions of the drug. What Malaysia has done is what a lot of governments are considering doing.

3. Sofosbuvir prices are excessive.

Sofosbuvir is an effective drug, but the overall returns are excessive. From 2014 to 2017, Gilead earned $55.5 billion from sofosbuvir based HCV drugs, including $19 billion in 2015. It is appropriate to curb the monopoly pricing of this drug, which has created financial stress for health systems around the world, including the United States.

4. Sofosbuvir was invented on a government grant.

The invention of sofosbuvir was partly funded by the U.S. government, a fact that was concealed by the inventors. Attached is a March 14, 2018 letter to Secretary of the Department of Health and Human Services (DHHS) Alex Azar, asking for an investigation into a failure to report NIH funding on US patent 7,964,580. This is the first patent in the FDA Orange Book for all Gilead sofosbuvir based drugs for HCV. KEI is asking the federal government to either take title to the patent, or to use a royalty free right in the patent to make compulsory licensing of sofosbuvir combination treatments more feasible under existing U.S. law. Unless that happens, the United States will not be able to make the treatment available to everyone who is infected with HCV.

5. Malaysia should be issuing more compulsory licenses, to address disparities in access to new drugs for cancer and other illnesses.

Pressuring Malaysia over the sofosbuvir compulsory licenses is probably more about stopping Malaysia granting compulsory licenses on overpriced drugs for cancer and rare diseases than it is about protecting Gilead. But the consequence of such pressure is a morally repugnant endorsement of unequal access to life saving drugs and needless suffering and premature

deaths. The United States needs to elevate this discussion, and not pander to drug company lobbies.

Sincerely

James Love
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