February 7, 2019

Daniel Lee,
Assistant U.S. Trade Representative for Innovation and Intellectual Property (Acting), Office of the United States Trade Representative.
Regarding: Docket number USTR-2018-0037, the 2019 Special 301

Knowledge Ecology International (KEI) requests the opportunity to testify at the hearing on the Special 301 list on February 27, 2019. We also provide the following comments.

KEI has provided comments and testified before the Office of the United States Trade Representative (USTR) Special 301 Subcommittee several times in previous years. We maintain a web page that includes all of the Special 301 Reports issued from 1989 to 2018, as well as links to comments by KEI and several other parties, at https://keionline.org/ustr/special301. This page includes a link to a table of each time a country has been included in the Special 301 list, which is also available here: https://bit.ly/2Sk2LA6.

For every year from 1989 to 2018, USTR placed an average of 41 countries on either the Watch List (WL) or the Priority Watch List (PWL), including an average of 11 countries on the Priority Watch List. Since 1999, the list has included an average of 3.5 countries for an Out-of-Cycle review.

As noted in the past, the criteria for being included on the list is notoriously vague. Canada has appeared on the 301 list 28 times, despite having high legal standards and lower rates of copyright infringement than the United States. Several other countries are on the list almost every year, without much to distinguish their policies and practices from their less frequently listed neighbors. One factor that seems to be highly significant to inclusion on the list is how large is the country GDP relative to other countries in a region.

The 301 list is driven by demands from lobbyists for the right holders, many of whom are former employees of USTR, other federal agencies, or Congress.

Our comments will touch on a few issues.

Using or threatening to use compulsory licensing of biomedical patents should not put countries on the list.

Compulsory licensing is permitted under every trade agreement the United States has signed, and its use is endorsed in the 2001 WTO Doha Declaration on TRIPS and Public Health, which in turn has been endorse and cited in many declarations and agreements.

The United States is, by far, the country that uses compulsory licensing the most. Following the 2006 U.S. Supreme Court decision, eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, every patent infringement case is a potential compulsory licensing case, if remedies for infringement are decided by a court. Before an injunction can be granted, a judge has to evaluate four factors. To obtain an injunction, the plaintiff has to demonstrate:

> (1) that it has suffered an irreparable injury;
> (2) that remedies available at law are inadequate to compensate for that injury;
> (3) that considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and
> (4) that the public interest would not be disserved by a permanent injunction.

In several cases where a court has decided that it is more equitable to permit an infringement going forward than to issue an injunction, the remedy is limited to the payment of royalties to the patent holder. These "running royalties" cases have benefited a number of businesses, such as eBay, Apple, Microsoft, Abbott Labs, Johnson and Johnson, Toyota, and Direct TV. KEI has a page reporting on several cases involving medical technologies, here: https://www.keionline.org/us-injunction-medical

In July 2017, the U.S. Senate Armed Services Committee sent a directive to the Department of Defense (DoD), in connection with the National Defense Authorization Act, to "exercise its rights" including march-in rights under § 203 of title 35, "whenever the price of a drug . . . is higher in the United States than the median price charged in the seven largest economies that have a per capita income at least half the per capita income of the United States." This is the text of the 2017 directive:

> **Licensing of federally owned medical inventions**
> The committee directs the Department of Defense (DOD) to exercise its rights under sections 209(d)(1) or 203 of title 35, United States Code, to authorize third parties to use inventions that benefited from DOD funding whenever the price of a drug, vaccine, or other medical technology is higher in the United States than the median price charged in the seven largest economies that have a per capita income at least half the per capita income of the United States.
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> 115TH Congress, 1st Session, 2017, Senate Report 115–125. National Defense Authorization Act for Fiscal Year 2018. Report to accompany S. 1519, on page 173. July 10, 2017.

On February 4, 2019, Clare Love, a veteran of the Vietnam war, and David Reed, wrote to Dr. Mark T. Esper, the Secretary of the Army, asking the Army to exercise its march-in rights for patents on the prostate cancer drug Xtandi, a product that had a 2018 list price of $159 thousand per year. From the petition:

> The petitioners are two prostate cancer patients, and are hereby asking the U.S. Army to use the federal government's royalty-free or march-in rights on the three patents listed in the FDA Orange Book for Xtandi, on the grounds that the price is not reasonable.
>
> We have provided evidence that the price of Xtandi in the United States is more than four times the median price in the seven high income countries identified by the U.S. Senate Armed Services Committee in 2017 to be used to determine if the U.S price on a DoD-funded drug is reasonable. We also note that the price in the U.S. is five times the reimbursed price in Japan (where Astellas is headquartered).

Today, legislation was introduced in the U.S. Senate and the House of Representatives, to provide robust compulsory licensing authority to be used in connections with negotiations over prices for drugs for the Medicare program. In January, even broader compulsory licensing legislation was introduced in both houses of Congress.

Given the challenges the U.S faces in curbing high drug prices, and also protecting patient access, it is important to have the ability to use the authority to issue compulsory licenses on biomedical patents.

Compulsory licensing, when used or threatened, provides governments leverage in negotiating drug prices, and that leverage can be exercised without resort to restrictive formularies or high patient copayments, thus ensuring that patients will have access and avoid fiscal toxicity when dealing with cancer or other severe illnesses.

To the extent that the U.S. government is concerned about foreign government free riding when it comes to financing biomedical R&D, there are more productive and more patient friendly ways of addressing the global issues than trade pressures that are designed to raise foreign drug prices. The United States can pressure foreign governments to expand public sector funding of R&D, to provide incentives that are not linked to drug prices, like market entry rewards, or to provide R&D subsidies, like the U.S. Orphan Drug Tax Credit.

Transparency of pharmaceutical markets is a global public good. The U.S. government should support efforts at the World Health Organization or in other fora to create global norms and practical mechanisms to provide greater transparency of drug prices and the outlays on R&D investments, including in particular, the expenditures on each clinical trial used to support the registration of a new drug or to justify an expanded marketing authorization for new uses.

The U.S. government should also work with other governments to ensure that there is routine and useful disclosure of know-how to make biologic products and services like CAR T. Such disclosures are necessary to introduce more competition for biologic drugs and cell and gene therapies, and to protect patients by ensuring that biosimilar products are safe and effective.

There are many technically complex issues addressed in the Special 301 list each year regarding the granting of, exceptions to, and enforcement of patents on drugs and other medical technologies, as well as the appropriate policies to protect test data for new drugs and vaccines, policies on pricing and reimbursement of new medicines. The USTR has generally acknowledged that countries "should…promote access to medicine for all," and then has punished them whenever they take steps to improve access or affordability. This includes countries with per capita incomes far below that of the United States.

In our view, the USTR needs to reframe its focus, from protecting and advancing the commercial interests of global drug companies (many of them based in Switzerland, Japan, Germany, France, Canada, Ireland, Denmark or the United Kingdom) to something more enlightened and forward looking. The United States is spending more money on health care and more money on drugs, being charged the highest prices in the world, and the very policies that will make other countries pay more will make things worse in the United States. As we are locking in global norms for intellectual property rights (IPR) and reimbursement policies that are designed to increase drug prices in foreign countries, we are also effectively creating a situation that will prevent the United States from implementing much-needed reforms.

The Special 301 list was created in 1989, when our population was much younger, and prices for drugs and insurance coverage were much lower. Today, the United States is slowly moving towards having both broader insurance coverage and an older population. In 2000, the percent of the US population 65 or older was 12 percent. By 2020, it will be 17 percent and by 2030, 21 percent.

Year	Population	Percent of Total Population
1990	31.2 million	12.5%
2000	35.0 million	12%
2010	40.3 million	13%
2020 (projected)	56 million	17%
2030 (projected)	74 million	21%
2040 (projected)	82 million	22%

2050 (projected)	88 million	22%
2060 (projected)	98 million	24%

Source: Population figures and projections from U.S. Census Bureau.

With workers entering the labor force later and having an increasing life expectancy, the challenges of paying for health care are large. Innovation in the areas of drugs, vaccines, diagnostics and new technologies like CAR T are important, and the United States has an interest in promoting both innovation and access to that innovation. USTR needs to look at a broader range of issues other than high drug prices, and most importantly, needs to look at the trade related aspects of funding the research that enters the public domain and advances science.

Also, the USTR needs to take a fresh look at proposals to delink research and development (R&D) incentives from product prices, not through the lens of companies that specialize in marketing drugs and profiting off of government-funded medical discoveries, but rather through the lens of employers, taxpayers and patients who pay for new technologies.

Copyright, related rights, software

On the copyright side, the United States should continue to advocate that foreign governments adopt balance in the copyright system so that law abiding companies can provide services that require fair use of copyrighted works. The United States should also address the global crisis in orphaned works, an issue made worse by extended copyright terms and restrictions on the requirements to register works (which is not required by the Rome Convention).

Similarly, the United States should expand its advocacy efforts to push back against foreign "ancillary copyright" regimes, which will plainly undermine the mandatory exceptions in the Berne Convention for quotations and the news of the day, and create new barriers to trade.

USTR should encourage foreign countries to adopt policies providing access to published research. The U.S. government has adopted policies at the NIH and other agencies to require that the research it funds enters open access archives. It is is in the U.S. interest that foreign governments adopt similar policies. For commentary, see: Open Access at a crossroads, October 11, 2018, Physics Today, DOI:10.1063/PT.6.2.20181011a.

The USTR needs to oppose efforts by the World Intellectual Property Organization to create a new layer of rights for broadcasters that will complicate access to works, and only benefit corporate owners who do not create, own or license works, but merely transmit them.

The USTR should not back norms that block government interventions to make software code or protocols transparent. We are facing enormous challenges in dealing with malware, software enabled fraud, voting machine security and a rapidly evolving environment of software to shape public opinion, influence sentencing and parole, data lockin of medical records, and thousands of other complex issues. Government have to have the flexibility to force transparency of code or protocols when appropriate.

Sincerely,

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