KEI comments on the 2023 USTR Special 301 Review

Comments provided by James Love, on behalf of

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1. **USTR might consider being more thoughtful and consistent regarding intellectual property policies or practices as a rationale for the US government to get involved.**

Since its inception, the USTR Special 301 list has had an *ad hoc*, lobbyist driven character. While the USTR response to the rights holder submissions does reflect the evolving views of each administration, it is frustrating to not have more clarity on some issues that are consistently raised by rights holders and also highlighted by public health and consumer rights groups.

On the one hand, the members of PhRMA and BIO frequently criticize governments that even entertain the possibility of granting a compulsory license on a medical technology. On the other hand, in numerous fora and under multiple administrations, the U.S. government has agreed that governments "can and should" interpret and implement trade agreements "in a manner supportive of" a country's right to protect public health and, in particular, to promote access to medicines for all. Apparently USTR's policy is either not clear to PhRMA and BIO, or USTR's actual policy is at a variance from the several formal declarations it has endorsed..

The US government often agrees in various declarations and decisions that governments can use the flexibilities in the TRIPS Agreement "to the full" to achieve the purpose of promoting "access to medicines for all." In the recent negotiations at the WTO on exceptions related to COVID-19, USTR highlighted the exceptions available in the TRIPS to expand access to medical technologies. Yet, rights holders clearly perceive that they need to inform USTR any time there is a hint that a country might actually use one of those flexibilities in seeking to address the vast global inequality in access to biomedical inventions.

While there are a plethora of issues that are presented to USTR by rights holders, USTR could begin to remove ambiguity regarding its policy on access to medicine for all by addressing a handful of core topics. For example, USTR could plainly state, even in the Federal Register notices soliciting comments, that the following should NOT be grounds for inclusion on the Special 301 list.

a. The grant of a compulsory license on a biomedical technology that is consistent with Article 30, 31 or 44 of the TRIPS.

b. The absence of a law or other policy linking drug or vaccine registration to patent state.

c. The absence of a law or other policy granting exclusive rights to pharmaceutical test data.

d. The absence of a law or other policy extending patent terms beyond the term required by the TRIPS Agreement.

e. Government efforts to control or negotiate prices for biomedical inventions.

Likewise, USTR could note that certain policies in the copyright and related rights area are also not grounds for inclusion in the 301 list, including. Among the protected policies and practices would be such topics as:

f. The introduction of fair use in national copyright laws.

g. The compulsory licensing of education materials when remuneration is available to authors and publishers.

2. USTR should object to efforts by the EU, Canada or other countries to impose restrictions on the use of quotations or news of the day.

The Berne Convention for the Protection of Literary and Artistic Works provides the public with a right in Article 10(1), to make "quotations from a work which has already been lawfully made available to the public." This exception is both mandatory, and non remunerative, in an article titled "Certain Free Uses of Works.'

The Berne Convention also provides in Article 2(8), a mandatory exception for "news of the day or to miscellaneous facts having the character of mere items of press information."

Both of these exceptions were considered important enough to be mandatory. However, as USTR is fully aware, several members of the European Union and legislators in Canada are seeking in a variety of measures and proposals to impose fees and restrictions on some uses of quotations or news of the day. These proposals, reportedly aimed largely at U.S. companies, effectively undermine the Berne Convention's mandatory exceptions and deserve a more spirited opposition from USTR.

3. USTR should be more proactive in requesting information from companies.

USTR should create, and as needed modify, standardized queries for companies to complete in order to improve the quality of information relevant to the Special 301 list.

For PhRMA and BIO members, USTR should ask for data on the patent landscape, public subsidies and number of units sold in different markets, in order to have the best evidence of access or a lack of access for any drug, cell therapy, gene therapy or other medical technology that is related to a rights holder 301 submission.

USTR should ask right holders and public health and consumer groups to suggest the market categories and stars for information requested that would be most informative, and advance the objectives of the World Health Organization transparency resolution, WHA72.8.

On the copyright side, USTR should ask right holders about the distribution of sales revenue or royalties to authors and performers, in various geographic areas.

4. **USTR should develop a proactive agenda on the trade related aspects of public goods.**

The US government is a large supplier of certain public goods, including for example, through our support for the Global Fund for AIDS, TB and Malaria, the digitization of books for persons with reading disabilities, the funding of basic science in a variety of fields, the free provision of GPS signals, responding to natural disasters, and many other goods or services that benefit the global community. Despite this largess, the world faces a chronic under supply of public goods, in part because of the lack of measures to provide incentives or obligations to share the costs. At the same time, trade agreements treat some subsidies as inappropriate. The current efforts to replenish the Global Fund or the failures of governments to share technology during the COVID-19 crisis remind us how important it is to address the trade related aspects of public goods.

KEI suggests USTR convene at least two meetings, one with US stakeholders, and one with other governments, to discuss the possible approaches USTR could take to address the chronic undersupply of public goods that have a cross border benefit.

In this regard, I would remind USTR that Paul Samuelson's 1953 definition of a "pure" public good was described, by him, as an extreme and not a limiting case. Global Public Goods need not be non-excludable or non rival in consumption, conditions that when taken together, exclude most of what governments do for their own citizens. See: 2020. James Love. The Use and Abuse of the Phrase "Global Public Good," *Developing Economics*, July 16, 2020.

5. **USTR should solicit comments on consequences of new uses of artificial intelligence on the current intellectual property system, including the trade related aspects.**

The first wave of discussions on artificial intelligence focused in part on whether or not a work or invention created by a machine could obtain a copyright or a patent for an invention. New services like ChatGPT or DALL·E 2 have stimulated considerable interest in the degree to which the services can misappropriate, copy, or devalue more traditional approaches to the creation of knowledge goods. As various AI projects become more mature and more widely used, there will likely be demands for new types of sui generis rights.

While USTR is not a lead actor in the development of policies for IP and AI, it should be listening to what is basically brainstorming right now on the possible trade related issues that may arise, due both to the rapidly evolving uses of AI, and also the likely unequal geographic distribution of successful AI projects.

One key aspect of these evolving debates concerns the data that trains AI. AI projects require massive amounts of data, and the large scale can lead to monopolistic outcomes. USTR itself does not have a good track record in addressing the measures necessary to control anticompetitive and predatory practices by monopolies, and might consider some staffing changes to bring some fresh thinking about the trade related aspects of the control of anticompetitive practices, as they relate to both AI and markets for data.