February 28, 2024

To: Claire Avery-Page, Director for Innovation and Intellectual Property, USTR
Via: Special301@ustr.eop.gov
From: Knowledge Ecology International (KEI)
Re: KEI Post-hearing Written Comments Regarding the 2024 USTR Special 301 Review as noticed in the Federal Register, 88 FR 84869, Docket: USTR–2023–0014

Knowledge Ecology International (KEI) provides the comments below following the hearing on February 21, 2024 regarding the Special 301 Review.

1. **Trade-related Aspects of Funding Biomedical R&D**

Question from HHS: ***Regarding the trade related aspects of funding biomedical R&D, we noted in our comments the need for the US to develop policy objectives for global public sector funding of biomedical R&D - what policies would we recommend? How would this relate to IP owners?***

The United States pays higher prices for medical inventions than other high income countries, and those high prices are often justified on the grounds that the U.S. market provides, by far, the most important incentive for investors in R&D. It doesn't matter where companies are located or where the R&D is conducted, every company wants to exploit the U.S. market, where prices have been surprisingly unconstrained, even when the patented inventions were funded by a US government agency.

As noted in the pre-hearing submission, with the aging US population, trade officials should address the trade related aspects of funding biomedical R&D, but need to come up with something other than “let’s have everyone else pay higher prices for drugs.”

The United States is not the only economy facing dramatic shifts in the age of its population. According to the World Bank, from 2000 to 2022, the percent of the U.S. population 65 or older increased from 12.3 to 17.1. That’s an increase of the proportion of 39.1 percent. For the entire world, the increase was 42 percent. For countries classified by the World Bank as high income, the percentage change was 41.1 percent. For countries classified as upper middle income, the percent change in the ratio was 72.6 percent. These are big changes, and explain why it’s becoming more difficult to force trading partners to have policies that require drug prices to increase.

The Special 301 list is a report on intellectual property protection and enforcement, but PhRMA, BIO and other trade associations continue to press USTR to address policies in countries that

involve drug pricing. When drug companies approach USTR, they claim that price controls or restrictive formalities for reimbursing products undermine the benefits of intellectual property protection, and, as we have seen in many FOIA requests and published cables, as well as in plurilateral and bilateral trade negotiations, the U.S. government frequently seeks changes in foreign government policies relating to drug pricing. What USTR does not address are the R&D subsidies or incentives to support R&D that are not linked to higher prices for drugs.

Table: Percent of Population 65 or older

Country/Region Name	2000	2022	Change	Percentage Increase in the Ratio
Brazil	5.5	9.9	4.4	79.5%
China	6.9	13.7	6.8	98.3%
Caribbean small states	5.7	8.6	2.9	51.2%
East Asia & Pacific (excluding high income)	6.3	11.7	5.4	85.0%
European Union	15.7	21.3	5.5	35.1%
High income countries	13.7	19.2	5.5	40.1%
India	4.5	6.9	2.4	53.5%
Japan	17.8	29.9	12.1	68.1%
Latin America & Caribbean	5.7	9.2	3.5	62.7%
Least developed countries: UN classification	3.2	3.7	0.5	15.7%
Low income countries	3.0	3.2	0.2	7.3%
Lower middle income countries	4.4	6.0	1.6	36.8%
Low & middle income countries	5.4	8.1	2.7	49.3%
Middle income countries	5.6	8.6	3.0	54.2%
OECD members	12.7	18.0	5.2	41.2%
Sub-Saharan Africa	2.9	3.0	0.1	3.2%
Upper middle income countries	6.7	11.6	4.9	72.6%
United States	12.3	17.1	4.8	39.1%
World	6.9	9.8	2.9	42.4%

The US public sector investments in biomedical R&D through the NIH, BARDA, CDC, FDA, DOD, DOE, the VA, the NSF and other agencies is significant, and largely unmatched by our trading partners. One obvious question concerns the global level of public sector funding of biomedical R&D, particularly since much of the US spending enters the public domain.

The U.S. government has rights in inventions it funds. Provisions in the Bayh-Dole Act (Section 202 and 209 of the Bayh-Dole Act) give the U.S. government a worldwide right to use

inventions, and also the ability to assert other rights required “to meeting the obligations of the United States under any treaty, international agreement, arrangement of cooperation, memorandum of understanding, or similar arrangement.”

Other governments that fund R&D may have certain rights in R&D that they fund.

Governments that reimburse or buy products have leverage to acquire some concession that could be used to share technologies or otherwise enable competition, and this leverage is enhanced when governments cooperate with each other.

Governments can collaborate to fund patent or know-how buyout funds, to make inventions and manufacturing know-how more available for competitive suppliers.

There is a proposal by Senators Sanders and Cassidy to have the U.S. National Academies study the feasibility and benefits of new incentive systems that are delinked from government granted exclusive rights in inventors, data or regulatory approvals.

The former CEO of GSK suggested that the prices for rare diseases are not based upon any particular principles, and that the highly arbitrary and unsustainable prices could be replaced with a system of alternative rewards delinked from monopolies.

If such reforms are implemented, the U.S. would have to ask trading partners to match U.S. funded market entry rewards for new products.

Transparency of the value chain for medical products has a trade related aspect. Drug companies often insist on extensive secrecy of prices, contract terms, R&D outlays, manufacturing costs, patent landscapes and other items, and governments are either lacking the leverage to get more transparency, or are bribed by companies with a promise to get better deals if there is more secrecy, resulting in weaker public sector negotiating positions globally. Global norms on transparency have a trade related aspect, similar to the trade related aspects of taxing corporations.

Today USTR looks at patent and other intellectual property issues without considering what our trading partners are doing on other matters highly relevant to biomedical R&D.

Even if USTR does not agree with KEI on what should be done, it should agree that a policy that focuses on IP protections but not national policies to subsidize R&D, require transparency, or pool technologies, is incomplete as regards our national interest.

The most important rationale for patents on medical inventions is not to enrich investors, but to use the incentives to advance innovations for the public.

While it is true that many members of Congress (including those on trade committees) want high prices everywhere to benefit the politically well connected companies and investors, with health

outcomes a secondary consideration, the public at large sees things differently. One measure of the public's views is found in the predictable campaign promises to do something to lower drug prices. I don't recall members of Congress from either party airing campaign ads promising to keep drug prices high or making sure prices on drugs for cancer or rare diseases are out of reach for most of the world's population.

2. **News of the Day and Quotation Rights**

By Copyright office: KEI's comments state that we should defend news of the day and quotation rights - what IP rights are at issue (might not have heard this right) and who are the problem countries/entities on this issue?

The problem governments include but are not limited to:

- The European Commission,
- Germany,
- Spain,
- Belgium, and
- Canada.

3. **Artificial Intelligence-related Text and Data Mining Exceptions**

By USTR: Regarding the AI data opt-out - what if all countries opt-out? If countries do the opt-out, should they be placed on the Special 301 list?

KEI's comments focused on the importance of distinguishing between different types of data and AI services, when it comes to training AI services. Specifically, it is our position that "A freedom to operate regime should be the general rule, subject to limited and narrow exceptions. In other words, the right to opt-out of training data should be the exception and not the rule, even for commercial services."

For example, we draw a distinction between an opt-out for music recordings, and opt-outs regarding matters concerning science, and biomedical science in particular, or AI services dealing with legal issues. Since it is impossible to know today where generative AI services will be useful and used, the opt-outs should be narrow and only allowed where there is a clear social benefit to restricting use of works or data to train the AI services.

It is unlikely that "all countries opt-out". Countries that create broad general opt-outs for commercial services could be put on the Special 301 list, but USTR does a lot of things that don't involve the Special 301 list, and the USTR response could involve other actions, including the development of soft norms, advocacy, and measures in trade agreements (similar in some

ways but different in kind to the poorly conceived and ill advised restrictions on transparency of software code or algorithms in trade agreements).