February 26, 2025

KEI Responses to Hearing Questions - 2025 Special 301 Review (docket number USTR-2024-0023)

1. From HHS: Regarding KEI's comment that USTR should develop policies on supply of public goods, can you comment on IP issues raised by that topic, and any developments (foreign countries particularly) that raise concerns re: providing protection of IP rights or that deny fair and equitable market access to US entities that rely on IP protection?

The question asks about "policies on supply of public goods," and also about foreign countries that "deny fair and equitable market access to US entities that rely on IP protection."

Until the recent efforts by DOGE to eliminate or shrink many government programs, the United States has been the most important funder and supplier of public goods for a number of international concerns. Many public goods, like measures to address famines, refugees or natural disasters, are not about IP policies or practices. However, the U.S. has also been the most important source of funds for basic science, and supported product related research and development in a variety of fields, including but not limited to biomedical therapeutics, diagnostics and vaccines, where IP policies are important. In some cases, the U.S. funding agencies have included provisions to expand access to R&D outputs. This includes obligations for open access publishing of articles reporting research outcomes, and concessionary licensing of patented inventions and rights in test data as well as access to know-how, cell lines and other biologic resources.

There is always pressure on funding agencies to make proprietary claims on R&D outputs and to license IP to for-profit companies. Some of the beneficiaries of licenses are domestic firms, but licenses are also given to many foreign owned firms. The political pressures to treat government funding of R&D as jobs and competitiveness programs are not exclusive to the United States. Other governments use public sector R&D funding to subsidize domestic firms and otherwise promote industrial policy objectives.

Collectively the world can realize significant benefits if governments increase funding for basic science entering the public domain, and license downstream inventions, data, know-how and biologic resources in ways that expand access to knowledge and products, consistent with cost effective incentive mechanisms.

KEI has been asking USTR to consider not only the traditional objective of ensuring that US entities are treated fairly, as regards the protection of intellectual property, but a broader set of trade related concerns. For example, if the NIH requires grant recipients to make publications available in open access repositories, USTR could press other governments to provide similar access, so that US researchers would have the same access to foreign government funded research that foreign

entities have to US funded research. Likewise, if the NIH imposes obligations for addressing equitable access to products that use NIH owned patents (See: https://www.keionline.org/40413), our trading partners could be asked to attach similar obligations, to provide a more level playing field and to enhance our own policy objectives regarding equitable access.

One analogy for the trade related aspects of public goods is spending on national defense. The United States often asks NATO partners to increase defense spending, and to share the costs of assisting Ukraine in its defense. The same type of asks can be made of trading partners for public goods: to share the costs of dealing with humanitarian programs, and with respect to IP related issues, to provide more public funding for biomedical research, an area where the United States government has been an outlier.

One related proposal KEI is associated with is to create a schedule within the WTO for the supply of public goods, modeled somewhat after the GATS.

There is a need for greater cooperation in supporting global public goods, in areas such as mitigating natural disasters, combating piracy, wildlife management and endangered species, refugee services, pandemic preparedness, developing new antibiotics, and more. Governments have tools to address these issues through taxation and regulatory measures on the local and the national level, but international cooperation in these areas suffer from a lack of enforceable mechanisms to ensure that collective action to supply public goods will be credible and sustainable over time. KEI has proposed the establishment of a mechanism at the World Trade Organization (WTO), leveraging the WTO Dispute Settlement Understanding (DSU) to ensure commitments by Member States are binding. These commitments to support particular public good initiatives would be made on a voluntary basis, but the WTO DSU would provide a mechanism to provide countries with confidence that partners will follow through on their respective funding commitments.

KEI proposes a meeting with the appropriate persons at USTR to discuss this proposal further, and to brief USTR on the reaction of other trading partners to the proposal.

2. From USTR: Regarding KEI's comment that USTR should develop policies on global public sector funding of biomedical R&D - What policy objectives and how does it relate to the denial of IP protection in foreign countries or the denial of fair and equitable market access to persons that rely on IP protection in those countries?

The current global framework for funding biomedical R&D relies upon the grant of drug monopolies and leads to high drug prices, prices that create unequal access, and financial strain on health systems and government, business, and household budgets.

All efforts to curb ever-rising drug prices are resisted under the assumption that any effort to lower prices would undermine R&D. If there is no progress in developing new methods to support R&D, other than high prices, we are continuing to expand systems of inequality, and rationing of access to new technologies.

USTR should work to support the global funding of biomedical R&D, whether through the WTO public goods agreement described above, or through other mechanisms, such as the previously debated WHO agreement on R&D.

3. From US Copyright Office: KEI comments note a pressing concern regarding the extent to which developers of AI services use copyright materials and non-copyrighted data to train AI services, what are the issues with using non-copyrighted data to train AI services? Do some countries prohibit the use of non-copyrighted data in AI training?

The current focus of many national policy reviews for IP in AI training data have focused on copyrighted works. That said, data of all sorts is often protected through trade secrets and technical protection measures, as well as other barriers to access. Biomedical data including, for example, patient medical records, clinical trial results, and regulatory files, have great potential for training AI services, but are also often protected by privacy laws and treated as confidential business records.

Data submitted to regulatory agencies is subject to the provisions of Article 39.3 of the TRIPS. This article provides both an obligation to protect access against unfair commercial use, a phrase that suggests remunerative uses are allowed, and an exception for cases where the use is "necessary to protect the public."

The TRIPS also allows governments to undertake measures to remedy or control anti-competitive practices. As noted in our February 25, 2025 submission to the UK IPO consultation on AI and copyright (https://www.keionline.org/40558), in some cases, governments may need to mandate sharing of data.

> Economies of scale may be significant in general, and for specific types of services, excessive concentration of control of data will be concerning. Creation of opt-in or opt-out rules for text and data mining will create entry barriers, some extremely high, for some types of services. We have focused frequently on biomedical research, where an opt-in rule creates the risk that a handful of highly concentrated biomedical journal publishers that hold the copyrights on published articles could engage in restrictive licensing to a handful of large pharma companies.
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> Beyond the risks of concentration raised by creating and opt-in or opt-out options, are those where economies of scale and the costs of assembling data lead to unwanted concentration. One can look at the experiences with Internet Search or Mapping services to appreciate how highly concentrated services can become. It may be important to treat some types of data or databases as essential facilities, and mandate some types of sharing of access.

KEI encourages governments to provide greater access to medical records and other biomedical data through data spaces approaches. From our UK IPO submission:

Data spaces is a term used to describe frameworks for secure and trusted data sharing. The objective is to create systems where organizations can exchange or provide controlled access to data, under agreed-upon rules, standards and infrastructure.

In decentralized systems, data remains held by various entities, but can be accessed by authorized parties for specific uses. For example, medical records data around the world is held by different government and private entities, and is subject to rules to protect the privacy of patients. Queries can be run on decentralized datasets, with the results benefiting researchers, while avoiding excessive concentration of the control over records, and allowing each organization holding the records to protect patient privacy according to relevant ethical and national legal obligations.

There has been some progress in these approaches in several European countries. Researchers in the United States could benefit greatly from greater access to European medical records, and could find ways to share better access to data from the United States. KEI suggests USTR review the activities of ELIXIR for some practical insights into the platforms and communities that are sharing data. (https://elixir-europe.org)

4. From USPTO: Noting that KEI asked that 2024 comments be incorporated to the record for this year's comments, any changes between last year and this year to specifically highlight?

As noted in our 2024 comments, USTR policies on the use of exceptions to exclusive rights in patents, data, biologic resources and other knowledge goods should be consistent with Paragraph 4 of the WTO Doha Declaration on TRIPS and Public Health. In the past, USTR has frequently criticized countries in the Special 301 Report for using or even proposing to use flexibilities in the TRIPS to obtain access to affordable medical products. Recently, USTR has largely abstained from this criticism and we urge USTR to continue this practice and reaffirm countries' rights and flexibilities laid out in the Doha Declaration.

The February 21, 2025 Presidential Memorandum titled "Defending American Companies and Innovators From Overseas Extortion and Unfair Fines and Penalties" (https://www.whitehouse.gov/presidential-actions/2025/02/defending-american-companies-and-innovators-from-overseas-extortion-and-unfair-fines-and-penalties/) does set out a mandate for "imposing tariffs and taking such other responsive actions necessary to mitigate the harm to the United States" from "any act, policy, or practice of a foreign government that could require a United States company to jeopardize its intellectual property."

In the area of IP and health technologies, USTR should not take actions against countries that use compulsory licenses or other measures to protect their public from excessive prices or shortages, and more generally are "supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all."