KEI Comments on USTR Request for Comment on Trump Executive Order on Foreign Nations Freeloading on American-Financed Innovation

Submitted to USTR, Docket ID: USTR-2025-0011.
June 27, 2025

KEI has provided a number of comments to USTR in the past addressing the trade related aspects of R&D or public goods, and a selection of these comments are attached below as an Annex.

The main points KEI would like to make are as follows:

1. High prices for medical technologies are not sustainable.

The world population is aging and that is certainly the case in the United States.

- From 2004 to 2024, the U.S. 65 and over population has increased while the child population has decreased.

- The U.S. Older Population Grew From 2010 to 2020 at the fastest rate since 1880 to 1890. The U.S. population age 65 and over grew nearly five times faster than the total population over the 100 years from 1920 to 2020, according to the 2020 Census.

- The number of Americans ages 65 and older is projected to increase from 58 million in 2022 to 82 million by 2050 (a 47% increase).

- In 2000, 12.4 percent of the U.S Population was 65 and over. Today 17 percent of the population is 65 and older, and this is expected to rise to 23 percent.

The roll-out prices for new medical technologies have been steadily increasing, and there has been a significant increase in very expensive treatments for rare diseases. (From 2000 to 2005, 21 percent of novel drugs were approved for Orphan indications. From 2020 to 2024, 54 percent of novel drugs were approved for Orphan indications). New cell and gene therapies are now being approved by the FDA for a growing number of indications, with staggering price tags.

Other countries are facing the same demographic shifts and the same challenges in providing universal access to medicines.

2. The United States has been an outlier in public sector funding of biomedical R&D.

The most important factor in advancing biomedical innovation has been the public sector investments and subsidies. The United States has funded everything from basic science to

later stage product development. The U.S. Orphan Drug Tax Credit, once at 50 percent and now 25 percent, is a unique subsidy for clinical trials for rare diseases.

The Trump administration recognizes the importance of increasing defense spending by NATO allies, and the same can be said for public sector investments in biomedical R&D.

Trade policies on public sector R&D spending can also address opportunities to pool public sector rights in patents and other IP with trading partners.

3. Improving the transparency of markets for medicines, vaccines, and other health products.

In 2019 the Trump Administration played an important and constructive role in the negotiations over the WHO resolution WHA72.8, on Improving the transparency of markets for medicines, vaccines, and other health products. Greater transparency of prices, units sold, revenues, clinical trial costs and outcomes, patent landscapes, and public sector subsidies is profoundly important in designing and evaluating a wide range of policies.

4. Biomedical Data

The European Union's new regulation on European Health Data Spaces is an incredibly ambitious and potentially highly consequential initiative to advance biomedical innovations. The United States is largely excluded from access to the enormous data resources that will be available for European researchers. See these slides, and the text of the regulation: REGULATION (EU) 2025/327 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847

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Annex: Selection of previous KEI comments to USTR on the trade related aspects of biomedical R&D

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2010. Docket ID: USTR-2010-0003, 2010 Special 301

- https://www.regulations.gov/docket/USTR-2010-0003
    - https://www.regulations.gov/comment/USTR-2010-0003-0274

KEI provides the following comments regarding the 2010 Special 301 Review, including but not limited to the Identification of Countries Under Section 182 of the Trade Act of 1974.
U.S.T.R. should evaluate the benefits of a more balanced trade policy that encourages policies that expand access to knowledge, or the supply of knowledge as a global public good, when such policies enhance our welfare and national interest. In this respect, KEI would like to meet with the U.S.T.R. to discuss, with other interested parties, the benefits of new global norms on access to government funded research, on possible strategies to move forward the various proposals for a biomedical R&D treaty, and on the proposal for a WTO agreement on the supply of public goods.

2014. Docket ID: USTR-2013-0040, 2014 Special 301

- https://www.regulations.gov/docket/USTR-2013-0040
    - https://www.regulations.gov/comment/USTR-2013-0040-0040

Patent ownership

. . . In 1982, 45 percent of all PCT patent applications were from the United States. By 2001, the US share was just under 40 percent. By 2009, the US share was less than 30 percent. In 2012,

the US share was 26.4 percent. From 1981 to 1996, the US share of PCT patents increased 8 times, and decreased 8 times. From 1997 to 2012, the US share decreased every year. . . .

In light of the decline of the U.S. share of patent ownership, the perspective of the USTR should likewise shift. Instead of the aggressive approach of placing nations on watch lists for addressing well recognized abuses of patent rights, such as excessive pricing of medical inventions, or opportunistic patents on technology incorporated in standards, the USTR should temper the ways in which it considers its foreign relations. The US is not the largest owner of world patents and should alter its policies to reflect that fact. KEI recommends that the policies adopted by the USTR take into account a more realistic view of the US's share of world patents.

2015. Docket Number USTR-2014-0025, 2015 Special 301

- https://www.regulations.gov/document/USTR-2014-0025-0001
    - https://www.regulations.gov/comment/USTR-2014-0025-0041
    - https://www.regulations.gov/comment/USTR-2014-0025-0081
    - https://www.regulations.gov/comment/USTR-2014-0025-0082
    - https://www.regulations.gov/comment/USTR-2014-0025-0084

Sharing of R&D Costs as Trade Policy

The United States is the leading investor in public and private sector medical R&D. Our country has an interest in expanding foreign investments in medical R&D, but this interest should not be defined as a partnership with drug companies to expand monopolies and raise prices. A more appropriate policy is to create a global framework to expand medical R&D spending, which may or may not involve expanding drug company profits. The investments by the NIH and other government agencies, and the subsidies such as the Orphan Drug tax credit expenditure, should become part of the larger trade policy conversation. To this end, supporting work at the WHO or other multilateral or plurilateral bodies to expand investments in R&D should be seen in a positive light. Rather than expand Roche's profits from the sale of TDM1, an excessively priced breast cancer drug, the US government should be seeking greater sharing of the costs of developing new antibiotic drugs, treatments for Ebola, research in dementia, a vaccine for HIV, new drugs for TB, open source diagnostics for cancer, or other health care priorities. As we face new health care challenges, and an aging population, the benefits of shifts in policy will become more evident.

The United States should be collaborating with other governments to obtain better prices on new drugs, not worse prices. The United States should expand transparency and technology transfer for the manufacture of biologic drugs, not increase secrecy and expand monopolies. The United States should be cooperating with other countries to fund unbiased clinical tests of new drugs, and not undermine the use of evidence based reimbursement or reward programs.

Finally, the USTR should lead and not impede efforts to implement delinkage of R&D costs

from the price of new medicines, vaccines, diagnostics and other medical technologies.

2016. Docket ID: USTR-2015-0022, 2016 Special 301

- https://www.regulations.gov/document/USTR-2015-0022-0001
    - https://www.regulations.gov/comment/USTR-2015-0022-0078

The United Nations Secretary General's High Level Panel (UNSGHLP) on access to medicines

On Sunday March 28, 2016, the United Nations SecretaryGeneral's High Level Panel (UNSGHLP) on access to medicines concluded a request for submissions, looking for ways to reconcile human rights and access with innovation. There were a very large number of thoughtful submissions for dozens of experts and stakeholders. Some of those submissions propose replacing the current focus of trade agreements on promoting high prices with new approaches that consider R&D as the central objective of global norm setting, and which lead to the progressive delinkage of R&D costs from product prices. The four submissions for which KEI was lead authors are as follows:

1. "The Need for Global Negotiations on Agreements to Fund R&D within the Context of a Progressive Delinking of R&D Costs from Product Prices". Supported by 12 organizations; 1 individual; 3 Members of European Parliament.

2. "Increasing the Transparency of Markets for Drugs, Vaccines, Diagnostics and other Medical Technologies". Supported by 17 organizations; 2 individuals; 3 Members of European Parliament.

3. "The Role of R&D Subsidies for Clinical Trials in Progressive Delinkage of R&D Costs from Product Prices"

4. "Trade Agreements and the Supply of Public Goods"

Copies of submissions here:
https://web.archive.org/web/20160320142900/http://www.keionline.org/node/2431

2017. Docket ID: USTR-2016-0026, 2017 Special 301

- https://www.regulations.gov/document/USTR-2016-0026-0001
    - https://www.regulations.gov/comment/USTR-2016-0026-0027

Trade Agreements and the Supply of Public Goods

KEI is among those disappointed by the attacks on the High-Level Panel by the Obama Administration, and we urge the Trump Administration to look at these issues with an open mind, considering the sobering alternatives facing U.S. taxpayers, employers, and consumers in paying for new drugs. There is no reason to treat the current business model for drug development as sacred because it is (1) insanely expensive and (2) based upon policy-induced and logically unnecessary rationing of access, two big flaws. To this end, the World Health Assembly in May will consider a proposal by India, supported by Brazil, to progressively delink R&D costs from the prices of cancer drugs:15 (OP2.5ter) [to conduct a [preliminary] (Brazil) feasibility study of creating a multi-country push and pull fund for cancer R&D, as an alternative to incentives-based intellectual property rights and/or regulatory monopolies and to progressively delink cancer R&D costs from product prices;]India USTR should engage in this delinkage discussion and provide constructive suggestions regarding the trade related issues (of which there are many) that policy makers should consider when evaluating delinkage proposals.

Parallel Trade

One of the areas where KEI's views are aligned with drug companies and publishers concerns certain cases of parallel trade. For certain copyrighted works, such as those involving entertainment (including computer games) or textbooks, and for certain patented goods, including most importantly medicine, when the development is financed through the product prices (as opposed to more forward looking delinkage models), parallel trade should not be allowed from lower income countries to higher income countries. USTR should explore the benefits of norms or agreements that would allow parallel trade in certain socially important goods (like medicines and textbooks), where some types of price discrimination is appropriate, between countries of roughly equal or higher incomes, but not allow (subject to appropriate exceptions) parallel imports from countries that have significantly lower incomes. A possible rule would be to limit parallel imports for such goods from countries that have per capita incomes less than 50 percent of the importing country. Such restrictions on parallel trade would not be appropriate for all goods. For example, It is particularly important that goods that are used to manufacture other goods be available in the United States at the best world prices.

Transparency

Globally, society has interests in transparency. Locally, a decision to be transparent can put a country at a disadvantage, for example, by making it more difficult to negotiate a discount on the price of a patented medicine or an academic journal. For some areas of public policy, global cooperation on transparency can be beneficial, including, for example, to gather better understanding of the costs of research and development, measuring both the access to and impact of medicines, and evaluating the fairness of the copyright system in rewarding authors and performers (as opposed to distributors). Government negotiations of new trade agreements also present important challenges for democracies. Negotiators want some space and secrecy to consider the contours of a possible agreement, but the public wants to have the opportunity

to monitor and influence agreements before they are too far along to make changes. In the past, USTR has promoted transparency of drug reimbursement policies, for the benefit of drug manufacturers, but in other ways, sought to reduce the transparency for the public, for example, by not giving the public the same type of access to negotiating texts, and including provisions in the TPP that prohibits regulators from asking for data on drug prices and other relevant economic information. We suggest the USTR hold a series of meetings to consider a broad set of issues about transparency, trade-related transparency, and trade policy making

2018. Docket ID: USTR-2017-0024, Special 301

- https://www.regulations.gov/document/USTR-2017-0024-0001
    - https://www.regulations.gov/comment/USTR-2017-0024-0023

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.

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.

2019 Docket ID: USTR-2018-0037, 2019 Special 301

- https://www.regulations.gov/document/USTR-2018-0037-0001
    - https://www.regulations.gov/comment/USTR-2018-0037-0026

NDAA Reference Pricing Directive

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.
>
> 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.

. . .

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2020. Docket ID: USTR-2019-0023

Alternatives to address innovation

The pharma industry has an insatiable appetite for new rent-seeking norms and actions. But governments can, should, and need to consider alternatives that don't pit affordability, access and equality against innovation.

For several years, drug companies have lobbied against efforts by the World Health Organization (WHO) to set global norms for funding research and development (R&D). More recently, drug companies have lobbied against global norms on the transparency of pharmaceutical markets, and most aggressively, against transparency of R&D costs.

It is in our interest, the interest of the United States, that foreign governments expand public sector financing of biomedical research. The U.S. government does a laudable job of funding billions of dollars in biomedical research as a public good, and spends billions every year to subsidize clinical trial costs. The U.S. could push other countries to raise the level of their biomedical R&D spending and clinical trial subsidies, as this could have a more pronounced positive impact on innovation than higher prices for drugs, vaccines and gene and cell therapies.

For the past two decades, PhRMA has opposed all efforts to pivot from IPR to R&D, regarding the focus of trade policy. To be sure, the pharma sector wants to claim that its policies are designed to enhance R&D spending, but when proposals have been made to create even soft norms on R&D funding, or to address the lack of transparency in R&D spending, pharma has mobilized opposition.

The large biomedical companies understand, perhaps better than some government officials, that a focus on R&D, rather than IPR, could undermine policies that protect price gouging, and

eliminate their biggest price gouging defense. While it is true that price gouging can spur innovation, so can lots of other cheaper, and less harmful measures, such as expanded R&D subsidies, enhanced government direct funding of research, or incentives like market entry rewards that are delinked from prices or monopolies.

One reason the U.S. government needs to rethink its strategy on the cross-border funding of biomedical R&D is that the U.S. is consistently the biggest victim of excessive pricing and anticompetitive practices, and is facing a significant aging of our population over the next 15 years, which will add more fiscal stress to our already costly and globally most costly health care system.

Delinking R&D incentives from prices

Among the many reforms being considered to address the crisis in affordability of medicines are those that would delink R&D costs, and in particular the incentives to invest, from the prices of products or services. More generally, this is about delinking R&D incentives from the use of temporary monopolies on products, services or inventions, including by using market entry rewards, as the incentive to invest in new treatments.

Delinkage has many advantages, including the ability to more directly reward improvements in health outcomes and by eliminating considerable waste in marketing and non-outcomes-improving or scientifically questionable medical research. Delinkage also can dramatically move prices closer to marginal costs, thereby eliminating price based rationing and fiscal toxicity, and of course, reduce the inequalities of access and outcomes. Why wouldn't governments want to at least conduct feasibility studies? Yet, pharma companies and the U.S. government have lobbied to block such studies at the WHO and elsewhere.

During the George W. Bush Administration, the USTR actually convened a meeting to discuss these issues. This needs to be revisited.

U.S. has an aging population

The U.S. Census projects the number of Americans ages 65 and older to nearly double from 52 million in 2018 to 95 million by 2060. The percent of the U.S. population over 65, which is now 16 percent, is projected to exceed 23 percent/2/. If policy makers are not taking this into account, they are ignoring where we are headed.

(Footnote 2. 2017 Census projections for 2060. Total US Population: 404.83 million, population 65+: 94.676 million. Percent of US population 65+: 23.4%. https://www.census.gov/data/tables/2017/demo/popproj/2017-summary-tables.html)

2021. Docket ID: USTR-2020-0041-0001, 2021 Special 301

- https://www.regulations.gov/document/USTR-2020-0041-0001
    - https://www.regulations.gov/comment/USTR-2020-0041-0049
    - https://www.regulations.gov/comment/USTR-2020-0041-0118

In the initial comments;

The United States is the largest government funder of biomedical research. It is in the interest of the United States for other countries to increase public sector outlays on and subsidies for biomedical research. The United States should end its efforts to raise prices for medical technologies in foreign countries, and instead, see a trade framework that encourages rather than discourages state biomedical R&D subsidies, as well as global agreements to share access to government funded research across borders, either as a global public good, or in some cases, between countries that will share rights with the United States.

In the response to questions from USTR:

Global Public Goods

KEI is among those supporting a global public goods approach, as regards manufacturing know-how and rights in inventions and data. Products are going to be in short supply for some time, and unequal access (as measured by timing of access) is inevitable, no matter what policy makers do. When money and power is unequal, there will also be unfairness. But while products are rival in consumption, the knowledge of how to manufacture a drug or vaccine could be shared openly and globally without depriving anyone of a product. The more widely shared the manufacturing knowledge, the faster will be vaccinations, and additional competition will lower prices. With the virus mutating, the speed at which vaccines are available is important.

The past emphasis on privatizing manufacturing know-how, even when research and development has been funded by government grants and research contracts, runs counter to the public goods approach. But governments can use a variety of measures, including coercion and incentives and subsidies, to move manufacturing know-how into the public domain. Government buyouts of proprietary manufacturing know-how are one policy option that is always on the table.

WTO Role

On March, 1, 2021, KEI wrote to Dr. Ngozi Okonjo-Iweala, the new Director-General of the World Trade Organization (WTO) regarding the WTO's COVID-19 response. KEI called on the WTO to do the following:

- Support Members opting in under the TRIPS Agreement Article 31bis;
- Provide model patent law exceptions to address pandemics or other emergencies;

- Establish modalities to facilitate the sharing of manufacturing know-how in a pandemic; and
- Establish modalities to consider the notion of a WTO agreement on the supply of public goods.

The last recommendation was as follows:

> **WTO Agreement on the Supply of Public Goods.** Establish modalities to consider the notion of a WTO agreement on the supply of public goods. As you rightly noted in your inaugural press conference on February 15, 2021, the pandemic is part of the problem of the global commons. The WTO has been asked to consider a new agreement, based in some ways on the GATS, to create voluntary offers of binding commitments to supply public goods. The COVID-19 crisis would have benefited if such an agreement had been in place.

Links

- The Use and Abuse of the Phrase "Global Public Good", https://www.globalpolicyjournal.com/blog/28/09/2020/use-and-abuse-phrase-global-public-good

2022. Docket ID: USTR-2021-0021, 2022 Special 301

- https://www.regulations.gov/document/USTR-2021-0021-0001
    - https://www.regulations.gov/comment/USTR-2021-0021-0044

The COVID crisis illustrates the importance of sharing manufacturing know-how and access to biological resources and providing global access to countermeasures.

Trade policies that promote the hoarding of intellectual property and manufacturing know-how are particularly harmful in a global public health crisis like the COVID pandemic.

There is no policy to address the trade related aspects of public goods.

The COVID 19 pandemic illustrates the weakness of trade policies as they relate to the importance of inducing the supply of global public goods. The U.S. is a major supplier of global public goods, and would benefit from measures to ensure greater global cooperation and sharing of the costs of supplying global public goods.

The United States is among the countries facing a crisis of providing timely and universal access to new biomedical inventions. Trade policies should be consistent with future efforts to delink biomedical R&D incentives from monopolies and high prices.

In order to delink R&D incentives from legal monopolies and high prices and to overcome patent thickets in new technologies, governments should have the freedom to refashion the patent system from one of strong exclusive rights to systems of liability rules, eliminating exclusive rights on products to be replaced with claims on market entry rewards and other innovation inducement incentives.

Transparency has trade related aspects.

The WHO resolution WHA72.8, "Improving the transparency of markets for medicines, vaccines, and other health products," sets out global norms to make the markets for medicines, vaccines, and other health products more transparent. There are trade related aspects of such initiatives. Every country wants to have information about the pharmaceutical value chain, but often have domestic demands to provide secrecy for a wide range of topics such as clinical trial costs, licensing arrangements, patent landscapes, prices and quantities of products sold, manufacturing methods and clinical trial outcomes. Trade policy should ensure that when transparency benefits everyone, governments cooperate to make transparency happen. There is also a need to work towards standards for sharing information about the pharmaceutical value chain, so that disclosures are more useful. One of the more appalling failures regarding transparency has been the COVID pandemic, where contracts, licensing terms, and prices and procurement agreements were often secret.

2022. Docket ID: USTR-2021-0021, Submission Trade related aspects of public goods

- https://www.regulations.gov/document/USTR-2021-0021-0001
    - https://www.regulations.gov/comment/USTR-2021-0021-0120

Trade related aspects of public goods

Introduction

One can think of the economy as including both public and private goods, each valued by society. There are trade related aspects of both, but also a significant asymmetry on the extent that the global trade agreements deal with them. In short, private goods get most of the attention, and public goods are relatively neglected.

Definitions of public goods

Before going further, a few words about definitions. Governments and other non-profit organizations play a significant role in providing a diverse set of goods and services, subsidies,

and incentives, and income transfers. No one would imagine a government restricting its role to goods which are both non-rival in consumption and non-excludable, Paul Samuelson's elegant 1954 [1] and 1955 [2] discussions of "pure" public goods notwithstanding.

Public goods are not limited to Paul Samuelson's well known and often misunderstood "extreme polar case." Samuelson himself noted that "the legitimate functions of government" include, in his view, such things as redistributions of incomes, paternalistic policies, situations "where 'atomistic competition' is not realistic" and "Myriad 'generalized economic and diseconomy' situations where private pecuniary interest can be expected to deviate from social interests." [2]

Writing in the Financial Times, in 2012, Martin Wolf said "The history of civilization is a history of public goods," [4] and this is a useful reminder of their importance.

For trade policy, public goods are largely ignored, even though they are as important globally as they are domestically.

The COVID 19 pandemic saw the desperate need to develop safe and effective vaccines, drugs and diagnostic tests, and to make them available globally. The Russian invasion of Ukraine has among its many elements the need to provide shelter and care for millions of refugees.

Discussions of global public goods include such topics as:

1. The need to patrol the high seas to protect against piracy,
2. mobilization of resources and measures to respond to natural disasters,
3. measures to reduce carbon emissions to combat global warming,
4. protecting wilderness areas and endangered species,
5. development of new drugs to overcome antimicrobial resistance to existing antibiotics,
6. open source distance education tools,
7. digital libraries and archives for education and research,
8. creating DAISY (the Digital Accessible Information System) format versions of books for persons who are blind or have other disabilities,
9. transparency of corporate activities,
10. disarmament and arms control,
11. research and development and other measures to control locust damage to crops, and
12. funding of basic science in all fields.

More examples are discussed below.

The public's need for public goods, local, regional and global, are enormous.

In the context of trade policy, there are an impressive array of agreements regulating the rights of investors, protecting the holders of patents, copyrights and trademarks, and measures to reduce tariffs and non-tariff barriers for trade in private goods. The USMCA, for example, includes a preamble, 34 chapters, 13 Agreement Annexes and 16 side letters. The WTO has

the GATT, the GATS, the TRIPS, and agreements on government procurement and civil aircraft. Neither the USMCA or the WTO have a chapter or agreement on the supply of public goods, although these and other agreements may even sanction some government funded research and development activities.

The United States Trade Representative (USTR) and the Directorate General for Trade of the European Commission (DG-Trade) both maintain lists of countries that do not adequately protect intellectual property rights. The new European Commission's "Report on the protection and enforcement of intellectual property rights in third countries" Brussels, SWD(2021), is the EU version of USTR's Special 301 list.

KEI has been involved in a series of proposals to enhance global cooperation to enhance the supply of public goods. A common challenge is the need to overcome the free rider problems when mobilizing resources or committing to policies that have cross border benefits.

One important negotiation in 2022 is the WHO consideration of a possible treaty for pandemic preparedness and response. Among the many areas where the WHO pandemic treaty could support the supply of global public goods are possible norms in R&D funding contracts to address access to inventions, know-how, data and biologic resources, agreements to share sequences of pathogens, enhanced public sector funding of countermeasures, cooperation among governments to provide public sector funding to support independent clinical trials to evaluate drugs or vaccines, and global cooperation on the funding of patent and know-how buyouts [6] or new incentives to invest in R&D that require open licensing of intellectual property, data and know-how.

Earlier KEI has worked with others to propose an agreement within the WTO on the supply of public goods. To this end, an experts meeting was held from March, 28, 2015 to March 29, 2015 at the Heinrich Böll Foundation (HBF) in Berlin, to consider a text for a World Trade Organization (WTO) Agreement for the Supply of Social/Public Goods (SGA). [9] Eighteen experts from eleven countries attended, and provided specific recommendations including possible text for an agreement, modeled partly on the WTO agreement on trade in services (the GATS), for WTO members to make voluntary binding commitments to supply public goods. The 29 page report from that meeting includes as its Annex A the Draft proposal. The definition of public/social goods is included here as an annex.

In earlier years, the USTR has engaged and offered feedback on proposals for a WHO biomedical R&D treaty and the proposed WTO Agreement on the Supply of Public Goods.

Suggestion

USTR is invited to have a meeting with KEI and others interested in this topic, to discuss the trade related issues for public goods in more detail.

Selected References

[1] 1954. Paul A. Samuelson, The Pure Theory of Public Expenditure,The Review of Economics and Statistics,Vol. 36, No 4 (Nov., 1954), pp. 387389.

[2] 1955. Paul Samuelson, Diagrammatic Exposition of a Theory of Public Expenditure, The Review of Economics and Statistics, Vol. 37, No 4 (Nov., 1955), pp. 350–356

[3] 1958. Paul Samuelson, Aspects of Public Expenditure Theories. The Review of Economics and Statistics, Vol 40, No 4 (Nov 1958), pp. 332–338.

[4] 2012. Martin Wolf. “The world’s hunger for public goods: It is unclear whether today’s states can — or will be allowed to — provide what we now demand,” Financial Times, January 24, 2012.

[5] 2020. James Love. The Use and Abuse of the Phrase “Global Public Good,” Developing Economics, July 16, 2020.

[6] 2021. James Love, Buying Know-How to Scale Vaccine Manufacturing. Medium. March 20, 2021.

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ANNEX, the Definition of public/social goods from the 2015 Berlin text.

1. For the purposes of this Agreement, public/social goods are defined as:

a. goods and services that are directly supplied, financed, subsidized, mandated or the supply is otherwise induced for the benefit of the public, and is limited to

b. goods (or services) for which consumption is not decided by the individual consumer but by the society to address a social purpose or public interest.

c. The definition of public/social goods shall be interpreted broadly to be inclusive of goods and services provided on a non-commercial basis by governments and intergovernmental organizations.

d. The definition public/social goods includes but is not limited to goods and services that are non-excludable and non-rivalrous in consumption.

e. The definition of public/social goods shall include goods and services relating to the production of and access to knowledge, the provision of security, humanitarian services, public health programs, the protection and enhancement of the environment, programs to promote development and alleviate poverty, and other purposes.

2. For the purposes of this Agreement, international public/social goods are defined as public/social goods that are directly or indirectly supplied by one Member for the benefit of the public in the territory of any other Member.

2023. Docket Number USTR-2022-0016, Special 301

- https://www.regulations.gov/document/USTR-2022-0016-0001
    - https://www.regulations.gov/comment/USTR-2022-0016-0038

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.

2024. Docket ID: USTR–2023–0014-0001

- https://www.regulations.gov/document/USTR-2023-0014-0001
    - https://www.regulations.gov/comment/USTR-2023-0014-0057
    - https://www.regulations.gov/comment/USTR-2023-0014-0080

In the initial comments:

Trade related aspects of funding biomedical R&D should focus less on intellectual property norms and more on the direct and indirect funding of research by the public sector.

During the COVID 19 pandemic, the United States public sector spending on biomedical R&D was enormous, both in levels and relative to other high income countries, when considered as a percentage of per capita income. The same is true for U.S. public sector spending on R&D relating to cancer, HIV/AIDS and countless other diseases. At times, the U.S. acquires rights in such research, such as the Bayh-Dole march in and government use rights in inventions funded by the federal government, or rights in clinical trial data. Other governments may also acquire rights in inventions, data, cell lines or know-how they fund.

The trade related aspects of biomedical R&D include many topics, including the levels and character of public sector funding, the rights that governments acquire, and transparency of the value chain. USTR needs to develop policy objectives for global public sector funding of biomedical R&D.

This is particularly important as the United States and indeed the entire world is experiencing a seismic shift in the age of our population.

In 2000, the US Bureau of the Census estimated that 11.9 percent of the U.S. population was 65 years and older, but things have changed, and are changing, a lot.

Year	Percent of population 65 or older
2000	11.9
2010	12.7
2020	16.8
2023	17.3

2030 est	20.6
2040 est	22.0
2050 est	22.8

For estimates:
https://www2.census.gov/programs-surveys/popproj/tables/2023/2023-summary-tables/np2023-t2.xlsx

Among other things, these changes mean there will be enormous challenges of providing access to biomedical innovations. The notion that biomedical inventions should continue to be given bullet-proof multi-decade monopolies on new products needs a reality check. Someone at USTR needs to start doing some math.

By taking a more balanced approach in the trade related aspects of biomedical R&D, it becomes more feasible to consider innovations in business models that are consistent with universal access, fiscal discipline and innovation. The spending in Europe or other high income regions on public sector biomedical R&D is important, and arguably more important than the prices paid for products. Going forward, far more attention needs to be given to the trade related aspects of funding biomedical R&D, not just the granting of patents on inventions.

Trade related aspects of public goods continue to be a neglected area of trade policy.

Climate change, refugee assistance, pandemic preparedness and response, global poverty reduction, famine relief, policing poverty on the high seas, open sourced biomedical research, locus control, and countless other global challenges are costly to address. KEi has proposed a WTO agreement on the supply of public goods that is based upon a schedule that enables WTO members to voluntarily make binding commitments to provide or resource heterogeneous public goods.

Even without a new WTO schedule for public goods, USTR can and should develop a policy on the trade related aspects of the supply of public goods.

In the post hearing comments:

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.

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 used nventions, 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.