



January 30, 2024

To: Claire Avery-Page, Director for Innovation and Intellectual Property, USTR  
From: James Love, Knowledge Ecology International (KEI)

Via: Special301@ustr.eop.gov

Re: KEI Comments and Request to Testify at Public Hearing Regarding the 2024 USTR Special 301 Review as noticed in the Federal Register, 88 FR 84869, Docket: USTR–2023–0014

KEI requests the opportunity to testify at the public hearing on February 21, 2024, and also provides the following comments for this year’s Special 301 list.

1. USTR policy 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 2001 the WTO adopted a declaration that stated the TRIPS agreement “can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.” The Declaration also reaffirmed “the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.”

DOHA WTO MINISTERIAL 2001: TRIPS  
WT/MIN(01)/DEC/2  
20 November 2001

Declaration on the TRIPS agreement and public health  
Adopted on 14 November 2001

4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

The United States government has frequently cited and endorsed this declaration or similar language in a plethora of UN resolutions and bilateral or regional trade agreements, but in the past, USTR has also 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.

2. USTR should address the threats to two important copyright exceptions, the quotation right and the news of the day exception.

As KEI has noted in the past, important trading partners of the U.S. have sought to impose related or ancillary rights or fees to use quotations or the news of the day. Both news of the day and quotations are mandatory exceptions in the Berne Convention.

**Berne Convention for the Protection of Literary and Artistic Works states:**

**Article 2, Protected works**

(8) The protection of this Convention shall not apply to news of the day or to miscellaneous facts having the character of mere items of press information.

**Article 10, Certain Free Uses of Works:**

(1) It shall be permissible to make quotations from a work which has already been lawfully made available to the public, provided that their making is compatible with fair practice, and their extent does not exceed that justified by the purpose, including quotations from newspaper articles and periodicals in the form of press summaries.

Two areas in general where these exceptions are being attacked are (a) to transfer income from companies providing Internet services such as search or social media to news organizations, and (b) to create commercial rights in the use of quotations or reported news of the day by generative artificial intelligence services.

KEI appreciates the intentions of governments that have attacked the quotation and news of the day exceptions in copyright law. There is a crisis in funding journalism, and a sense that there is unfair profiting from the work of others. That said, we are concerned and opposed to a remedy that undermines the quotation or news of the day exceptions. Rights or fees attached quotations or news of the day create harmful and potentially dangerous limits on access to knowledge.

KEI is not opposed to governments taxing technology companies, including such measures as taxes tied to profits, revenues or market valuation. What we specifically object to are taxes, fees or rights associated with using quotations or news of the day.

In 2022 the US Copyright Office issued “Copyright Protections for Publishers: A Report of the Register of Copyright.”<sup>1</sup>

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<sup>1</sup> <https://www.copyright.gov/policy/publishersprotections/202206-Publishers-Protections-Study.pdf>

Included in the report is a June 30, 2022 letter to Senators Leahy, Tillis, Hirono, Cornyn, Klobuchar, and Coons, by Shira Perlmutter, the Register of Copyrights and Director of the U.S. Copyright Office. Her letter included these passages:

Following a series of hearings on reforms to digital copyright law, you requested that the Copyright Office undertake a study to assess the viability of establishing "ancillary copyright" protections for press publishers, similar to protections now being implemented in Europe, that would require online news aggregators to pay publishers for excerpts of content they provide for others to view.

...

After carefully evaluating the information provided, the Office does not recommend adopting additional copyright-like rights for press publishers in the United States. We have concluded that ancillary copyright protections have not been shown to be necessary in light of publishers' existing rights, and would likely be ineffective so long as publishers depend on news aggregators for discoverability. Moreover, to the extent that any ancillary copyright protections would lack traditional copyright limitations and exceptions, they would raise significant policy and Constitutional concerns. . .

The Executive Summary of that report concludes with this paragraph:

The Office recognizes that adequate funding for journalism may currently be at risk, and that there are implications for the press's essential role in our system of government. But the challenges for press publishers do not appear to be copyright-specific. It has not been established that any shortcomings in copyright law pose an obstacle to incentivizing journalism or that new copyright-like protections would solve the problems that press publishers face.

USTR is often tasked with promoting US norms for intellectual property rights globally. USTR should defend the quotation or news of the day exceptions to copyright, and USTR should oppose the global adoption of ancillary copyright regimes or other laws that place liabilities on links to news stories.

3. Text and data mining exceptions are important for the development of article intelligence service, and under threat in some countries.

The European Directive on text and data mining provides a robust text and data mining exception for non-commercial researchers, but permits an opt-out for commercial uses.

The public's use of AI will not depend entirely on non-commercial services.

We can fruitfully debate the appropriateness of an opt-out of data for training AI for some purposes, particularly certain cultural works such as music and visual art. But for many other areas, an

opt-out will inappropriately degrade important services and present risks of monopolistic outcomes or dangerously flawed services.

Among the several areas where an opt-out will be particularly harmful are those relating to data on development of new biomedical products, legal services and safety, to name a few.

Some of these issues are addressed in the attached article by James Love, “We Need Smart Intellectual Property Laws for Artificial Intelligence “One-size-fits-all” regulation will sideline medical and research benefits promised by the advent of artificial intelligence,” *Scientific American*, August 7, 2023.

“Differences between who owns what matter. It’s one thing to have the copyright holder of a popular music recording opt out of a database; it’s another if an important scientific paper is left out over licensing disputes. When AI is used in hospitals and in gene therapy, do you really want to exclude relevant information from the training database?”

A variety of AI services will be developed, with enormous potential for benefits and risks, and society will have to manage both, but governments should not be enacting restrictive rules regarding the uses of data. In some fields, like the law or medicine, you want the AI services to know everything possible. 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.

4. 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.

5. 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.

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