

2021 Special 301 Review

USTR-2020-0041-0001

Comments of Knowledge Ecology International (KEI)

To: Daniel Lee, Assistant U.S. Trade Representative for Innovation and Intellectual Property (Acting), Office of the United States Trade Representative.

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KEI is a frequent commenter on the USTR Special 301 review. Our comments will address an issue concerning the procedures, as well as the policies the USTR is seeking to advance.

1. Allow the public to respond to industry requests for trade pressures

The Special 301 submissions are primarily from rights holders and their representatives, and contain assertions of facts and U.S. self interest. Until we see what the industry is asking of the USTR, we can only speculate on what misleading or erroneous data or bad policy proposals that may be advanced.

The hearings have provided some opportunities to respond to the initial industry objections, and there will be none this year.

We are among those who want the USTR to provide a more formal way to respond in writing to the initial industry comments. USTR can issue another FR notice, or extend the comment period so that we can respond to comments not yet filed by industry.

2. Objectives of the Special 301 review should be re-evaluated to reflect changes over time.

Over time, the Special 301 review can benefit from periodic modifications of context, process and objectives to reflect changing circumstances and learning from past experiences.

Since the Special 301 list was first published in 1989, the world has changed.

In 1995, the WTO and the TRIPS Agreement came into force, creating a set of global rules for the minimum protection of intellectual property rights, as well as a system of resolving disputes over those rules.

In 1996 WIPO adopted two new treaties, the WIPO Copyright Treaty (WCT) and the WIPO Performances and Phonograms Treaty (WPPT). Today there are 107 contracting parties of the WPPT and 108 members of the WCT. The WIPO Beijing Treaty on Audiovisual Performances was adopted in 2012, and currently has 38 contracting parties.

Countless bilateral and regional trade agreements that have chapters on intellectual property have been signed, including not only those with the United States as a partner, but those with members that have a strong preference for high standards for intellectual property protection, such as the European Union, Switzerland, Japan and Australia.

There have also been a series of agreements that seek to create protections for the public. In 1999 the World Health Organization adopted the first of several agreements that provided more consideration of health. [WHA52.19](#), The WHO Revised drug strategy, states that “there are trade issues which require a public health perspective,” and urged WHO Member States “to ensure that public health interests are paramount in pharmaceutical and health policies.” The United States, under President Bill Clinton, supported this language.

In 2000, President Clinton issued [Executive Order 13155](#)—Access to HIV/AIDS Pharmaceuticals and Medical Technologies, which stated:

Section 1. Policy. (a) In administering sections 301–310 of the Trade Act of 1974, the United States shall not seek, through negotiation or otherwise, the revocation or revision of any intellectual property law or policy of a beneficiary sub-Saharan African country, as determined by the President, that regulates HIV/AIDS pharmaceuticals or medical technologies if the law or policy of the country:

(1) promotes access to HIV/AIDS pharmaceuticals or medical technologies for affected populations in that country; and

(2) provides adequate and effective intellectual property protection consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) referred to in section 101(d)(15) of the Uruguay Round Agreements Act (19 U.S.C. 3511(d)(15)).

In 2001, the World Trade Organization (WTO) adopted the Doha Declaration on the TRIPS agreement and public health, [WT/MIN\(01\)/DEC/2](#), which stated “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 May 2007, USTR reached a bipartisan consensus on trade with members of Congress of trade that include a number of walk-backs in free trade agreements on matters concerning access to medicine.

Also in 2007, the World Intellectual Property Organization (WIPO) adopted a development agenda, the sought to create balance, and promote access to knowledge.

In 2013, the WIPO Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired or Otherwise Print Disabled was adopted, and today has 78 contracting parties. The treaty mandates a minimum set of exceptions to rights, to facilitate access.

The United States and the world have also seen dramatic changes in information and medical technologies and business models.

Among our more dominant industries globally are digital services such as Internet search engines or platforms for publishing and sharing user generated content, services that cannot function without sufficient flexibility and exceptions to rights in copyright laws. Attempts in Europe to create rights in snippets of text and information from news articles create conflicts with the mandatory exceptions in Articles 2(8) and 10(1) of the Berne.

Following a stream of mergers, a growing number of scientific journals and textbooks were owned by non-US companies, and today many disputes over education exceptions pit US educators and graduate students against foreign owned publishers.

Patent thickets became a growing problem for manufacturers and software publishers. In 2006, the U.S. Supreme Court issued an opinion in *eBay Inc. v. MercExchange, L.L.C.* that effectively allowed every patent infringement case to consider a compulsory license as an alternative to an injunction. Beginning in 2011, China emerged as the country with the largest number of patent applications. In 2013, USTR overrode a USITC exclusion order and cease and desist order for Apple Inc. smartphones and tablet computers that infringed a U.S. patent owned by Samsung Electronics.

The current COVID-19 pandemic presents the entire world with many challenges including those relating to intellectual property. During periods when schools and libraries are closed, having access to controlled digital lending over the Internet is essential. There is a massive need to scale the manufacturing of diagnostic tests, therapeutics and vaccines, and this includes the need for access to rights in inventions, designs and data, as well as access to manufacturing know-how.

Today the costs of new medical technologies, including diagnostic tests, drugs, vaccines, and cell and gene therapies, have become a significant barrier to access and affordability, and the cause of shameful disparities of access globally.

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 are will share share rights with the United States.

The USTR should not advance norms or discourage practices that are important for reforms that delink biomedical R&D incentives from prices or exclusive rights in products or services.

USTR should not prevent any country from creating patent exceptions for gene and cell therapies that are the types of exceptions allowed under Article 27(3)(a) of the TRIPS agreement or the provisions for limiting remedies to infringement found in 35 USC § 287.

USTR should not enter into, maintain or enforce any bilateral, regional, plurilateral or multilateral agreements on damages for infringement that exceed the standards set out in the TRIPS agreement. Flexibility in the implementation of Article 44 of the TRIPS agreement is necessary to address the Orphan Works problem in the United States and to create liability rules for cases where exclusive rights are harmful but remuneration to inventors or authors is in the public interest.

The United States should cease its intervention in South African negotiations over copyright reform, and end all opposition to compulsory licenses for patented inventions that satisfy the WTO TRIPS requirements.

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