



February 8, 2018

Sung Chang,  
Director for Innovation and Intellectual Property  
Office of US Trade Representative  
[special301@ustr.eop.gov](mailto:special301@ustr.eop.gov)

Regarding Docket No. USTR-2017-0024, Special 301 list

Dear Sung Chang,

Knowledge Ecology International (KEI) requests the opportunity to testify at the hearing on the Special 301 list on February 27, 2018. We also provide the following comments.

KEI has testified before the Office of the United States Trade Representative (USTR) Special 301 Subcommittee many times and also commented on the list as well as its uses. We maintain a web page that includes all of the Special 301 Reports issued from 1989 to 2017, as well as links to comments by KEI and other parties.[1]

For every year from 1989 to 2017, USTR placed an average of 41 countries on either the Watch List (WL) or the Priority Watch List (PWL), including an average of 11 countries on the Priority Watch List.

Thus far the USTR has published 29 Special 301 lists. The criteria for being included on the list is notoriously vague. Canada has appeared on list 27 times, despite having high legal standards and lower rates of copyright infringement than the United States. Several other countries are on the list almost every year, without much to distinguish their policies and practices from their less frequently listed neighbors. One factor that seems to be highly significant to inclusion on the list is how large is the GDP or GNI per capita. More to the point, this is a list driven by lobbyists for the right holders, many of whom are former employees of USTR, other federal agencies, or Congress.

The Special 301 committee is essentially tasked with editing the submissions by PhRMA, BIO, MPAA, the International Intellectual Property Alliance (IIPA), and others right holder lobbies, and after consultation with the Department of State and other agencies, then punishing countries that do not abide by USTR's wishes for changes in their domestic practices and laws.

It would more interesting and useful for USTR to develop and outline the policies and norms that it wants to promote through the Special 301 list and its follow-on enforcement actions, without having every talking point framed by PhRMA, IIPA members and other right holder groups.

This is particularly useful today when the entire world is now seeking ways to deal with high and unaffordable drug prices, and after the United States and the whole world has benefited enormously from legitimate exceptions to copyright that expand access to knowledge.

There are many technically complex issues addressed in the Special 301 list each year regarding the granting of, exceptions to, and enforcement of patents on drugs and other medical technologies, as well as the appropriate policies to protect test data for new drugs and vaccines, policies on pricing and reimbursement of new medicines. The USTR has generally acknowledged that countries “should...promote access to medicine for all,” and then has punished them whenever they take steps to improve access or affordability. This includes countries with per capita incomes far below that of the United States.

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.

<b>Year</b>	<b>Population</b>	<b>Percent of Total Population</b>
1990	31.2 million	12.5%
2000	35.0 million	12%
2010	40.3 million	13%
2020 <i>(projected)</i>	56 million	17%
2030 <i>(projected)</i>	74 million	21%
2040 <i>(projected)</i>	82 million	22%
2050 <i>(projected)</i>	88 million	22%
2060 <i>(projected)</i>	98 million	24%

*Source: Population figures and projections from U.S. Census Bureau.*

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.

On the copyright side, the United States should continue to advocate that foreign governments adopt balance in the copyright system so that law abiding companies can provide services that require fair use of copyrighted works. The United States should also address the global crisis in orphaned works, an issue made worse by extended copyright terms and restrictions on the requirements to register works (which is not required by the Rome Convention).

The USTR needs to oppose efforts by the World Intellectual Property Organization to create a new layer of rights for broadcasters that will complicate access to works, and only benefit corporate owners who do not create, own or license works, but merely transmit them.

Similarly, the United States should expand its advocacy efforts to push back against foreign “ancillary copyright” regimes, which seek to undermine the mandatory exceptions in the Berne Convention for quotations and the news of the day.

Sincerely,



James Love



Claire Cassedy

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[1] <https://keionline.org/ustr/special301>