KEI submission to Docket Number USTR20140025, "2015 Special 301 Review"

TO: Susan Wilson, Director for Intellectual Property and Innovation,
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The following is a request by Knowledge Ecology International to testify at the hearing on the 2015 Special 301 review.

The annual Special 301 process begins with the assumption that the most important challenge is to identify and rank governments on the basis of how much pressure is justified to accommodate the demands of various copyright, patent holder and pharmaceutical companies. The submissions by the right holders are relatively unburdened with obligations justify the policies they promote - only to identify a well articulated wish list of policy changes, and to spell the names of the countries.

Often USTR appears to take as a given that right-holder lobby groups have interests consistent with the public interest, or at least, the interests of US citizens as a whole. Suggesting the contrary is evidence that access to knowledge and knowledge goods is more important to the U.S. economy. We are also concerned about fairness and the welfare of persons with lower incomes.

Our submission will briefly touch on some of the evidence to support our view that the USTR trade policy is harming the national interest, slowing economic growth, undermining accountability, and contributing to unfair outcomes as regards access to medical technologies. We will begin with a discussion regarding medical technologies, and close with comments about copyright policy.

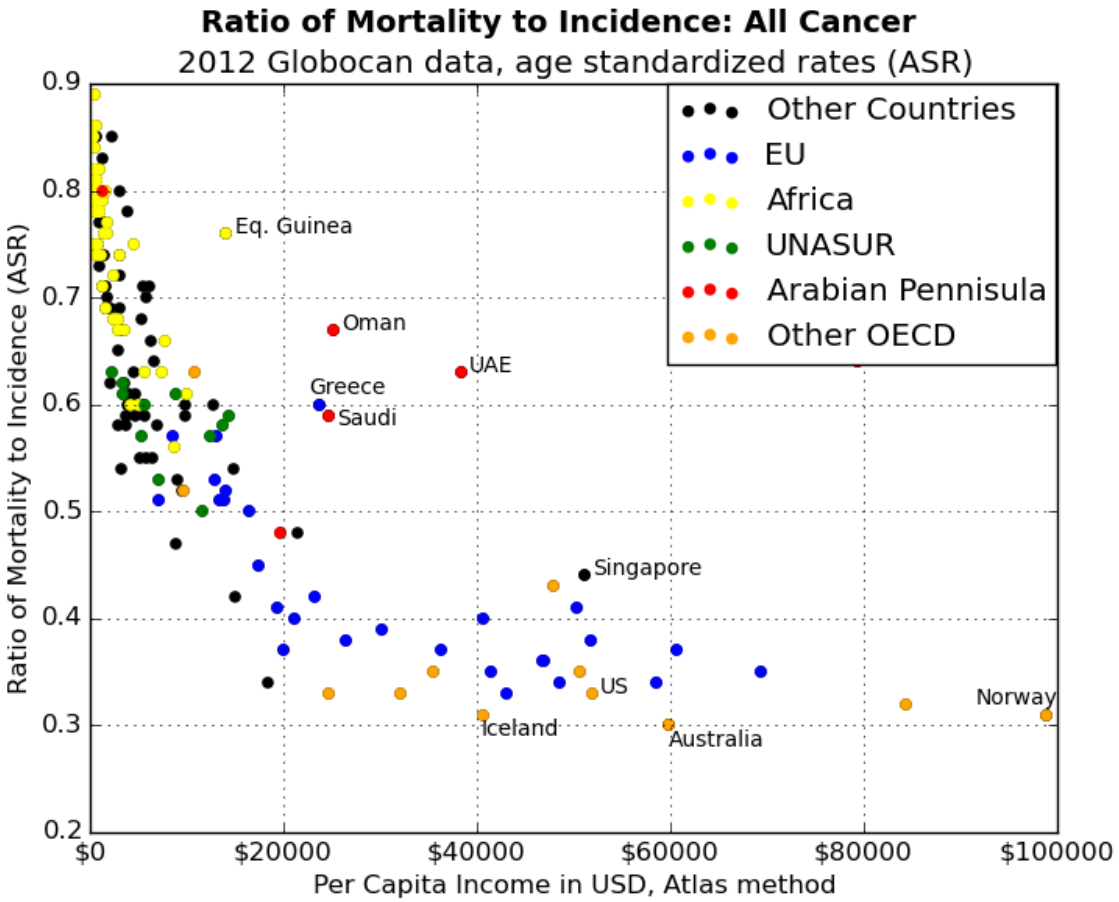
Medical Technologies

USTR's trade advocacy for medical technologies often focuses on patents, exclusive rights in test data, and government policies to control prices and/or reimbursement of costs. In recent years there has been a new emphasis on confidential business information and trade secrets. Collectively, these efforts are designed to expand the legal monopolies for the sale of new drugs and medical devices including diagnostic tests, and to undermine efforts to curb high prices and/or make products more affordable. There is also a conflict between the regulation and evaluation of new medicines, and the secrecy of clinical trial data.

While US trade policies are directed at both high and low income countries, the impact of trade policies on prices of goods is stronger and more consequential for lower income countries.

At present, there is great inequality in access to new drugs, vaccines, diagnostic tests and other medical technologies, also considerable inequality in terms of outcomes. Not all of the unequal outcomes are a consequences of intellectual property rights, but some are.

The following graphs illustrate a particular metric for unequal comes, the ratio of mortality to incidence, as measured on the Y axis, compared to per capita incomes, as measured on the X axis, for cancer. The data, from the World Health Organization for cancer and from the World Bank for incomes, shows a predictable negative correlation between average incomes and the probability of dying of cancer.



In the past five years (2010 to 2014), the FDA has approved an astonishing 41 new molecular entities for the treatment of cancer. Many of these new drugs are effective for specific types of cancer, and some are true game changing treatments. Thirteen of the 41 new cancer

drugs were approved as biologic products, or 32 percent of the total. In 2014, 10 new cancer drugs were approved, of which 5, or 50 percent, were approved as biologic products.

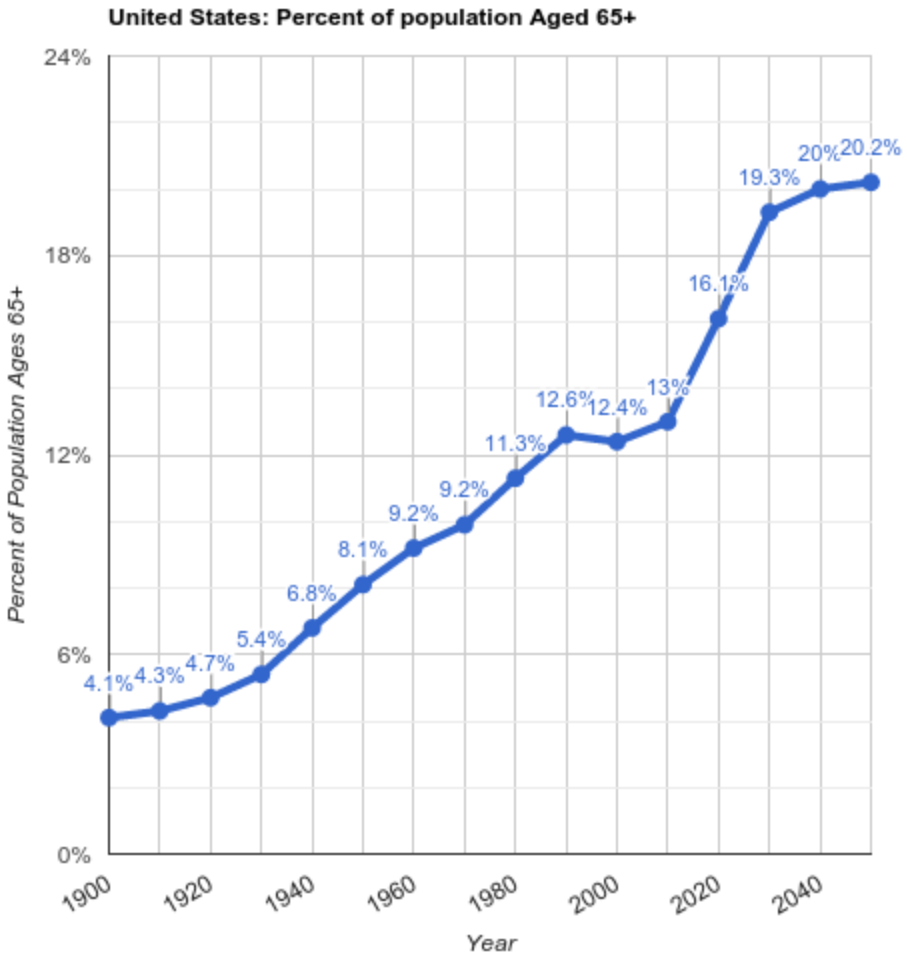
Of the 41 new cancer drugs approved from 2010 to 2014, 27, or 66 percent, were approved as Orphan Drugs, qualifying for a 50 percent US tax credit subsidy for clinical trials. In 2014, 9 of 10 new cancer drugs qualified for the Orphan Drug Tax Credit. The number of patients in clinical trials was considerably smaller for cancer drugs. For the 5 year period, the average number of patients in trials for cancer drugs was less than 30 percent of the number of patients in trials for non-cancer drugs. The combination of a 50 percent tax credit and the small number of patients in trials are among the factors that suggest there are lower costs for testing cancer drugs than for non-cancer drugs.

High prices have limited access to these new drugs. As documented extensively in our 2014 Special 301 submission, and in countless articles in academic and policy journals and in the news media, the impact of high prices range from tightening of eligibility requirements and higher co-payments to a complete lack of access, depending upon the country and the status of the patients. In high income countries, the access barriers are becoming harder to ignore and predictably worse over time, and in so called middle and low income countries, disparities in access are severe.

We are regularly contacted by patients seeking access to high priced cancer drugs. One possibility is for a country to break the patent monopoly and to import a less expensive version from a generic or biosimilar manufacturer, but his option is increasingly becoming impossible, due to the extensive efforts by USTR and other US federal agencies to cut off the supply of low cost drugs. The problems are particularly acute for biologic drugs, which may require overcoming long periods of test data exclusivity, trade secrets on the know how to make the drugs and complex regulatory barriers to entry, in addition to the patent issues. If USTR continues to make things worse, the consequences are obvious and deplorable -- cancer patients will have unequal access to new drugs.

The United States has an aging population.

Today, perhaps 14 percent of the US population is 65 or older. By 2020, that percentage is expected to grow to 16.1 percent, and to 19.3 percent by 2030. Health care outlays are higher for older populations. The targets of US Special 301 trade pressures often are developing countries with much younger populations. To the extent that USTR drives the prices of cancer drugs higher, it will have a significant impact on taxpayers, employers and patients in the United States, and make US employers less competitive in world markets.



Source: The Administration for Community Living (ACL), U.S. Department of Health and Human Services.

The majority of new drugs are foreign owned.

There were 160 new molecular entities approved by the US FDA from 2010 to 2014. Of these, 76, or 46 percent, were registered by US firms, and 84, or 53 percent were registered by foreign firms. In the area of cancer, two Swiss firms, Roche and Novartis, one a part owner of the other, have the largest share of revenue for cancer. For 2013, the respective shares of the global market for oncology drugs was reported at 34.3 percent for Roche, and 10.8 percent for Novartis, or 45.1 percent between the two Swiss firms.

Firms that are thought of as U.S. firms often have more employees overseas than in the United States. For example, in 2013 Congressional testimony, Pfizer said that two thirds of its

workforce was located outside of the United States.[1] Johnson and Johnson reported that in 2012, 63 percent of its workforce was located outside of North America.[2]

The Information Economy and Copyright Policy

Software publishers are an important industry, but overall, they are a relatively small source of employment for computer programmers and scientists. According to the Bureau of Labor Statistics (BLS), just 9.6 percent of developers of software applications, 6.6 percent of computer programmers, 5 percent of software developers for systems software, and 2.7 percent of web developers are employed by software publishers. For database and network administrators, the percentages are even lower.

Occupation Code	Occupation title	Employment (All) May 2013	Employment NAICS 511200 - Software Publishers, May 2013	Employment, Other, May 2013	Percent, Software publishers	Percent other
15-1111	Computer and Information Research Scientists	24,380	2,860	21,520	11.7%	88.3%
15-1131	Computer Programmers	312,340	20,630	291,710	6.6%	93.4%
15-1132	Software Developers, Applications	643,830	61,750	582,080	9.6%	90.4%
15-1133	Software Developers, Systems Software	373,510	18,750	354,760	5.0%	95.0%
15-1134	Web Developers	112,820	3,040	109,780	2.7%	97.3%
15-1141	Database Administrators	114,910	2360	112,550	2.1%	97.9%

[1] Roy F. Waldron, Chief Intellectual Property Counsel, Pfizer, Inc., Before the United States House of Representatives Energy & Commerce Committee Subcommittee on Commerce, Manufacturing and Trade June 27, 2013. " Pfizer employs more than 90,000 individuals worldwide, including over 30,000 people in the United States"

[2] http://www.jnj.com/caring/citizenship-sustainability/strategic-framework/Workforce-Statistics

15-1142	Network and Computer Systems Administrators	362,310	4590	357,720	1.3%	98.7%
15-1143	Computer Network Architects	141,270	1840	139,430	1.3%	98.7%
15-1150	Computer Support Specialists	706,360	21720	684,640	3.1%	96.9%
15-1151	Computer User Support Specialists	541,250	18880	522,370	3.5%	96.5%
15-1152	Computer Network Support Specialists	165,100	2830	162,270	1.7%	98.3%
15-1199	Computer Occupations, All Other	196,280	3630	192,650	1.8%	98.2%

The most dynamic sectors of the information economy are services that are customized for businesses, governments and others using free software platforms.

Perhaps the industry with the most outsized influence compared to employment is the sound recording industry. BLS reports just 15.8 thousand employees for sector NAICS 512200 - Sound Recording Industries, in 2013.[3] The Motion Picture industry is larger, but more than one third of the Motion Picture industry is employed to distribute pictures in theaters, and involves generally low wage jobs, such as selling popcorn at theaters.[4]

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 T-DM1, an excessively priced breast cancer drug, the US government should be seeking

[3] http://www.bls.gov/oes/current/naics4_512200.htm
[4] http://www.bls.gov/web/empsit/ceseeb1a.htm.

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.

Access to knowledge as Trade Policy

A sustainable economy should be designed to make consumers better off. USTR instead has supported wrongheaded policies such as forcing trading partners to extend copyright protection beyond 50 years after an author is dead (harming performers, textbook publishers and consumers), narrowing the legal framework for copyright exceptions (restrictive three-step language in treaties), and ramping up damages and liability for infringements, creating new risks for the technology companies that are growing the fastest and generating the most wealth in the United States, and blocking discussions at WIPO to create a lawful path to access (as necessary as legal offers to respect for copyright).

In the end, access to knowledge is undervalued at USTR, and that is because of the unbalance between the consumer and publisher lobby on copyright issues. Access to knowledge can lead to better outcomes in employment, innovation, health, democratic governance and a host of other areas critical to development. Because no one at USTR knows how to measure the benefits of access to knowledge, we are stuck with mindless and harmful assertions that access denying and freedom restricting IPR measures create jobs and raise incomes.

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