

2016 Special 301 Review: Identification of Countries Under Section 182 of the Trade Act of 1974

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March 4, 2016 USTR Special 301 hearing KEI Reply Comment

The following includes a summary of the comments at our March 1, 2016 testimony, plus additional comments on submissions by several industry right holder groups

1. Right Holders Target Countries with Big Markets.

We have reviewed the submissions of PhRMA, BIO, BSA, IIPA and the US Chamber of Commerce's Global IP Center, among others. One thing that jumps out at you is that the primary predictor of whether or not a country is targeted by industry is the size of its economy. In Northern Africa, South America and Asia, being big means being a target.

We are attaching an excel spreadsheet (assuming we can upload it) that lists data on population, income (measured by GNI) by region.

- In South America, the seven largest economies were targeted for various watch lists by the 5 industry trade groups. The smallest 5 economies, not once.
- In North Africa, the two largest economies were targeted. The three smaller economies were not.
- In sub-Saharan Africa, only Nigeria was targeted. Nigeria has the largest economy in Sub-Saharan Africa.
- In the Asia Pacific region, 7 of the 8 largest (Japan was the exception) and 11 of the 16 largest economies were targeted. No county with a 2013 GNI less than \$162 billion was targeted.
- In Central America, the country with the highest per capita income was the only one targeted (Panama).

2. The BSA submission

We agree with and appreciate the concerns of BSA regarding government involvement in the use of unlicensed software.

We also understand and appreciate BSA's concerns over government policies that discriminate against foreign suppliers of software. Here we note also that the activities of the United States in spying on everyone, including anyone working for a foreign government, creates an environment where people around the world have legitimate concerns about backdoors and surveillance.

BSA has also raised concerns about rules that ban government use of cloud-based email programs and require data to remain within countries, and we also understand those concerns. However, again, the Snowden revelations of US spying and the lack of effective regulation of consumer privacy contribute to these problems. So long as the United States is seen as an aggressive actor in surveillance and as having weak protections on privacy, these problems will probably get worse. Tim Cook at Apple is trying to explain this to the FBI right now.

We disagree with the BSA's opposition to government mandates to make source code of software open, but again, open source code allows third parties to find surveillance backdoors, to address the need for greater interoperability between programs, and to ensure competition, particularly in the many markets where monopoly power exists.

3. The CCIA Testimony

We agree that ancillary copyright is a threat both to U.S. internet companies, and more generally, a threat to the public, and undermines access to knowledge. Governments have legitimate concerns over tax avoidance by companies, but taxing quotations and/or hypertext links is not the solution. We agree this is a violation of TRIPS and a barrier to trade.

We recommend USTR place countries doing this on the Priority Watch list, and consider an out-of-cycle review.

4. The PhRMA, BIO and US Chamber submissions

PhRMA targeted 20 countries in the Special 301. This included complaints about reimbursement policies in 18 countries, making pricing rather than IPR the most common topic.

In the United States, a 2015 Kaiser Family Foundation survey found 72 percent of the public believes that drug costs are unreasonable.¹

¹ <http://kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-august-2015/>

According to another survey, nearly seven-eighths of the country's top healthcare leaders favor the government taking a bigger role in curbing the rising cost of prescription drugs, 86% supported giving the federal government the authority to negotiate drug prices on behalf of Medicare and Medicaid beneficiaries.²

We also note that both Democratic candidates and Donald Trump for the GOP are campaigning to introduce tough curbs on high drug prices.

If you think your job is to keep drug prices high, you might talk with the rest of America about that.

India

A number of the submissions supported by the pharmaceutical industry have targeted India. India is important both because it is a large country with more than a billion persons, and because it is frequently looked to as a supplier of affordable generic products in other countries.

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According to the World Bank Poverty headcount, 58 percent of the population of India (751 million persons) live on less than \$3.10 per day.

Several submissions make reference to an agreement by India to not issue any more compulsory licenses.⁴ The U.S. Chamber states that: "Industry continues to be concerned by the potential threat of compulsory licensing. While the Government of India of India has privately reassured Industry that it would not use Compulsory Licenses for commercial purposes, a public commitment to forego using compulsory licensing for commercial purposes would enhance legal certainty for innovative industries."

Likewise, the U.S.-India Business council states:

Despite compulsory licensing denials, Industry continues to be concerned by the potential threat of compulsory licensing. The Government of India has privately reassured [Industry] it would not use Compulsory Licenses for commercial purposes. USIBC would be further encouraged if the Government of India made a public commitment to forego using compulsory licensing for commercial purposes and in public emergencies only, which would greatly enhance legal certainty for innovative industries.

² <http://www.modernhealthcare.com/article/20151114/MAGAZINE/311149963>

³ James Love. "The production of generic drugs in India: A new trade agreement with the EU would hinder access to drugs in developing countries," *BMJ* 2011; 342:d1694.

⁴ <http://keionline.org/node/2427>

If such an agreement in fact exists, this is extremely troubling news, and the terms of the agreement should be made public, and subject to the outrage that it deserves. This sort of pressure is basically a declaration of war on poor cancer patients (where most of the compulsory licenses have been targeted lately). Who goes into public service to keep new cancer drugs away from poor people living in developing countries?

While the impact of pressures on India are most consequential for developing countries, there are consequences also for higher income countries.

KEI is working on compulsory licensing cases in several countries, and like others will look toward India to play a role in providing a supply of products.

In 2016, KEI asked the US government to use its royalty free or march-in rights in patents for the prostate cancer drug Xtandi. (See: <http://keionine.org/xtandi>). This product was invented at UCLA on grants from the Army and the NIH, and is sold to US residents at a price of \$129,000 USD per year by Astellas, the Japan owned firm that acquired the licenses to the UCLA patents on the drug. The price in the United States is far higher than in any other country, even though it was invented on US government grants. If we succeed in that effort, we would consider sourcing generic products from India.

Indonesia

Indonesia had a 2014 GNI per capita of \$3,630 USD.⁵ According to the World Bank, 42 percent of the population (106 million persons) live on \$3.10 or less per day.

PhRMA wants Indonesia on the priority watch list, in part complaining about compulsory licenses issued in 2004, 2007 and 2012. If Indonesia did not issue those compulsory licenses, the consequences would have been people dying for lack of access to affordable drugs.

The members of the Special 301 committee organized by the Administration apparently have been assigned extraordinary life or death power over people living far away in conditions of poverty. Don't follow PhRMA's appalling recommendations.

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

On Sunday March 28, 2016, the United Nations Secretary-General'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

⁵ Source: World Bank (Atlas Method). <http://data.worldbank.org/country/indonesia>

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 De-linking 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: <http://www.keionline.org/node/2431>