

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

**Docket ID:** USTR-2015-0022

**Agency:** Office of United States Trade Representative (USTR)

**Parent Agency:** Executive Office of the President (EOP)

March 1, 2016 USTR Special 301 hearing UACT Statement

The Union for Affordable Cancer Treatment (UACT) is a volunteer organization, a union of people affected by cancer, their family members and friends, people who take care of people with cancer, health care professionals and cancer researchers committed to increasing access to effective cancer treatment and care. We are particularly concerned about the rapidly escalating cost of cancer medication.

UACT members agree with PhRMA's comment that "Advances in biotechnology and genomics are propelling the discovery of new medicines to treat a range of chronic and infectious diseases."

We note, as PhRMA did in its comments, that the American Cancer Society (in an article dated Jan. 7, 2016) reported that cancer death rates have been reduced nearly 23 percent since 1991. <http://www.cancer.org/cancer/news/news/cancerstatistics-report-death-rate-down-23-percent-in-21-years>.

And, for many patients, cancer has become a chronic disease that when well-treated, including with new targeted therapies, can be controlled and allows patients to live a long and useful life.

However, PhRMA is asking for trade policies that make these drugs more expensive, and which restrict access.

*India*

PhRMA wants India to be placed on the "priority watch list" because although India has only once made use of compulsory licensing of patents on essential life-saving cancer drugs, it could happen again, even though India has already faced much pressure not to issue such licenses.

## Quote

"The Indian Government appears to have taken a more measured and cautious approach in responding to recent CL cases, including the denial of two CLs this year. We are encouraged by this trend. However, the grounds for issuing a CL under the provisions are broad, vague and appear to include criteria that are not clearly related to legitimate health emergencies. The Ministry of Health (MOH) continues to make recommendations to impose CLs on certain anti-cancer medicines under the special provisions of Section 92 of India's Patents Act, which would make it even more difficult for patent owners to defend their patents."

In support of this comment, PhRMA makes reference to a compulsory license for the cancer drug Dasatinib, which was proposed, but like other several cases involving expensive cancer drugs, was never issued, after pressure from industry and USTR.

Again, we strongly object to the pharmaceutical industry misrepresentation of the WTO rules, particularly on the issue of national emergencies.

We want to quote from the WTO F.A.Q. page the following statement regarding Compulsory licensing:

Quote:

**"Does there have to be an emergency?"**

Not necessarily. This is a common misunderstanding. The TRIPS Agreement does not specifically list the reasons that might be used to justify compulsory licensing. However, the Doha Declaration on TRIPS and Public Health confirms that countries are free to determine the grounds for granting compulsory licences.

. . . .

For "national emergencies", "other circumstances of extreme urgency" or "public non-commercial use" (or "government use") or anti-competitive practices, there is no need to try first for a voluntary licence. It's the only instance when the TRIPS Agreement specifically links emergencies to compulsory licensing.

[https://www.wto.org/english/tratop\\_e/trips\\_e/public\\_health\\_faq\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm)

We welcomed the Indian Supreme Court rejection of the Bayer appeal of the Nexavar compulsory license, that PhRMA complained about in its comments. At the heart of that case was the fact that Bayer was charging \$65,000 USD per year, in India, for a cancer drug, and only

a small number of the patients that needed the drug were able to afford it. What is unfortunate is that India has been pressured to not issue more of these compulsory licenses.

PhRMA wants the USTR to ensure free reign to their greed while patients do not have any hope to have access.

India is particularly important because it has the potential to supply affordable generic drugs also to other countries.

High prices for cancer drugs lead to rationing of access around the world. For the cancer patients who are unable to have access to a drug that they need, this means a painful and unnecessarily swift death.

### *Korea*

UACT would like to comment on the PhRMA request to place Korea on the Watch List for its Independent Review Mechanism (IRM).

Under Article 5.3(5)(e) of the U.S.-Korea Free Trade Agreement and the side letter, Korea agreed to “make available an independent review process that may be invoked at the request of an applicant directly affected by a [pricing/reimbursement] recommendation or determination.”

PhRMA complains that the Korean Government has taken the position that reimbursed prices negotiated with pharmaceutical companies should not be subject to the IRM because the National Health Insurance Service (NHIS) does not make “determinations” and merely negotiates the final price at which a company will be reimbursed.

PhRMA notes that "Local data indicates that from 2007 through 2012, NHIS determined not to reimburse 59 (20.3 percent) of the 291 new medicines for which it was tasked to negotiate the reimbursed price. For anti-cancer drugs, the rejection rate (37.9 percent) was even higher – NHIS decided to reimburse only 18 of the 29 anti-cancer drugs that Korea’s Health Insurance Review and Service Agency had determined should be reimbursed.

In Korea, patients do not have reimbursements for a large number of cancer drugs. But why? The high prices for the drugs are restricting access. If high prices are blocking access in Korea, the government of Korea should be free to take measures to break drug monopolies, so prices fall. PhRMA is highlighting the negative consequences of high prices. Korea should put the monopoly at risk, and not the patients. But the U.S. Korea FTA makes that more difficult.

### *Test data*

PhRMA is using the 301 process to pressure countries to provide exclusive rights to clinical trial data, to further block generic or biosimilar versions of drugs. PhRMA critiqued 15 countries for their failure to provide exclusive rights in test data, including countries like Vietnam, Egypt, and Thailand where most people are very poor.

PhRMA says data exclusivity “is a carefully balanced mechanism that improves access to medicines of all kinds,” citing the Hatch-Waxman Act, which passed over 30 years ago under very specific circumstances in the United States, and which does not provide exceptions to the test data monopoly.

### *Put the monopoly, not the patients at risk*

When the prices for life saving cancer drugs are too high for any government, the best option is better price regulation or compulsory licensing of the patents. The worst option is of course to prevent access to life saving drugs.

### *What is the Impact of Policy on Access?*

We call upon the USTR to initiate a period impact assessment to report upon the specific implications of the IPR policies that it has endorsed and continues to endorse through the Special 301 process and international trade agreements, on patients, and their families.

Specifically, we ask for detailed data that would illuminate precisely how many cancer patients suffer and die or die too soon, because of the lack of an affordable generic or biosimilar medicine that they could have accessed via compulsory license, were it not for pressure by the USTR and others. We can thank PhRMA for providing some data on the restricted access to cancer drugs in Korea, but this is not just a problem in Korea.

The findings of such a report would be an important addition to the factors taken into consideration by policy-makers.

The data for this impact assessment should include a review of historical reports of cancer incidence, mortality and years of life lost. USTR should also encourage and facilitate the future collection of this data by cancer type. This impact assessment should also record the historical

and future access to and cost of cancer treatment by medicines. Documentation of this data would illustrate the number of patients eligible for newer, costlier cancer treatments who are forced to forgo treatment due to financial burden caused by these medicines.

*Focus on R&D rather than IPR*

Instead of preventing access and innovation of anti-cancer drugs, USTR should include in its assessment of our trading partners, their role in supporting investment in R&D, including public sector funding of R&D, through programs similar to what the NIH does. The focus on high prices kills patients, and there are better options and better targets for trade policy. Focus on R&D not just IPR.

The USTR could also begin to collect data on government programs to fund medical R&D through grants, research contracts, and other methods, which contribute to innovation, and which do not depend upon high drug prices.

UACT is one of many groups now asking the UN to initiate negotiations on “the need for global negotiations on agreements to fund R&D within the context of a progressive delinking of R&D costs from product prices,” and for “increasing the transparency of markets for drugs, vaccines, diagnostics and other medical technologies.”

USTR should abandon its support of high drug prices, and engage in the reforms that would result in better policy coherence and better outcomes for cancer patients everywhere.