



February 5, 2015

UACT submission to Docket Number USTR-2014-0025, "2015 Special 301 Review"
via <http://www.regulations.gov/>

TO: Susan Wilson, Director for Intellectual Property and Innovation,
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UACT is the Union for Affordable Cancer Treatment, an international network of people affected by cancer, who share the conviction that cancer treatment and care should be available everywhere for everyone regardless of gender, age, or nationality. More information about UACT is available at <http://cancerunion.org>

The following, including attachments, constitutes UACT's submission to the "2015 Special 301 Review and its notice of intent to testify at the Special 301 Public Hearing Tuesday, February 24, 2015.

UACT objects to the United States Trade Representative (USTR) pressure on foreign governments to reject measures, including compulsory licenses, limits of the granting of patents, cost containment and price controls and other mechanisms to provide their population with affordable cancer drugs.

As a recent report by Oxfam indicated:¹

According to the World Health Organization, cancer is one of the leading causes of death around the world, with 8.2 million deaths in 2012. More than 60 percent of the world's new cases of cancer occur in Africa, Asia, and Central and South America and these regions account for 70 percent of the world's cancer deaths.

¹ ACCESS TO CANCER TREATMENT, A study of medicine pricing issues with recommendations for improving access to cancer medication A report prepared for OXFAM By Ellen 't Hoen, LL.M. Paris, 2 May 2014. <http://oxf.am/ZTdi>

In low- and middle-income countries, expensive treatments for cancer are not widely available. Unsustainable cancer medication pricing has increasingly become a global issue, creating access challenges in low-and middle-income but also high-income countries.

Today, we have a handful of "game changer drugs" in the cancer treatment field. By game changers, we mean drugs that add time and quality to the lives of cancer patients.

For example, let us look at dasatinib, a drug for a rare form of leukemia. For UACT, the dasatinib dispute between the USA and India illustrated the failing of US trade policy and its impact on cancer patients. In a previous submission to USTR during the 2014 Special 301 Out-of-Cycle Review of India on October 29, 2014, UACT pointed out the impact of USTR pressure on access to treatment for the rare form of Leukemia.

The Bristol-Myers Squibb price for dasatinib is more than \$100 per day, in a county with a per capita income of \$4.30 per day, which makes it unreachable for the majority of leukemia patients in India. US government opposition to a compulsory license on dasatinib is a de facto endorsement of an excessive price, and will have predictably harsh consequences for leukemia patients who have developed resistance to imatinib.

There are other "game changer drugs" such as Herceptin or Kadcyla (formerly known as T-DM1) for advanced breast cancer (HER2 positive). Most recently, the FDA approved the Pfizer drug Ibrance which is a life saver for patients with the most common estrogen positive (but HER2 negative) advanced breast cancer. All these drugs are near or over \$100,000 a year. These treatments are not accessible to most women on earth and even hardly available in Europe (the UK NICE has rejected Kadcyla and in some European countries patients are not even tested because they will not get Herceptin or Kadcyla). In the US, to access treatment, patients have to rely on the employers (including medicare and other government programs or agencies) who have to pay higher and higher premiums and of course their health insurances. Indeed very few individuals in the US could afford to pay out of pocket these kind of treatments. But without these drugs, most women with advanced breast cancer die of a premature death. I myself have lived the last 4 and a half years of my life thanks to access to these drugs. However, it is heartbreaking for me to know that only a few breast cancer patients have access to the same treatments that are keeping me alive today.

UACT is challenging the idea that USTR is advancing US interests by promoting stronger monopolies of medicines and preventing access to these treatments. The UACT argument is based upon the following:

1. While we recognize that developing new drugs is expensive, we know that BMS, Roche or Pfizer in fact benefited extensively from U.S. government research subsidies, including NIH funded research and clinical trials, universities (public and private) and a 50 percent tax credit to fund trials.

2. The price of these cancer drugs is excessive everywhere for everyone on the planet especially for drugs developed with extensive US government subsidies.
3. UACT believes that trade pressures to prevent other countries from using legal mechanisms such as compulsory licensing to manufacture generics and provide access to cancer patients in resource poor setting is immoral and bad foreign policy.
4. USTR, this Committee, must recognize that there is no alternatives to these life saving drugs, and cancer patients cannot continue to be held hostage in a system of threats to ration drugs.
5. US citizens are especially harmed by the high prices on cancer drugs in part because of an aging population that is more likely to require cancer related chemotherapy. I would refer the Committee to the October 29, 2014 letter from UACT to Ambassador Michael Froman (available at: <http://cancerunion.org/actions.html>) which discusses in details the demographic changes in the United States, and the impact of extremely high cancer drug prices on the competitiveness of the U.S. workforce, which collectively has to pay for cancer drugs that are more expensive in the United States than anywhere else.

In conclusion, UACT reaffirms its opposition to USTR trade policies that prevent access to treatment to the majority of cancer patients on this planet and create an unnecessary and harmful scarcity of drugs that can save, extend and improve the lives of cancer patients around the globe.

We ask that USTR spends more time designing and advancing trade policies that allow countries to push back on high drug prices, while expanding funding for medical R&D, including for better cancer drugs and diagnostic tools.

Sincerely,

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