

## UACT Supplemental Response

In the matter of the Office of United States Trade Representative (USTR) Notice: 2015 Special 301 Review: Identification of Countries Under Section 182 of the Trade Act of 1974  
Docket ID: USTR-2014-0025

February 27, 2015

TO: Susan Wilson, Director for Intellectual Property and Innovation,  
Office of the United States Trade Representative, Special301@ustr.eop.gov.

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 attached Letters to President Monaco (<http://cancerunion.org/files/UACT-Tufts-24Nov2014.pdf>) and Dr. DiMasi ([http://cancerunion.org/files/UACTLetterDiMasi\\_Feb2015.pdf](http://cancerunion.org/files/UACTLetterDiMasi_Feb2015.pdf)), constitutes UACT's follow up responses to questions regarding UACT submission to the "2015 Special 301 Review", February 2015:

UACT would like to thank the Committee's Chair and the Committee itself for inviting us to follow up with replies to the questions asked during the Hearing on February 24, 2015. We remain available for any other questions you might have.

*Question 1. Is anything in the 2014 Special 301 Report regarding compulsory licenses inconsistent with the Doha Declaration and USTR/U.S. government support for Doha?*

Where in some paragraphs of the 2014 Report USTR makes overtures in support of the Doha Declaration, numerous other paragraphs reveal a government actually opposed to anything a country might do to actually address its public health challenges. This is Orwellian and has an impact on a huge number of cancer patients often dealing with tremendous health and financial challenges all over the world.

The 2014 Report includes passages claiming support of Doha, such as:

The United States is firmly of the view that international obligations such as those in the TRIPS Agreement have sufficient flexibility to allow trading partners to address the serious public health problems that they may face. Consistent with this view, the United States respects its trading partners' rights to grant compulsory licenses in a manner consistent with the provisions of the

TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health, and encourages its trading partners to consider ways to address their public health challenges while maintaining IPR systems that promote innovation.

[...]

The United States also strongly supports the WTO General Council Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health concluded in August 2003. Under this decision, Members are permitted, in accordance with specified procedures, to issue compulsory licenses to export pharmaceutical products to countries that cannot produce drugs for themselves. (p.25)

Yet, in the same 2014 Report, USTR admits to “monitoring compulsory licenses” in a manner that more closely resembles pressuring than monitoring:

Second, while bearing in mind the Doha Declaration on TRIPS and Public Health, discussed in the Intellectual Property and Health Policy section of this Report, the United States also continues to monitor developments concerning compulsory licensing of patents in India. The United States urges India to provide greater transparency about its ongoing inter-ministerial process that is considering over a dozen patented medicines as candidates for government initiated compulsory licenses, and urges India to allow opportunities for input by rights holders, as appropriate, with respect to decisions concerning compulsory licenses. (p.40)

USTR’s focus on the judicial processes of sovereign nations, and the questioning of their highest court’s decisions, is most inconsistent with the U.S. government’s so-called support for the spirit and the letter of Doha:

In addition, the United States continues to be concerned with the rationale underlying a decision by India’s Controller-General of Patents to grant a compulsory license under Section 84 of India’s Patents Act (which allows private parties to initiate proceedings seeking a compulsory [2 Novartis AG v. Union of India & Others, Civ. App. Nos. 2706-2716 (Supreme Court, April 1, 2013), paragraphs 103, 104, and 192 (emphasis added), license of a patented article), as upheld by a recent judgment of the IPAB.] The grant of the compulsory license was based, in part, on the innovator’s failure to “work” the patent in India because it imported its products, rather than manufacturing them in India. The United States recognizes that, on appeal, the IPAB modified the Controller-General’s reasoning to clarify that “in some cases” the “working” requirement could be met solely by importation. The IPAB, however, rejected the innovator’s explanation that economic factors prevented manufacturing in India, stating, “the patentee must show why it could not be locally

manufactured. A mere statement to that effect is not sufficient[,] there must be evidence.”<sup>3</sup> The IPAB did not clarify the circumstances under which the “working” requirement would be met without manufacturing in India. (pp. 40-41)

For UACT, efforts to stop India or any other country from maintaining the capacity to manufacture cancer drugs can have a terrible impact on cancer patients in India, in the developing world and also in the U.S.

For example, in 2011, the President of the United States, Barack Obama issued an Executive Order (Oct. 31, 2011,) so that the chemotherapy drug (Doxil GENERIC NAME(S): DOXORUBICIN HCL PEGYLATED LIPOSOMAL) manufactured by SUN, an Indian Company, could be distributed in the US where there was a shortage. This drug is used to treat many types of cancer (e.g., ovarian cancer, breast cancer, AIDS-related Kaposi's sarcoma, multiple myeloma). In February 2012, to address the shortage of doxorubicin hydrochloride liposome injection, the FDA announced it would exercise enforcement discretion for temporary controlled importation of Lipodox (doxorubicin hydrochloride liposome injection), an alternative to Doxil produced by Sun and its authorized distributor, Caraco Pharmaceutical Laboratories Ltd. that is not approved in the United States. Enforcement discretion was also used to release one lot of Janssen's Doxil made under an unapproved manufacturing process. I myself benefitted from the executive order and was prescribed the chemotherapy drug during that time.

In addition to monitoring those “failing” countries that issue compulsory licenses, USTR additionally “monitors” the following countries for not issuing data exclusivity regulations -- regulations which in fact are not required under TRIPS (countries listed in bold):

**Russia** has not issued regulations clarifying the protection against the unfair commercial use, as well as unauthorized disclosure, of test and other data generated to obtain marketing approval for pharmaceutical products. (p.43)

**Argentina** also fails to provide effective protection against unfair commercial use or unauthorized disclosure of test and other data generated to obtain marketing approval for pharmaceutical products. (p.44)

The United States also urges **Chile** to provide adequate protection against unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products. (p.44)

The United States continues to encourage **Indonesia** to provide an effective system for protecting against the unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain

marketing approval for pharmaceutical and agricultural chemical products. (p.45)

The United States continues to encourage **Pakistan** to provide an effective system for protecting against unfair commercial use, as well as unauthorized disclosure, of tests and other data generated to obtain marketing approval for pharmaceutical products. (p.46)

The United States continues to encourage **Thailand** to provide an effective system for protecting against the unfair commercial use, as well as unauthorized disclosure, of test or other data generated to obtain marketing approval for pharmaceutical and agricultural chemical products. (p.46)

The United States also continues to encourage **Venezuela** to provide an effective system for protecting against the unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products. (pp.46-47)

Concerns also persist with respect to **Brazil's** inadequate protection against unfair commercial use of undisclosed test and other data generated to obtain marketing approval for pharmaceutical products. (p.48)

In addition, **Colombia's** limitations on the patentability of certain pharmaceuticals and challenges related to pharmaceutical and agrochemical data protection are areas of concern. (p.50)

Pharmaceutical patent holders report a number of concerns, including poorly defined exceptions to **Costa Rica's** data exclusivity regime. (p.50)

[**Ecuador's**] lack of protection against unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical (51)

The United States urges **Egypt** to clarify its protection against the unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval of pharmaceutical products. (52)

**Vietnam** should clarify its system for protecting against the unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products(58)

Yet, in another "Orwellian" take of the spirit of Doha, the U.S. government recognizes that IP influences prices, but objects to price controls that may help provide greater access to medicines. For example, the Report states:

The United States also recognizes the role of IP protection in the development of new medicines, while being mindful of the effect of IP protection on prices. The assessments set forth in this Report are based on various critical factors, including, where relevant, the Doha Declaration on the TRIPS Agreement and Public Health. (25)

*2. Innovation is important. Considering that it costs \$2.6 billion to develop a new drug, how do you suggest we protect innovation? Additionally, cost is just one element of lack of access, it can also be attributed to many other things.*

UACT was surprised and in fact quite disturbed by the mention of this unproven "\$2.6 billion" figure several times during the February 24, 2015 Hearing and especially during the follow-up questions. We would like to clarify the following:

On November 18, 2014, the Tufts Center for the Study of Drug Development (CSDD) announced at a press Conference that the "Cost to Develop and Win Marketing Approval for a New Drug Is \$2.6 Billion." What was available to the public was not a study - but rather a handful of media talking points. As far as we know, there is no study available for USTR or anyone else to read, at this point.

The main point of the press conference was to establish that drug development costs were \$2.6 billion for a new drug, a figure more than a billion dollars higher than a 2012 AstraZeneca-funded study by the Office of Health Economics, and 3.2 times higher than an earlier estimate published by CSDD in 2003.

Already in November 2014, we feared that some parties would undoubtedly read the new "Tufts" study as a justification of high drug prices, including the very high prices for new drugs to treat cancer, a characterization that fits the two previous studies on this topic published by Joseph DiMasi and his co-authors. However, we did not imagine that the U.S. government would mention, endorse, or even use in any way the figure without anyone having been provided with the details to justify the so-called results.

UACT noticed early the lack of transparency regarding the data used to make the "estimates", and highlighted that the failure to disclose the study itself, created a situation where the public was being asked to trust the study authors and Tufts University on an issue that is often used to justify high drug prices. We thus sent letters to Anthony P. Monaco, Office of the President, Tufts University, with copies to Michael Baenen, Chief of Staff, and Peter Dolan, Chairman of the Board of Trustees, Tufts University, regarding the Tufts University press conference

announcing an estimate of \$2.6 billion as the R&D costs for new drugs. The letter asked Tufts to provide more transparency about the funding of the press conference and the study, and to answer several questions about the relevance of the study to new treatments for cancer. Our questions about the relevance of the study to cancer mentioned considerable evidence that cancer drugs have smaller clinical trials, and frequent access to a 50 percent US tax credit for orphan drugs.

In his reply, President Monaco referred UACT to DiMasi for direct response. On February 3, 2015, following the direction of Tufts University President Anthony Monaco, UACT sent a letter to the principal researchers of the study on drug R&D costs, Joseph DiMasi of Tufts University, as well as Henry Grabowski of Duke University and Ronald Hansen of the University of Rochester. The letter to Dr. DiMasi reiterated our concerns about the lack of details about the study data, funding, and applicability to cancer drugs. We have not received Dr. DiMasi's reply yet.

We hope that USTR will itself require the authors and sponsors of the so-called study to make data available to all before using its mythical figure of \$2.6 billion. I certainly hope that this mythical figure will not find its way into the 2015 Report.

*3. The U.S. is bearing the cost of medicines worldwide, therefore the U.S. needs to reach more markets in order to be able to lower the price in the US.*

UACT remains puzzled by this assertion. There is no evidence that the prices of cancer drugs in the U.S. was ever "lowered" at any point in time unless the drug became generic or unless price controls and compulsory licenses were used. There is plenty of evidence that deep public sector subsidies for the development of cancer drugs, including the 50 percent tax credit available to 9 of 10 new cancer drugs approved in 2014, did not lead to any lower prices for the drugs. On the contrary, the R&D subsidies are associated with the highest prices.

*4. How do you suggest we deal with the problem of counterfeit drugs as for example the issue of online pharmacy supplying low cost counterfeit medicines?*

The United States should regulate legitimate parallel trade, learning from the experience in Europe, where parallel trade has long been accepted, and regulated.

UACT has yet to adopt positions on the issue of parallel trade between countries of different incomes. However, UACT is more generally in favor of the delinkage of R&D costs from drug prices, as this would be a much more powerful way to address concerns over counterfeit drugs, because it would drive prices closer to manufacturing costs. At present, the super high mark up over manufacturing costs is an economic incentive to engage in the crime of counterfeiting drugs. So in this sense, high prices induce counterfeiting activity.

## 5. DHHS: *Is UACT focusing on affordability only?*

UACT is a new organization. More information on our partners and actions are available at [uact.org](http://uact.org). Our agenda consists of seven critical areas:

### 1. Access and affordability

Cancer drugs should be affordable and available, everywhere, for everyone. Pricing of products so they are not available to those who need them should be illegal, and subject to effective remedies, including fines and removal of legal monopolies.

### 2. Trade related issues

Global norms concerning "access to medicine for all" includes cancer medicines. The 2001 Doha Declaration on TRIPS and Public Health applies to treatments for cancer, including, in particular, Paragraphs 4, 5, 6 and 7.

### 3. Improving access under current legal and trade frameworks

Intellectual property rights on new cancer drugs and diagnostics should include limitations and exceptions on rights, in order to prevent abuses of such rights, such as excessive pricing, denial of access to rights in inventions and data for follow-on products, and more generally to protect the public interest.

Intellectual property rights in test data, when granted, should be subject to exceptions to rights, in order to prevent abuses of rights, and to protect the public interest. Trade secrets protections should not be used to prevent broader access to clinical trials data, or to prevent governments from providing legitimate access to know-how regarding the manufacture of drugs, vaccines or diagnostic devices.

Rules for registering biosimilar drugs should not be designed to create unreasonable burdens on the biosimilar product, or require drug developers to conduct trials that are unnecessary.

### 4. WHO Essential drugs list

The WHO should reform the model list for essential medicines, to include drugs that are medically important to cancer patients, when such drugs are available at affordable prices.

## 5. Longer run reforms, and research and development

Governments need to migrate to a system of delinkage of R&D costs from product prices, for drugs, vaccines and diagnostic tools. The appropriate way to deal with global free riding for cancer research is a global R&D treaty or trade agreement, rather than agreements on cancer IPR or prices.

To reform the incentive for product development, governments should replace legal monopolies with cash rewards for successes in product development. This includes monopolies associated with patents on inventions, exclusive rights in test data, and the growing number of *sui generis* monopolies such as orphan drug exclusivity, designed to induce private investments in drug development.

## 6. Research and development

Research and development of new cancer drugs requires a mixture of financing approaches, including both push and pull mechanisms. Among the pull mechanisms, patent monopolies should be replaced with innovation inducement prizes. Direct government funding for research is also very important, for everything from basic research through late stage clinical trials.

Governments that fund research on new treatments and diagnostics for cancer should ensure that such research is available as a public good.

More research is needed for the development of inexpensive and effective diagnostic tools for cancer that can be used in resource poor settings. In order to fund R&D for low cost diagnostics, new business models and R&D funding models are needed, based upon the delinkage of R&D costs from product prices.

## 7. Improve transparency

Increased transparency is needed on the part of pharmaceutical companies and government drug approval agencies. Information concerning the costs of R&D, the prices of drugs, revenue generated by specific drugs, and any adverse effects should be made available to the public.

In order to foster greater availability of pricing information, a database of cancer drugs and drug prices should be curated, with the involvement and assistance of cancer patients. Cancer patients and consumers should be included at the price negotiation table with pharmaceutical companies and third-party insurers.

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