

## Oral Submission to the U.S. Trade Representative for the 2012 Special 301 Review

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Good morning. Thank you for having me. I continue to believe that having a public hearing as part of the 301 process is important. My comments today will be in the vein of continuing the trend toward making this a more open, fair and legal process.

I want to focus my remarks on one key ask – which is that use this year’s report respond in writing to the comments that public interest organizations and other critics of past reports make in this hearing. This is a requirement of good governance as well as of the Administrative Procedures Act.

My statement addresses the following points:

1. THIS PROCESS IS AND SHOULD BE GOVERNED BY THE APA.....1
2. THREATENING TRADE SANCTIONS THROUGH SPECIAL 301 VIOLATES THE WTO DISPUTE SETTLEMENT UNDERSTANDING .....2
3. NON-DISCRIMINATORY REIMBURSEMENT PROGRAMS THAT REDUCE MEDICINE PRICES ARE BEYOND THE SCOPE OF YOUR STATUTORY MANDATE.....2
4. “INTELLECTUAL PROPERTY” UNDER 301 INCLUDES LIMITATIONS AND EXCEPTIONS .....3

### 1. This process is and should be governed by the APA

It has been repeatedly submitted in the past that this is an informal agency adjudication under the Administrative Procedures Act. Informal adjudication includes any statutorily required decision making process, especially including applying statutory standards to pass conduct, that may or may not require a hearing and is neither formal adjudication nor rulemaking. Informal adjudication includes action, like 301, done by "inspections, conferences and negotiations." [Final Report of the Attorney General's Committee on Administrative Procedure](#) (Senate Document No. 8, 77th Congress, First Session, 1941). The APA requires that such processes be operated in a reasonable fashion – free of action that is “arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with the law.” 5 U.S.C. § 706(a)(2).

This process acts arbitrarily, and is legally vulnerable for so doing, when it accepts inputs from public interest organizations and businesses with competing views and challenges to the program and ignores them in the report itself. It is a hallmark of just administrative process that reasons are offered for administrative action.

## **2. Threatening Trade Sanctions through Special 301 Violates the WTO Dispute Settlement Understanding**

One major argument the 301 Report needs to respond to is the assertion that this process is unlawful because it violates the WTO.

WTO DSU, art. 23.2 states:

“Members shall not make a determination to the effect that a violation has occurred, that benefits have been nullified or impaired or that the attainment of any objective of the covered agreements has been impeded, except through recourse to dispute settlement in accordance with the rules and procedures of this understanding.”

In the Panel Report in United States – Sections 301-310 of the Trade Act of 1974, a WTO panel upheld the continuation of Section 301 after the WTO only if used after, and as a means to implement, DSU findings. It also clearly signaled that it is not a valid justification to say that sanctions themselves will only flow from the DSU. The panel said:(¶ 7.89)

“Members faced with a threat of unilateral action, especially when it emanates from an economically powerful Member, may in effect be forced to give in to the demands imposed by the Member exerting the threat... To put it differently, merely carrying a big stick is, in many cases, as effective a means to having one's way as actually using the stick. The **threat alone** of conduct prohibited by the WTO would enable the Member concerned to exert undue leverage on other Members. It would disrupt the very stability and equilibrium which multilateral dispute resolution was meant to foster and consequently establish, namely equal protection of both large and small, powerful and less powerful Members through the consistent application of a set of rules and procedures.”

In the part of the report that describes the administration's use of this program, it should explain the statement of administration policy and advise countries how Special 301 complies with WTO decision. Why is being elevated to the priority watch list not a threat of illegal sanctions?

## **3. Non-discriminatory reimbursement programs that reduce medicine prices are beyond the scope of the 301 statutory mandate**

Special 301's criticism of pharmaceutical reimbursement programs is not authorized by statute.

In the hearing last year, Pharma's Jay Taylor explained his application of Special 301 to drug pricing with this:

Taylor: “Yes I think it fits squarely into 301. If you have a single payer system that devalues our company that comes back and effects research and development here in the US.”

This is clearly not an adequate interpretation of the statutory standard. To include countries as a 301 “identification,” USTR must make a factual finding that the alleged conduct will

- (A) deny adequate and effective protection of intellectual property rights, or
- (B) deny fair and equitable market access to United States persons that rely upon intellectual property protection.

Pharma pins its requests for listing on grafting the definition of “market access” from the general Section 301 statute, not the more specific 301 process. Special 301 has its own definition of market access. 19 USC 2242 states:

(b) Special rules for identifications

(3) The Trade Representative may identify a foreign country under subsection (a)(1)(B) of this section only if the Trade Representative finds that there is a factual basis for the denial of fair and equitable market access as a result of the violation of international law or agreement, or the existence of barriers, referred to in subsection (d)(3) of this section.

(d)(3) A foreign country denies fair and equitable market access if the foreign country effectively denies access to a market for a product protected by a copyright or related right, patent, trademark, mask work, trade secret, or plant breeder’s right, through the use of laws, procedures, practices, or regulations which—

(A) violate provisions of international law or international agreements to which both the United States and the foreign country are parties, or

(B) constitute discriminatory nontariff trade barriers.

To list a reimbursement program for cost restraining properties that do not violate any international agreement, they must be “discriminatory.”

#### **4. “Intellectual property” under 301 includes limitations and exceptions**

PK and CCIA have argued that “adequate and effective IP” includes limitations and exceptions. USTR’s representative challenged that reading in questioning at the hearing last year, but did not offer USTRs own interpretation of why 301 does not require a balanced interpretation of intellectual property.

CCIA and public knowledge have asked in the past that Special 301 include listings based on inadequate limitations and exceptions or over-zealous enforcement practices that

threaten internet businesses. These issues are never included in the report and there is no explanation why. Consider, for example, the specific countries listed for inadequate intellectual property limitations and exceptions that threaten US internet businesses in [CCIA's Report](#) and in the [Press](#). The report should explain, for example, why it does not list Belgium in the report for holding Google liable for copyright violations for indexing websites. Why is France not on the list for holding E-Bay secondarily liable for all trademark infringement on its site, and for nominal use of marks without permission of the rights holder – a standard that basically prevents all advertising of used goods.

Likewise, in its best practices section, the report needs to report on best practices along the full range of practices, not those that benefit a select subsection of US businesses. Where it rejects the submissions of some, it should offer a reason.