USTR-2010-003
2010 SPECIAL 301 REVIEW, SEC. 182 OF THE TRADE ACT OF 1974

TESTIMONY OF SEAN FLYNN
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ON BEHALF OF AD HOC COALITION ON INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES[1]

MARCH 3, 2010

I want to start by thanking USTR for this opportunity to submit comments and for improving the process this year.

PROCESS

This year the process is vastly improved, including this opportunity to submit oral comments in a public hearing.

Although this year is a vast improvement, it could still use vast improvements to the meet the high standards for transparency and openness to public interest input that is hallmark of this administration.

Special 301 is an adjudication. Its purpose is to judge the past conduct of foreign nations against statutory standards. This is contrasted with a rule making in administrative law – which is a process for setting forward looking norms.

Despite being an adjudication, the participation process offered is a light form of notice and comment rulemaking procedure. I say "light"' because there is no opportunity to comment on a draft rule as there is in many notice and comment processes.

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Special 301 should be extended the procedural protections required when an adjudication process is required by statute to be determined on the record after opportunity for an agency hearing. This is necessary to air the full range of legal and factual disputes in USTR application of staturoy standards to past conduct.

I would also like to note that it is a problem that this forum adjudicates foreign practices, but is held in the U.S. with no ability to give comments by video conference or other remote facility.

We would be happy to meet with you further on procedural changes.

CALL FOR CHANGE

The USTR policy on the protection of intellectual property rights should be consistent with other US policies and commitments, including:

- TRIPS provisions that address the importance of balance and national discretion, including Articles 1, 6, 7, 8 and 40;
- Support for multilateral dispute resolution in the WTO;
- the 2001 WTO Doha Declaration on TRIPS and Public Health;
- the 2008 World Health Organization (WHO) Global Strategy on Public Health, Innovation and Intellectual Property Rights set out in WHA61.21;
- the World Intellectual Property Organization (WIPO) Development Agenda;
- ethical guidelines of the Declaration of Helsinki;
- Congressional policy supporting the Doha declaration and opposing the use of Special 301 to promote TRIPS plus IP standards,
- Obama administration policy to “increase access to affordable drugs” in developing countries, including through support for “the rights of sovereign

nations to access quality-assured, low-cost generic medication to meet their pressing public health needs under the WTO's Declaration on Trade Related Aspects of Intellectual Property Rights (TRIPS)."

- International human rights obligations.

BAN TRIPS-PLUS PRESSURE

Global health organizations call on the Administration to stop using Special 301 to promote TRIPS-plus policies that endanger access to medicines for millions of people around the world.

As recounted in our written submission, as late as 2009, Special 301 has been used to pressure developing countries to limit every major TRIPS flexibility that can be used to promote access to medicines. USTR has pressed countries to limit grounds for compulsory licenses, restrict freedom to define the scope of patentability, prohibit parallel importation, extend patents beyond 20 years, implement "linkage" between drug registration and assertions of patent protection, adopt U.S. or EU-style "data exclusivity" rules, and do away with evidence-based formularies and other price and competition restrictions on pharmaceutical monopoly power.

These policies are often based on a flawed principle that the world will prosper if every country adopts a one size fits all IP and economic policy modeled on the U.S. But the WHO and numerous experts have effectively rebutted that idea, and it was rejected in the TRIPS negotiations.

The problem in short is this – monopolies on needed drugs in countries with high income inequality drives companies to serve only the very rich. If every country adopts high level IP monopolies and gets rid of price controls, we know that only a sliver of the world population will

be served with the medicines they need. We cannot accept that. Countries must have flexibility to cater for their local conditions.

ENDORSE THE DOHA DECLARATION IN FULL

Special 301 requires USTR to annually publish in the Federal Register a list of countries that deny "adequate and effective protection of intellectual property" or deny fair and equitable market access for U.S. firms that rely on intellectual property. These standards must be interpreted in light of the 2001 Doha Declaration on the TRIPS Agreement and Public Health, affirming the "the right of WTO Members to use, *to the full*, the provisions in the TRIPS Agreement, which provide flexibility" to "promote access to medicines for all."

Although past 301 reports have mentioned support for the Doha Declaration in principle, it has never explained how the promotion of TRIPS plus standards can be squared with the Doha commitment to support TRIPs flexibilities "in full."

START WITH CLINTON ADMINISTRATION POLICIES ON ACCESS TO MEDICINES

This administration's starting point should be the 1999-2000 Clinton Administration policies that began to balance US industry desires with protections for access to medicines.

In 2000, the 301 Report included its fullest support for access to medicines principles ever, including a new structure that included HHS on the 301 sub-committee "**to ensure that the application of U.S. trade law related to intellectual property remains sufficiently flexible to respond to public health crises."**

The policy further stated: "should a government determine to avail itself of the flexibility the TRIPS Agreement provides to address a health care crisis, the United States will raise no objection."

We dispute that public health interests end with the concept of a "crisis." The Obama administration policy more helpfully discusses public health "needs." But the concept of having structured public health input in the 301 process on par with industry and commerce officials is important.

The Clinton administration also passed Executive Order 13155, banning the use of 301 to push TRIPS plus policies in sub-Saharan Africa. It is time to extend that principle to all developing countries.

REVIEW UNILATERAL ADJUDICATIONS UNDER WTO

The Administration should undertake an urgent review of legislative and policy changes necessary to bring Special 301 into compliance with the WTO's ban on unilateral adjudication of trade disputes. Under Special 301, USTR decides for itself what policies violate the TRIPS Agreement. And it has frequently done so under frivolous legal interpretations, such as that Article 39.3 requires data exclusivity when such a proposal was specifically amended out of the Article during TRIPS negotiations.

In your 2010 report, you should explain how USTR believes that 301 complies with the WTO and subject that legal opinion to challenge.

PROMOTE PRO-INNOVATION POLICIES

The U.S. government could use the Special 301 process to pursue pro-innovation policies. For example, it could encourage our trading partners to invest more in public sector R&D, including open source projects, and could highlight best practices to promote access to knowledge, such as the NIH policies to provide open access to published scholarly and scientific research when the research benefited from government funding.