Obama Administration Wants to Eliminate References to Doha Declaration in UN Political Declaration on Non-Communicable Diseases

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The United States and the European Union are using a United Nations High Level Meeting on Non-Communicable Diseases (NCDs) to effectively renegotiate a landmark agreement on intellectual property rights and public health.



What is at stake is an interpretation of the diseases covered by a 2001 WTO agreement that says that intellectual property rights should be implemented in a manner that promotes "access to medicine for all." The issue is whether the UN recognizes the relevance of the <u>Doha Declaration on TRIPS and</u> <u>Public Health</u>, which was negotiated on November 14, 2001, during a contentiousness and dramatic WTO ministerial meeting in Doha Qatar. The key language in the 2001 document reads as follows:

As President Obama's chief trade negotiator, Ambassador Ron Kirk has taken a hard line on pharmaceutical IPR and pricing issues. <u>Photo by Third</u> <u>Way</u>.

4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

The 2001 Doha Declaration came about largely because of the very visible crisis surrounding access to patented medicines to treat AIDS. The Bush Administration and the European Commission sought to narrow the understanding about health and intellectual property so it only applied to AIDS, or a limited set of infectious diseases. That effort failed in 2001 and again in 2003, during an interpretation of another section of the agreement. Since then, the U.S. and the European Commission have generally accepted references to the Doha Declaration on TRIPS and Public Health in World Health Resolutions, such as WHA61.21, in 2008, and in several bilateral and regional trade agreements, including in the final text of the Anti-Counterfeiting Trade Agreement (ACTA), which was completed in December of 2010. However, in a number of cases, the US and the EU have also asserted that the Doha Declaration is in fact limited to AIDS, infectious diseases or epidemics. These backtracking interpretations have always been strategic, when the US and the EU wanted to push back against a developing country effort to use compulsory licensing of patents for anything other than drugs for AIDS.

The UN negotiation on Non-Communicable Diseases has been, from the start, deeply influenced by companies that hold patents on drugs, diagnostics and medical devices for cancer, diabetes and heart disease. (See also reporting by Deborah Cohen in the BMJ).

In April, the World Health Organization sponsored a Global Forum on NCDs in Moscow. Sandeep Kishore attended the Moscow meeting, on behalf of several public health groups (Medecins Sans Frontieres, Knowledge Ecology International, the Young Professionals Chronic Disease Network, Universities Allied for Essential Medicines, Oxfam, Health Action International and The Third World Network). Kishore told KEI:

"The Director General of the IFPMA (Eduardo Pisani) chaired the essential medicines session at the WHO Global Forum in Moscow. There was no substantive response to our civil society recommendations when presented at this session."

According to Kishore, at another meeting in New York on June 16, an IFPMA representative was grouped as civil society, served as a panelist and was given a high profile opportunity to present the industry recommendations.

Just a few months earlier, there was a major battle to preserve language on Trade-Related Intellectual Property Rights (TRIPS) flexibilities and the Doha Declaration on TRIPS in the <u>political declaration on</u> <u>HIV/AIDS</u>. In those negotiations, developing countries faced similar opposition, and the U.S. delegation in particular tried to block any reference to TRIPS or the Doha Declaration. However, in the HIV declaration, the language on TRIPS and the Doha declaration survived.

For the non-communicable diseases resolution, negotiations on the draft declaration resumed from September 1-2, 2011 to resolve contentious areas of the document. The most recent draft contains so-called compromise text for paragraphs 34h and 48bis of the draft which references TRIPS flexibilities, but avoids any mention of the Doha Declaration. The relevant portions of these paragraphs currently read:

34h: Promote access to comprehensive and cost-effective prevention, treatment and care for the integrated management of NCDs, including, inter alia, increased access to affordable, safe, effective and quality medicines and diagnostics and other technologies, including through the full use of TRIPS flexibilites.

48bis: Urge relevant international organizations to continue to provide technical assistance and capacity building to developing countries, especially to the least developed countries, in the areas of NCD prevention and control and promotion of access to medicines for all, including through the full use of TRIPS flexibilities and provisions.

Compare this language to that found in the political declaration on HIV/AIDS from June:

71a: The use, to the full, of existing flexibilities under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement specifically geared to promoting access to and trade of medicines; and, while recognizing the importance of the intellectual property rights regime in contributing towards a more effective AIDS response, ensure that intellectual property rights provisions in trade agreements do not undermine these existing flexibilities, as confirmed by the Doha Declaration on TRIPS Agreement and Public Health, and call for early acceptance of the amendment to Article 31 of the TRIPS Agreement, as adopted by the General Council of the World Trade Organization in its decision of 6 December 2005

By seeking to eliminate any references to the Doha Declaration, the U.S. appears to be asserting that the "access to medicine for all" provisions in the Doha Declaration do not apply to drugs for cancer and other non-communicable diseases.

That position of the Obama White House can be contrasted to the George W. Bush Administration.

Under George W. Bush, the U.S. agreed to the language of the 1) Doha Declaration on TRIPS in 2001, 2) the August 30, 2003 WTO decision, 3) the 2005 WTO agreement on an amendment to the TRIPS Agreement, and 4) the World Health Assembly (WHA) Resolution 61.21 in 2008, also known as the Global strategy and plan of action on public health, innovation and intellectual property. The Bush Administration not only agreed to the language contained in the Doha Declaration itself, but continued to reaffirm its commitment to the text of the declaration, including in the WHA Global strategy and plan of action, which specifically noted that for developing countries:

it is important for WHO Member States and the WHO Secretariat to recognize and better address the increasing prevalence of noncommunicable diseases in those countries.

Meanhwhile, since 2010, compulsory licenses have been issued in the U.S. for <u>contact lenses</u> as well as a <u>device to treat aortic valve stenosis</u>.

Why is this controversy important? The US has conceded that compulsory licenses can be used for NCDs, an issue of no controversy legally, but politically sensitive. However, by removing the reference to the Doha Declaration, and maintaining the political position that the Doha Declaration does not apply to NCDs, the White House seeks to eliminate the "access to medicine for all" standard, and to raise doubts about the application of other elements of the Doha Declaration, including paragraphs 5, 6 and 7 to NCDs, if not legally, at least politically.

In a related development, on September 10, 2011, during the Chicago round of negotiations on the <u>Trans</u> <u>Pacific Partnership Agreement</u>, *Inside US Trade* reported the US negotiators will abandon a May 10, 2007 agreement that the Bush Administration reached with the Democrats in the House of Representatives. Specifically, USTR will revisit the May 10, 2007 pro-health positions on pharmaceutical patent extensions, linkage of patents with drug registration, and data exclusivity, in certain developing countries. The details of the new White House position will be made public on September 12, 2011.

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