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Congress of the United States
House of Representatives
Washington, DC 20515-0530

HENRY A. WAXMAN
30th District, California

April 27, 2010

The Honorable Ron Kirk
United States Trade Representative
600 17th Street, NW
Washington, DC 20508

Dear Ambassador Kirk:

I understand that your office is in the process of preparing the U.S. Trade Representative's 2010 "Special 301 Report," an annual compilation of concerns regarding the intellectual property (IP) protections of some of our country's trading partners. I am writing to urge that this Report reflect the Administration's interest in the issue of international access to medicines.

In my view, Special 301 Reports have not taken a balanced approach in addressing this issue in the past. Instead, those Reports have been used to pressure developing countries to adopt pharmaceutical IP policies that threaten the availability of affordable, essential medicines in those nations. This year's Report offers an opportunity to revisit the problem – and to signal the Administration's support for international access to effective medicines. My concerns about previous Special 301 Reports and the basis for a different, more balanced approach in preparing this year's Report are described below.

The Global Need for Safe and Affordable Medicines

Soon after taking office, President Obama announced a comprehensive global health strategy to reduce illness and mortality through U.S. foreign AID programs worldwide. The scope of the challenge is enormous.

According to UNAIDS, in 2007, there were an estimated 33 million people living with HIV, and two million others died of AIDS.[1] In 2008, an estimated 1.3 million people died from tuberculosis.[2] Malaria kills as many as two million people each year.[3] In total, infectious

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[1] UNAIDS, *2008 Report on the Global AIDS Epidemic: Status of the Global HIV Epidemic* (2008) (online at data.unaids.org/pub/GlobalReport/2008/jc1510_2008_global_report_pp29_62_en.pdf).

[2] World Health Organization, *Fact Sheet No. 104: Tuberculosis: Infection and Transmission* (Mar. 2010) (online at www.who.int/mediacentre/factsheets/fs104/en/).

diseases killed an estimated 13.6 million people in 2008, the majority of whom lived in developing countries.[4] Treatable but noninfectious chronic illnesses are also leading causes of death in the developing world. Such diseases, including cancer, cardiovascular disease, diabetes and chronic respiratory disease, killed an estimated 35 million people globally in 2005, with 80% of those deaths in developing countries.[5]

Despite the high incidence of disease in developing countries, an estimated 1.7 billion people worldwide have no access to essential medicines.[6]

A principal strategy used by developing nations to improve access to lifesaving drugs has been to authorize the production or importation of low-cost generic medicines. A prime example of the success of this approach is the impact of generic drug availability on the cost of HIV treatment. In May 2000, one year of a basic antiretroviral treatment for a person with HIV cost approximately $10,000, far beyond what most people in developing nations could afford.[7] Once generic alternatives entered the market, prices for brand and generic versions declined steeply. As a result, in low-income countries today, the same HIV regimen can cost as little as $87 per patient annually.[8]

Despite this great success, the pace of expansion of access to HIV treatment is threatened by the higher costs of newer first-line treatments, which have fewer toxic side effects but can cost up to twice as much per year.[9] And when patients become resistant and require second-line treatments, the costs are up to six times higher than the cheapest first-line regimen. Since it is likely that HIV therapies developed more recently will be patented in more countries, these drugs

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[3] Doctors Without Borders, *Campaign for Access to Essential Medicines* (2004) (online at www.accessmed-msf.org/documents/campaignbrochure2004.pdf).

[4] Global Health Council, *Global View* (online at www.globalhealth.org/infectious_diseases/global_view/).

[5] World Health Organization, *2008-2013 Action Plan for the Global Strategy for the Prevention and Control of Noncommunicable Diseases* (2008) (online at http://whqlibdoc.who.int/publications/2009/9789241597418_eng.pdf).

[7] All-Party Parliamentary Group on AIDS, *The Treatment Timebomb* (July 2009) (online at http://www.aidsportal.org/repos/APPGTimebomb091.pdf)

[8] *Id.*

[9] Medecins Sans Frontiers, Campaign for Access to Essential Medicines, *Untangling the Web of Price Reductions* (2009) (online at http://utw.msfaccess.org/).

will remain out of reach for the developing world until generic alternatives become available.[10] Addressing this growing problem is necessary if we are to meet international HIV/AIDS treatment goals – and will mean the difference between life and death for patients in the developing world.

TRIPS and the Doha Declaration

The 1994 agreement on Trade Related Aspects of Intellectual Property (TRIPS) -- to which the United States is a signatory -- established an international framework within the World Trade Organization (WTO) for protecting trademarks, copyrights, and patents.[11] It included the requirement that all countries implement 20-year patent protections for all products, including pharmaceuticals.

In 2001, the United States and the other 142 WTO Members signed the Doha Declaration, which states that the TRIPS agreement "can and should be interpreted and implemented in a manner supportive of WTO Members' rights to protect public health, and in particular, to promote access to medicines for all."[12] The Declaration highlighted that while the TRIPS agreement established minimum requirements for patent and other IP protections, countries retain the flexibility to undertake certain public health measures to ensure their citizens' access to essential medicines. For example, the Declaration includes express affirmations of the right of developing nations to authorize the production of generic versions of patented drugs ("compulsory licensing") and to import patented drugs at the lowest price available ("parallel importation").[13]

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[10] Under the TRIPS agreement (see infra, note 11), countries' obligations to implement a system of 20-year patents on all products, including medicines, were staggered based on the development level of the country. India, the largest worldwide generics producer, was required to transition to the new system by 2005. Therefore, drugs introduced in India after 2005 are more likely to be patent protected than those introduced before. The transition period for the least-developed countries will end in 2016, leading to increased patent protections in pharmaceuticals in the poorest countries in the world...

[11] World Trade Organization, *Agreement on Trade-Related Aspects of Intellectual Property Rights* (1994) (TRIPS).

[12] Paragraph 4, 'Declaration on the TRIPS Agreement and Public Health', WTO Ministerial Conference — Fourth Session, WT/MIN(01)/DEC/2, adopted 14 November 2001. (Doha Declaration).

[13] Doha Declaration, Paragraph 5.

President Obama has expressed his full support of the Doha Declaration, endorsing "the rights of sovereign nations to access quality-assured, low-cost generic medication to meet their pressing public health needs" under the TRIPS agreement.[14]

Past Special 301 Reports

In recent years, despite the United States' commitment to the Doha Declaration, Special 301 Reports have been used to pressure developing countries to adopt pharmaceutical protection rules that go beyond their obligations under the TRIPS agreement, limiting the scope of actions such countries could take to promote access to medicines.

In an independent analysis, the Government Accountability Office identified many such examples of pressure to implement policies beyond countries' TRIPS obligations.[15] For example, GAO found that some of the most commonly cited concerns related to countries that did not ban parallel importation of more affordable drugs, even though parallel importation is permitted under TRIPS, as expressly affirmed in the Doha Declaration.[16]

Special 301 Reports have also pressed countries to limit grounds for compulsory licenses; restrict freedom to define the scope of patentability; provide for the extension of patent terms beyond 20 years; implement "linkage" between drug registration and assertions of patent protection; and eliminate evidence-based formularies and other price and competition restrictions on pharmaceutical monopoly power.[17]

None of these policies is a requirement under TRIPS. As a result, the Special 301 Reports have repeatedly left an impression that the United States is willing to narrow our trading partners' rights under TRIPS and, in turn, ignore or dismiss altogether their public health needs in favor of increased pharmaceutical protections.[18] For example, in the 2007 Special 301

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[14] "The Obama-Biden plan to combat global HIV/AIDS" http://change.gov/pages/the_obama_biden_plan_to_combat_global_hiv_aids/.

[15] Government Accountability Office, *Intellectual Property: U.S. Trade Policy Guidance on WTO Declaration on Access to Medicines May Need Clarification* (Sept. 2007) (online at http://www.gao.gov/new.items/d071198.pdf).

[16] *Id.*

[17] *Id.*

[18] See United States House of Representatives, Committee On Government Reform – Minority Staff, Special Investigations Division, Trade Agreements and Access To Medications Under The Bush Administration, Prepared For Rep. Henry A. Waxman (June 2005); Letter from Rep. Henry Waxman, United States House of Representatives, et. al. to The Honorable Susan Schwab, United States Trade Representative (Jun. 20, 2007), available

Report, USTR criticized Thailand by elevating it to the "Priority Watch List" shortly after its government issued compulsory licenses on three pharmaceutical products. The report included additional concerns about IP protections in Thailand, and claimed that the USTR's concern about the compulsory licenses was based on a "lack of transparency and due process." However, the timing and focus of the downgrade led many to interpret U.S. policy as condemning the use of compulsory licenses, even though compulsory licensing, within certain guidelines, is permitted under TRIPS.

Counterfeiting

The treatment of counterfeit medicines in this year's Special 301 Report will be of particular interest to many observers. Considerable attention has been drawn to this issue by the ongoing negotiation of the Anti-Counterfeiting Trade Agreement. While definitions of "counterfeit drugs" vary, the World Health Organization considers counterfeit drugs to be those "deliberately and fraudulently mislabeled with respect to identity and/or source."[19]

It has come to my attention that in recent months, anti-counterfeiting enforcement measures normally reserved for cases involving willful and fraudulent mislabeling have been employed by European Union custom officials to seize shipments of generic AIDS, Alzheimer's, heart, and other medicines en route to developing countries.[20]

The medicines, mostly produced in India and seized en route to countries where their patent status was not in question, were not alleged to be mislabeled. Rather, European customs officials defended the drug seizures as part of a broader "anti-counterfeiting drive" based on challenges to their patent status in the countries through which the drugs were transiting.[21]

The conflation of anti-counterfeit measures with patent enforcement is problematic for two reasons. First, as the European seizures demonstrate, an over-broad definition of "counterfeit" can hinder the flow of safe and effective generic medicines. Second, when anti-counterfeiting measures are framed as a strategy to improve the safety and quality of medicines, the larger problem of substandard medicines remains unaddressed. While many counterfeit

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at http://waxman.house.gov/News/DocumentSingle.aspx?DocumentID=153595; Letter from Rep. Henry Waxman, United States House of Representatives, et. al. to The Honorable Susan Schwab, United States Trade Representative (Apr. 9, 2008), available at http://waxman.house.gov/UploadedFiles/letter_special_301__04-09-08.pdf.

[19] World Health Organization, *Counterfeit drugs: report of a WHO/IFPMA Workshop* (1992).

[20] *India Prepares EU Trade Complaint*, The Wall Street Journal (Aug. 6, 2009) (online at http://online.wsj.com/article/SB124949598103308449.html).

[21] *Id.*

medicines are substandard -- unsafe, ineffective, or both -- the majority of substandard medicines are *not* counterfeit.[22] Focusing on anti-counterfeit campaigns in this context as a means of serving public health interests ignores the bigger problem of substandard medicines in the developing world.

In the interests of public health, in the Special 301 Report and elsewhere, USTR should make certain that anti-counterfeiting measures are not mischaracterized as comprehensive approaches to addressing substandard medicines. Further, I believe it is critical for USTR to take the unequivocal position in the 2010 Special 301 Report that patents and patent enforcement measures are outside the scope of anti-counterfeiting policy.

Conclusion

Since May 10, 2007, when Congress reached an agreement to revise the intellectual property provisions of pending free trade agreements, USTR has begun to take meaningful steps to strike a better balance between encouraging pharmaceutical innovation and ensuring access to medicines in developing countries.

Under your leadership, USTR has taken further strides in this direction, including resolving long-standing differences with Israel over pharmaceutical IP issues, paving the way for Israel's removal from the Special 301 Report. USTR has also undertaken an unprecedented initiative to expand public participation in the Special 301 Report process, accepting submissions and holding a public hearing with testimony from both private and public entities.

This year provides an important opportunity for the Special 301 Report to reflect a true recognition of developing countries' essential medicine needs and to balance them appropriately with pharmaceutical intellectual property concerns. To that end, I urge you to ensure that developing countries are not criticized for TRIPS-compliant public health measures in this year's Report and to clearly delineate the appropriate scope of anti-counterfeiting initiatives.

Sincerely,

HENRY A. WAXMAN
Member of Congress

[22] Caudron et al., "Substandard medicines in resource-poor settings: a problem that can no longer be ignored," *Tropical Medicine and International Health* (Aug. 2008).