

Notice of Intent to Testify
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Matthew M. Kavanagh
Senior Policy Analyst, Health GAP (Global Access Project)
Fellow, University of Pennsylvania
208 S. 37th Street, Suite 246
Philadelphia, PA 19104
matthew@healthgap.org +1 202-486-2488

The Obama administration is currently violating both the spirit and the letter of the Doha Declaration. As such, it should remove the following countries from listing based on pharmaceutical policy which is compliant with TRIPS:

Special 301: Algeria, Chile, China, India, Indonesia, Pakistan, Thailand, Venezuela

301: Brazil, Colombia, Dominican Republic, Ecuador, Egypt, Lebanon, Mexico, Peru, Philippines, Tajikistan, Turkey, Vietnam, and Paraguay

Background

Global health issues have grown increasingly important in the strategic thinking of the United States over the past fifteen years. Rapid scientific and technological advancement has created new opportunities to address intractable health problems. AIDS, reproductive and child health and non-communicable diseases have new solutions and the urgent obligation to ensure access to medicines and health technologies by impoverished people in both the global North and South is growing. The high cost of these medicines, however, is a growing threat to the expansion and sustainability of public health programs around the world. In addition to the strategic and moral considerations, national laws and international agreements increasingly obligate states to promote the right to health. However, the demands being placed by the United States in order to avoid being listed on the Special 301 undermine both the U.S.'s global health goals and the obligation of listed states to provide for the health of their populations.

Human right to health & The Obligation of Governments to Promote Public Health

The first mention of the international right to health came in the 1996 World Health Organization constitution which recognized “The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being...”¹ The Universal Declaration of Human Rights followed in 1948, recognizing an international human right to health.² Article 25 of the Declaration states: “Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including... medical care and necessary social services, and the right to security in the event of... sickness...”³ Subsequently, as an implementing treaty for the UDHR, many nations adopted the International Covenant on Economic, Social and Cultural Rights (ICESCR).⁴ Article 12 of that agreement states that parties “recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.” Since then a wide variety of additional treaties have recognized the right to health, including the binding Convention on the Rights of the Child,⁵ which has been ratified by every State in the world except for two (the United States of America and Somalia), and the major conventions on elimination of racism⁶ and discrimination against women.⁷

In addition to these international rights, a growing number of countries in every region of the world include a right to health in their constitutions.⁸ As of 2004 67.5% of the constitutions of the world had a provision addressing health.⁹

Global Health Developments Raise New Urgency on Medicines

New AIDS Science: HIV Treatment Can End the AIDS Crisis

¹ CONST. OF THE WORLD HEALTH ORG. pmbl. (opened for signatures July 22, 1946).

² Universal Declaration of Human Rights, G.A. Res. 217A (III), U.N. Doc. A/810 at 71 (1948).

³ Id.

⁴ International Covenant on Economic, Social and Cultural Rights, G.A. Res. 2200, U.N. GAOR, 21st Sess., Supp. No. 16, at 49, U.N. Doc. A/6316 (1966).

⁵ Convention on the Rights of the Child, G.A. Res. 44/25, U.N. GAOR, 44th Sess., Supp. No. 49, at 169, U.N. Doc. A/44/49 (1989).

⁶ International Convention on the Elimination of All Forms of Racial Discrimination, G.A. Res. 2106, U.N. GAOR, 20th Sess., Supp. No. 14, at 49, U.N. Doc. A/6014 (1966) (see article 5(e)(iv) for the right to “public health, medical care, social security and social services”).

⁷ Convention on the Elimination of All Forms of Discrimination Against Women, G.A. Res. 34/180, U.N. GAOR, 34th Sess., Supp. No. 46, at 196, U.N. Doc. A/RES/34/180 (1980).

⁸ World Health Organization, SEA-HHR-02, *The Right to Health in the Constitutions of Member States of the World Health Organization South-East Asia Region*, 2011.

⁹ Eleanor D. Kinney & Brian Alexander Clark Provisions for Health and Health Care in the Constitutions of the Countries of the World 37 CORNELL INT’L L.J. 285 (2004)

AIDS remains a catastrophe for communities around the world—especially in Africa. It is still the leading cause of needless death among women of reproductive age¹⁰ and the economic impact of HIV in highly affected countries is staggering.

But the past two years have presented stunningly good news in the science of AIDS—perhaps the best since the advent of triple combination anti-retroviral treatment (ARVs) in the mid-1990s. Studies have now confirmed what has long been biologically plausible: *anti-retroviral HIV treatment is also HIV prevention*. A recent National Institutes of Health-funded randomized control study demonstrated that people living with HIV who were on ARV treatment not only remain healthy but are 96% *less likely to transmit HIV*.¹¹ This confirms the understanding that ART, by dramatically lowering viral load, is among the most effective modes of prevention¹² (which has been the basis for virtually eliminating HIV transmission from mothers to children).¹³ Indeed, studies in San Francisco,¹⁴ Taiwan, and Vancouver¹⁵ have shown that substantially expanded access to ART has helped lower the viral load of entire communities, which has been associated with reductions in new infections of as much as 50%, much of which is attributable to ARVs.

This finding has the potential to revolutionize the global response to HIV and has major implications for AIDS programs in the global South. Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases, wrote in *Science*, “The fact that treatment of HIV-infected adults is also prevention gives us the wherewithal, even in the absence of an effective vaccine, to begin to control and ultimately end the AIDS pandemic.”¹⁶ The policy response has been robust: several countries in Africa responded immediately by revising their national AIDS strategies

¹⁰ World Health Organization. Women and health: today’s evidence tomorrow’s agenda. Geneva, Switzerland: World Health Organization; 2009: xvii-91. Available at: <http://www.who.int/gender/documents/9789241563857/en/index.html>. Accessed November 10, 2009

¹¹ Cohen et al., Prevention of HIV-1 Infection with Early Antiretroviral Therapy, *N Engl J Med* 2011; 365:493-505, 11 August 2011. www.nejm.org/doi/full/10.1056/NEJMoa1105243

¹² Quinn TC, et al. (2000) Viral load and heterosexual transmission of human immunodeficiency virus type 1. Rakai Project Study Group. *N Engl J Med* 342: 921-929.

¹³ Tovanabutra S, Robison V, Wongtrakul J, Sennun S, Suriyanon V, et al. (2002) Male viral load and heterosexual transmission of HIV-1 subtype E in northern Thailand. *J Acquir Immune Defic Syndr* 29: 275-283.

¹⁴ MMWR (2006) Achievements in public health. Reduction in perinatal transmission of HIV infection--United States, 1985-2005. *Morb Mortal Wkly Rep* 55: 592-597.

¹⁵ Das M, Chu P, Santos GM, Scheer S, Vittinghoff E, McFarland W, Colfax GN. Decreases in community viral load are accompanied by reductions in new HIV infections in San Francisco. *PLoS One*. 2010 Jun 10;5(6):e11068.

¹⁶ Montaner JS, et al Association of highly active antiretroviral therapy coverage, population viral load, and yearly new HIV diagnoses in British Columbia, Canada: a population-based study. *The Lancet*. 2010.

¹⁶ Fauci, A. “AIDS: Let Science Inform Policy,” *Science*, v333: 1 July 2011.

and treatment guidelines to accelerate the pace of scale HIV treatment roll out—planning to get newer drugs to more people earlier in their disease to halt both deaths and new infections.¹⁷ The World Health Organization is, at the time of writing, in the process of revising their guidelines to provide earlier HIV treatment. And, after publicly questioning the cost effectiveness of HIV treatment,¹⁸ the Obama administration dramatically reversed course and pledged to help countries rapidly scale up access to ARVs. This culminated in Secretary Hillary Clinton’s launch of the new U.S. Government blueprint for “Creating an AIDS-free Generation” in November 2012 which outlined a plan for concrete impact on HIV incidence in the countries receiving U.S. assistance through “combination prevention” led by the use of ARVs.¹⁹

Yet translating these important scientific breakthroughs into reality will require earlier and broader access to affordable anti-retroviral medicines, including the newer, more effective drugs that are currently under layers of patent protection in both wealthy and developing countries.

Conflicting Goals of Global Health & IP

There is a growing disconnect between the promotion of global health progress and the looming crisis of high priced monopoly-controlled medicines. Programs such as the U.S. President’s Emergency Plan for AIDS Relief depend on low-priced generic drugs for their success²⁰ and yet the newer medicines that will be critical for expansion of the programs are unlikely to be available in low-cost versions.²¹ Meanwhile efforts on overall development and health from USAID are increasingly in conflict with the IP rules that USTR is demanding.

In the context of national health needs and a global marketplace for drugs, each country has to balance competing interests. Overly strong intellectual property leads to excessive monopoly costs to individuals, the overall economy, and government effectiveness (e.g. health systems that must pay for drugs). IP results in static inefficiency by its very nature and, as economists such as Joseph Stiglitz have argued, overly strong IP is incredibly distortionary on both markets for important

¹⁷ See, e.g. Uganda and Malawi ART guidelines, on file with the author.

¹⁸ See, e.g. Colleen C. Denny; Ezekiel J. Emanuel, “US Health Aid Beyond PEPFAR: The Mother & Child Campaign,” JAMA. 2008;300(17):2048-2051.

¹⁹ U.S. Department of State, *PEPFAR Blueprint: Creating an AIDS-free Generation*, November 2012.

²⁰ Holmes CB, Coggin W, Jamieson D, Mihm H, Granich R, Savio P, Hope M, Ryan C, Moloney-Kitts M, Goosby EP, Dybul M., “Use of generic antiretroviral agents and cost savings in PEPFAR treatment programs,” JAMA. 2010 Jul 21;304(3):313-20. doi: 10.1001/jama.2010.993.

²¹ MSF Access Campaign, *Untangling The Web of Antiretroviral Price Reductions*, 15th Edition, July 2012.

goods and on innovation.²² Intellectual property laws are justified as important, however, to deal with the problem of excessive free-riding that result in underinvestment in research.²³

In the pre-World Trade Organization era that balance was struck by many now-developed countries limiting patents.²⁴ A 1988 World Intellectual Property Organization study showed that 49 of the 98 signatories to the Paris Convention for the Protection of Industrial Property—which included both developed countries and many developing countries that had become signatories under colonial rule--excluded pharmaceutical products.²⁵ Where they did allow for patenting on pharmaceuticals it was largely through *process* patents rather than *product* patents, with the rationale that for “areas of great social impact, where the major government concern was ensuring an adequate domestic supply,” product patents would be counterproductive.²⁶

It was in that context that a significant portion of the world’s pharmaceutical capacity was built. This included Northern pharmaceutical powerhouses like Switzerland, where patents on pharmaceutical products were explicitly prohibited by the constitution until 1977 and Italy, which only allowed pharmaceutical patents in 1978, at which point it was the fifth largest world producer of pharmaceuticals and the seventh largest exporter.²⁷

Today India has emerged as the most important global South player in pharmaceuticals—the “pharmacy of the developing world.” In 1970 when India began transformation of its patent system

²² Joseph E. Stiglitz, 57 *Duke Law Journal* 1693 (2008).

²³ Diwan, I. and D. Rodrik (1991), ‘Patents, Appropriate Technology, and North-South Trade’, *Journal of International Economics*, 63, 79-90.

²⁴ Carlos Correa, *Integrating public health concerns into patent legislation in developing countries* (Geneva: South Centre, 2000)

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²⁵ Listing countries that exclude pharmaceutical products: “Argentina, Australia, Bolivia, Brazil, Bulgaria, Canada, Chad, China, Colombia, Cuba, Czechoslovakia, Ecuador, Egypt, Finland, German Democratic Republic, Ghana, Greece, Hungary, Iceland, India, Iran, Iraq, Lebanon, Libya, Malawi, Mexico, Monaco, Mongolia, Morocco, New Zealand, Norway, Pakistan, Peru, Poland, Portugal, Republic of Korea, Romania, Soviet Union, Spain, Syria, Thailand, Tunisia, Turkey, Uruguay, Venezuela, Viet Nam, Yugoslavia, Zambia, Zimbabwe. WIPO, *Existence, Scope and Form of Generally Internationally Accepted and Applied Standards / Norms for the Protection of Intellectual Property*, (15 SEPTEMBER 1988) at 80; available at [http://www.tripsagreement.net/documents/GATTdocs/erally_Internationally_Accepted_and_Applied_Standards_&_Nor ms_for_the_Protection_of_IP_-_Revision_E_E.pdf](http://www.tripsagreement.net/documents/GATTdocs/erally_Internationally_Accepted_and_Applied_Standards_&_Norms_for_the_Protection_of_IP_-_Revision_E_E.pdf).

²⁶ Claudio Frischtak, “The Protection of Intellectual Property Rights and Industrial Technology Development in Brazil,” *Industry and Energy Department Working Paper, Industry Series Paper 13*, Washington DC: World Bank (1989).

²⁷ Michele Boldrin and David K. Levine, *Against Intellectual Monopoly*, Cambridge University Press (2008) at 245. Xuan Li, The Impact of Higher Standards in Patent Protection for Pharmaceutical Industries under the TRIPS Agreement, *UNU Wider Research Paper* No. 2008/36, (April 2008).

from its colonial roots, it was producing less than 25% of its own medicines and was paying some of the highest prices in the world for key medicines.²⁸ The Indian Patent act of 1970 substituted a variety of more limited IP measures—providing only for patents on pharmaceutical processes rather than on products and for a very limited period—just 7 years.²⁹ Combined with substantial public investment in the pharmaceutical sector, the result was transformative—twenty years later in 1991 Indian firms accounted for 70% of the bulk drugs and 80% of formulations produced in the country.³⁰

Under the Trade Related Aspects of Intellectual Property and Services Agreement (TRIPS) member states were required to implement twenty year patents, patents on all sectors including pharmaceuticals, and both product and process patents. There were, however, some important text that at least nodded toward the need to protect public health. Article 7 of TRIPS stated that:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

While Article 8 added that:

*Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.*³¹

The Doha Declaration: Intended Policy Space for Public Health

²⁸ Jean O. Lanjouw, ‘The Introduction of Pharmaceutical Product Patents in India: Heartless Exploitation of the Poor and Suffering?’, *Working Paper 6366, NBER*, (1998),

²⁹ Chaudhuri S. *The WTO and India’s pharmaceuticals industry: patent protection TRIPS and developing countries*. Oxford University Press, 2005.

³⁰ Lanjouw, supra note ____ quoting Hamied, Y. K. (1993) "Patents and the Pharmaceutical Industry: A Review," Presentation at the International Conference on Patent Regime Proposed in the Uruguay Round, New Delhi. Cipla, Ltd.

³¹ TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 320 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994)

Shortly after TRIPS was signed, multinational pharmaceutical companies began an aggressive campaign to interpret TRIPS in a IP-maximalist manner. These came to a head in the public health arena in 1998 when MNPCs sued the South African government over the Mandela government's law making use of what many understood were pro-health "flexibilities" in TRIPS. In retaliation the U.S. placed South Africa on the 301 watch list, suspended key trading privileges, and applied intense diplomatic pressure to reverse the law. The case turned into a three year trans-national confrontation over public health and the limits of TRIPS that ended only through a concerted campaign by AIDS treatment activists and public health groups.³²

In the lead up to the 2001 WTO ministerial two special sessions of the TRIPS Council were held and over 40 different statements and proposals were made on the issue of TRIPS and Public Health. The result of the ministerial meeting was the Doha Declaration on TRIPS and Public Health.

It said, in part:

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.*³³

As one important UNDP document on the subject notes, the Doha Declaration was meant "not as the creation of such policy space but instead **confirming** the right of WTO member states to make effective use of existing TRIPS flexibilities [emphasis original]."³⁴

Doha's Legal Flexibilities

³² Patricia Siplon, *Drugs into Bodies: Global AIDS Treatment Activism*; William W. Fischer and Cyrill P. Rigamonti (2005) *The South Africa AIDS Controversy*. Harvard Law School.

³³ World Trade Organization, *Declaration on the TRIPS Agreement and Public Health*, TW/MIN(01)/DEC/2, Adopted 14 November 2001; Sec. 4.

³⁴ Carlos Correa and Duncan Matthews, *The Doha Declaration Ten Years on and Its Impact on Access to Medicines*, UNDP, 20 December 2011.

A variety of specific IP issues were raised in relation to the Doha Declaration. Many subsequent interpretations have stressed the wording “these flexibilities include” in the *chapeau* of Paragraph 5 to support the contention that the issues specifically listed in the declaration were illustrative rather than an exhaustive list.³⁵

Compulsory Licenses: Article 31 of the TRIPS agreement specifically allows for the issuing of compulsory licenses, providing a way for governments to compel patent holders to grant non-exclusive use of the patent to the government and/or generic producers in exchange for a reasonable royalty. The U.S. and others argued that only a very limited use was permitted under TRIPS and only in public health emergencies. As such, this was a chief question for Doha. The Declaration agreed that, “Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.”³⁶

Parallel Importation: There was a specific discussion at Doha confirming that Paragraph 6 of TRIPS puts determination of the exhaustion of intellectual property rights entirely in the hands of countries. By establishing an international exhaustion regime countries could allow import of drugs from countries where they were sold at lower prices.

LMIC Country Extension: The Doha Declaration extended the deadline to implement TRIPS for countries designated by the UN as “least developed countries” to 2016. At the time of writing the LDCs have formally requested a further and indefinite extension, which the U.S. should support.

Data Exclusivity: This has been a deeply contentious issue since TRIPS was signed and required that countries protect

“undisclosed test or other data... against unfair commercial use. In addition, Members shall protect such data against disclosure except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.”³⁷

The U.S. interpreted TRIPS as essentially creating a property interest in the data itself and requiring governments to grant a period of exclusive use. As Aaron Fellmeth documents, however, this

³⁵ See e.g. Carlos Correa and Duncan Matthews, *The Doha Declaration Ten Years on and Its Impact on Access to Medicines*, UNDP, 20 December 2011.

³⁶ Doha Declaration Section 4b

³⁷ TRIPS Art 39.3

specific proposal was actually rejected during the TRIPS negotiations.³⁸ We find nothing in TRIPS that prevents government use of this data for registering drugs as safe and effective—suggesting this had little to do with “unfair commercial practices.”³⁹ In their paper presented at Doha, developing countries noted that “The Agreement clearly avoids the treatment of undisclosed information as a “property” and does not require granting “exclusive” rights to the owner of the data.” Instead, they found, the protection was against “dishonest commercial practices” but that “Article 39.3 does permit a national competent authority to rely on data in its possession to assess a second and further applications, relating to the same drug, since this would not imply any ‘unfair commercial use.’”⁴⁰

There are several other “flexibilities” that are generally thought to fall under the Doha declaration’s general public health mandates.⁴¹ These include:

Linkage: The Doha Declaration also did not fully settle the obligation of countries to link marketing approval with patents. In many countries, including the EU for many years, there was no formal burden on the often under-resourced Drug Regulatory Agency—charged with protecting health and safety—to check patent status before granting approval to drugs. Recently, however, this has been a major demand of U.S. within Special—creating a major non-patent barrier to introduction of generics.⁴²

Scope of Patentability: The ability to define what constitutes an “invention” has been one flexibility to limit over patenting and is a right of countries within the WTO requirements to offer patents to processes and products that are new, involve an inventive step and are capable of industrial

³⁸ Aaron Xavier Fellmeth, “Secrecy, Monopoly, and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data Under the TRIPS Agreement,” *Harvard International Law Journal*, 45: 2 443, at 455 and, on the same page, quoting the USTR General Counsel opinion that 39.3 requires data “not be sued to support, clear or otherwise review other applications for marketing approval for a set amount of time unless authorized by the original submitter of the data. Any other definition of this term would be inconsistent with the logic and with the negotiating history.”

³⁹ See, e.g. Brook Baker, (2008), “Ending Drug Registration Apartheid: Taming Data Exclusivity and Patent/Registration Linkage,” *American Journal of Law and Medicine* 34

⁴⁰ “Developing Country Paper,” at section 39 & 40.

⁴¹ See, e.g. “Using TRIPS Flexibilities to Improve Access to HIV Treatment,” *UNAIDS/UNDP/WHO Policy Brief*, available at http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2049_PolicyBrief_TRIP_S_en.pdf

⁴² Brook Baker supra note 51.

application. If the scope of what can be patented is narrowly tailored then it can limit the number of patents overall, including on medicines.

Opposition Mechanisms: Countries are allowed under TRIPS to set up mechanisms to allow generic companies and all other interested parties (such as patient groups) to challenge whether a patent meets the standards of a country's laws. Challenges can be allowed both before and after the granting of the patent, though pre-grant oppositions have been both especially important in preventing improvidently granted patents. It is unclear why the U.S. would oppose this measure.

Flexibilities & Drug Prices: The Cases of India, Thailand and Lopinivir/Ritonovir

The cost of AIDS drugs in the global South have fallen from over \$10,000 per patient per year in 2000 to \$119 for the World Health Organization recommended first line therapy.⁴³ In Northern countries with restrictive pre-1995 patent regimes these prices have not fallen anywhere near as substantially, but where generic competition was introduced the result was a massive price reduction. Figure 1 shows a oft-referred to graph from the Medcins Sans Frontier *Untangling the Web of Antiretroviral Price Reductions* report showing just how drastically prices fell with the introduction of generic versions of key drugs after 2000.

Similarly important price differentials have developed on malaria, cancer, heart disease, and other drugs.⁴⁴ Figure 2 shows the less dramatic but still important path of artemisinin combination therapy used to treat malaria. At each step, increased generic competition has driven price reductions such that within just a few years the price was less than a quarter of the originator price.

To understand just how these price reductions came to be we have to look to India. Today, India supplies 20% of the entire world's generic medicines the majority of essential generic medicines to the global South, and 80% of generic antiretroviral AIDS drugs.⁴⁵ Most African nations are largely or completely reliant on the robust Indian generic sector for affordable medicines for HIV. In

⁴³ MSF Access Campaign, *Untangling The Web of Antiretroviral Price Reductions*, 15th Edition, July 2012.

⁴⁴ Clinton Foundation.

⁴⁵ Gwynne, P. "Biotech in the BRICyard," *Scientific American Worldview*, <http://www.saworldview.com/article/biotech-in-the-bricyard>. Waning B., et.al "A lifeline to treatment: the role of Indian generic manufacturers in supplying antiretroviral medicines to developing countries," *Journal of the International AIDS Society*, 2010, 13:35.

developing countries, largely outside Africa, unable to access generic versions of this same set of medicines due to patent barriers the costs have remained about ten times this generic price.⁴⁶

Most of these medicines, however, were first patented in the pre-1995 period before TRIPS came into force.⁴⁷ In the new TRIPS era MNPCs quickly began putting patent applications into the required “mailbox” for consideration in India by 2005. The new TRIPS-compliant 2005 Amended India Patents Act dramatically changed the patent landscape. Today over 2,347 patents on medicines have been granted by India⁴⁸ including several on key AIDS drugs.⁴⁹ The result, as shown in Figure 3 is that many of the drugs discovered in the last several decades are likely to be patented in much of the global South including in India, making affordable generic versions much less available.

India, however, had made use of many of the important flexibilities included within TRIPS and affirmed at the Doha Declaration. This has allowed activists, doctors, and generic companies in India to access a few of the especially important newer medicines.

The case of Lopinavir/Ritonavir, sold as Kaletra or Aluvia by Chicago-based Abbott Laboratories is an especially instructive example. In the U.S. Kaletra costs \$8,000-\$13,000 per patient per year⁵⁰ and is covered by several overlapping patents. As of 2012 the lowest global price, however, was \$368 from Abbott and \$371 generically.⁵¹ The price dropped dramatically in the last decade because of the introduction of generic versions, with the originator company offering a series of price reductions to try to stay ahead of the generic price. This was only possible because the drug does not have patent protection in India.

The first patent on Lopinavir/Ritonavir was granted in 1996 with a subsequent 2004 patent filed for the heat stable version of the medicine—post-TRIPS patents.⁵² But India’s post-TRIPS 2005

⁴⁶ Ibid.

⁴⁷ Suerie Moon, Natasha Sunderji, Esteban Burrone, Pascale Boulet, Chan Park, Julia Shen, and Ellen ‘t Hoen, *ARV patents on the rise? An analysis of ARV patent status in 75 low and middle income countries*, XIX AIDS Conference, Washington 25 July 2012.

⁴⁸ Correa, C. *Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing*. The South Centre, Research Paper 41, September 2011 at 7.

⁴⁹ Medicines Patent Pool, *Patent Status Data Base for Selected HIV Medicines*, available at <http://www.medicinespatentpool.org/LICENSING/Patent-Status-of-ARVs>

⁵⁰ Price comparisons across a series of online pharmacies for shipment to the U.S. by the author 12/12.

⁵¹ MSF Access Campaign, *Untangling The Web of Antiretroviral Price Reductions*, 15th Edition, July 2012.

⁵² Id.

patent law made use of several important flexibilities. Perhaps most importantly, section 3(d) of India's patent law restricts the scope of patentability. It states,

*"the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such process results in a new product or employs at least one new reactant."*⁵³

The law also allows for pre-grant opposition by any concerned party. In the case of Lopinavir/Ritonavir, patient groups and generic producers successfully challenged patent on the grounds that the basic medicine had long been known and, as such, it did not represent a product which is new or novel "and hence not involving inventive step." Similar processes led to the withdrawal of the patent applications on lamivudine/zidovudine and the rejection of patent applications for other key AIDS drugs including tenofovir, darunavir, and nevirapine syrup.⁵⁴ allowing generic companies in India to continue to supply affordable versions in India and throughout the developing world.

Importantly, Indian law also does not require data exclusivity, which would have created a major non-patent barrier to generics production.

The existence of Indian-generically made lopinavir/ritonavir also has impacts on other countries' ability to use flexibilities themselves. In January of 2007 Thailand issued a compulsory license for the drug⁵⁵ citing high costs for second-line AIDS treatment that threatened to undermine the public health system's medicine program. Under Abbott's voluntary programs, Thailand did not qualify for the low price options and instead was paying thousands of dollars per patient per year. Through the CL it was able to make government use of the patent, importing generic versions from India, and paying Abbott a royalty.

⁵³ Section 3d of the Indian Patent Act of 2005.

⁵⁴ <http://patentoppositions.org/>

⁵⁵ See Decree of Department of Disease Control Regarding Exploitation of Patent on Drugs & Medical Supplies by the Government on Combination Drug Between Lopinavir & Ritonavir, Issued 29 January 2007 and available online at <http://www.keionline.org/content/view/90/1> citing as its reason "it is still difficult to get accessed [sic] to some effective and safer anti-retrovirals. The high price of these patented anti-retrovirals have hindered their accessibility under the universal access policy because of patent protection by law, then there's no competition. The government cannot allocate enough budget."

These are the success stories of ability of TRIPS flexibilities to ensure affordable medicines. They suggest that the Doha Declaration has had some important affect: key flexibilities still exist under TRIPS that *do* allow countries of the global South policy space to prioritize public health within their IP regimes.

Whey, then, would the U.S. oppose their use by listing countries on the Special 301 list?

US Special 301

In the Special 301 process USTR is to identify countries that do not provide "adequate and effective protection of intellectual property" or who "deny fair and equitable market access to United States persons that rely upon intellectual property protection" ⁵⁶ and to label those engaged in "the most onerous or egregious acts, policies, or practices" on IP in the eyes of USTR as "priority foreign countries."⁵⁷ If the acts, practices, or policies continue, the USTR is authorized to retaliate by increasing duties, withdrawing trade preferences, or other retaliatory trade actions.⁵⁸

In implementing the law, instead of naming "priority countries" the USTR has instead created the Special 301 Watch List and the Priority Watch List,⁵⁹ which imply increasing levels of threat of retaliatory action. The area of pharmaceuticals has been one of the most important focuses of Special 301—the yearly submissions of the Pharmaceutical Research and Manufacturers of America (PhRMA) and, more recently, Biotechnology Industry Organization (BIO) largely drive the list of countries cited for pharmaceutical patent issues.⁶⁰

Today the U.S. is unreasonably demanding TRIPS+ measures and placing countries on the watch lists for TRIPS compliant measures. The U.S. cited compulsory licensing and parallel importing in Columbia and Peru in 1996, for example, in putting them on the watch list. Data exclusivity has become a bigger and bigger issue—starting with Argentina in 1995. Being placed on the Special 301 list was clearly a threat of retaliation in practice. In July of 1987, the USTR began a 301

⁵⁶ 19 U.S.C. § 2242(a)(1)(A) (1988).

⁵⁷ Id § 2242(a)(1) (A), (B) and (C)

⁵⁸ 19 U.S.C. § 2416(b) and 19 USC § 2411

⁵⁹ Only a few early years did the U.S. use the term "priority foreign country." Instead it quickly shifted to watch lists, a practice supported by industry as reported in: Office of the United States Trade Representative, *Fact Sheet "Special 301 "on Intellectual Property*, May 25, 1989 available at www.keionline.org/sites/default/files/ustr_special301_1989.pdf

⁶⁰ See list of submissions compiled by Knowledge Ecology International, available at <http://www.keionline.org/ustr/special301>

investigation of Brazil on the issue of patent protection for pharmaceutical products, which eventually led to stiff tariff penalties less than two months before the meeting of Trade Ministers at the December mid-term review in Montreal. It imposed tariffs on Brazilian paper products, non-benzenoid drugs and consumer electronic items.

In 1997, USTR announced sanctions against Argentina—withdrawing duty-free trade preferences on \$260 million worth of goods—because of Argentina’s use of TRIPS flexibilities including compulsory licensing, parallel imports and, largely, for not having data exclusivity.⁶¹ And in 1999 the U.S. similarly threatened the GSP status of the Dominican Republic for its compulsory licensing and lack of linkage.⁶²

I have looked at the Special 301 reports for 24 years ranging from 1989 to 2012. I coded each country for each year based whether the appeared on either the Priority Watch List or Watch List specifically for pharmaceutical related issues and whether data exclusivity was listed as a reason for being listed in either category.⁶³ This analysis leaves out any listings specifically focused on failure to implement the uncontentious interpretation of TRIPS—such as post-TRIPS allegations of failure to enact product patents. As such, the listings are largely coded for TRIPS+ provisions desired by the U.S. I also examined the reasons countries were down-graded or left the list altogether.

As can be seen in Table 4 included here the number of countries listed has grown over time, reaching its first high in 2001 as the Doha Declaration was being negotiated. We might have hoped that after the Doha Declaration, recognizing the right of countries to protect public health, there would be a sharp fall off of pressure on countries for exercising TRIPS flexibilities through Special 301 listing. But, as can be observed, listings have grown over time and stand today slightly higher than at the time of the Doha Declaration.

⁶¹ USTR Press Release, January 15th, 1997 “USTR-Designate Barshefsky Announces GSP Sanctions Against Argentina for Continuing IPR Problems,” available at <http://www.cptech.org/ip/health/c/argentina/ustrpr-january1997.html> and USTR, Report on Special 301 Review, 30 April 1997. *And see* letter from Ralph Nader, James Love, and Robert Weissman to Presidnet Clinton available at <http://www.cptech.org/pharm/USTRJune91997.html>

⁶² USTR, “USTR Announces Resutls of Special 301 Annual Review,” 30 April 1999.

⁶³ The Special 301 reports take a narrative, rather than a chart or numerical form. As such, I developed a coding strategy in which countries were generally only listed if specific pharmaceutical issues were explicitly mentioned. Generalized comments about patents were not included unless in the years immediately prior and following specific pharmaceutical issues caused listing, in which case it was assumed this was just an omission in text without change in policy pressure.

This finding is all the more notable, however, because the current number does not include all those countries who left the Special 301 list after succumbing to U.S. pressure to change their laws. For example, Columbia was delisted in 2003 and Mexico in 2004 after adopting data exclusivity and, in Mexico, linkage while Thailand briefly had no pharmaceutical listing in 2001 and 2002 after implementing data exclusivity. I found no examples where countries previously listed were removed from the list because the U.S. acknowledged its use of TRIPS flexibilities to protect public health. Where such references were made, they were actually along with decisions to list a country for use of TRIPS flexibilities such as compulsory licenses—suggesting these were largely pro-forma rather than substantive.

Reading the reports in succession clearly shows a ratcheting up of U.S. demands of countries. By 2012 countries were expected to, not only meet TRIPS requirements but also implement data exclusivity, linkage, and expansive patentability while avoiding the use of compulsory licenses and parallel importation in order to avoid being listed.

The Thai case explored previously is instructive. When Thailand issued a TRIPS-compliant compulsory license on lopinavir/ritonavir to ensure affordable HIV medicines, they were immediately upgraded to the Priority Watch List explicitly because of it.⁶⁴ The U.S. also retaliated by removing millions of dollars in trade preferences.⁶⁵ Thailand remains on the Priority Watch List to this day and, while the administration increasingly references the Doha Declaration and Thailand's right to issue the CLs it did, vague "concern" over their issuing leaves little question why Thailand is listed.

More recently, India in 2012 issued a compulsory license on Bayer's cancer drug Nexavar, resulting in threats from the US Congress and U.S. Patent and Trademark Office to file a formal WTO dispute.

⁶⁴ The report noted "In late 2006 and early 2007, there were further indications of a weakening of respect for patents, as the Thai Government announced decisions to issue compulsory licenses for several patented pharmaceutical products. While the United States acknowledges a country's ability to issue such licenses in accordance with WTO rules, the lack of transparency and due process exhibited in Thailand represents a serious concern. These actions have compounded previously expressed concerns such as delay in the granting of patents and weak protection against unfair commercial use for data generated to obtain marketing approval." USTR, 2007 *Special 301 Report* at 27.

⁶⁵ Petchanet Pratuangkrai, "US Will Cut GSP Benefits: Health Ministry urged not to retaliate with compulsory licensing of drugs," *The Nation*, 29 June 2007 available at http://www.nationmultimedia.com/2007/06/29/business/business_30038072.php and Chalida Ekvitthayavechnukul "GSP 'loss' to be evaluated: Move in wake of being placed on US watch list," *The Nation* 9 May 2007. http://nationmultimedia.com/2007/05/09/business/business_30033715.php

“In the case of India, I was quite dismayed and surprised when they did, indeed, decide to grant that compulsory license for a reason that, I think, did not meet international standards and was not due to, for instance, a national crisis,” testified Teresa Stanek Rea, Deputy Director of the USPTO.⁶⁶

Conclusion

We find ourselves in a period of breathtaking possibilities in global health. Scientists, heads of state, and civil society groups around the world talk of ending AIDS for the next generation, making huge progress against cancer worldwide, addressing long-neglected tropical diseases, and even eliminating long-lingering diseases from the planet—all in the near future. But the cost of medicines worldwide threaten to undermine these efforts—bankrupting public health efforts and widening the health gap between North and South.

The Doha Declaration on TRIPS and Public Health was an important watershed in acknowledging the need to balance public health priorities with global trading rules.

It is our contention that the current administration is violating both the spirit and the letter of the Doha declaration with the Special 301 listings.

This push is undermining U.S. global health goals and the ability of countries to observe the health rights of their people. USTR should immediately launch a revision of the list—removing all countries that meet TRIPS obligations from listing based on pharmaceuticals.

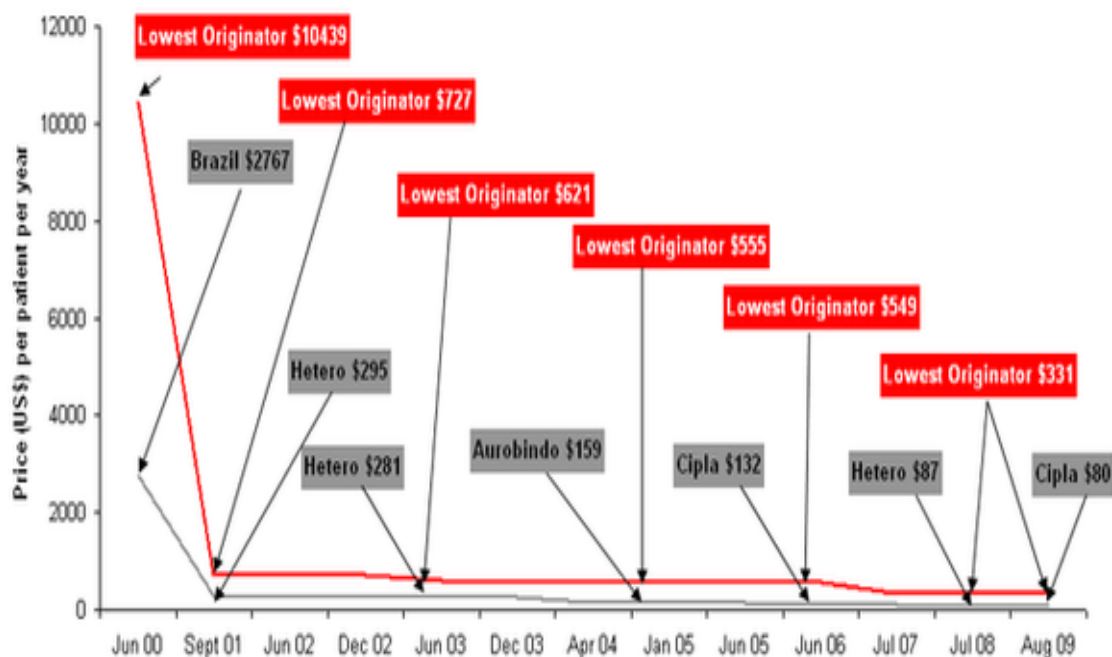
On that basis the following countries should be removed from the 2013 list.

Special 301: Algeria, Chile, China, India, Indonesia, Pakistan, Thailand, Venezuela

301: Brazil, Colombia, Dominican Republic, Ecuador, Egypt, Lebanon, Mexico, Peru, Philippines, Tajikistan, Turkey, Vietnam, and Paraguay

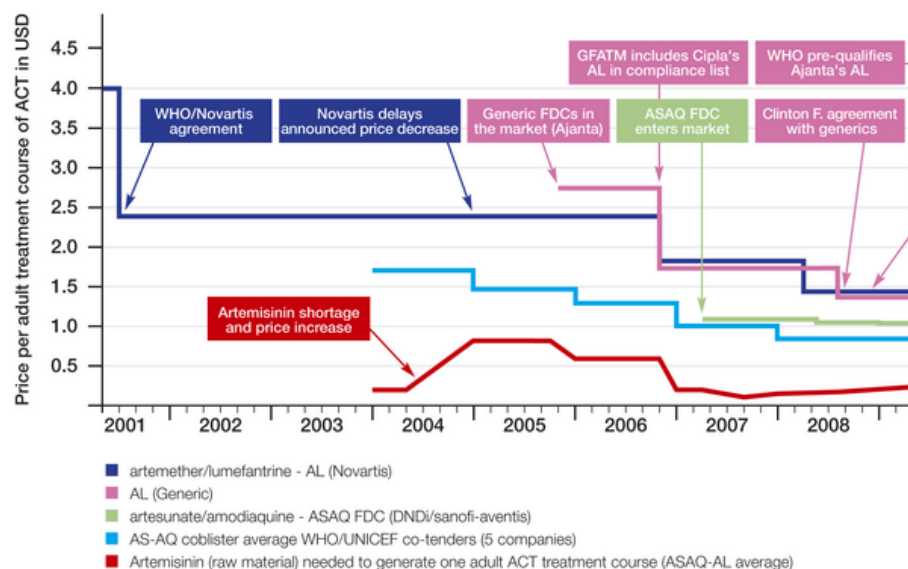
⁶⁶ “International IP Enforcement,” Hearing Before the Subcommittee on Intellectual Property, Competition, and the Internet of the House Judiciary Committee, 12th Congress, 27 June 2012 at 16, available at judiciary.house.gov/hearings/printers/112th/112-119_74817.PDF

Table 1



Source: MSF Access Campaign, *Untangling The Web of Antiretroviral Price Reductions*, 15th Edition, July 2012.

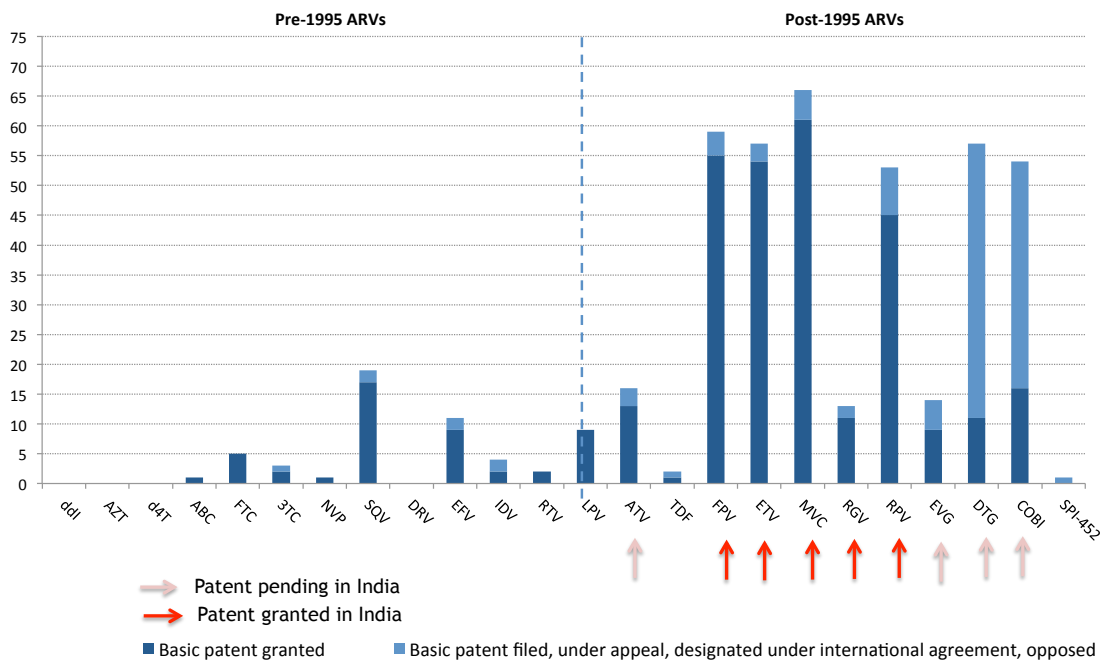
Table 2



Prices exclude main carriage/freight and insurance costs

Source: Moon S, Pérez Casas C, Kindermans J-M, de Smet M, von Schoen-Angerer T (2009) Focusing on Quality Patient Care in the New Global Subsidy for Malaria Medicines. *PLoS Med* 6(7): e1000106. doi:10.1371/journal.pmed.1000106

Table 3



Source: Suerie Moon, Natasha Sunderji, Esteban Burrone, Pascale Boulet, Chan Park, Julia Shen, and Ellen 't Hoen, *ARV patents on the rise? An analysis of ARV patent status in 75 low and middle income countries*, XIX AIDS Conference, Washington 25 July 2012.

Table 4

