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ESSENTIAL MEDICINES BEYOND GUILT TRIPS AND ACTA-ING UP: A GLOBAL PHARMAFORUM FOR A NEW ERA?

By some estimates, over eleven million people die every year for lack of access to effective medicines. The vast majority succumb to lack of access to medications. An increasing number and proportion of people are suffering and dying because they take the only drugs available to them: potentially lethal counterfeit medicines. Like Janus, this human tragedy has two different but interrelated faces that must be tackled together if we are to stem the flow of unnecessary deaths and disabilities: access and quality.

There are two multilateral fora with a natural mandate to fight the scourge of premature deaths due to lack of access to medicines. The first forum is the World Health Organization (WHO), whose mandate encompasses “the attainment by all peoples of the highest possible level of health”.¹ However, the WHO has proved unequal to the task. The second forum is the World Trade Organization (WTO). The mandate of the WTO is simply to “provide the common institutional framework for the conduct of trade relations among its Members”. It was not conceived as a system to promote health and has only reluctantly waded into those waters. Nonetheless, the unavoidable consequences of international trade on the transmission of disease have meant that the WTO construct has been pulled into the global health debate. In addition, an anomaly in the system – the TRIPS Agreement – together with the WTO’s unique and effective enforcement powers, has made the WTO quite possibly the most powerful health actor in the world today.

¹ Article 1 of Constitution of the World Health Organization states, unequivocally, that “*The objective of the World Health Organization [...] shall be the attainment by all peoples of the highest possible level of health.*” 22 July 1946.

This paper argues that the limitations that both the WHO and the WTO suffer in dealing with the politically, economically and emotionally charged issue of equitable access to effective medicines mean that neither organization is the right forum to tackle this issue. Instead a new mixed organization based on public private partnership principles – the “Global PharmaForum” should be set up with a double mandate to ensure access to legitimate drugs by the dispossessed and to fight the rising threat that counterfeit drugs pose to health and security on a global level. The fact that criminal trade in fake drugs is increasingly an issue of serious global concern means that this is the right time for a paradigm shift in global distribution of pharmaceuticals.

I. The Need for a Global PharmaForum: A Tale of Two Scarcities

Guilt TRIPS: Drug Distribution in a divided world

The first – and until recently, the only – face of drug access scarcity is the fact large numbers of the world population simply cannot afford medicines. This is the problem that Article 31 of the TRIPS and the Doha declaration seek to address. By and large, only the social security net provided by public and/or private insurance puts pharmaceutical drugs within the reach of most individuals, even in the developed world. However, only two-thirds of the world’s population has access to medicines and treatments as part of a private or government-sponsored health insurance scheme. The remaining one-third of humanity has to fend for itself, often with tragic consequences.² Inevitably, the insurance have-nots are mainly concentrated in the geographical areas and

² World Health Organization, *Equitable access to essential medicines: a framework for collective action*, POL’Y PERSP. on MEDS. (Mar. 2004), <http://apps.who.int/medicinedocs/pdf/s4962e/s4962e.pdf>.

social classes with the least resources and thus least able to pay for drugs out of pocket. For example, in the poorest parts of Africa and Asia, the percentage of people with no access to medical and drug insurance is estimated to be over 50%.³ By contrast, the virtual totality of the population is covered in Europe, Canada and Australia. And in the United States, only 85% of the population is covered by insurance, be it public or private.⁴ Thus, over 10 million people lose their lives every year largely for lack of access to essential medicines⁵ due to the “market distortion”⁶ that health insurance provides.

Drug manufacturing is big business. The total market in pharmaceutical drugs is estimated at \$650 billion⁷ and represents fifty-five percent of all global health trade.⁸ Even with no change in the global drug distribution system, the size of the market is only set to increase as the population ages and new and more effective drugs prolong life and increase its quality. Some forecast that the drug market will grow to \$900 billion by 2011.⁹ Although the need for drugs is universal, the drug market is unequal and highly polarized. North America, Europe, and Japan account for 75% of sales.¹⁰ Nor is access the only divide between the developed world and the rest: developed countries produce

³ *Id.*

⁴ These are 2009 data from the US Census Bureau. U.S. Census Bureau, <https://census.gov>.

⁵ Defined by the WHO as “those that satisfy the priority health care needs of the population.” 4.2 *Description of essential medicines*, World Health Organization (2003), <http://apps.who.int/medicinedocs/en/d/Js4875e/5.2.html#Js4875e.5.2>.

⁶ Henry Aaron, *Serious and Unstable Condition: Financing America’s Health Care*, Brookings Inst. (1991).

⁷ Generic drugs amount to 10% of this market. Richard D. Smith et al., *Trade, TRIPS and pharmaceuticals*, 373 *The Lancet* 684 (Jan. 22, 2009), [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(08\)61779-1/abstract](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(08)61779-1/abstract).

⁸ *Id.*

⁹ *Id.*

¹⁰ *Id.*

and export high-value patented pharmaceuticals and developing countries import expensive patented pharmaceuticals and manufacture and export low-value generics and alternative medicines.¹¹

The combined populations of the countries that account for 75% of world consumption of drugs amount to only about 800 million (or roughly 13%) out of a total world population of 6 billion. This means that drug companies stand to increase their revenues substantially by reaching out to some of the remaining five billion, even at a discounted price. It is a platitude to say that the economic interest of pharmaceutical companies is clearly on the side of putting their products within reach of more people, and yet the existing systems have failed to give effect to this self-evident reality. Of course, the interest of governments and private citizens is also on the side of extending access to medicines. Until now neither free markets nor the WHO nor the WTO international trade liberalization mechanisms have proved the right catalyst. It is this failure that has enabled the appearance of a new and sinister actor into the health game in the form of counterpharma.

ACTA-ing Up: The Emergence of Counterpharma

The other, and even more, insidious face of Janus, is the problem of counterfeit medicines (“counterpharma”). Some sources estimate that upwards of a million people died as a result of consuming fake medicines in 2009.¹² Unlike the victims of mere scarcity, the victims of counterfeit drugs – compounds with no biological effect at best and pathogenic or lethal effects at worst -- believe they have obtained the means to get

¹¹ Id.

¹² Pavol Stracansky, *Fake Medicines may Kill a Million a Year*, INTER PRESS SER. (Oct. 28 2010), <http://www.ipsnews.net/2010/10/fake-medicines-may-kill-a-million-a-year/>.

better and have spent their precious resources paying for that hope. From a moral standpoint then, provision of counterpharma represents the ultimate violation in that it destroys the hope, the life and the health of the most vulnerable.

Counterpharma is big business, and getting bigger every year both in absolute economic terms and in market share. According to the Office for Drugs and Crime, counterfeit goods represented \$75 billion revenues for crime in 2009, up 92% since 2005.¹³ Of course, the providers of counterpharma do not pay taxes in the countries where they operate, resulting in a loss of revenue for governments. It is also estimated that 50% of drugs sold online from sites with no address are fake. They represent approximately 20% of the market.¹⁴ Counterpharma is 10.5bn euro market in Europe alone,¹⁵ with 34 million fake tablets seized in a 2-month period in 2009.¹⁶

Counterpharma is also dangerous business, both at the individual and societal level, and this is the concern that ACTA seeks to address. Counterfeit drugs kill more people than illegal narcotics.¹⁷ But beyond the personal tragedy of one million deaths lurks another potential danger. At the societal level, the proliferation of dangerous counterpharma and other counterfeit products undermines the trust of citizens in their government. One of the fundamental duties of government – one that underpins its legitimacy – is the protection of the citizenry against public dangers. Citizens of all countries consider that the government has a basic duty to ensure the safety of food,

¹³ *Id.*

¹⁴ *Id.*

¹⁵ Italy spent an estimated \$3.6 billion and Germany spent an estimated \$2.7 billion. *Id.*

¹⁶ *Id.*

¹⁷ Charles R. McManis, *The Proposed Anti-Counterfeiting Trade Agreement (ACTA): Two Tales of a Treaty*, 46 HOUS. L. REV. 1235, 1243 (2009).

water, the environment and to the extent they are available, medicines. There is increasing evidence that counterpharma manufacturing and distribution occur as part of organized IP crime rings, sometimes with links to international terrorism.¹⁸ Dr. Moises Naim, Editor in Chief of Foreign Policy magazine, estimated the commercial losses due to IP piracy in general at \$500 billion in 2004 and noted that this shadow trade is growing at eight times the speed of legal trade. Moreover, Dr. Naim believes that these criminal rings are often part of terrorist networks.¹⁹

INTERPOL has added the fight against IP crime to its mandate and made it one of its top six priority areas.²⁰ The agency is working with other international organizations and the police forces of several countries as well pharmaceutical companies and other private actors on “Operation Jupiter.” Phase IV of Operation Jupiter focused on Argentina, Brazil, Chile, Bolivia and Peru and resulted in the seizure of a significant amount of dangerous “medicines.”²¹

Thus, for the first time, all actors have a common interest in cooperation based on a benefit each will derive – and the challenge is providing the right framework to allow this to happen. Governments, the citizenry and legitimate, tax-paying law-abiding private enterprise in developing countries all have reason to be as concerned over international

¹⁸ *Id.* at 1239.

¹⁹ *Id.* at 1244 (citing Moises Naim, *ILLICIT: HOW SMUGGLERS, TRAFFICKERS AND COPYCATS ARE HIJACKING THE GLOBAL ECON.* 217-20 (2005).

²⁰ INTERPOL Home Page, Crime Areas, (last visited Nov. 21 2009), <http://www.interpol.int/default>. The other areas are: (1) drugs and criminal organizations, (2) fugitives, (3) public safety and terrorism, (4) trafficking in human beings and (5) corruption. *See* McManis, *supra* note 17, at 1239.

²¹ McManis, *supra* note 17, at 1241. These included toys made from hospital waste and over 3,000 pills purporting to be the abortifacient Cytotec and other drugs. In addition, A RAND Corporation report has identified this geographical are as “the most important center for financing Islamic terrorism outside the Middle East.”

counterpharma as their counterparts in the developed world. Until now, each actor has had its own discrete and individual interest. While nobody ever wanted eleven million people to die unnecessarily and countless millions of others suffer needlessly, financial and political realities meant there was no real incentive for a global solution involving real cooperation.

It is ironic that the confluence of the two faces of Janus that provides the incentive and the opportunity to create a working system where none exists today, and the hybrid nature of the Global PharmaForum may make it successful where international organizations have failed.

1. International Organizations and the Two Faces of Janus

The role of WHO

The WHO is the only international organization dedicated to promoting health.²² The first stated objective of the WHO is “the attainment by all peoples of the highest possible level of health”.²³ Moreover, the Preamble to the Constitution states that “the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition”, and that “[t]he health of all peoples is fundamental to the attainment of peace and security and is dependent on the full cooperation of individuals and States”, so that it is important to extend “to all peoples of the benefits of medical, psychological and

²² The United Nations International Covenant on Economic, Social and Cultural Rights recognizes “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health” and directs members to take certain measures to advance this right. However, this is not the exclusive, or even the principal, subject matter of the Treaty.

²³ World Health Organization Const. ch. 1, art. 1.

related knowledge [because it is] is essential to the fullest attainment of health.”²⁴ A detailed discussion of the workings of WHO is beyond the scope of this paper, but the WHO suffers from 4 major shortcomings that prevent it from being a truly effective forum for drug equity (1) its constitution only grants it an advisory and a fact-gathering role in most matters, so that it can only issue recommendations,²⁵ (2) it is an intergovernmental organization and therefore, (3) it operates by consensus, and lastly, (4) it lacks an enforcement mechanism and enforcement powers. Nonetheless, the WHO fulfills a crucial role in providing the strength of its credibility and reputation to bring the issues to general awareness,²⁶ create a global consensus around the existence and scope of the problem, and monitor progress.²⁷ The WHO has a mandate and a track record of

²⁴ *Id.* at Preamble.

²⁵ The role of WHO in this respect is changing. The Framework Convention for Tobacco Control is binding and the International Health Regulations are mandatory. However, the harms of tobacco are well-recognized globally, and there are no detectable health benefits associated with the consumption of tobacco products. The fight against tobacco is thus unique in that few can argue that it is not a “public bad,” and therefore it is possible to reach an international consensus around the need to fight tobacco use.

²⁶ For example, a WHO brochure titled “Counterfeit Drugs Kill!” notes that there are areas in Africa and Asia and Latin America where 30% of the medicines are fake; and that in many countries that are part of the former Soviet Union, the proportion of fake drugs amounts to 20% of the market. Int’l Med. Prod. Anti-Counterfeiting Task Force & WHO, *Counterfeit Drugs Kill!*, 3 (2008).

https://www.gphf.org/images/downloads/library/whoimpact2008_counterfeit_drugs_kill.pdf.

²⁷ For example, in 2008 the World Health Assembly passed Resolution WHA 61.21 “Global Strategy and plan of action on public health, innovation and intellectual property to “promote new thinking on innovation and access to medicines.” This only one of many resolutions on this topic, however it is significant because it ties drug distribution with intellectual property rights and the TRIPS.

cooperation with other international agencies.²⁸ These three elements are valuable assets that WHO can contribute to Global PharmaForum.

Medicines and the WTO: An uneasy fit

The default setting in the WTO system can be summarized as “yes to trade”. The overarching rule for the international trade system is that governments must facilitate international trade by eliminating elements in their legal systems or practices that can function as *de jure* and/or *de facto* barriers to trade. The purpose of the WTO system, as set forth in the Preamble of the Agreement Establishing the World Trade Organization, is to “provide the common institutional framework for the conduct of trade relations among ... Members...with a view to raising standards of living, ensuring full employment and a large and steadily growing of real income and effective demand, and expanding the production of and trade in goods and services, while allowing for the optimal use of the world’s resources in accordance with the objective of sustainable development, seeking both to protect and preserve the environment and to enhance the means for doing so...” It is noteworthy that preservation and protection of the environment are specifically mentioned as general goals, but preservation and protection of human life and health are not.

So where does health in general, and access to essential medicines in particular, fit in the international free trade construct? In an awkward place, it turns out. Health is

²⁸ For example, in 2008, the International Criminal Police Organization (INTERPOL) teamed up with WHO as part of WHO’s International Medical Products Anti-counterfeiting Taskforce (IMPACT) to launch Operation Mamba specifically targeting counterpharma products in Tanzania and Uganda. According to INTERPOL, “counterfeit medical products pose a major risk to public health and are becoming increasingly prevalent in all parts of the world, particularly in Africa.”

widely considered to be a basic human right.²⁹ Basic human rights are not often the objects of international trade. At the same time, trade in medicines and medical devices and supplies must be “trade in goods” within the meaning of the General Agreement on Tariffs and Trade, just as provision of health services and personnel must be “trade in services” as defined in the General Agreement on Trade in Services. So health is both a complex construct that cannot comfortably fit into a pure trade model and an important part of trade and relations between nations. By necessity, trade in goods must encompass a health element: pathogens know no borders -- and neither does an individual’s need for curative drugs or treatment vary depending on his or her geographical location. These complexities mean both that health concerns must somehow be incorporated into the framework as allowable trade restrictions in a framework designed to promote and facilitate trade and that trade can be used as a political instrument to achieve important public health goals.

Any measure that seeks to act as a derogation to the fundamental principle of “yes to trade” must be justified as circumspect in both scope and time if it is to survive scrutiny.³⁰ This principle is reflected in various parts of the WTO construct, including

²⁹ For example, the United Nations International Covenant on Economic, Social and Cultural rights, which the United States has not ratified, recognizes “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.” *Programme on Women’s Economic, Social and Cultural Rights, Human Rights for All: International Covenant on Economic, Social and Cultural Rights: A Handbook* (Aug. 2015), http://www.pwescr.org/PWESCR_Handbook_on_ESCR.pdf.

³⁰ This is known (depending on the Agreement in question) as the principles of rationality (a measure must bear a rational connection with an important health goal) or necessity (a measure must be necessary to achieve an important health goal). In both cases, the measure must additionally be justified as proportional, nondiscriminatory and the least restrictive means to achieve the proffered health goal.

Article XX of the General Agreement on Tariffs and Trade (“GATT”), the Agreement on Technical Barriers to Trade (“TBT”), and the Agreement on the Application of Sanitary and Phytosanitary Measures (“SPS”).³¹ The health provisions of the WTO system that apply to restrictions on trade in goods (such as pharmaceutical products) derive from Article XX of the General Agreement on Tariffs and Trade (“GATT”), adopted in 1947. Article XX permits countries to adopt measures “necessary to protect ... human ... life or health”³² or “essential to the acquisition or distribution of products in general or local short supply”³³ and directs Members to follow the “principle that all contracting parties are entitled to an equitable share of the international supply of such products”³⁴ as long as such measures are neither discriminatory as between countries where the same conditions prevail nor a “disguised restriction on international trade”.³⁵ The follow-up, more specific Agreement on the Application of Sanitary and Phytosanitary Measures (“SPS”) came into force almost 50 years later, in 1995. Its purpose is to elaborate on the application of Article XX of the GATT to health. The SPS is concerned with trade in potential vectors of disease rather than curative drugs, and discussion of it is therefore outside the scope of this paper, except to mention that it is the only agreement in the WTO system specifically addressing human health. The SPS operates as a “positive” agreement, i.e., an exception to the general rule of free trade and openness to be invoked sparingly, as an emergency measure and for as short a time as possible.

³¹ The General Agreement on Trade in Services (GATS) contains a similar provision in Art. 14 (General Exceptions), but since medicines are clearly goods, a discussion of the health-related provisions of the GATS is outside the scope of this paper.

³² Article XX (b).

³³ *Id.* at (j).

³⁴ *Id.*

³⁵ *Id.* at “chapeau.”

Trade in pharmaceutical products is addressed specifically not as part of the health construct of Article XX of the GATT or the provisions of the SPS, but as part of the Intellectual Property regime of the TRIPS agreements, where it has proved to be a very controversial area rife with political ramifications.

Guilt TRIPS

The regulation of international trade in pharmaceutical products mostly falls under another “positive” agreement: the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). TRIPS deviates from the general Member State centered WTO construct in that it is a means for enforcement and protection of private (non-state) rights. However, it is different from SPS and TBT in that the trade-restricting provisions of TRIPS are not meant to be applied sparingly or for a short period.

The stated purpose of TRIPS is “to reduce distortions and impediments to international trade”³⁶ by promoting respect for intellectual property rights. At the same time, TRIPS seeks to “ensure” that the mechanisms to enforce those rights “do not themselves become barriers to trade.”³⁷ This is inherently a difficult balance to strike because the very purpose of intellectual property rights in general, and of patents in particular, is to restrain trade by granting a temporary monopoly right over the sale, distribution or production of a good. As is the case with the WTO system in general, health fits uneasily into this framework. The TRIPS was not written with health in mind, as evidenced by the fact that the World Intellectual Property Organization (“WIPO”) is the only organization mentioned in the TRIPS Preamble. The Preamble talks about

³⁶ General Agreement on Tariffs and Trade 1947, 1 Jan. 1948, 55 U.N.T.S. 194.

³⁷ *Id.*

establishing a mutually supportive relationship between WTO and “other relevant international organizations” and makes no mention of the WHO. At the same time, there are exceptions (known as “flexibilities”) in the TRIPS agreement that apply to health, and at least two articles (articles 30 and 31) and an annex in addition to several subsequent declarations and interpretations are devoted to constructing an exception to the TRIPS regime for distribution of essential medical goods.

The temporary monopoly accorded by the patent regime is necessary in order to ensure that extraordinary profits act as an incentive for the huge (and risky) investments needed to develop new complex products such as drugs.³⁸ Thus, the international patent regime – or rather, the lack of one -- offers a clear example of the tension between sovereign autonomy and integration that underlies and sometimes undermines the WTO construct.

Although it is believed that the first patents system was developed in Venice as early as the fifteenth century,³⁹ some European countries did not even have patents laws until well into the twentieth century.⁴⁰ Today patent grant and enforcement remain national in nature, and there are wide differences in the development of national patents laws and the enforcement of patents across countries. There is no such thing as an “international patent.” The Patent Cooperation Treaty (“PCT”), signed in 1970 and administered by the World Intellectual Property Organization, allows an inventor to file a

³⁸ The cost of developing a new drug is estimated at \$800 million to \$2 billion. Neil Masia, *The Cost of Developing a New Drug*, <http://www.america.gov/st/business-english/2008/April/20080429230904myleen0.5233981.html> (last visited Dec. 9, 2010).

³⁹ Edward C. Walterscheid, *The Early Evolution of the United States Patent Law: Antecedents* (Part 1), 76 J. PAT. & TRADEMARK OFF. SOC'Y 697, 709 (1994).

⁴⁰ *Id.*

unified patent application that can ultimately (once approved) be funneled down for approval in PCT member countries.⁴¹ Although this may be a step in the right direction, it does not go far enough to facilitate trade in essential medicines. The PCT allows an applicant to file a uniform patent application that will be reviewed by the WIPO, but the applicant must still apply country by country after the patent is obtained, and the patent may or may not be granted in each country. Since the international process takes at least eighteen months, fragmentation results in considerable delays.

This is the lacuna that the TRIPS and ACTA seek to remedy, by obligating Member States to respect each other's patent rights. However, because the largest number of international PCT applications still come from the United States (32.7% or 53,521 out of a total of 164,000 patent applications filed),⁴² Europe and a few other countries, this regime is perceived as favoring the rights of rich countries at the expense of the citizens of poor countries who cannot afford fund investors' extraordinary profits.

Health first appears in TRIPS in Article 8, as one of the "flexibilities" of the agreement. Modeled after Article XX(b) of the GATT, Article 8 of the TRIPS recognizes

⁴¹ When an inventor files an application with PCT, patent prosecution begins with an international phase during which an International Preliminary Examining Authority reviews the application. After the favorable opinion of the authority is issued, the patentee has thirty months to file an application with the national authorities of every PCT Member country in which it wishes to have its patent registered and enforced. This is known as the national phase.

⁴² *Global Economic Slowdown Impacts 2008 International Patent Filings*, WORLD INTELL. PROP. ORG., (Jan. 27, 2009), http://www.wipo.int/pressroom/en/articles/2009/article_0002.html. The top position of US inventors has been consistent for the past 30 years, but other countries are catching up fast. China, Korea and Sweden each filed 12% of received applications, and there were increases in applications from middle-income countries such as Brazil. *Id.*

the general right of Members to adopt measures to protect public health,⁴³ and “to prevent the abuse of intellectual property rights by rights holders.”⁴⁴ Section 5 of the TRIPS deals with patents and is heavily influenced by U.S. patent law. Article 30 allows Members to create limited exceptions to the exclusive rights conferred by a patent “provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account the legitimate interests of third parties.” Article 31 “Other Use Without Authorization of the Right Holder” goes further and is more specific. It allows a Member to effectively break a patent and manufacture a product so long as it has first sought the approval of the patent holder on reasonable commercial terms and conditions.⁴⁵ Even after those efforts have failed, the patent holder is still owed “adequate remuneration ... taking into account the economic value of the authorization”⁴⁶ Article 31 provides for independent review of any use or remuneration decisions by a higher authority in the receiving Member.⁴⁷ On its face, Articles 30 and 31 favor less developed countries because they allow them the latitude to declare that breaking a patent is “necessary to protect public health” under Article 8 and thus either the “legitimate interests of third parties” (i.e., sick people) under Article 30 or a law of a Member country under Article 31 permits use of the patent without the consent of its holder. Moreover, for uses under Article 31 – known as the compulsory licensing regime – the fact that the reviewing authority for the

⁴³ Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, Annex 1C, 1869 U.N.T.S. 323, Article 8(1).

⁴⁴ *Id.* at 323, Article 8(2).

⁴⁵ *Id.* at 333, Article 31(b).

⁴⁶ *Id.* at 333, Article 31(h)

⁴⁷ *Id.* at 333, Article 31(i) & (j).

appropriateness of both the measure and the remuneration the patentee is to receive sits in the recipient Member would seem to give developing countries great leeway in supplying their citizens with life-saving patented medicines. Article 31 has an important limitation because it requires that the country implementing a compulsory license have its own production capabilities. Of course, the countries where essential medicines are scarce are the ones least likely to have the necessary industrial capabilities.⁴⁸ Beginning in 2001, the signatories to TRIPS sought to clarify Articles 30 and 31 in the Doha Declaration and subsequent documents, to make them flexible enough to allow medicines to be manufactured in one LDC country with industrial capabilities to be shipped to another without such capabilities.⁴⁹ And yet ten million people are still dying every year for lack of access to those medicines and the compulsory licensing regime has only been invoked and implemented once, with mixed results. In 2007, Rwanda and Canada issued a compulsory license for an antiretroviral drug and began the process of exporting the Canadian-made drug to Rwanda. The ensuing bureaucratic nightmare has acted as a

⁴⁸ The absurdity of this regime was highlighted in December 2008, when a shipment of generic blood pressure drugs in transit from India to Brazil was seized in the Netherlands. In May 2010, India and Brazil launched a trade case against the European Union. This resulted in some embarrassment for the European Union, and officials had to issue a statement assuring the world that they did not intend to halt export of generic drugs, but rather to stop dangerous counterfeits.

⁴⁹ In Article 6 of the Doha declaration, the Members “recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement,” and “...instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.” In 2005, Members agreed to create a mechanism to facilitate export of patented medicines and generics. However, to this date, the amendment has not been put into effect, as not enough WTO member countries have ratified it.

deterrent for others. Moreover, there has been no successful compulsory license case involving a US pharmaceutical company.

ACTA-ing Up

The theoretical constructs of free trade under Articles 30 and 31 of TRIPS have failed to deliver their stated objective of making essential medicines more available to parts of the world where they are desperately needed, even after the Doha Declaration. Someone was bound to step into this breach and propose a seeming solution to this seeming market failure. The new actor is the global trade in counterpharma. It began doing business in impoverished areas and is now extending its reach substantially, to Western Europe and even the United States. The Anti-Counterfeiting Trade Agreement (“ACTA”) is an international effort to combat all forms of intellectual property violations as undermining “legitimate trade and the sustainable development of the world economy”, a cause of “significant financial losses for right holders and legitimate businesses” and a “source of revenue for organized crime.”⁵⁰

The ACTA is a stepped-up enforcement mechanism that will replace Part III of TRIPS for its adherents.⁵¹ In its Preamble, ACTA recognizes the principles of the Doha Declaration but stops short of creating a health-specific exception for essential medicines and goods.

⁵⁰ ACTA Preamble.

⁵¹ Article 2.2 says damages can include lost profits, the value of the infringed good or service, measured by the market price, or the retail price. But this section does not apply to patents, and neither does the section on border measures. However Section 5, in TRIPS had only Art. 61 – Criminal Procedures, has been replaced by 4 articles on criminal procedures and enforcement, including provisions that a country may “initiate investigation or legal action” ex officio. Art. 2.17

ACTA has been problematic from its very conception. Eleven countries,⁵² including the United States and the European Union, met in secret for months to discuss and negotiate a supplement to the TRIPS agreement that would increase enforcement of intellectual property rights. The drafts of the proposed agreement were kept secret for a long time. However, there are no public secrets in the era of Wikileaks and instant communication. Soon emerging countries like India, China and Brazil as well as global public opinion were denouncing the secret nature of the talks, and the fact that it appeared that certain industry representatives were obtaining information that was not available to the public.⁵³ Critics of ACTA called it a further attempt to bolster the profits of intellectual property owners while socializing the cost of enforcement at the expense of developing countries. At the outset, developing nations expressed a concern that the definition of counterfeit might include generic drugs, thus making medicines even more unavailable.⁵⁴

A draft of the ACTA was finally publicly released in April 2010, and in the United States, the release made clear that generic drugs would not be affected by the ACTA regime.⁵⁵ By September, the parties to the negotiations clarified that ACTA would not cover generic drugs. The final text of ACTA was adopted in October 2010 and formally published in April 2011.⁵⁶

⁵² Australia, Canada, the European Union, Japan, Korea, Mexico, Morocco, New Zealand, Singapore, Switzerland and the United States. The EU negotiated as a block, so it is counted as one country.

⁵³ McManis, *supra*, note 17.

⁵⁵ OFF. OF U.S. TRADE REPRESENTATIVE, Anti-Counterfeiting Trade Agreement, www.ustr.gov/acta.

⁵⁶ *Id.*

Ironically, the fact that counterpharma is extending its reach to the developed world and that ACTA is perceived there as necessary to protect the viability of expensive research and development of new drugs, while developing nations see it as posing an additional threat to access to safe drugs in poor countries, offers an opportunity for the creation of a more fair medicine distribution system as the interests of the medicines haves and have-nots converge. Counterpharma threatens the profits and worldwide reputation of legitimate pharmaceutical companies as much as it threatens the lives of the victims of fake drugs and the other criminal activities of the gangs that supply them. It is a problem that neither potential patients, nor pharmaceutical companies, nor developed, nor developing nations can ignore, and all must work together in order to solve it. Moreover, the demonstrated ties between counterpharma, organized crime, and terrorism mean that developed nations need the political cooperation of the developing nations where counterpharma finds its roots to eradicate it, and therefore, that the latter are, for the first time, in a position to extract concessions on access to legitimate medicines in return.

III. Towards a Global Pharma Forum

The Global Fund – A Starting Model?

The Global Fund to Fight AIDS, Tuberculosis, and Malaria (“Fund”) was established in 2002. By many measures, the Fund has been a resounding success. It is estimated that the Fund has saved 4.9 million lives by judicious appropriation, allocation, and distribution of US\$19.2 billion and then US\$10 billion respectively across 144

countries.⁵⁷ The Fund was born out of an academic article in *The Lancet* in 2001 published in 2001,⁵⁸ and the idea travelled to the G8 meeting in Genoa with UN Secretary General Kofi Annan, who issued a “call to action” to reverse the spread of those three infectious diseases. The April 2001 Genoa Summit is most remembered because it was the scenario for unprecedented violent citizen protests against globalization and its impact on developing and developed countries, and the establishment of the Fund is perhaps its greatest accomplishment. For the Fund was not only a new and daring paradigm for cooperation whose time had come, but it was also set up in record time. The Fund model aligns with the principles of the Millennium Development Goals and has received wide praise for its transparency and effectiveness. It was established as a public private partnership designed to ensure maximum participation and buy-in while retaining effectiveness.⁵⁹ In all, the Fund has managed to minimize political friction while fostering inclusiveness to produce swift and concrete results. Perhaps the success of the Fund is due in part to the fact that its mission is narrowly defined and circumscribed to fighting three diseases.

Innovative Approaches and The Global PharmaForum

⁵⁷ *The Global Fund: Replenishment and Redefinition in 2010*, 375 *THE LANCET* 865 (Mar. 13, 2010), [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(10\)60366-2/fulltext?elsca1=TL-110310&elsca2=email&elsca3=segment](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(10)60366-2/fulltext?elsca1=TL-110310&elsca2=email&elsca3=segment).

⁵⁸ Amir Attaran & Jeffrey Sachs, *Defining and Refining International Support for Combating the AIDS Pandemic*, 357 *THE LANCET* 57, 57-61 (Jan. 6, 2001).

⁵⁹ To this end, the Fund was incorporated under Swiss law under a Headquarters Agreement that grants it and its staff limited immunity. The money is administered by the World Bank under an Administrative Agreement. While in the beginning the WHO provided certain administrative services to the Fund, that arrangement was terminated in 2009, and the Fund is now a fully autonomous organization.

The idea of a new and specific fund to address the problem of access to drugs is not completely new, and the Fund has often been cited as a model. However, much has changed in the few years since the Fund was established. In a January 2010 article published in *The Lancet*, Amitava Banerjee et al.⁶⁰ offer an alternative idea, the Health Impact Fund (“HIF”) as the best way to tackle the pharma crisis. Banerjee et al. blame the role of TRIPS in enforcing patents for the current scarcity and state “TRIPS has widened the health gap between high-income countries and developing countries.”⁶¹ However, they do not offer any supporting evidence for this blanket statement. The HIF focuses on reducing the impact of pharmaceutical patents on drug accessibility. Pharmaceutical companies would have a chance to register their new products with the Fund, and would “receive, for a defined period of time (eg, 10 years), a share of fixed remuneration from a reward pool. The fund would disburse at least \$6 billion annually, paying each registrant a share that corresponds to the registrant’s contribution to the global health effect of all registered products, as estimated with a global impact assessment exercise.”⁶² The Fund would be supported by governments with an additional initial commitment of, for example, 0.03% of their gross GDP that would become binding once disbursements reach \$6 billion a year.

Unfortunately, it is unlikely that in the current global financial climate governments and their taxpayers will have any appetite for additional commitments to what amounts to foreign aid. Moreover, the Fund by and large ignores the problem of

⁶⁰ Amitava Banerjee et al., *The Health Impact Fund: Incentives for Improving Access to Medicines*, 375 *THE LANCET* 166, 166-69 (Jan. 9, 2010), [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(09\)61296-4/abstract](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(09)61296-4/abstract).

⁶¹ *Id.* at 166.

⁶² *Id.* at 166-67.

counterpharma and the need to find mechanisms to enlist the help of developing countries in fighting it. Thus, the HIF focuses on one aspect of the problem and simply does not go far enough. It also fails to provide a realistic funding mechanism.

The Global Pharmaforum

In a challenging global financial climate, only projects that can clearly and directly tie cost to benefit are likely to be funded. For a cost to be directly tied to benefit, it needs to be (1) discrete, (2) predictable, and (3) ultimately recoverable. Because the issue of access to drugs involves both commercial and non-commercial actors, the costs and the benefits need not be directly financial. Moreover, buy-in is crucial for cooperation, so each stakeholder must feel adequately represented in the decision-making of the forum.

In order to ensure adequate representation of and buy-in from each stakeholder, the board of the Global PharmaForum would be composed of four clusters of three members each for a total of twelve members. This limited number of board members ensures that the number of decision makers is small enough to be swift and effective. Cluster One would be international organizations – the WHO, the WTO and INTERPOL. Cluster Two would be three countries with a large number of pharmaceutical IP owners. Cluster Three would be composed of three pharmaceutical companies, two from developed countries, and one from a middle or low-income country. Cluster Four would include two developing countries and a representative of civil society.

The mandate of the Global Pharma Forum would be to periodically designate new drugs to combat widespread diseases as of “global public interest”⁶³ and negotiate a

⁶³ Based on the WHO definition of essential medicines.

compensation formula with the rights holders so that the drug can be made available in low-income countries at an agreed discount. The contributions from and benefits to, the stakeholders would be as follows:

Cluster One: WHO contributes its research, technical and monitoring capabilities, its prestige and international recognition and global political access. It continues to push for awareness of the problem and make recommendations for solutions. In return, it is relieved from the politically-laden task of negotiating a commercial agreement (a task for which it is ill-suited), and can advance its health agenda without being criticized for excluding non-state actors from the table. WTO's contribution is crucial, in the form of its enforcement mechanism. The WTO dispute resolution mechanism is internationally recognized as effective and as having no peer in the international system. Access to this enforcement mechanism provides an incentive for parties to find a solution. For WTO, the advantage is in removing the contentious issue of access to medicines – and the problem of eleven million preventable deaths a year -- from its free trade agenda.

INTERPOL contributes its intelligence and enforcement resources, as well as the fact that its very presence on the board signals that criminal enforcement will be taken seriously and gains additional access and intelligence. INTERPOL's presence also allows the flow of intelligence about criminal activity to flow without requiring the involvement of the other international organizations.

Cluster Two – The countries with numerous rightholders contribute their ability to ultimately control the pharma companies as well as intelligence and resources in the fight against crime. In return, they receive additional cooperation from countries where crime and terrorist rings are developing. Rather than a percentage of GDP, countries contribute

a fixed, scaled amount based on the size of their pharmaceutical industry with a credit given for contributions from private foundations that are not tied to pharmaceutical companies.

Cluster Three – The pharmaceutical companies obtain access to a larger market under legally improved conditions and with recognition of their right to fair and negotiated compensation for use of their intellectual property. In exchange for a schedule of discounts based on the recipient country's income and the marginal cost of producing additional units of each medication, pharma receives support from the recipient countries and INTERPOL in enforcing their rights and ensuring that medications are not re-exported to third countries and a stepped-up commitment to the fight against counterpharma. The financial contribution of pharma is based on a scale tied to increased revenues from additional sales volume and total worldwide revenues.

Cluster Four – Countries that need drugs get them at a group-negotiated discount, without resorting to the cumbersome and ineffective compulsory licensing regime. In return, they commit to (1) stepped-up cooperation with enforcement authorities and pharma to combat international crime and terrorism, and (2) the development of health insurance programs that will help put drugs within the reach of their citizens. Their financial contribution is based on a scale that takes into account increased productivity due to improved health conditions and increased tax receipts connected with the replacement of tax-free illegal economic activity with legitimate, tax-paying business.

The story of international trade is ultimately the story of the political and economic tension between integration and autonomy. The tension is mainly felt at the governmental level, but in the case of IP rights, the only private property rights

specifically recognized in the WTO construct, the tension extends to private actors as well. In order for any new mechanism to elicit support, therefore, it must demonstrate that the benefit in the form of cooperation or economic gain exceeds the cost in terms of autonomy renounced or economic gain lost. The Global PharmaForum takes the best elements of each of the institutions involved in health and requires a contribution from while assuring a benefit to, each of the stakeholders in the health game.