

## **IMPORT SAFETY RULES SHOULD NOT HINDER LEGITIMATE GENERIC DRUG MARKETS**

Boston University School of Law Working Paper No. 09-25  
(May 19, 2009)

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## **Import Safety Rules Should Not Hinder Legitimate Generic Drug Markets**

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Appearing in *IMPORT SAFETY: REGULATORY GOVERNANCE IN THE GLOBAL ECONOMY* (Cary Coglianese, Adam Finkel, & David Zaring, eds., 2009) (The University of Pennsylvania Press).

**Abstract:** Trade agreement negotiations are routinely cloaked in secrecy, a model that may have suited the Eighteenth Century, but has no place in modern democracies. Transparency deficits have led to capture by powerful industries, sometimes to the detriment of public health. This is a standard account of the WTO TRIPS Agreement, but the pattern is being repeated, in a new regime, in the Anti-Counterfeiting Trade Agreement (ACTA) and related efforts. In the context of pharmaceuticals, ACTA should be limited to deliberate trademark violations and should not be expanded to encompass other intellectual property rights such as patent infringement. Recent seizures of generic medicines by Dutch authorities highlight the danger to legitimate and valuable global generic drug markets from overzealous enforcement of border control regimes.

### **I. Trade & Health Policy In The Shroud of Diplomatic Secrecy**

Woodrow Wilson decried secret diplomacy in the wake of the Great War and famously called for “open covenants of peace, openly arrived at” as the first of his Fourteen Points.

Woodrow Wilson is studiously ignored today in global trade negotiations. At the dawn of the 21<sup>st</sup> Century, democratic governments still negotiate thousand-page trade agreements in secret, without transparent accountability for the interests being horse-traded. Complex rules – many that affect import safety and public health -- are negotiated and implemented without resort to

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the kind of public notice and comment provisions that apply to many domestic lawmaking processes around the world. The result is too often trade and health policymaking by stealth, with significant potential for rent seeking by powerful companies lobbying for particular outcomes.

Consumers are poorly represented at trade talks. They are underrepresented in powerful lobbying institutions and must rely on the general democratic process, mediated through layers of administrative and political intermediaries. In the U.S., “fast track” trade promotion authority prevents Congress from amending trade deals, deepening the democracy deficit. Negotiations occur in diplomatic secrecy, as if the participants were discussing troop movements or royal succession in Metternich’s Europe. These models are completely inappropriate for health and trade policy in modern democracies.

Not everyone is unrepresented at these negotiations. As Susan K. Sell (1998; 2003) has aptly noted, the global intellectual property (IP) industry has been central to the formation, operation and extension of global IP rules, especially through the World Trade Organization’s Agreement on Trade-Related Intellectual Property (TRIPS). Indeed, she concludes that U.S. and European IP industries were the primary impetus for TRIPS, with the film and music industries leading the way on copyright, the pharmaceutical industry on patent, and the information technology industries supporting both. Unlike consumer representatives, industry has direct access to these talks through the trade advisory committee process in the U.S. and other countries, but public health representatives have been excluded, despite litigation from public health groups calling for representation (Shaffer et al 2005).

Laurence Helfer (2004) and others have noted the “regime shift” that occurred when IP industry leaders became frustrated with the lack of enthusiasm for extensions of global IP rules

at the World Intellectual Property Organization (WIPO). The new forum became the WTO, with IP issues relabeled as “trade-related.” But the TRIPS Agreement has its discontents. One significant casualty of the TRIPS process was public health, which was afforded inadequate attention prior to adoption. Even some global IP industries are not satisfied with TRIPS, despite many successes such as binding international dispute resolution, early implementation by most developing nations, and many successful negotiations to add TRIPS + provisions to bilateral and multilateral trade agreements. Notably, the pharmaceutical industry and the United States Trade Representative (USTR) have strongly opposed actions by Brazil and Thailand to exercise rights reserved to them regarding compulsory licenses of patents under Article 31 of TRIPS. While the USTR has complained loudly and threatened unilateral sanctions, if the U.S. took this issue to the WTO Dispute Settlement Body, Brazil and Thailand would be heavily favored to win (Outterson 2009). IP industry leaders now express frustration with the dispute resolution mechanism of the WTO – widely regarded as one of its strongest provisions – and have begun to create new institutions to ramp up enforcement of global IP rights without the restrictions of the WTO. Regime shifting begets regime proliferation.

In these contexts, this chapter examines recent attempts to strengthen border enforcement procedures against counterfeit goods, often under the guise of import safety. Recent examples include the proposed (but secret) Anti-Counterfeiting Trade Agreement (ACTA) and a related anti-counterfeiting effort, the International Medical Product Anti-Counterfeiting Taskforce (“IMPACT”). This chapter will focus on one particular category of imported goods for which safety concerns have been aired: patented pharmaceuticals. The primary concern is that secret trade negotiations may be used to delay global access to generic drugs, with potentially significant impact on public health. Regime shifting, diplomatic secrecy and rent seeking all

converge in ACTA and IMPACT, and in this environment companies may be able to achieve goals that could not survive the light of day, such as the suppression of the important and legitimate global trade in generic medicines.

Recent seizures of generic medication by Dutch customs officials highlight the danger from over zealous border protection regimes based on intellectual property. Brazilian officials have identified over a dozen incidents where authorities have confiscated generic drugs in transit passing through Dutch ports in 2008 (Statement by Brazil 2009; KEI 2009). Most notably, in November of 2008, AIDS medications purchased by The Clinton Foundation through UNITAID were confiscated on the grounds that the shipments contained “counterfeit” goods, when in fact there was neither misrepresentation as to source nor patent infringement (Pandeya 2009). These drugs were manufactured in India and en route to Nigeria where they would have been able to treat 166 HIV positive individuals for three months (Pandeya 2009; HAI et al. 2009). These generic drugs are legitimate products, prequalified by the WHO, and fully compliant with patent and trademark laws in India, Nigeria, and under TRIPS (UNITAID 2009). A Dutch patent holder instigated the seizure, even though the drugs were not being marketed in Europe but merely being transshipped through Schipol airport on their way to Nigeria. This action has been strongly condemned (HAI et al. 2009; UNITAID 2009). As one Health Action International official said, “[t]his is a grave situation. If the shipment is not allowed to pass, HIV positive Nigerians will miss out on critical treatment. We’re concerned about what appears to be confusion between counterfeit medicines that kill people and generic medicines that save lives” (HAI et al. 2009).

This incident was followed by the confiscation of 500 kilograms of the generic blood pressure medication losartan potassium in December of 2008 (ICTSD 2009a). The drug was en

route from India to Brazil and is not under patent in either country, yet it was seized while in port by Dutch officials at the request of the company that supposedly holds the patent rights to the drug in the Netherlands (ICTSD 2009b). These drugs were held for 36 days and sent back to India on their release (Statement by Brazil 2009). Whether a drug is under patent in the country of transit is “utterly irrelevant” (ICTSD 2009a) to whether the product is legitimate, which is why these seizures have sparked such controversy.

Dutch officials claim these seizures are authorized under EC Regulation No. 1383/2003, which allows IP right holders to petition customs officials to act “when goods are suspected of infringing an intellectual property right” (MSF 2009:1; EC Council Regulation 1383/2003). This regulation goes beyond what TRIPS requires of customs officials. Article 51 of TRIPS sets out what actions border officials must take when dealing with suspected counterfeit or pirated goods and in a footnote states, “[i]t is understood that there shall be no obligation to apply such procedures to imports of goods put on the market in another country by or with the consent of the right holder [ie., parallel traded goods], or *to goods in transit*” (emphasis added) (TRIPS 1994:Art. 51). Enforcement of this regulation is particularly problematic in light of the Doha Declaration’s mandate that TRIPS “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” (Doha Declaration 2001, par. 4). Many countries lack pharmaceutical manufacturing facilities, and so they rely on imports from other countries. Seizure of in-transit goods for alleged patent infringement threatens their access to generic medicines (MSF 2009:1-2).

As we can see, trade policy and health policy intersect at the border. Drug companies have found that “fear moves the needle of consumer perception” (DeLauro 2003), and the recent

activity of IMPACT and ACTA highlights the need to ensure the pharmaceutical industry is not able to reduce access to medicines by confusing unsafe drugs with legitimate generics and parallel imports. Under the guise of import safety, IP customs enforcement rules may hinder the flow of life-saving generic medicines. In this chapter, the root of these difficulties will be traced to recent attempts to expand what constitutes a “counterfeit” drug. In the next section, I propose a lexicon for pharmaceutical import safety rules, focusing on the historic understanding of counterfeit products under trademark law. Patent-based pharmaceutical companies appear to be unhappy with this legal history, for they are supporting a regime shift to a new global trade agreement, the Anti-Counterfeiting Trade Agreement (ACTA), which expands traditional concepts to incorporate all IP rights under the rubric of counterfeiting. This Agreement and similar norm setting activities under IMPACT are the subjects of Section III. I conclude that the term “counterfeit drug” should be limited to deliberate violations of trademark law, and not be expanded to include other IP disputes such as alleged patent infringement. Import safety and intellectual property law serve different interests and should not be conflated.

## **II. A Lexicon for Pharmaceutical Import Safety**

In the context of medicines, many different meanings are attached to the words *fake*, *substandard*, or *counterfeit*. These terms are often used in a way that encompasses everything from safe and effective drugs from legitimate Canadian pharmacies to drugs that are criminally contaminated with poisons. Patent, trademark, and drug safety issues are unnecessarily conflated. To help ensure a safe, effective supply of medication across international borders, it is important to understand these problems as distinct issues. (MSF 2008a; Outterson & Smith 2006).

### A. Counterfeit Medicines

The term *counterfeit* should be reserved for goods that violate trademark laws, misrepresenting the source of the goods. The classic definition of counterfeit under U.S. law focuses exclusively on violations of trademark law and does not concern itself with patent or copyright infringement (15 USC Sec.1127; 19 USC Sec.1526(e)). Some luxury goods are prone to counterfeiting – including perfumes, expensive watches, designer handbags, and famous label clothing. The key complaint is that consumers have been misled as to the source of the goods through the use of a spurious trademark.<sup>1</sup> Counterfeit drugs are falsely sold under the trademark of a branded product. These drugs defraud consumers, whether or not the product would otherwise meet regulatory standards.

The prevailing definition from the WHO adopts this approach in its first sentence but sows some seeds of confusion in the remainder of the definition:

“A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.” (WHO 2009a, par. 10; WHO 1992)

The second sentence is best understood as a list of problems one could encounter with counterfeit medicines. In other settings, the WHO clearly distinguishes counterfeits from

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<sup>1</sup> Trademark violations are also possible even if the original purchaser knew the item was counterfeit. An example would be a consumer who knowingly bought a cheap watch bearing a false Rolex trademark. In that case, the original consumer was not deceived, and yet a trademark violation may be found on other grounds, such as confusion to other consumers.

substandard medicines (WHO 2009b, par. 10; Park 2009:3). TRIPS also follows suit, defining counterfeit goods as violating trademark law:

[A]ny goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation (TRIPS 1994:Art. 51, n.14).

Thus in accordance with TRIPS, the term “counterfeit” only refers to goods that bear an identical or indistinguishable trademark without authorization of the trademark holder. In this respect, TRIPS is quite similar to U.S. law (15 USC Sec.1127; 19 USC Sec.1526(e)). Current U.S. law, the TRIPS Agreement, and the historic WHO definitions all agree: counterfeit drugs must bear a false trademark.

### **B. Substandard, Contaminated or Adulterated Medicines**

*Substandard, contaminated or adulterated* medicines are a health risk, whether through substandard manufacturing processes, improper marketing authorizations, or inadequate attention to supply chain issues. These drugs threaten public health as a regulatory risk, without any necessary connection to IP law. Import safety rules should focus assiduously on these safety issues rather than IP disputes. Daniel Cahoy calls for nuanced responses to the drug quality problem (2008:428-432). National drug regulatory authorities may need more resources, and manufacturers may be required to invest in quality control procedures in their plants and throughout the supply chain. Other chapters in this book describe new approaches to regulating product quality and safety, which may well need to be adopted by governments around the world.

Global pharmaceutical companies with impeccable credentials may nevertheless face manufacturing problems resulting in substandard drugs (Essential Action 2008:2). Drugs sold in the U.S. may contain incorrect levels of active ingredients and many are produced using raw materials manufactured in India, China, or other countries where the FDA has not historically inspected manufacturing facilities adequately (Essential Action 2008:2). Confusing these drugs with criminal counterfeits bearing a false trademark does nothing to further legitimate discussion of these important public health issues. From a public health perspective, the focus should be on removing all substandard medication from the supply chain, counterfeit or not, and on efforts to help improve the quality of legitimate pharmaceutical products (Caudron 2008:1070; Cahoy 2008:428-432). This is a drug regulatory and import safety issue, not an intellectual property problem.

The fact that some counterfeit drugs also present safety issues does not alter this conclusion. It is certainly likely that drugs with deliberate trademark infringement (counterfeits) may have heightened safety risks. These medicines are more likely to have been produced in a manufacturing facility that was not operating under Good Manufacturing Practices (GMP), and the supply chain will almost necessarily be less secure. But the same cannot be said for medicines that are only subject to patent disputes and do not bear a deliberately false trademark. These medicines are produced openly, in facilities that are inspected by the FDA. The patent dispute is likely to be a battle over entry by a reputable generic company, seeking to compete once the patent has expired. That drug is likely to be just as safe as any other in the U.S. market. By comparison, criminally adulterated or substandard drugs are unlikely to involve a patent dispute.

### C. Generics Drugs Are Safe and Effective

When imprecise terms like *fake* are used, or terms like *counterfeit* or *substandard* used imprecisely, some drugs with positive public health effects are improperly lumped with criminal operations (MSF 2008a). The primary error is to conflate alleged patent infringement with deliberate counterfeiting of a trademark. The generic drug trade in the U.S. is entirely legal, delivering high quality drugs at a fraction of branded prices. While reliable data are not available, theoretical models predict fewer counterfeit products within the U.S. generic sector, because generic prices are much lower and few are sold under branded trademarks (Outterson 2005b). The generic drug industry is frequently sued on patent infringement grounds, but these suits are part of the typical process for generic entry. If a drug is legally generic in both the country of production and the destination market, customs authorities in third countries should not impound it during transit. And yet this is exactly what happened in the case of the Dutch seizures discussed above.

In a second situation called parallel trade, the brand owner places a drug on the market in one country at a lower price, but complains if consumers or wholesalers resell the drug in other countries, where higher prices prevail. Parallel trade in pharmaceuticals is entirely legal within Europe. In no sense are these drugs counterfeit. They fully comply with all applicable laws, including TRIPS (Outterson 2005b), and significant safety issues haven't been reported. Parallel trade is generally legal in the U.S., but drug safety legislation outlawed parallel trade in medicines. For example, a U.S. citizen who purchases drugs from a Canadian pharmacy and brings those drugs back into the U.S. violates federal law. But unlike criminally counterfeit or contaminated products, these Canadian drugs are just as safe and effective as those sold in the U.S. Moreover, they may actually be, in a certain sense, more effective than their U.S.

counterparts because they are cheaper, making it more likely patients will comply with their prescribed drug regime. This trade is driven not by criminals, but by consumers desperate for affordable medicines. The primary harm of this activity is lost pharmaceutical patent rents, not damage to patient health (Outterson & Smith 2006:533). This trade may improve social welfare by increasing access to medication and may have an overall positive effect if U.S. patent rents are supra optimal (Outterson 2005b). These drugs may pose significant import safety issues, especially if purchased over the Internet without proof of actual source. In recent Congressional legislation, bills to encourage drug importation would legalize some of this parallel trade; these bills also feature enhanced import safety provisions.

Unlicensed generic antiretroviral (ARV) drugs for AIDS provide a final example. These drugs may be made under compulsory license, through voluntary agreements, or without a license, but they provide an affordable way to treat some of the millions suffering from AIDS. Many of these drugs are prequalified by the WHO, approved by the FDA, and paid for with U.S. government funds, yet would still violate patent law if sold in the U.S. (Outterson & Smith 2006:534). These rules are not related to safety at all, but are solely focused on protecting the patent rents of the pharmaceutical industry. Promoting pharmaceutical innovation is a legitimate policy option, but should not be confused with import safety or public health.

#### **D. The Traditional Definition of Counterfeit Medicines Should Not Be Expanded To Include Alleged Violations of Other IP Laws**

The traditional WHO definition of counterfeit focuses on trademark issues of drugs “deliberately and fraudulently mislabeled with respect to identity and/or source” (WHO 2009a, par. 10), but some patent-based drug companies are now attempting to expand the definition to

include any violation of any IP right, however technical or arcane. For example, a United Nations Interregional Crime and Justice Research Institute report recently defined counterfeiting as “illegal reproduction or imitation of products, given that this illegality is the result of a violation of *any type of intellectual property rights*” (emphasis added) (Park 2009:2; UNICRI 2007). Likewise, ACTA is reported to apply to any violation of IP rights, broadly interpreted. While this is advantageous to pharmaceutical companies seeking to enhance intellectual property rights beyond what TRIPS requires, it does nothing to further the public health and may harm the public health by making it more difficult to access medicines. This shift illustrates the need for a transparent and accountable process in IMPACT and ACTA.

A second example of IP expansion is criminal penalties for counterfeiting. While TRIPS requires criminalization of deliberate trademark counterfeiting, member countries are under no obligation to criminalize other acts of trademark infringement or infringement of other intellectual property rights (Park 2009:8-14). The distinction between criminal counterfeiting and civil trademark infringement is especially important in the context of pharmaceuticals. Civil trademark infringement disputes are common between generic pharmaceutical manufacturers and their brand named counterparts. Generic drugs are often given names derived from the international non-proprietary name (INN) of the medical ingredient, names that occasionally sound similar to the drug’s brand name (Park 2009:12). These generic drugs improve access to medication and pose no risk to public health. Generics should not be confused with criminal counterfeits.

Under TRIPS, the only conduct that must be criminalized is “willful trademark counterfeiting or copyright piracy on a commercial scale” (Park 2009:14; TRIPS 1994:Art. 61). This distinction is also found in U.S. law (Rierson 2008). Nothing in TRIPS requires

criminalization of patent infringement (Park 2009:18), and given the frequency with which pharmaceutical patents are found invalid or not infringed in suits against generic manufacturers, there is a strong argument against criminalizing alleged patent infringement (Park 2009:19).

Furthermore, the Doha Declaration's mandate that TRIPS be interpreted in a way "supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all" (Doha Declaration 2001) suggests that IP laws should not interfere with access to generic medicines and parallel imports. Criminalizing unintentional acts of infringement by generic manufacturers will likely chill entry of affordable generic drugs into the market (Park 2009:16-19).

#### **E. Counterfeit Statistics Are Not Reliable**

Statistics on counterfeit medicine are widely distributed but are neither reliable nor transparent (Outterson & Smith 2005:527). Estimates on the scope of the counterfeit drug problem vary greatly. Estimates on prevalence in various countries range from 1% to 50% of the drug supply, with reports of 40%, 30%, 17%, and 10% (Bird 2008:389). Recently, IMPACT estimated the prevalence of counterfeit medicines to be less than 1% of sales in developed countries – despite the fact that the potential profit of criminal counterfeiters is highest in these countries – and between 10% and 30% in developing countries, where the profit potential is lower. These estimates do not come from peer-reviewed journals, and many actually come from the pharmaceutical companies themselves (Park 2009:23-24).

In many of these studies, substandard, adulterated, parallel traded and generic drugs have been improperly conflated with deliberate violations of trademark law (counterfeits), often under the imprecise catch-all category of "fake." The few studies that did differentiate found the

majority of the problematic drugs bore genuine trademarks but were substandard. For example, in India it has been estimated that 8.19 – 10.64% of drugs are substandard (but apparently bearing a proper trademark), while only 0.24 – 0.47% are actually counterfeit in the trademark sense (Park 2009:25; Outterson & Smith 2006). The primary health issue appears to be drug quality, not criminal counterfeiting.

For the most part, drug companies are hesitant to release information on counterfeit drugs, as this information could harm the reputation of their branded products (Outterson & Smith 2006:527; Essential Action 2008:2). The Pharmaceutical Security Institute (PSI), an industry organization formed by major drug companies, maintains the most comprehensive global database of counterfeit drug information, but researchers (Outterson & Smith 2006:527), the WHO, health authorities, and the public are not given access to this database.

Several proposals have been put forward to remedy the problem of insufficient data. The federal government could fund surveillance to ensure the integrity of the U.S. drug market (Outterson & Smith 2006:529). The WHO has begun some limited surveillance studies in developing countries (WHO 2009a:par. 27; WHO 2009b:Annex, par. 4). Surveillance requires randomized purchases within a market and testing the drugs for compliance with drug regulatory procedures. The results of these studies should be made widely available and performed in a manner that supported accurate cross comparisons. Other proposals would require pharmaceutical companies to report potentially problematic drugs to the regulatory agencies, which would then work to confirm the report and decide whether to alert law enforcement personnel and the public (Maybarduk 2007:5; Cockburn et al. 2005; H. R. Res. 3297 §3(b)).

With respect to truly counterfeit products, TRIPS requires member states to “promote the exchange of information and cooperation between customs authorities with regard to trade in

counterfeit trademarks.” (TRIPS 1994:Art. 69). It appears no country has yet required pharmaceutical companies or PSI to disclose information to the public under Article 69 (Maybarduk 2007:5). However, in 2003, U.S. pharmaceutical companies entered into a voluntary agreement with the FDA to report instances of counterfeit drugs within five days (Cockburn 2005). This data is not available to the public.

### **III. Rent Seeking Regime Shifts: IMPACT and ACTA**

The efforts with Anti-Counterfeiting Trade Agreement (ACTA) were preceded by a public-private organization. IMPACT seeks to expand border enforcement against drugs subject to IP disputes. This effort goes well beyond the TRIPS, WHO and U.S. definitions of counterfeit, and may reduce access to desirable generic drugs or cheaper brand name drugs parallel traded from other countries. This section will examine the norm setting activities in IMPACT since 2006, before turning to ACTA. Both efforts seek new IP and customs enforcement rules for an expanded array of products. These expanded definitions may serve the interests of patent-based drug companies, but the impact on public health is less sanguine.

#### **A. IMPACT**

IMPACT is a voluntary organization including international organizations, governments, and private business associations. Participants include the World Health Organization (WHO) and the International Federation of Pharmaceutical Manufacturers Associations, the global lobbying arm of the patent-based drug companies. IMPACT was unveiled at a conference which took place in Rome in 16-18 February 2006 (WHO 2009b: par. 6). During 2008, a significant controversy arose regarding the relationship between IMPACT and WHO. IMPACT promoted

itself as a WHO project involving all 193 WHO member states. In late 2008, developing countries blocked a WHO resolution supporting IMPACT's work, wary of its IP and public health implications (Third World Network 2008:21). In April 2009, the WHO clarified its role in IMPACT and began to offer more transparency on the process (WHO 2009b).

One IMPACT norm-setting project is the Model Elements for National Legislation ("Model Elements"), which strengthens intellectual property protection beyond TRIPS requirements (Third World Network 2008:24-27). If adopted, the Model Elements may create non-tariff barriers to generic medicines. The Model Elements also fail to explicitly recognize parallel importation and TRIPS flexibilities like compulsory licensing, which provide a legal method of improving access to medication (Third World Network 2008:24-27). WHO is the primary United Nations agency for health and is ideally suited to balance the dual health imperatives of drug safety and access to essential medicines. To date, it does not appear that WHO has discussed this issue at IMPACT. A more transparent process might broaden the scope of the inquiry, and draw other voices into the discussion.

Industry officials have a strong incentive to discourage the use of TRIPS flexibilities by confusing these drugs with criminal counterfeits, and it appears they are using IMPACT to pursue this agenda (Sell 2008:13). It seems that members of the private sector were heavily involved in drafting the Model Elements, while many WHO member states had little input (Third World Network 2008:25).

IMPACT has also had some success in pushing developing countries to adopt laws providing for stronger intellectual property protection. Kenya's recently enacted Anti-Counterfeiting Act provides several measures aimed at targeting the general availability of counterfeit goods in the country (MSF 2008b; HAIA 2008; Kenya 2008). While the bill does

have some positive aspects, it also contains several provisions that could hamper the government's ability to provide access to essential medicine to the estimated 1.4 million Kenyans living with HIV/AIDS (GHR Kenya n.d.). The bill needlessly confuses counterfeiting with violations of non-trademark intellectual property rights (MSF 2008b; HAIA 2008; Anti-Counterfeiting Act 2008). The bill also weakens existing Kenyan legislation allowing parallel imports (HAIA 2008). Uganda, where over 5% of the adult population is infected with HIV/AIDS (GHR Uganda n.d.), is also considering a similar bill (Matthew 2009). The Ugandan legislation reportedly calls for the death penalty for drug "counterfeiters;" the mixture of imprecise definitions and capital punishment may chill legitimate markets in generic drugs.

In another norm-setting project, IMPACT has proposed modifying the traditional WHO definition of counterfeit:

A medical product is counterfeit when there is a false representation in relation to its identity and/or source. This applies to the product, its container or other packaging or labeling information. Counterfeiting can apply to both branded and generic products. Counterfeits may include products with correct ingredients/components, with wrong ingredients/components, without active ingredients, with incorrect amounts of active ingredients, or with fake packaging.

Violations or disputes concerning patents must not be confused with counterfeiting of medical products. Medical products (whether generic or branded) that are not authorized for marketing in a given country but authorized elsewhere are not considered counterfeit. Substandard batches of, or quality defects or non-compliance with Good Manufacturing Practices/Good Distribution Practices (GMP/GDP) in legitimate medical products must not be confused with counterfeiting (WHO 2008).

This proposed definition partially addresses the confusion between patent infringement, drug registration, and trademark counterfeiting, but also raises several concerns. Although the definition states that patent disputes must not be "confused" with counterfeiting, it does not say patent violations *are not* counterfeiting. Notably, the definition fails to say if counterfeiting must be done deliberately or whether criminal intent or careless behaviors are necessary elements.

The distinction between civil and criminal violations of trademark has a long history under U.S. law, and is also expressed in TRIPS. Significant modifications to these principles should not be made in obscurity.

The definition is unclear whether the term “identity” refers to the INN (the “international non-proprietary name” or generic name, a global standard that cannot be trademarked). In the proposed definition, the term is described non-exhaustively to *include* any “misleading statement with respect to name, composition, strength or other elements.” Generic drugs often appear similar to their brand named counterparts with regard to taste, shape, or color. IMPACT expands the definition of counterfeit to include false representations of identity or source applied to “the product, its container or other packaging or labeling information.” This raises the possibility that generic versions of off-patent drugs could be considered counterfeit on the basis of similar trade dress or drug labeling (Third World Network 2008:36-39).

The goal of any legal reforms in this area should be to remove goods bearing deliberately false trademarks (counterfeits) from the supply chain, while encouraging legitimate low-cost generic drug markets. A troubling aspect of IMPACT is that norms are being set that potentially will alter common law and statutory rules in many countries, and those changes may occur without much democratic debate. IMPACT’s working groups are not accessible to the public, nor are public health groups with knowledge of IP laws invited to participate. The process is driven by the patent-based pharmaceutical companies which stand to benefit financially from hindering generic competition.

## **B. The Anti-Counterfeiting Trade Agreement (ACTA)**

In addition to the legislative changes being encouraged by IMPACT, international laws on counterfeit goods may soon be dramatically altered by the Anti-Counterfeiting Trade Agreement (ACTA). ACTA is being negotiated by 13 countries, led by the U.S. and the European Union (Kaminski 2009:247). It is difficult to say anything definitive about ACTA when this chapter was written (May 2009), because the negotiations are taking place in secret, and no verified draft of the agreement has been circulated (Kaminski 2009:247,251). A purported draft is available on Wikileaks, which represents the only publicly available detailed information on ACTA.

ACTA is designed “to bridge the gap between laws on the books and strong enforcement on the ground” (USTR 2008). Given recent seizures of generic medications suspected of violating patent laws, it will be important to watch the development of this agreement and to examine the potential impact it could have on legitimate trade in generic medications and parallel imports.

Several points are notable in the leaked drafts, which we can only assume are authentic. First, the 20 May 2008 and 25 June 2008 ACTA texts covered only trademark and copyright (ACTA 2008a, b; Kaminski 2009); in the text dated 7 July 2008 the scope was expanded to cover all intellectual property rights described in TRIPS (ACTA 2008c: art. 2.7 (1)). This is precisely the expansion of IP rights criticized with respect to IMPACT. Second, ACTA proposes to modify existing criminal standards and sanctions (ACTA 2008e: sec. 3), as well as border measures, giving customs officials more authority to seize and destroy infringing shipments and to disclose information to right holders on those shipments (ACTA 2008b: sec. 2; Kaminski 2009:251-254). One proposal by Japan would expand the definition of “counterfeit” well beyond the accepted bounds of “willful trademark counterfeiting” to include criminal penalties

for “trademark infringement caused by confusingly similar trademark goods” (ACTA 2008e: art. 2.14(1)). These changes could expose generic manufacturers to significant risks without justification. Third, the U.S. proposed that ACTA cover “in-transit” shipments as well as import and export (ACTA 2008b: art. 2.6(1)), the precise issue raised by the Dutch seizures. Fourth, the September 2008 proposal from the EU requires the parties to “ensure that, where a judicial decision is taken finding an infringement of an intellectual property right, the judicial authorities may issue against the infringer an injunction...” (ACTA 2008d: art. 2.7). After the recent U.S. Supreme Court decision in *Ebay* (2006), modification of U.S. law may be required, which would be a very controversial move. Finally, the Canadian “non-paper” dated 9 June 2008 discusses the creation of the ACTA Oversight Council, with institutional powers and capacities, including dispute resolution. Clearly, a new international organization is being formed.

It is important not to be too distracted by the details in ACTA, because we are speculating in the shadows rather than engaging in a transparent and robust debate. But it certainly seems plausible that public health concerns are raised by some of the provisions of ACTA, and should be fully vetted with open and democratic processes. Both Canada and the European Parliament have called for transparency in the ACTA negotiations, but reportedly the U.S. government is blocking disclosure as a national security secret (Geist 2009). Perhaps the Obama Administration will say “Yes We Can” to disclosure and public debate.

#### **IV. Conclusion**

Drugs that bear a deliberately false trademark must be kept out of the market. But removing counterfeits will not eliminate all problems with substandard, contaminated and adulterated drugs, as many unsafe drugs are not counterfeits. Moreover, an overly expansive

definition of the term “counterfeit” (especially one that expands beyond trademark law to include patent disputes) may impede access to medication by reducing access to life saving generic medications and by preventing parallel importation. Recent attempts to conflate these categories damages public health and confuses issues of import safety with patent policy.

Equally significant is the recent strategy to create additional global institutions as regime-shifting fora to expand IP enforcement, diverting import safety resources to serve the IP goals of patent-based drug companies. Given the significant public health issues at stake, these efforts should not proceed without transparency and significant democratic engagement. Recent seizures of generic drugs, suspected of infringing patents in a transit country, highlight the need to ensure the definition of counterfeit is not stretched beyond what TRIPS requires to criminalize legitimate, socially desirable behavior.

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