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### ACTA and Public Health

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# ACTA AND PUBLIC HEALTH

*Peter Maybarduk*<sup>1</sup>

## ABSTRACT

Although the term “anti-counterfeiting” suggests an agreement limited to preventing trade in counterfeit products, ACTA’s draft provisions, to date,<sup>2</sup> would set new minimum enforcement standards for a range of intellectual property rights. In several areas, these standards could impede legitimate competition, shortchange legal process and shift costs of enforcing private commercial rights to the public.

The parties to ACTA have agreed to narrow some of its provisions in recent months. Despite these improvements to its text, ACTA continues to present risks for global access to medicines, including potentially restricting free transit of generics, imposing chilling effects on the medicines trade, and limiting flexibilities in intellectual property (IP) rules.

The parties have cited protecting consumers from unsafe products as a primary benefit of ACTA. But among IP infringements, only willful trademark counterfeiting of potentially dangerous classes of products poses a categorical public safety risk. Outside the context of counterfeiting, IP infringement analysis is not related to health. Moreover, ACTA diverts attention and resources away from more direct and comprehensive public safety measures.

ACTA’s most significant public health costs may come from its narrative positioning and precedent. ACTA does not adequately distinguish between criminal activity and civil infringements occurring in the context of market competition—a problem that concerns consumer groups and intellectual property owners alike.

Several parties to ACTA now rightly suggest narrowing the agreement’s scope altogether. Public health analysis leads to the conclusion that ACTA should be scaled back to cover only willful commercial scale trademark counterfeiting.

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<sup>2</sup> This paper refers to the August 25, 2010 draft unless otherwise noted. Anti-Counterfeiting Trade Agreement Informal Predecisional/Deliberative Draft: Aug. 25, 2010, PIJIP IP ENFORCEMENT DATABASE, <http://sites.google.com/site/iipenforcement/acta> (follow “Full Leaked Text Dated August 25, 2010” hyperlink) [hereinafter ACTA Draft – Aug. 25, 2010].

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### I. OVERVIEW: ACTA & PUBLIC HEALTH

Although the term “anti-counterfeiting” suggests an agreement limited to preventing trade in counterfeit products, ACTA’s draft provisions, to date, would set new minimum enforcement standards for a range of intellectual property rights. In several areas, these standards could impede legitimate competition, shortchange legal process, and shift costs of enforcing private commercial rights to the public. ACTA’s draft text blurs key distinctions between market competition and criminal activity and takes a step toward creating *de facto* international intellectual property regimes. Under its broader proposed terms, ACTA, not unlike a counterfeit, misrepresents its true ingredients to the public.

Some of ACTA’s draft provisions continue to present risks for global access to medicines. These include potentially restricting the free transit of

lifesaving and cost-lowering generic medicines. ACTA could impose potentially chilling effects on the medicines trade and limit the use of key flexibilities in intellectual property rules. ACTA could make it easier for major pharmaceutical companies to seek to limit or deter generic market entry worldwide by projecting national intellectual property regimes into the customs regulation of global trade. Even given recent improvements to its text, ACTA could still establish the scope of the European Union's controversial customs regulation 1383/2003<sup>3</sup>—which has led to customs actions stopping lifesaving medicines in transit to developing countries—as a default international norm.

Expanding an anti-counterfeiting agreement beyond counterfeits does not similarly expand its benefits to consumers. Willful, commercial scale trademark counterfeiting is a criminal offense under the World Trade Organization's Agreement on Trade Related Aspects of Intellectual Property (TRIPS)<sup>4</sup> and appropriately targeted by law enforcement. But civil IP infringements—including among others patent and “similar” trademarks or trade dress—are not criminal acts, and do not generally represent a fraud on the public. Civil infringements are typically commercial disputes between legitimate entities, for which traditional legal remedies are and should be available. Civil infringements do not require preemptive law enforcement interdiction, be it *ex officio* or on a rights holder application, wherever they appear in the channels of commerce. Instead, assessing infringement requires judicial process, and often expert legal analysis, that is outside the competence of customs and other law enforcement authorities.

ACTA's draft text does not adequately distinguish between criminal activity and civil infringement. The Intellectual Property Owners Association and other industry groups share this concern.<sup>5</sup> Major businesses commonly find themselves on either side of infringement disputes. ACTA's draft terms would impose legal uncertainty and costs, while tainting commercial disputes with the air of criminality. Indeed, it is difficult to identify compelling public rationales for many of ACTA's provisions, or the proposed ongoing work of

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<sup>3</sup> Council Regulation 1383/2003, 2003 O.J. (L 196) 7 [hereinafter Council Reg. 1383/2003].

<sup>4</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, art. 61, 108 Stat. 4809, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement].

<sup>5</sup> Intellectual Property Owners Association letter to USTR (June 25, 2010) *available at* <http://www.ipo.org/AM/Template.cfm?Section=Home&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=26347>. See also “ECIS' concerns on the impact of the Anti-Counterfeiting Trade Agreement (“ACTA”),” European Committee for Interoperable Systems, Sept. 17, 2010, *available at*: <http://www.ecis.eu/documents/ECISACTApositionpaper.pdf>.

an ACTA Committee, when applied to civil infringements.

The parties to ACTA have cited protecting consumers from unsafe products as a primary benefit of the agreement. But among intellectual property infringements, only willful trademark counterfeiting of certain potentially dangerous classes of products poses a categorical public safety risk. Willful counterfeit medicines, by definition and by dint of being illegal, are not registered with drug regulatory authorities and hence not regulated—and therefore cannot be considered safe for consumption.

By contrast, civil infringements do not pose an inherent safety risk. Outside the context of counterfeiting, IP infringement analysis is not reasonably related to health, and does not contribute to public safety. Instead, expanding ACTA's scope to cover civil infringements targets market competition preemptively, including registered generic medicines, without benefits to public safety, and to the detriment of public health interests including access to medicines. Moreover, ACTA diverts resources and attention away from more direct and comprehensive measures to protect the public from unsafe products.

This white paper reviews some of the proposed ACTA terms that create risks for access to medicines, and offers suggestions for improvement. The paper then clarifies the relationship between classes of infringement and health and safety, and reviews the harmful precedent ACTA could set by treating alleged civil infringements and market activity under the narrative of counterfeiting. This public health analysis leads to the conclusion that ACTA should be scaled back to cover only criminal, willful, commercial scale trademark counterfeiting.

## II. ACCESS TO MEDICINES: ACTA'S CONTINUING RISKS

Market competition plays a key role in improving global access to medicines by reducing costs over time to levels where governments and donors can scale-up treatment coverage. For example, over the last ten years, global competition and generic medicines have produced a revolution in HIV/AIDS treatment, reducing prices from \$10,000 to \$100 per person per year in developing countries, and enabling more than five million people worldwide to access lifesaving antiretroviral therapy. Competition remains every bit as vital today to expand access to new drugs, including among many others expensive second and third-line HIV/AIDS treatments.

### A. *Impeding the Transit of Generics*

ACTA's text no longer requires countries to provide special preemptive

border measures for patents. Nevertheless, the Border Measures section may still prejudice the interests of competition and access. To improve the scope of ACTA's Border Measures section, the parties should reject the EU/Switzerland proposal, and adopt in its place a sole, modified US/Sing/Aus/NZ/J/Can provision: "*Parties shall provide for the provisions related to border measures to be applied in cases of [willful] trade mark counterfeiting and copyright piracy [on a commercial scale].*"<sup>6</sup>

ACTA's proposed Border Measures have raised concerns from the first leaked draft. Under some early proposals, ACTA would have required countries to empower customs agents to seize medicines on mere suspicion or rights holder allegation of patent infringement, ahead of judicial process, even if the medicines were simply in transit through the port. This mirrors what has happened under European Council Regulation 1383/2003.<sup>7</sup> Many times, customs agents detained or seized shipments of generic medicines from India en route to other developing countries.<sup>8</sup> While not all case details are available, it is clear that in some instances the medicines were not even under patent in India or the destination country. India and Brazil have since initiated procedures at the WTO to review the TRIPS compliance of Council Regulation 1383/2003, and some legal scholars argue the regulation may violate principles of territoriality and the General Agreement on Tariffs and Trade.<sup>9</sup>

Enforcement measures that rights holders can trigger automatically and *ex parte* are prone to abuse. Measures that customs authorities take on their own initiative, *ex officio*, are prone to inaccuracy and over enforcement. Generics firms are often smaller than patent-based pharmaceutical firms, and operate on lower margins of return. Special border measures could jeopardize not only particular shipments of generic medicines, but the business model for the relatively small-scale generics industry, and the access to medicines interests that rely on it. In response to the medicines detentions, several Indian generics producers are reported to have altered economical transshipment through Europe in favor of alternative and more costly routes. Diversion of such medicines from Europe could also risk the storage and distribution

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<sup>6</sup> ACTA Draft – Aug. 25, 2010, *supra* note 2, Sec. 2, Art. 2.X: Scope of the Border Measures.

<sup>7</sup> Council Reg. 1383/2003, *supra* note 3.

<sup>8</sup> Press Release, Health Action International, Another seizure of generic medicines destined for a developing country, this time in Frankfurt (June 5, 2009), *available at* <http://www.haiweb.org/19062009/5%20Jun%202009%20Press%20release%20Seizure%20of%20generic%20medicines%20in%20Frankfurt.pdf>.

<sup>9</sup> For a discussion of territoriality, GATT Article V, TRIPS and implications for border measures applied to in transit goods, *see* XAVIER SEUBA, FREE TRADE OF PHARMACEUTICAL PRODUCTS: THE LIMITS OF INTELLECTUAL PROPERTY ENFORCEMENT AT THE BORDER 16 (ICTSD, ed. 2010).

practices of health-related NGOs that use warehouses in Europe as way stations for products eventually distributed to developing countries in Africa and Latin America.

But the most unfortunate consequence of such border measures could be wrongly tethering the public image of generic drugs to that of counterfeits requiring concerted police action. This danger is not speculative. Medical professionals worldwide struggle against stigma and propaganda that insinuates generics represent second-class treatment. Recent East African anti-counterfeiting bills effectively criminalize the generics trade, by extending criminal penalties to infringements of any intellectual property right held anywhere in the world. ACTA, as a flagship IP enforcement proposal, must actively discourage, rather than encourage, the trend to treat generics and civil infringement claims with policing measures designed for counterfeits.

### 1. Improvements and Outstanding Concerns

Access to medicines concerns and controversy seem to have persuaded the ACTA parties to revise the agreement's text. ACTA no longer requires countries to apply extraordinary border measures to patents. This is a clear and important improvement, and some negotiators and trade officials now maintain that this resolves any access concerns in the agreement. However, there are at least two outstanding concerns in ACTA's border measures.

#### a. The EU's Proposed Default Rule

First, the EU/Switzerland proposal still assumes a default position that ACTA's border measures will apply to all classes of intellectual property, including patents. Countries may exclude patents if they choose: “[EU/CH]: For the purposes of this section, ‘goods infringing an intellectual property right’ means goods infringing any of the intellectual property rights covered by TRIPS.\* However, Parties may decide to exclude from the scope of this section, certain rights other than trademarks, copyrights and GIs...”<sup>10</sup>

A default rule such as this, even if not a requirement, still establishes a norm. If the parties adopt the EU/CH proposal, then ACTA would promote a presumption in favor of applying special border measures to patents wherever the agreement's considerable influence may extend.

Emerging global IP enforcement trends make this concern all the more

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<sup>10</sup> ACTA Draft – Aug. 25, 2010, *supra* note 2, Ch. 2, Sec. 2, provisions on Scope. [\* The provisions of this section shall also apply to confusingly similar trademark goods.]

salient. EC Council Regulation 1383/2003 still applies to patents (although it is under review). The EU is exporting similar standards through economic partnership agreements. East African nations are debating new laws, regulations and proposed laws that impose much broader and harsher border measures. An ACTA assumption that preemptive border measures—*ex ante, ex parte, ex officio*—should commonly apply to patents, even with safeguards in place, still lends legitimacy and momentum to a flawed idea. Adopting the recommended and modified US/Sing/Aus/NZ/J/Can provision, above, would correct this particular problem.

#### b. Civil Trademark Claims

Second, and also under the EU/Switzerland proposal, ACTA would still require countries to apply special border measures to geographic indicators and to all classes of trademark and copyright infringement—not only willful counterfeiting and piracy. The inclusion of civil trademark claims in ACTA’s border measures creates risks for access to medicines similar to those raised by patents.

In intellectual property usage, the term “counterfeit” applies correctly to a subset of trademark infringement. Under the TRIPS Agreement,<sup>11</sup> “counterfeit trademark goods shall mean any 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[.]” This definition is incorporated into the latest ACTA text under General Definitions (previously at footnote 23).

A trademark counterfeit is distinct from a case in which the commercial design or packaging of one firm’s registered medicine is alleged to create a “likelihood of confusion”<sup>12</sup> with another firm’s established trademark. For example, pharmaceutical firms sometimes give their products commercial names derived in part from an active ingredient’s international nonproprietary name (INN).<sup>13</sup> Branded and generic products based on the same active ingredient may therefore bear similar names. Generic medicines also sometimes feature packaging or pill design with similar qualities to

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<sup>11</sup> TRIPS Agreement, *supra* note 4, art. 51 n. 14.

<sup>12</sup> See, e.g., *id.* art. 16.1; Council Directive 89/104/EEC Art. 5.1(b), 1989 O.J. (L 40) replaced by Council Directive 2008/95/EC Art. 5, 2008 O.J. (L 299/25) ; and Trade Marks Act of 1994, 1994, c. 26, § 10.2 (U.K.). For US and EU case articulations of the “likelihood of confusion” standard, see *infra* note 15.

<sup>13</sup> See, e.g., Chan S. Park, *Legal Aspects of Defining “Counterfeit Medicines”*: A Discussion Paper, (World Health Org. Regional Office for South-East Asia, 2009).

established marks, specifically because the products are therapeutically equivalent, and designed for consumers' interchangeable use. Many pharmacies place generics on their shelves next to brand-name products, often featuring somewhat similar coloring or designs.<sup>14</sup> Similar packaging is used to communicate a similar (bioequivalent) product. Policy goals favoring generic substitution support this general practice.

Similar marketing names or similar packaging for drugs sometimes do form the basis of civil trademark infringement claims. Trademark owners have a legitimate commercial interest in defending their marks. Judicial recourse is, and should be, available in such circumstances. But in neither case has the generics manufacturer fraudulently misrepresented the source or identity of its product. And neither would be properly termed "counterfeiting."

ACTA should reflect this distinction. Civil trademark claims typically require a weighing of many factors.<sup>15</sup> Assessing infringement requires legal process and analysis outside the competence of customs authorities. Notably, courts have tended to grant narrower trademark and trade dress protection to pharmaceuticals than to other classes of products.<sup>16</sup> This is due to the functionality of pill design, as well as the consumer interests served by communicating bioequivalence. The risk is high that customs agents, encouraged to stop as much infringing activity as possible, would sometimes apply trademark infringement standards too zealously. At least one recent EU customs detention of generic medicines in transit cited—wrongly, it turned

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<sup>14</sup> See e.g., Sean Flynn & Amy Kapczynski, *Counterfeit Versus "Confusingly Similar" Products*, PIJIP BLOG (May 7, 2010), <http://www.wcl.american.edu/pijip/go/pijip05072010>.

<sup>15</sup> In the United States, federal courts tend to apply multifactor tests, such as these from the Ninth Circuit Court of Appeals, to measure "likelihood of confusion": strength of the mark, proximity of the goods, similarity of the marks, evidence of actual confusion, marketing channels used, type of goods and the degree of care likely to be exercised by the purchaser, defendant's intent in selecting the mark, and likelihood of expansion of the product lines. *AMF, Inc. v. Sleekcraft Boats*, 599 F.2d 341, 348 (9<sup>th</sup> Cir. 1979). The court noted, "the list is not exhaustive. Other variables may come into play depending on the particular facts presented." *Id.* at 348 n. 11. See also *Polaroid Corp. v. Polarad Elect. Corp.*, 287 F.2d 492 (2d Cir.1961).

In regard to European standards for analyzing a community trademark under First Council Directive, 89/104/EEC, 1989 O.J. (L40) 1, art. 5.1(b), courts use a "global assessment test" which requires all circumstances of and surrounding the good be taken into account. Factors include assumption of an "ordinary consumer" viewpoint, overall impression of the mark, level of distinctiveness, weight of similarity of the goods against similarity of the marks, risk of public confusion as to economic source of the goods. See Case C-251/95, *Sabel v. Puma*, 1997 E.C.R. I-6191; Case C-39/1997, *Canon v. MGM*, 1998 E.C.R. I-5507; Case C-342/97, *Lloyd Schuhfabrik Meyer & Co GmbH v. Klijsen Handel BV*, 1999 E.C.R. I-3819; Case C-425/98, *Marca Mode CV v. Adidas AG*, 2000 E.C.R. I-4861.

<sup>16</sup> See Public Citizen Research Note, "Trademark and Trade Dress Infringement Standards for Generic Pharmaceuticals," Arielle Singh, July 31, 2010 [on file with author]; see also, e.g., *Shire U.S., Inc., v. Barr Labs., Inc.*, 329 F.3d 348, 344-35 (3d Cir. 2003).

out—trademark infringement grounds.<sup>17</sup> And the potential for spurious claims and rights holder abuse applies to civil trademark infringement much as it does to patents.

A better standard would target willful counterfeits specifically and exclusively. There may be reason to distinguish between cases of willful trademark counterfeiting and cases of arguable counterfeiting where no intent to fraudulently misrepresent source is evident. Note the TRIPS definition of counterfeiting does not require a showing of intent. The “substantially indistinguishable mark” counterfeiting standard could also be different in some limited cases than a standard of fraudulent misrepresentation of source. Perhaps one firm could use a packaging design nearly identical to an established design, but employ a different name. This could amount to “substantially indistinguishable” use of a mark or trade dress classifying the product, in some analysis, as counterfeit, but it might still represent more an effort to indicate similarity (or bioequivalence) to the first product than an effort to claim the product is actually produced by the other company.

Notably, TRIPS creates an enforcement distinction between counterfeiting in general and cases of “willful trademark counterfeiting on a commercial scale,” the latter being subject to criminal penalties (Article 61). This is the appropriate standard for special border measures intended to target activity that cannot be adequately addressed by civil judicial process. While the intent of the alleged infringer may not always be evident, this is initially true of many law enforcement targets. It remains important to apply the legal standard most rationally related to the policy goal of stopping criminal counterfeiting, and to maintain a clear and consistent distinction between alleged civil infringement and criminal activity in enforcement procedures.

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<sup>17</sup> According to Health Action International:

*A shipment of the antibiotic, Amoxicillin, manufactured in India and destined for the Republic of Vanuatu in the Pacific, was seized by customs officials on 5 May, 2009, while in transit through Frankfurt, Germany. Amoxicillin is an essential medicine used to treat a wide range of bacterial infections. In this latest case, customs authorities seized a shipment of 3,047,000 pills of Amoxicillin (250 mg), worth approximately 28,000 Euros for four weeks before releasing it to Vanuatu. The batch was detained on grounds of suspected trademark infringement. This quantity of tablets is equivalent to 76,000 courses of treatment. Customs authorities then informed GlaxoSmithKline (GSK), which received the letter on 13 May. Seven days later, GSK informed the German customs authorities that there was no trademark infringement. GSK is the former patent holder for “Amoxil”, a brand name amoxicillin. There is no valid reason for detaining these medicines especially since the name “Amoxicillin” is an international nonproprietary name (INN).*

Press Release, Health Action International, Another seizure of generic medicines destined for a developing country, this time in Frankfurt (June 5, 2009), available at <http://www.haiweb.org/19062009/5%20Jun%202009%20Press%20release%20Seizure%20of%20generic%20medicines%20in%20Frankfurt.pdf>.

### *B. Imposing Chilling Effects on the Medicines Trade*

ACTA's proposed norms on liability still leave too much uncertain. A particular area of concern, requiring greater attention and scrutiny from the Parties, is intermediary liability. An EU/Switzerland proposal would provide for general availability of injunctive relief against "intermediaries whose services are used by a third party to infringe an intellectual property right."<sup>18</sup> In the context of pharmaceuticals, such injunctions might include, for example, orders to cease sales to a generics firm. Intermediaries might include shippers and the manufacturers of active pharmaceutical ingredients, and potentially reach or influence the medicines procurement decisions of agencies such as the Global Fund. The uncertain reach of injunctions could contribute to a chilling market for medicines. A new note available from law professor Brook Baker describes in further detail the potentially disruptive effect of a broad ACTA intermediary liability provision on the global medicines trade.<sup>19</sup>

ACTA's Article 2.4, "Information Related to Infringement," would require countries to make available, upon justified request of the right holder, court orders requiring alleged infringers to identify distributors and other business partners or contractors throughout the production chain. This provision opens up possibilities for rights holders to harass contractors that work with their competition. The provision becomes more concerning when taken in concert with recent proposed U.S. legislation to establish lists of importers that "have a history of attempting to import goods that infringe intellectual property rights"<sup>20</sup> and of "low-risk importers."<sup>21</sup> If these and similar proposals are applied broadly to civil infringements, as is currently proposed, contractors in the medicines supply chain could reason that working with generics firms attracts unwanted negative attention, and that their business interests might be better served working with rights holders.

More generally, if ACTA's scope remains broad, low-capitalized generics firms (as well as major transnational companies which also defend against infringement claims) will have to account for uncertainty and new potential

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<sup>18</sup> ACTA Section 1: Civil Enforcement, Article 2.X Injunctions 2, ACTA Draft – Aug. 25, 2010, *supra* note 2.

<sup>19</sup> Brook K. Baker, *ACTA – Risks of Intermediary Liability in Access to Medicines*, (PIJIP Research Paper No. 1, American Univ. Washington College of Law, Sept. 2010), *available at* <http://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1001&context=research>.

<sup>20</sup> Customs Facilitation and Trade Enforcement Reauthorization Act of 2009, S. 1631, 111th Cong. § 234 (2009).

<sup>21</sup> Trade Enforcement Act of 2009, S. 1466, 111th Cong. § 225 (2009).

costs, including shipping delays, storage and perhaps destruction fees,<sup>22</sup> and litigation.

### C. Limiting Flexibilities in Intellectual Property Rules

Knowledge Ecology International has written extensively on ACTA's evolving, but as yet inadequate, allowance for flexibility on damages rules and the availability of injunctions.<sup>23</sup> Under TRIPS Article 44.2, countries are not required to make injunctive relief available in all circumstances, because other important national interests, such as reducing medicine costs through the government use of patents or keeping health products on the market, could be compromised.<sup>24</sup> Similarly, rigid damages and injunctions rules can limit innovation, by uniformly seeking to prevent or punish infringement, rather than providing adequate compensation in those particular cases where use of a proprietary invention might advance technological development.

KEI has pointed out that ACTA's provisions on damages and injunctions may conflict with numerous national laws affecting many economic sectors. Here, again, limiting ACTA's scope would reduce the number of potential conflicts. A separate helpful step would be to adopt the Canada/Australia/Singapore proposal expressly subjecting ACTA's civil enforcement injunction provisions "to any statutory limitations under its domestic law."<sup>25</sup>

## III. PUBLIC SAFETY

Parties to ACTA have frequently cited the agreement as a means to protect the public from unsafe counterfeit products. But most classes of intellectual property infringements do not raise health and safety concerns by their nature. Criminal trademark counterfeiting can be an exception, and can be appropriately targeted *ex officio* by law enforcement under the TRIPS Agreement. However, criminal trademark counterfeiting should be distinguished not only from patents and other classes of intellectual property, but also from civil trademark infringement involving similar marks, product names and trade dress. If ACTA's scope remains broad, its public health costs are likely to outweigh its benefits.

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<sup>22</sup> See ACTA Draft – Aug. 25, 2010, *supra* note 2, Art. 2.12.

<sup>23</sup> See James Love, *Comments on ACTA Provisions on Damages and Injunctions*, Knowledge Ecology International, April 6, 2010, available at: [http://keionline.org/sites/default/files/kei\\_rn\\_2010\\_1.pdf](http://keionline.org/sites/default/files/kei_rn_2010_1.pdf).

<sup>24</sup> See TRIPS Agreement, *supra* note 4, Art. 44.2.

<sup>25</sup> See ACTA Draft – August 25, 2010, *supra* note 2, Sec. 1, Art. 2.X: Injunctions.

### A. *Patents and Supplementary Protection Certificates*

Patent infringement analysis is not related to counterfeiting, fraudulent misrepresentation of source, health or safety. Patent infringement pertains to alleged use of claimed proprietary inventions, not to fake marks, deliberate mislabeling or absent required assessments of safety. Indeed, patent infringement cases allege putting the patented technology to use. In almost all cases, the alleged infringer is attempting to manufacture or market a legitimate medicine. Patent infringement actions are civil and commercial disputes. Rather than protecting public health, imprecise or overly broad patent enforcement measures could obstruct competition and potentially risk access to medicines.

Supplementary protection certificates are patent extensions for medicines, and hence the same analysis applies.

### B. *Copyright*

Copyright analysis is not reasonably related to health or safety. More particularly, copyright analysis should not be used to challenge the content of product textual labeling, which is often required by drug regulatory authorities.

### C. *Geographical Indications*

The use, or misuse, of a place name does not reveal the safety of the product. Even if a company appropriates the name of a region to indicate characteristics of a product or a production method, rather than its place of production, this does not suggest the product is unsafe.<sup>26</sup>

### D. *Trademarks—Willful counterfeiting vs. civil, similar infringement*

Even in the trademark context, civil infringements (*e.g.*, “similar” marks and dress) do not pose a general risk to public health. Among IP infringements, only willful trademark counterfeiting of potentially dangerous classes of products can be said to pose such an inherent risk.

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<sup>26</sup> Arguments to the contrary would require that a product’s safety depend on a particular place of origin or production. It is hard to think of such an example to which Geographical Indications could apply. Arguments that a place name confuses consumers or that a particular product’s characteristics or quality depends on the place of production are distinct from arguments that its safety is so dependent.

In order to be a willful trademark counterfeit, a product must fraudulently misrepresent its source by counterfeiting a protected mark. Such a product could not be approved by a drug regulatory authority. The imitated medicine may be approved, but the counterfeit is not.<sup>27</sup> In other words, willful trademark counterfeit medicines, by definition and by dint of being illegal, are not registered with drug regulatory authorities, and hence not regulated—and therefore cannot be considered safe for consumption. In medicines, the TRIPS standard for criminal trademark infringement—willful trademark counterfeiting on a commercial scale—is a category that rightly triggers public health concern. It is appropriate that law enforcement, including customs authorities, intervene in such circumstances.

But medicines (or other goods) that correctly describe their source and ingredients, yet bear a similar marketing name, symbol or pill design that could infringe a protected trademark or trade dress, cannot be said to pose such a risk. Law enforcement actions that detain or impose extrajudicial costs on companies for their use of similar marks do not protect the public from unsafe medicines or target criminal enterprises. Rather, these actions potentially hinder competition and the interests of global access to medicines.<sup>28</sup>

Public safety arguments do not support expanding ACTA's scope beyond willful trademark counterfeiting.

#### *E. ACTA's Opportunity Cost for Direct Public Safety Measures*

Criminal, willful trademark counterfeit medicines are unsafe. But some falsified and unsafe medicines do not misappropriate qualifying trademarks, and hence fall beyond trademark law's reach. These include some falsified and fraudulently mislabeled medicines termed "counterfeits" by the World Health Organization and other health agencies. Trademark and intellectual property are ultimately indirect and under inclusive frameworks for combating these falsified medicines. Trademark and IP are also inadequate to address the more common problems of quality shortfalls, inefficacy and pharmaceutical fraud.

Indeed some and perhaps many of the examples of other unsafe products mentioned as motives for ACTA and other IP enforcement measures are unlikely to be counterfeits in the trademark sense. Rather than misappropriating a protected mark, these fakes are likely to be counterfeits

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<sup>27</sup> If in some unlikely scenario, the counterfeit's producer sought marketing approval for the counterfeit, the application itself would necessarily be fraudulent.

<sup>28</sup> See also CAMPAIGN FOR ACCESS TO ESSENTIAL MEDICINES, PATIENTS FIRST: ACCESS TO SAFE, QUALITY, AND EFFECTIVE DRUGS, (Medecins Sans Frontières, ed. Apr. 2010).

within the meaning of the laws or regulatory frameworks typically governing their product class—for example, unapproved electrical components, aircraft parts, and medicines. Intellectual property is not the most effective framework for addressing most of these safety concerns. Instead, their respective regulatory frameworks are. Trademark law may not reach many of them.

Drug regulatory authority typically provides a more complete framework for addressing falsified medicines. Selling a falsified or adulterated medicine is typically a criminal offense, whether it infringes a trademark or not. A pharmaceutical product that fraudulently misrepresents its source or ingredients is, inherently and necessarily, not registered or approved for sale, and can be removed from the channels of commerce in accordance with drug regulatory authority. In this sense, inspection for fake packaging is even more a traditional consumer protection and drug regulatory test than it is a trademark law test. Drug regulatory authority can be, and often is, coupled appropriately with law enforcement to target falsified medicines, criminal activity and threats to public safety directly, rather than through a filtering prism of commercial IP rights.

New attention to extraordinary intellectual property enforcement measures may come at an opportunity cost for attention to more direct and effective consumer protection and drug regulatory frameworks. Officially, “nothing in [ACTA] creates any obligation with respect to the distribution of resources as between enforcement of intellectual property rights and enforcement of law in general.”<sup>29</sup> Nevertheless, ACTA’s chapters on International Cooperation, Enforcement Practices, and Institutional Arrangements contemplate the establishment of an ACTA Committee,<sup>30</sup> observatories, and consistent international law enforcement cooperation and technical assistance on intellectual property, which will necessarily entail new investments and the allocation of scarce law enforcement resources.

Moreover, because ACTA and other TRIPS-plus enforcement measures are often advanced as means to combat unsafe products and protect consumers, they divert resources, public attention and political capital that otherwise could be harnessed to improve more direct and comprehensive regulatory and law enforcement measures.

There may also be reason to examine whether rights holders or other commercial interests, seeking to protect consumer confidence in sometimes-counterfeited brands, could use ACTA to argue against requirements to disclose what they know about fakes in the market. Private companies often

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<sup>29</sup> ACTA Draft – Aug. 25, 2010, *supra* note 2, Ch. One, Art. 1.2.2.

<sup>30</sup> *Id.* at Ch. Five, Art. 5.2.

have the first or most complete accounts of falsified products but do not always share what they know.<sup>31</sup> To assist in the detection of falsified medicines, countries could require companies to disclose information they have about potentially dangerous fakes in the channels of commerce, and share the information with global law enforcement partners.<sup>32</sup> The Joint Strategic Plan recently announced by the U.S. Intellectual Property Enforcement Coordinator incorporates one such proposal.<sup>33</sup> But ACTA includes assurances that, “Nothing [in the referenced sections] shall require any Party to disclose information which . . . would prejudice the legitimate commercial interests of particular enterprises, public or private.”<sup>34</sup> ACTA’s frequent deference to confidential information could be read to limit the disclosure and international sharing of information that could help protect consumers.

#### IV. DISTINGUISHING COMPETITION AND CRIMINALITY

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<sup>31</sup> For example, the Pharmaceutical Security Institute (PSI), formed by fourteen pharmaceutical companies in 2002, recorded seventy-six cases of “counterfeiting” in 2004. The U.S. Food and Drug Administration only knew of fifty-eight. BUKO PHARMA-KAMPAGNE, COUNTERFEIT MEDICINES – WHAT ARE THE PROBLEMS? 5 (2007) *available at* [http://www.bukopharma.de/Service/Archiv/E2007\\_01\\_special.pdf](http://www.bukopharma.de/Service/Archiv/E2007_01_special.pdf) [hereinafter BUKO]. Some consider PSI’s counterfeiting database the world’s best, yet it “is not accessible to the WHO, health authorities or the public.” Robert Cockburn et al., *The global threat of counterfeit drugs: why industry and governments must communicate the dangers*, 2 *Pub. Libr. Sci. Med.* 302, 305 (2005) [hereinafter PLoS].

In some cases, companies have been accused of being slow to report such knowledge, for fear of reducing public confidence in their brands—endangering public health in the process. For example, in 1995, GSK allegedly asked the Ghanaian government not to alert the public of the presence of fake halofantrine antimalarial syrup in the market, allegedly for the sake of the company’s reputation. *See* BUKO, PLoS. GSK also was reluctant to share information about fake syrup with the authors of the PLoS article. PLoS at 305. In 1998, the Brazilian government accused Schering do Brasil of failing to disclose knowledge of counterfeit contraceptives for thirty days (a court cancelled the government’s fine on appeal). *Id.* In 2002 in Kansas City, BMS and Eli Lilly settled for \$72 million with the families of deceased victims of counterfeit drugs, possibly to avoid the precedent that drug companies could be held liable for failing to disseminate information about counterfeits. *Id.* There are, of course, counterexamples. “In 2002, Johnson and Johnson issued 200,000 letters to health care professionals in the US warning them of fake Procrit... within one week of being notified of a severe counterfeit problem.” *Id.*

<sup>32</sup> For more information on proposed mandatory disclosure requirements, *see* Letter from Public Citizen to Directorate-General for Taxation and Customs Union, European Commission (May 25, 2010), *available at* <http://citizen.org/Page.aspx?pid=3458> (commenting on DG TAXUD consultation paper “Review of EU legislation on customs enforcement of intellectual property rights”).

<sup>33</sup> OFFICE OF THE U.S. INTELL. PROP. ENFORCEMENT COORDINATOR, OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, 2010 JOINT STRATEGIC PLAN ON INTELLECTUAL PROPERTY ENFORCEMENT (Jun. 2010).

<sup>34</sup> ACTA Draft – Aug. 25, 2010, *supra* note 2, Art. 3.1.4.

ACTA's draft text applies extraordinary rules and *ex officio* law enforcement measures appropriate to criminal activity to the context of market competition and civil infringement. Consumers and industry groups share this concern. The Intellectual Property Owners Association, which includes major brand-name pharmaceutical companies on its Board of Directors, wrote USTR expressing concern that:

ACTA goes far beyond addressing the subject matter of counterfeiting . . . [and] encompasses issues that are most appropriately handled as civil infringement causes of action in most jurisdictions around the world, and especially so in the case of the United States. . . . [T]he language of ACTA should be tailored to reflect the narrower stated purpose of an anti-counterfeiting agreement. Thus, IPO urges USTR to review ACTA to ensure that the scope of the Act is appropriately limited to its stated purpose of addressing the limited, though important, subset of infringement known as "counterfeiting."<sup>35</sup>

The European Committee for Interoperable Systems (ECIS), with membership including major firms such as IBM and Sun Microsystems, agrees, and it "urges the European Commission to ensure that ACTA only applies to acts of counterfeiting and piracy, and that it does not apply to all intellectual property rights."<sup>36</sup>

Law enforcement can appropriately target willful counterfeiting by spotting fakes and following leads to track criminal operations. But other intellectual property infringements—civil infringements, including among others patent and "similar," non-counterfeit trademark infringement—are not criminal acts and do not generally represent a fraud on the public. Civil infringements are generally commercial disputes between legitimate entities, for which traditional legal remedies are and should be available. The parties are generally known and can be served with legal process. Because civil infringements are not fakes, and the parties generally do not operate in a cloak of secrecy in the manner of criminal organizations, they do not require preemptive law enforcement interdiction (be it *ex officio* or on a rights holder application) wherever they appear in the channels of commerce.

#### A. Border Enforcement Measures

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<sup>35</sup> Intellectual Property Owners Association letter to USTR, *supra* note 5.

<sup>36</sup> "ECIS' concerns on the impact of the Anti-Counterfeiting Trade Agreement (ACTA)," *supra* note 5.

The inclusion of civil infringements (geographical indications as well) in ACTA's draft border measures section places customs authorities in the role of arbiters in commercial disputes. Rights holders could use this customs authority to launch harassing actions against legitimate competitors. Customs authorities are less prepared than courts to separate well founded from spurious rights holder claims. ACTA's limited and discretionary provisions providing for payment of a security,<sup>37</sup> while important, may prove inadequate if, as seems likely, many allegations of infringement are never fully resolved. Moreover, customs agents operating under directives and incentives to stop as much infringing activity as possible will be likely to err on the side of over enforcement. This will come with costs to legitimate companies including unwanted legal expenses and uncertainty. This includes intellectual property owners, which, in the course of doing business, find themselves on each side of infringement disputes.

Customs and law enforcement should be considered competent to act on their own authority against criminal, willful commercial scale trademark counterfeiting and willful commercial scale copyright piracy. And of course, judicial orders or equivalent legal process can properly empower customs and law enforcement to take action against a particular civil infringement. But customs and law enforcement are not competent to arbitrate civil intellectual property infringements on their own authority, or upon the mere application of a rights holder.<sup>38</sup>

### *B. Goods in Transit Provisions*

These factors apply equally to goods entering or exiting customs territory and goods in transit. But if ACTA continues to cover civil infringements, then any provisions applicable to goods in transit should still be limited specifically to criminal, willful counterfeiting and piracy. Commercial rights held in one state should not impede the free movement of legitimate goods that are not destined for that market. In accordance with the foundational principle of territoriality, intellectual property rights are state-specific (or, in some European Community cases, regional) in scope and application.<sup>39</sup>

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<sup>37</sup> ACTA Draft – Aug. 25, 2010, *supra* note 1, Art. 2.9.

<sup>38</sup> *Id.* at Art. 2.10 states “Each Party shall adopt or maintain a procedure by which their competent authorities may determine, within a reasonable period of time ... whether the suspected infringing goods infringe an intellectual property right.” But law enforcement agencies are not competent to assess patent infringement or civil trademark claims. And if defendants contest the claim of infringement, resolution of the case would seem to require either adversarial hearings (and perhaps litigation), leading to a longer than reasonable period—or shortchanging legal process.

<sup>39</sup> For a discussion of territoriality, GATT Article V, TRIPS and implications for border

Rights held may be different in the exporting country, transit countries, and the destination country. Stopping legitimate in transit goods may create a *de facto* international intellectual property regime, beyond the appropriate territorial scope of state authority, with global costs for competition.

#### V. ACTA AS A NARRATIVE AND PRECEDENT

ACTA's greatest public health costs may come not from the substantive effects of its particular terms—even though these are potentially serious—but rather from its narrative positioning and precedent. ACTA is a harbinger. As an IP enforcement agreement and ongoing Committee comprising major economies, ACTA would establish rules and broader norms some other countries would follow. The policy goals first articulated by the initial parties to ACTA would stand as rationales for its specific terms, and establish a narrative for enforcement initiatives to come.

ACTA's narrative suggests that intellectual property enforcement protects consumers from unsafe products. A better understanding of this relationship is considerably more narrow and complex. Applied prescriptively, this idea can be dangerous and misleading, supporting the application of incomplete and indirect intellectual property frameworks rather than much more effective and comprehensive regulatory measures against unsafe products. IP enforcement training programs operated by the U.S. Patent and Trademark Office are running this risk right now by advertising IP as a prime tool against unsafe products in countries with very limited public resources.

ACTA shifts the historic responsibility of exercising market vigilance to identify infringement from private rights holders to public law enforcement, at a corresponding cost to taxpayers. And while ACTA's scope continues to narrow, the overarching narrative continues to suggest that the varying classes of intellectual property can be conflated, and treated with similar remedies to achieve similar ends. ACTA, under its proposed terms, still treats many or all classes of infringement, including the inevitable commercial infringement disputes between major businesses, under the general heading "counterfeits."

This narrative diminishes the context and flexibility that has informed the development of copyright, patent, and trademark law, among other classes of IP rules, over many years. If all classes of alleged infringement can be thought of loosely and preemptively as theft, counterfeiting and piracy, a separate narrative supporting public interests through contextually appropriate remedies quickly fades. This is part of the importance of maintaining clear distinctions between willful counterfeiting and civil trademark claims. It is a

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measures applied to in transit goods, *see* XAVIER SEUBA, *supra* note 8, at 16.

dividing line between competition and conceptions of criminality. Allowing that line to slide sets a harmful legal precedent for enforcement measures and remedies, and supports a rigid view of intellectual property hostile to the flexibilities that support access to medicines and other public interests.

The interests of public health suggest ACTA's scope must be narrowed and tailored. Otherwise, the agreement should be abandoned.<sup>40</sup> More broadly, advocates and policy analysts should contest ACTA's broadest narrative, and articulate alternative visions that support the public interests in safety, competition, innovation, and access over the long term.

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<sup>40</sup> For a consensus document reflecting the concerns of over ninety academics, practitioners and public interest organizations from six continents, *see* INTERNATIONAL EXPERTS FIND THAT PENDING ANTI-COUNTERFEITING TRADE AGREEMENT THREATENS PUBLIC INTERESTS (Program on Information Justice and Intellectual Property, Washington College of Law, ed. June 23, 2010) *available at* <http://www.wcl.american.edu/pijip/go/acta-communicate>.