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### ACTA: Risks of Third Party Enforcement for Access to Medicines

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# ACTA – RISKS OF THIRD-PARTY ENFORCEMENT FOR ACCESS TO MEDICINES

*Brook K. Baker*<sup>1</sup>

## ABSTRACT

In its current near-final draft form, the Anti-Counterfeiting Trade Agreement [ACTA] being negotiated plurilaterally—and largely secretly—by a self-selected group of countries proposes to allow preliminary and final injunctive relief against third parties (third-party enforcement) to prevent infringement of intellectual property rights and/or to prevent infringing goods from entering into the channels of commerce. There is lingering uncertainty whether the relevant civil enforcement section will apply to the entire range of intellectual property rights or whether patents will be excluded. If patents are excluded, the dangers in ACTA would be reduced but not eliminated—new globalized forms of third-party enforcement would still pose unprecedented risks to the lawful trade of generic medicines. Extending third-party liability and imposing interlocutory and/or permanent injunctions against (1) innocent active pharmaceutical ingredient suppliers whose materials are used in the manufacture of patent infringing medicines or in mislabeled products without their knowledge, (2) transporters who use international channels of trade through countries where the “patent manufacturing fiction” or “trademark confusion” claims might apply, and (3) other actors in the global procurement and supply of medicines, could interfere with goal of robust generic competition and access to medicine. Under the risk of preliminary and permanent injunctions, and contempt of court sanctions for violating such injunctions, API suppliers would predictably shy away from selling base ingredients to generic producers, entities like the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) the U.S. PEPFAR Supply Chain Management System (SCMS) could be deterred from funding the purchase of generic medicines, and shippers might refuse to transport finished generic medicines through ordinary transshipment routes involving ACTA signatories. Health activists must collaborate globally to eliminate or at the very least reduce these risks.

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<b>ABSTRACT</b> .....	<b>1</b>
I. INTRODUCTION.....	2
II. ACTA’S KEY PROVISIONS: MOVEMENT FROM INTERMEDIARY TO THIRD-PARTY ENFORCEMENT.....	3
III. APPLYING INTERMEDIARY LIABILITY AND THIRD-PARTY ENFORCEMENT TO PHARMACEUTICALS.....	7
IV. ACTA NEGOTIATORS ARE PURSUING PHARMA’S ENFORCEMENT GOALS BOTH IN ACTA AND IN TRADE AGREEMENTS .....	12
V. CONCLUSION.....	13

## I. INTRODUCTION

In its current, near-final draft form,<sup>2</sup> the Anti-Counterfeiting Trade Agreement (ACTA) being negotiated plurilaterally—and largely secretly—by a self-selected group of countries<sup>3</sup> proposes to allow preliminary and final injunctive relief against third parties (third-party enforcement) to prevent infringement of intellectual property rights and/or to prevent infringing goods from entering into the channels of commerce. There is lingering uncertainty whether the relevant civil enforcement and injunction section will apply to the entire range of intellectual property rights<sup>4</sup> covered by the TRIPS Agreement<sup>5</sup> or whether patents will be excluded as proposed by the U.S.<sup>6</sup> If patents are excluded the health risks in ACTA will be reduced but not eliminated. In the context of access to medicines, new globalized forms of third-party enforcement, like its predecessor, intermediary service provider liability, poses unprecedented risks to the

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<sup>2</sup> Consolidated Text—Anti-Counterfeiting Trade Agreement, Informal Predecisional/Deliberative Draft: Oct. 2, 2010, PIJIP IP ENFORCEMENT DATABASE, <http://sites.google.com/site/iipenforcement/acta> (follow “Official Text - October 2, 2010” hyperlink) [hereinafter ACTA – Oct. 2, 2010] (reflecting changes made during September 2010 Tokyo Round).

<sup>3</sup> In October 2007 the United States, the European Community, Switzerland and Japan simultaneously announced that they would negotiate a new intellectual property enforcement treaty. Australia, the Republic of Korea, New Zealand, Mexico, Jordan, Morocco, Singapore, the United Arab Emirates and Canada have joined the negotiations.

<sup>4</sup> According to proposed Art. 1.X: Definitions, “intellectual property means all categories of intellectual property that are the subject of Sections 1 through 7 of Part II of the Agreement on Trade-Related Aspects of Intellectual Property Rights.” ACTA – Oct. 2, 2010. Those sections of TRIPS, in turn cover: copyrights and related rights; trademarks; geographical indications; industrial designs; patents; layouts (topographies) of integrated circuits; and protection of undisclosed information.

<sup>5</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization (1994), *available at* [http://www.wto.org/english/tratop\\_e/trips\\_e/t\\_agm0\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm).

<sup>6</sup> ACTA – Oct. 2, 2010, *supra* note 2, n.2: {US: For the purpose of this Agreement, Parties agree that patents do not fall within the scope of this Section.}.

lawful trade of generic medicines. Extending third-party enforcement and imposing interlocutory and permanent injunctions against (1) innocent active pharmaceutical ingredient (API) suppliers whose materials are used in the manufacture of patent infringing medicines or in mislabeled products without their knowledge, (2) transporters who use international channels of commerce through countries where the “patent manufacturing fiction” or “trademark confusion” claims might apply, and (3) other actors in the global procurement, supply, and even registration of medicines, could interfere with the goal of robust generic competition and access to medicine. Under the risk of injunctions and contempt of court penalties, API and other suppliers would predictably shy away from selling base ingredients to generic producers, entities like the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), the U.S. PEPFAR Supply Chain Management System (SCMS) could be deterred from funding the purchase of generic medicines, and shippers might refuse to transport finished generic medicines through ordinary transshipment routes involving ACTA signatories. These threats to access to medicines must be addressed by a global coalition of AIDS, health, and trade activists.

## II. ACTA’S KEY PROVISIONS: MOVEMENT FROM INTERMEDIARY TO THIRD-PARTY ENFORCEMENT

The Public Predecisional/Deliberative Draft of the Anti-Counterfeiting Trade Agreement dated April 2010<sup>7</sup> (April Predecisional Draft) contained multiple threats to access to medicines. The mostly widely discussed issue involved the seizure of goods-in-transit following the detention of multiple drug shipments by Dutch customs authorities in 2008 and 2009 under the authority of Council Regulation (EC) No. 1383/2003.<sup>8</sup> Dutch authorities applied the judicially created rule that the IP status of in-transit medicines should be judged under the fiction that the medicines had been manufactured in the Netherlands<sup>9</sup> and thus responded to Big Pharma seizure

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<sup>7</sup> Anti-Counterfeiting Trade Agreement, Public Predecisional/Deliberative Draft: April 21, 2010 PIJIP IP ENFORCEMENT DATABASE, <http://sites.google.com/site/iipenforcement/acta> (follow “Official Consolidated ACTA Text Prepared for Public Release, April 21, 2010” hyperlink) [hereinafter ACTA Draft – Apr. 21, 2010].

<sup>8</sup> Council Regulation 1383/2003, 2003 O.J. (L 196/7) (EC), available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:196:0007:0014:EN:PDF>.

<sup>9</sup> Cf. *Sosecal v. Sisvel*, District Court in The Hague (2008), available at [http://www.eplawpatentblog.com/PDF\\_December09/The%20Hague%20DC%20Sisvel%20v%20Sosecal%20EN.pdf](http://www.eplawpatentblog.com/PDF_December09/The%20Hague%20DC%20Sisvel%20v%20Sosecal%20EN.pdf). See Frederick J. Abbott, *Seizures of Generic Pharmaceuticals in Transit Based on Allegations of Patent Infringement: A Threat to International Trade, Development and Public Welfare*, 1 W.I.P.O.J., 43, 47 (2009); Frank Eijsvogels, *SISVEL V.*

requests by impounding and delaying shipments of life-saving medicines bound from India, where they had been lawfully manufactured and exported, to countries in Africa and Latin America, where they would have been lawfully imported, marketed and consumed. These seizures and the E.U.'s delayed and defensive response to expressions of diplomatic and human rights concern prompted India and Brazil to initiate dispute resolution procedures at the World Trade Organization.<sup>10</sup>

Unfortunately, the risks of the April Predecisional Draft to public health and to the lawful international trade of generic medicines are not limited to border-seizures by customs agents policing phantom patent rights. A risk also arose from provisions that subjected so-called "intermediaries" to interlocutory and permanent injunctions, known elsewhere as interdicts. The use of such injunctions against API manufacturers, international shippers, and other participants in the global trade of medicines could inhibit supply and distribution systems and thereby deter generic entry, robust generic competition, and legitimate international trade of generic medicines of assured quality, especially if the civil enforcement provisions were to be applied with respect to all intellectual property rights as proposed by some negotiators, including the E.C.<sup>11</sup>

Bracketed Article 2.X.2: Injunctions provided that "The Parties [may] shall ensure that right holders are in a position to apply for an injunction against [infringing] intermediaries whose services are used by a third party to infringe an intellectual property right."<sup>12</sup> Footnote 8 noted that the "conditions and procedures relating to such injunction will be left to each Party's legal system." Earlier leaks revealed that this article was proposed

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SOSECAL: ACTING AGAINST TRANSIT GOODS STILL POSSIBLE UNDER THE ANTI PIRACY REGULATION IN THE NETHERLANDS, IP Intelligence Eur. (Howrey L.L.P., Amsterdam, Netherlands), 2008, 10.

<sup>10</sup> European Union and a Member State [India] – Seizure of Generic Drugs in Transit, WTO Dispute Settlement DS408, *available at* [http://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds408\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds408_e.htm) and European Union and a Member State [Brazil] – Seizure of Generic Drugs in Transit, WTO Dispute Settlement DS409, *available at* [http://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds409\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds409_e.htm); *see generally* Third World Network, *India, Brazil raise dispute over EU drug seizures*, 6924 SUNS May 17, 2010, *available at* <http://www.twinside.org.sg/title2/wto.info/2010/twninfo100509.htm>; Intellectual Property Watch, *Consultations on WTO Drug Transit Case Continue*, September 16, 2010, *available at* <http://www.ip-watch.org/weblog/2010/09/16/consultations-on-wto-case-on-drugs-in-transit-continue/>; C.H. Unnikrishan, *India may move WTO as it seeks to resolve EU dispute*, *livemint.com*, October 10, 2010, *available at* <http://www.livemint.com/2010/10/11225420/India-may-move-WTO-as-it-seeks.html>.

<sup>11</sup> ACTA Draft – Apr. 21, 2010, *supra* note 7, art. 2.1 contains alternative coverage proposals: any intellectual property right vs. copyrights and related rights and trademarks only.

by the European Commission. Similarly, bracketed Article 2.5X provided that “[a]n interlocutory injunction may also be issued, under the same conditions {to prevent any imminent infringement of an intellectual property right}, against any [infringing] intermediary whose services are being used by a third party to infringe an intellectual property right.”<sup>13</sup> It was undecided whether the provision of injunctions against intermediaries would be mandatory (shall ... ensure) or permissive (may ... ensure). In either event, there would be an *in terrorem* effect. A related concept to intermediary liability was the proposed criminal responsibility of persons or entities that incite, aid, or abet cases of willful trademark counterfeiting or copyright or related rights piracy on a commercial scale.<sup>14</sup> The enforcement of intermediary liability would have been facilitated by proposed Article 2.4, which allowed broad discovery of intermediary activities, particularly those involving production and distribution, during civil enforcement procedures against alleged infringers.<sup>15</sup>

The key operative term, “intermediaries,” was undefined in the April Predecisional Draft, as was the alternative term “infringing intermediary.” Likewise, what constituted “services” used by another to infringe an intellectual property right was also unclear. Previously, the concept “intermediary services” had been analyzed most closely with respect to internet service providers (ISPs).<sup>16</sup> In these circumstances, an ISP that merely provided facilities that were used by others for an infringement, i.e. to download a digital copy of a song, book or movie, might be interdicted. Given the lack of definition, access-to-knowledge activists were concerned

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<sup>12</sup> ACTA Draft – Apr. 21, 2010, *supra* note 7.

<sup>13</sup> *Id.*

<sup>14</sup> *Id.* art. 2.15.2.

<sup>15</sup> *Id.* art. 2.4 [“Without prejudice to other statutory provisions which, in particular, govern the protection of confidentiality of information sources or the processing of personal data,] Each Party shall provide that in civil judicial proceedings concerning the enforcement of [intellectual property rights][copyright or related rights and trademarks], its judicial authorities shall have the authority upon a justified request of the right holder, to order the [alleged] infringer [including an alleged infringer] to provide, [for the purpose of collecting evidence] any [relevant] information [information on the origin and distribution network of the infringing goods or services][in the form as prescribed in its applicable laws and regulations] that the infringer possesses or controls, [where appropriate,] to the right holder or to the judicial authorities. Such information may include information regarding any person or persons involved in any aspect of the infringement and regarding the means of production or distribution channel of such goods or services, including the identification of third persons involved in the production and distribution of the infringing goods or services or in their channels of distribution. [For greater clarity, this provision does not apply to the extent that it would conflict with common law or statutory privileges, such as legal professional privilege.]”)

<sup>16</sup> These concerns have not been completely eliminated in the new ACTA text. Michael Geist, *ACTA Lite: The U.S. Cave on the Internet Chapter Complete*, October 6, 2010, available at <http://www.michaelgeist.ca/content/view/5352/125/>.

that the terms “intermediaries” or “infringing intermediaries” might not only be applied to ISPs but might also be extended to libraries, cultural institutions, and educational institutions, although their application to mail or telecommunications providers was deemed unlikely.<sup>17</sup> Internet and copyright activists were also concerned that providing for injunctions might create incentives for ISPs and other intermediaries to take on new roles as extra-judicial enforcement arms of the courts and, most especially, of rights holders.

In part because of health activist concern about the impact of intermediary liability on access to medicines<sup>18</sup> and because of a lack of clarity about the territorial reach of injunctive powers, the intermediary liability language of in the April Predecisional Draft was dropped in the September 2010 Consolidated Text of ACTA and the concept of third-party enforcement was introduced in its place. Pursuant to the revised Civil Enforcement—Provision Measures section: “Each Party shall provide that its judicial authorities shall have the authority to order prompt and effective provisional measures: against a party, or where appropriate, *against a third party over whom the relevant judicial authority exercises jurisdiction, to prevent an infringement of any intellectual property rights from occurring, and in particular to prevent infringing goods from entering into the channels of commerce.*”<sup>19</sup> Likewise, with respect to its Civil Enforcement Injunctions section: “Each Party shall provide that, in civil judicial proceedings concerning the enforcement of intellectual property rights, its judicial authorities shall have the authority to issue an order against a party to desist from an infringement, and inter alia, an order to that party or, where appropriate, *to a third party over whom the relevant judicial authority exercises jurisdiction, to prevent infringing goods from entering into the channels of commerce.*”<sup>20</sup>

Admittedly, the necessity of having a personal and territorial jurisdiction over a third party is at least referenced by the amended text,<sup>21</sup>

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<sup>17</sup> See Kimberlee Weatherall, THE ANTI-COUNTERFEITING TRADE AGREEMENT: ANALYSIS OF THE JANUARY CONSOLIDATED TEXT (April 2010), available at <http://works.bepress.com/cgi/viewcontent.cgi?article=1019&context=kimweatherall>.

<sup>18</sup> See, e.g., Program on Information Justice and Intellectual Property, *International Experts Find that Pending Anti-Counterfeiting Trade Agreement Threatens Public Interests* (Jun. 23, 2010), available at <http://www.wcl.american.edu/pijip/go/acta-communicue>; Berkeley Declaration on Intellectual Property Enforcement and Access to Medicines, 2010, available at [http://www.law.berkeley.edu/files/Berkeley\\_Declaration.pdf](http://www.law.berkeley.edu/files/Berkeley_Declaration.pdf); AVAAZ, ACTA – People Before Profit, available at <http://www.avaaz.org/en/acta/>.

<sup>19</sup> ACTA, *supra* note 2, Art. 2.5:1(a) (emphasis added).

<sup>20</sup> *Id.* Art. 2.X.1 (emphasis added).

<sup>21</sup> Injunctions are usually limited in their application to activities occurring within the geographic territory of the issuing jurisdiction, but jurisdiction sometimes extends to

but an additional confusing phrase—*entering into the channels of commerce*—enters the picture. It is unclear why provisional measures can be used to address any intellectual property infringement, of which preventing the infringing goods from entering the channels of commerce is but one example, but that final injunctions are limited solely to preventing infringing goods from entering into channels of commerce. Paradoxically, provisional measures might be used to temporarily enjoin production, before full commercialization, but final injunctions might not be able to do so, depending on the eventual interpretation of how long, deep, and wide the channels of commerce actually are.

The April Predecisional Draft provision requiring production of information "regarding any person or persons involved in any aspect of the infringement and regarding the means of production or distribution channel of such goods and services," has been adopted unchanged.<sup>22</sup> With respect to criminal enforcement, the April Predecisional Draft provision has been modified somewhat to exclude incitement and to require that "Each party shall ensure that criminal liability for aiding and abetting is available under its law."<sup>23</sup>

### III. APPLYING INTERMEDIARY LIABILITY AND THIRD-PARTY ENFORCEMENT TO PHARMACEUTICALS

In the context of access to medicines, the concept "intermediary services" was quite ominous. Services were obviously provided by ISPs that allowed suppliers to market medicines on-line, and, also in the pharmaceutical context, by shipping agents.<sup>24</sup> However, services were also

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extraterritorial activities that adversely impact in-territory interests. Under a strict territorial rule, to enjoin third-party enablement of IP infringement in India, first there would have to be an infringement of a territorial IP right in India that the third party was facilitating, and second, the injunction would have to be issued in India against the importation, manufacturing, or export of the third-party-provided service or materials. However, if more expansive extra-territorial jurisdiction applied, the transit country could issue an injunction against the third party's activities in other countries to the extent that those activities had or would predictably impact in-territory events. In such circumstances, a third party might be enjoined in the Netherlands for supplying APIs to an infringing generic manufacturer in India that had or intended to transship through the Netherlands.

A full discussion of extraterritorial jurisdiction is clearly beyond the scope of this short article, but a discussion of some of the relevant principles can be found in American Law Institute, *INTELLECTUAL PROPERTY PRINCIPLES GOVERNING JURISDICTION, CHOICE OF LAW, AND JUDGMENTS IN TRANSNATIONAL DISPUTES* (2008).

<sup>22</sup> ACTA, *supra* note 2, Art. 2.4.

<sup>23</sup> *Id.* art. 2.14:4.

<sup>24</sup> See Thomas Schachl, *German Federal Supreme Court Confirms Broad Responsibility of Forwarding Agents for Handled Goods; Increased Requirements to Examine Compliance of Handled Goods With German Patent Law*, THE BARDEHLE



supplied by lawyers and accountants, communications service providers, and factory workers. Although we do not usually consider suppliers of components—for example, API and inert ingredient suppliers—to be providing a “service,” if components were deemed to be services, then all medicines component suppliers could have been found to be “intermediaries” who had contributed services instantiated in to the manufacture and distribution of the final-product, an IP-infringing generic medicine, and would thus be subject to an injunction.<sup>25</sup>

Finally, and perhaps more ominously, many others who helped to fund or facilitate purchases of generic drugs as they as they moved through the stream of international commerce from producer to consumer could have faced intermediary liability. For example, the Global Fund solicits and funds country-led proposals for funding priority disease prevention, treatment, and care.<sup>26</sup> More to the point, it now provides a voluntary pooled-procurement service for medicines<sup>27</sup> and maintains tight control over purchases of particular tuberculosis<sup>28</sup> and malaria<sup>29</sup> medicines. Will the Global Fund—and similarly funding/facilitating services such as those offered by UNITAID,<sup>30</sup> the Clinton Health Access Initiative (CHAI),<sup>31</sup>

PAGENBERG IP REPORT (Bardehle Pagenberg, Düsseldorf, Ger.), 2010/I, at 6 (summarizing a German Court ruling granting injunctive relief against a shipping agent who delivered allegedly patent infringing MP3 players), *available at* [http://www.bardehle.com/fileadmin/bardehle/sonstiges/IP\\_Reports/IP\\_Report\\_2010\\_I.pdf](http://www.bardehle.com/fileadmin/bardehle/sonstiges/IP_Reports/IP_Report_2010_I.pdf). *See also* Trade Enforcement Act of 2009, S. 1466, 111th Cong. § 223(2)(C)-(D) (2009), *and* Customs Facilitation and Trade Enforcement Reauthorization Act of 2009, S. 1631, 111th Cong. § 234(a)-(d) (2009) (supporting the inference that the enforcement agenda seeks to disrupt each and every link in the distribution chain). *See* ACTA Draft – Apr. 21, 2010, *supra* note 7, § 2, art. 2.4 (supporting the argument that intermediary liability will routinely extend to shippers by including a direct reference to distribution and channels of distribution).

<sup>25</sup> *See* ACTA, *supra* note 7, §2 art. 2.3(2) (obviously permitting the destruction of APIs used in the “manufacture” of generic medicines).

<sup>26</sup> About the Global Fund, *available at* <http://www.theglobalfund.org/en/about/?lang=en>.

<sup>27</sup> *See Global Fund Observer*, AIDSPAN, <http://www.aidspace.org/documents/gfo/GFO-Issue-127.htm> (last visited Aug. 27, 2010) (“[Principal Recipients] from 37 countries . . . have joined the Voluntary Pooled Procurement (VPP) system. Discussions are ongoing with PRs from another 20 countries. The VPP has now registered 130 orders, with a total value of \$335 million. Ten countries have signed up for capacity building and supply chain management assistance.”).

<sup>28</sup> *See* THE GLOBAL FUND, GUIDE TO THE GLOBAL FUND’S POLICIES ON PROCUREMENT AND SUPPLY MANAGEMENT 12 (2009) (“All procurement of medications for Multi-Drug Resistant TB (tuberculosis) must be conducted through the Green Light Committee.”), *available at* [http://www.theglobalfund.org/documents/psm/pp\\_guidelines\\_procurement\\_supplymanagement\\_en.pdf](http://www.theglobalfund.org/documents/psm/pp_guidelines_procurement_supplymanagement_en.pdf).

<sup>29</sup> *See Affordable Medicines Facility – malaria*, THE GLOBAL FUND, <http://www.theglobalfund.org/en/Amfm/> (last visited Aug. 27, 2010).

<sup>30</sup> *See* UNITAID, UNITAID CONST. §1, *available at* [http://www.unitaid.eu/images/governance/utd\\_constitution\\_05-07\\_en.pdf](http://www.unitaid.eu/images/governance/utd_constitution_05-07_en.pdf) (describing that as part of the WHO, UNITAID’s express mission is to increase market impact on access to

SCMS,<sup>32</sup> IDA Foundation,<sup>33</sup> Medecins San Frontieres,<sup>34</sup> and even UNICEF<sup>35</sup>—fear that their access-to-medicines resources and activities could have been considered intermediary services to third-party infringers whose medicines might inadvertently violate a fictional in-transit patent rule or an opaque in-transit trademark confusion rule?<sup>36</sup> Even further afield, could a drug regulatory authority that registered a generic medicine that later violated a fictional in-transit patent rule or an in-transit trademark confusion rule also have been held liable for intermediary-service liability?<sup>37</sup>

Unfortunately, the switch to the concept of third-party enforcement in the current ACTA text does little or nothing to allay the risks to access to generic medicines described above. One can still gather information about third parties with respect to means of production and distribution channels; one may still seek temporary and permanent injunctions against third parties to prevent infringing goods from entering channels of commerce, and in the case of provisional measures also temporarily enjoin other alleged acts of infringement; and the state may still impose criminal sanctions against those who aid and abet criminal infringement activities.

In particular, there are many uncertainties in the meaning and scope of application of these provisions with respect to the entering into the channels of commerce concept. Distributors and transporters seem at particular risk as they may directly enable a territorial infringement by transporting the infringing product or content into the country of enforcement and thereby place infringing products squarely in the middle of channels of commerce. In addition, component suppliers might also be liable to provisional

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HIV/AIDS, TB and malaria medicines by increasing market competition.).

<sup>31</sup> See Clinton Health Access Initiative, <http://www.clintonfoundation.org/what-we-do/clinton-health-access-initiative/> (describing the goals and purpose of CHAI).

<sup>32</sup> See Supply Chain Management System, <http://scms.pfscm.org/scms/about> (describing the mission and purpose of the SCMS).

<sup>33</sup> See IDA Foundation, <http://www.ida.nl/> (describing the mission and purpose of the IDA).

<sup>34</sup> See Medecins Sans Frontieres, <http://www.msf.org/msfinternational/content/medical/pharmaceutical/index.cfm?&mode=view> (listing information about MSF's drug procurement policies and activities).

<sup>35</sup> See UNICEF, <http://www.unicef.org/supply/index.html>.

<sup>36</sup> See THE GLOBAL FUND, *supra* note 28, at 20 (detailing The Global Fund's current requirements that recipients comply with national laws and applicable international obligations in the field of intellectual property). Because of intermediary liability concerns, will The Global Fund now have take on new duties to double-check and confirm the intellectual property status of medicines purchases it finances under international law (the TRIPS Agreement), the law of the country of use, and the law of every transit country?

<sup>37</sup> Drug regulatory authorities typically assess medicines for quality, safety, and efficacy and therefore register (or approve) the medicine for marketing within the country. By doing so, drug regulatory authorities would arguably enable the lawful distribution and

measures since enjoining them could arguably prevent the offending product from being made in the first place at the front end of the “entering” into the channels of commerce continuum. Similarly, it is conceivable, though perhaps not as likely, that other enablers of commercialization, including procurement agents like Medicines San Frontiere and the International Dispensary Association, funders like PEPFAR, the Global Fund, and UNITAID, and regulators like drug regulatory authorities could also be temporarily enjoined to prevent the commercialization and distribution of alleged IP infringing products. Whether criminal “aiding and abetting” extends to suppliers of subsidiary materials and other enablers, who thereby contribute either to the production or commercialization of the offending products, is perhaps less certain; but the possibility of criminal liability is certainly troubling.

It is clearly possible that APIs and even inert ingredients can be used in the manufacture of patent infringing products. Likewise, it is possible that non-patent-infringing medicines might be intentionally or misleadingly mislabeled so as to allegedly infringe a valid trademark. In these circumstances and under existing law, the right holder ordinarily would have full recourse against the infringer in the country of manufacture and/or the country of marketing and use. However, it was undesirable to impose a second tier of liability on third-party suppliers and distributors who often lacked knowledge of the IP status of the product at issue. It would clog the channels of commerce to require suppliers and shippers to double-check the patent and eventual trademark status of all of their customers. In such circumstances, suppliers and shippers might choose to boycott generic manufacturers altogether rather than risk civil and perhaps even criminal sanctions.<sup>38</sup>

Moreover, ACTA will still allow border/customs enforcement procedures by right holders and ex-officio at export, in-transit, and import borders with respect to alleged trademark and copyright claims.<sup>39</sup> Patent-related seizures had previously been made based on the in-country manufacturing fiction<sup>40</sup> and thus could obviously have implicated third

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sale of alleged IP infringing medicines and thus be subject to intermediary liability.

<sup>38</sup> See ACTA Draft – Apr. 21, 2010, *supra* note 7, art. 2.15(2) and ACTA – Oct. 2, 2010, *supra* note 2, art. 2.14.4 (imposing criminal sanctions on those who aid and abet willful trademark counterfeiting or copyright or related rights piracy on a commercial scale).

<sup>39</sup> ACTA, *supra* note 2, Section 3: Border Measures.

<sup>40</sup> See Request for Consultations by India, *European Union and a Member State – Seizure of Generic Drugs in Transit*, WT/DS408/1 (May 19, 2010) (requesting consultations over multiple European seizures of in-transit generic medicines on alleged patent grounds, especially in the Netherlands, including one case involving AIDS medicines purchased by UNITAID and being shipped from India to Nigeria), *available at*

parties had the coverage of the border measures provision not been changed to exclude patents.<sup>41</sup> Although trademark-related seizures have been fewer,<sup>42</sup> a third-party API supplier, procurement service, or shipper, could still be alleged to have contributed to an eventual product that was misleadingly or confusingly labeled. One plausible ground for mistaken assessment of confusion might arise from the fact that both a brand name and generic drug will display the required international non-proprietary name (INN) for the active ingredient. Moreover, both the brand name holder and the generic company might use portions of the INN in their own brand names. In these circumstances, allegations of actionable trademark confusion and of third-party liability could arise. Similarly, to avoid confusion for consumers and to maintain bioequivalence,<sup>43</sup> the trade dress of a branded and generic medicine might also be appropriately similar but trade-dress confusing.<sup>44</sup> Once again, third parties might be held liable even under border measures that are limited to trademark and copyright violations. Moreover, in the unlikely event that the trademark issue rose to the level of willful trademark counterfeiting on a commercial scale, third-party supplies and distributors could constitute criminal aiding and abetting; an innocent supplier to a producer, who later turned out to be a willful counterfeiter, could suddenly be deemed a criminal offender under Article 2.14.4 of ACTA.

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[http://www.worldtradelaw.net/cr/ds408-1\(cr\).pdf](http://www.worldtradelaw.net/cr/ds408-1(cr).pdf).

<sup>41</sup> ACTA, *supra* note 2, footnote 6.

<sup>42</sup> See 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.ip-watch.org/weblog/wp-content/uploads/2009/06/june-5-press-release-frankfurt-seizure.pdf> (describing an in-transit seizure of generic Amoxicillin from India to the Republic of Vanuatu by German customs officials on May 5, 2009, because of alleged trademark confusion with GlaxoSmithKline's off-patent brand name medicine "Amoxil").

<sup>43</sup> Medicines are said to be bioequivalent if generic versions have the same mode of administration (e.g., oral capsule or tablet) and the same rate of absorption and elimination of the active ingredient(s) in the human body as the original, previously registered product. Bioequivalence tests merely require a so-called crossover studies, involving a relatively small number of human subjects, instead of the expense and delay of duplicative Phase I-III clinical trials. See, e.g., Food and Drug Admin., Guidance for Industry: Statistical Approaches to Establishing Bioequivalence (2001), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070244.pdf>. Because the size and shape of a medicine can affect the bioequivalence of a generic medicine with its comparator, generic manufacturers often need to make their medicine's trade dress (appearance) close to that of the originator. Although generic manufacturers should never affix a trademark or to stamp a pill with the originator's brand, the overall similarity of appearance might reasonably confuse a customs agent.

<sup>44</sup> See Sean Flynn, *Note on ACTA and Access to Medicines* (2010), available at <http://www.wcl.american.edu/pijip/go/blog-post/note-on-acta-and-access-to-medicines>.

IV. ACTA NEGOTIATORS ARE PURSUING PHRMA'S ENFORCEMENT GOALS  
BOTH IN ACTA AND IN TRADE AGREEMENTS

The European Commission, when releasing the April Predecisional Draft, asserted that "ACTA will not hamper access to generic medicines."<sup>45</sup> However, the analysis above shows otherwise. Confirming health advocates fears, the Pharmaceutical Research and Manufacturers of America (PhRMA) has advocated even more extreme and precisely defined application. In PhRMA's Comments to the USTR on ACTA (2008), PhRMA wanted the Agreement to explicitly impose intermediary liability on Internet Service Providers and other operators, on entities that engage in parallel trade, on suppliers of APIs and other bulk pharmaceutical ingredients, and on distributors of generic medicines.

1. PhRMA Recommendation: Establish liability for Internet Service Providers and Other Operators that Facilitate Trade in Counterfeit Medical Products. *"Expressly prohibit online activities that directly or indirectly facilitate trade in counterfeit medical products and provide legal incentives for ISPs and online intermediaries to cooperate with legitimate manufacturers in combating counterfeiting activities. . . . We note that Korea recently implemented a system for taking down web sites selling counterfeits, and recommend examination of that system for possible adaptation and use in other countries to combat online counterfeit medicines."*

2. PhRMA Recommendation: Provide Effective Border Enforcement against the Importation and Exportation of Counterfeit Medical Products. *"[W]ithout effective controls against diversion, parallel trade in pharmaceuticals becomes a potential pathway for the introduction of counterfeit medical products. ACTA members should also be required to prohibit the distribution of medical products diverted from legitimate distribution channels and such distribution of diverted products should be treated as a counterfeiting offense."*

3. PhRMA Recommendation: Ensure that criminal and administrative remedies extend to all upstream and downstream links in the drug counterfeiting channel, including the supply of unauthorized bulk chemicals and the distribution of finished

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<sup>45</sup> Press Release, European Commission, Anti-Counterfeiting Trade Agreement: European Commission Welcomes Release of Negotiation Documents (Apr. 21, 2010), available at <http://trade.ec.europa.eu/doclib/press/index.cfm?id=552>.

counterfeit products. *“Effective anti-counterfeiting enforcement depends critically upon law enforcement’s ability to block so-called chokepoints in the counterfeiting manufacture and distribution channel, from the upstream supply of raw materials to the downstream distribution of finished products. In the case of counterfeit medical products, this holistic approach to enforcement necessitates effective enforcement tools and remedies to stop the unauthorized manufacture and supply (both domestic and international) of the bulk chemicals used to produce counterfeit medical products, as well as measures to prevent the unauthorized wholesale and retail distribution of counterfeit products.”*<sup>46</sup>

Equally troubling is the fact that the U.S. and E.C. will not stop with ACTA with respect to third-party enforcement. Even before ACTA, they have incorporated provisions requiring enforcement measures against third parties. For example, in the EU/Colombia/Peru EPA,<sup>47</sup> there is an article on provisional and precautionary measures, Art. 232, that states that “parties shall provide that the judicial authorities may, at the request of the applicant, issue an interlocutory injunction against any party intended to prevent any imminent infringement...”<sup>48</sup> Even more problematic are provisions on injunctions, Art. 234. There, footnote 64 states that injunctions can be applied not only against the infringer, but also against those whose services have been used to infringe IPR to the extent that have been involved in the process. The meaning of “involved in the process” is remarkably imprecise. Pursuant to the preceding analysis, does it mean that an NGO buying an allegedly infringing medicines will not be able to deliver the medicines to its patients or that a drug regulatory authority can be enjoined from registering a medicine?

## V. CONCLUSION

PhRMA and its ACTA negotiating surrogates have vigorous ambitions that ACTA and other enforcement treaties be applied upstream and downstream to manufacturing, supply, and distribution channels to stop parallel and generic trade in medicines. Although their tools of preference

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<sup>46</sup> James Love, *PhRMA Comments on ACTA: ISP Liability, Parallel Trade and Generic APIs*, Knowledge Ecology International, July 5, 2008, available at <http://keionline.org/node/73>.

<sup>47</sup> See <http://www.bilaterals.org/spip.php?article17138>.

<sup>48</sup> This could potentially be used against NGOs or international medicines programmes trying to deliver generics. However, this possibility depends upon national legislation providing it, since the article starts by saying “in accordance with their domestic legislation”. States therefore preserve their margin of maneuver.

include broad inclusion of the intellectual property rights, border/in-transit measures, and ubiquitous injunctions that might interfere with government use licenses and judicially-granted royalty schemes, PhRMA and its captive trade negotiators also want to use third-party enforcement measures to dampen generic trade. The dangers to third parties under ACTA are not limited to ISPs; the danger extends to all who contribute to the supply, manufacture, registration, procurement, and distribution of generic medicines that must go through the choke-points of international trade where ephemeral and fictional patent and trademark-confusion rights might prevent the cross-border trade of medicines lawfully produced in the country of export and lawfully consumed in the country of import.

Although it is very late in the game to slow down the ACTA juggernaut, which has now reached its final stages,<sup>49</sup> there are still opportunities at the national level to challenge the agreement substantively and procedurally. Even if ACTA comes into force and is enacted in particular countries, much can be done to corral its interpretation to minimize the reach of third-party enforcement, to narrowly construe its jurisdictional reach, to strictly define “entering into the channels of commerce,” and to limit aider and abettor criminal liability. Health advocates must join forces internationally to eliminate or reduce the risks to access to medicines codified in the proposed ACTA text. Advocate can still try to forestall ACTA’s approval at the national level and to narrow and ameliorate provisions in implementing legislation that could adversely impact supplier, distributors and enablers of generic trade in low-cost generic medicines of assured quality.

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<sup>49</sup> Press Release, Eur. Comm’n: Trade, Joint Statement from all Negotiating Parties to ACTA (Oct. 2, 2010), *available at* <http://trade.ec.europa.eu/doclib/press/index.cfm?id=623&serie=370&langId=en>.