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## ACTA - risks of third-party enforcement for access to medicines

Brook K. Baker

*Northeastern University School of Law*

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

BROOK K. BAKER\*

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## INTRODUCTION

In its current yet to be ratified form,<sup>1</sup> the Anti-Counterfeiting Trade Agreement (“ACTA”), negotiated under general secrecy among a self-selected group of countries,<sup>2</sup> proposes to allow

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\* Professor, Northeastern University School of Law; Honorary Research Fellow, University of KwaZulu Natal; Health GAP Policy Analyst.

1. Anti-Counterfeiting Trade Agreement, Dec. 3, 2010 [hereinafter ACTA Text—Dec. 3, 2010], *available at* <http://www.dfat.gov.au/trade/acta/Final-ACTA-text-following-legal-verification.pdf>. The ACTA text has undergone a series of revisions as it approached finalization. The most current version, dated December 3, 2010, is the result of final textual scrubbing following legal verification. An earlier version, subtitled “Subject to Legal Review,” was dated November 15, 2010. *See* Anti-Counterfeiting Trade Agreement: Subject to Legal Review, Nov. 15, 2010 [hereinafter ACTA Draft—Nov. 15, 2010], *available at* [http://www.ustr.gov/webfm\\_send/2379](http://www.ustr.gov/webfm_send/2379). The first quasi-official text was titled “Consolidated Text—Anti-Counterfeiting Trade Agreement, Informal Predecisional/ Deliberative Draft.” *See* Anti-Counterfeiting Trade Agreement: Informal Predecisional/Deliberative Draft, Oct. 2, 2010 [hereinafter ACTA Draft—Oct. 2, 2010], *available at* [http://www.ustr.gov/webfm\\_send/2338](http://www.ustr.gov/webfm_send/2338) (reflecting changes made during the September 2010 Tokyo Round, which included changes to both Section 3 and Section 5 of Chapter 2).

2. *See* Eddan Katz & Gwen Hinze, *The Impact of the Anti-Counterfeiting Trade Agreement on the Knowledge Economy: The Accountability of the Office of*

preliminary and final injunctive relief against third parties (“third-party enforcement”) to prevent infringement of intellectual property (“IP”) rights and/or to prevent infringing goods from entering into the channels of commerce.<sup>3</sup> After a behind-the-scenes battle, the relevant civil enforcement and injunction section of ACTA no longer applies automatically to the entire range of IP rights<sup>4</sup> covered by the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS Agreement”),<sup>5</sup> but rather permits parties to exclude patents and undisclosed data,<sup>6</sup> as proposed by the U.S.<sup>7</sup> Similarly and more effectively, there is an absolute exclusion of patents from the border enforcement section.<sup>8</sup> Even though patents may be excluded from civil enforcement measures and are definitely excluded from border measures, the health risks in ACTA have not been eliminated. In the context of access to medicines, new globalized forms of third-party enforcement, like its draft predecessor, intermediary service provider

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*the U.S. Trade Representative for the Creation of IP Enforcement Norms Through Executive Trade Agreements*, 35 YALE J. INT'L L. ONLINE 24, 26-27 (2009), <http://www.yjil.org/docs/pub/o-35-katz-hinze-ACTA-on-knowledge-economy.pdf> (stating “[o]n October 23, 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, and Canada have joined the negotiations. *Id.*

3. See ACTA Text—Dec. 3, 2010, *supra* note 1, arts. 8, 12; *infra* Part I.

4. See ACTA Draft—Oct. 2, 2010, *supra* note 1, art. 1.X (indicating “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”). Those sections cover: copyrights and related rights, trademarks, geographical indications, industrial designs, patents, layouts (topographies) of integrated circuits, and protection of undisclosed information. See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, pts. II:1-7, 108 Stat. 4809, 1869 U.N.T.S. 299 [hereinafter TRIPS].

5. TRIPS pt. II.

6. See ACTA Text—Dec. 3, 2010, *supra* note 1, art. 7 n.2 (“A Party may exclude patents and protection of undisclosed information from the scope of this Section.”) (emphasis added).

7. See ACTA Draft—Oct. 2, 2010, *supra* note 1, art. 2.1 n.2 (noting the United States chose to exclude patents from Section 2).

8. See ACTA Text—Dec. 3, 2010, *supra* note 1, art. 13 n.6 (stating “the Parties agree that patents and protection of undisclosed information *do not fall within* the scope” of the Border Measures section) (emphasis added).

enforcement,<sup>9</sup> poses unprecedented risks to the lawful trade of generic medicines. Extending third-party enforcement and imposing provisional measures and permanent injunctions could interfere with the goals of robust generic competition and access to medicine when applied against (1) innocent active pharmaceutical ingredient (“API”) suppliers whose materials are used in the manufacturing 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. 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. Likewise, entities like the Global Fund to Fight AIDS, Tuberculosis and Malaria (“Global Fund”) and 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 remain to be addressed by a global coalition of AIDS, health, and trade activists.

### I. 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 (“April Predecisional Draft”),<sup>10</sup> contained multiple threats to access to medicines. The most 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,<sup>11</sup> under the authority

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9. The concept of intermediary service provider, discussed further, *infra* Part I, applies not to entities that directly infringe IP rights but rather those entities that provide services that contributed to the creation and distribution of an IP infringing product.

10. Anti-Counterfeiting Trade Agreement: PUBLIC Predecisional/Deliberative Draft, Apr. 21, 2010 [hereinafter ACTA Draft—Apr. 21, 2010], *available at* [http://trade.ec.europa.eu/doclib/docs/2010/april/tradoc\\_146029.pdf](http://trade.ec.europa.eu/doclib/docs/2010/april/tradoc_146029.pdf).

11. *See EC Customs Law*, TPA CUSTOMS NEWSLETTER (TPA Global,

of Council Regulation (EC) No. 1383/2003.<sup>12</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>13</sup> The authorities thus responded to Big Pharma seizure requests by impounding and delaying shipments of life-saving medicines sent 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 European Union'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>14</sup>

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Amsterdam, Neth.), Nov. 2009, at 2, available at [http://www.tpa-global.com/PDF/Publications/011109\\_TPA-Customs\\_Newsletter.pdf](http://www.tpa-global.com/PDF/Publications/011109_TPA-Customs_Newsletter.pdf) (summarizing an incident on December 4, 2008, where Dutch authorities seized an air shipment of generic medicine on suspicion that it was counterfeit, and held it for thirty-six days).

12. See Council Regulation 1383/2003, 2003 O.J. (L 196) 7 (EC) (outlining a policy in the European Union that customs action can be taken against goods that are suspected of violating intellectual property rights).

13. The fiction that the product was manufactured in the Netherlands, despite having been actually produced elsewhere, permits Dutch authorities to apply and enforce a product's territorial patent status in the Netherlands despite the fact that the product is not intended for commercialization there. See Frederick M. Abbott, *Seizure of Generic Pharmaceuticals in Transit Based on Allegations of Patent Infringement: A Threat to International Trade, Development and Public Welfare*, 1 WIPO J. 43, 43 (2009) (noting that the European Union's amended border control regulations gave permission to E.U. patent holders to demand seizure of goods such as medicines in transit); cf. *Sosecal v. Sisvel*, Rechtbanks-Gravenhage [District Court in The Hague], July 18, 2008, 311378/KG ZA 08-617 (Neth.) (discussing the manufacturing fiction with regard to a shipment of MP4 players); Frank Eijsvogels, *Sisel v. Sosecal: Acting Against Transit Goods Still Possible Under the Anti Piracy Regulation in the Netherlands*, IP INTELLIGENCE EUR. (Howrey L.L.P., Amsterdam, Neth.), Autumn 2008, at 10 (stating that under *Sisvel*, transit goods may be detained as may be goods intended for the country that serves as their point of entry into the European Union).

14. See *Dispute Settlement: Dispute DS408, European Union and a Member State [India] -- Seizure of Generic Drugs in Transit*, WORLD TRADE ORG., [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) (last updated June 22, 2010) (relaying the initiation of consultations by India with the European Union and the Netherlands regarding repeated seizures on the basis of patent infringement); *Dispute Settlement: Dispute DS409, European Union and a Member State [Brazil] -- Seizure of Generic Drugs in Transit*, WORLD TRADE ORG., [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) (last updated June 22, 2010) (reporting that Brazil requested consultations with the

Unfortunately, the risks of the April Predecisional Draft to public health and to the lawful international trade of generic medicines were 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 extend to all IP rights as proposed by some negotiators, including the European Community.<sup>15</sup>

Bracketed Article 2.X.2 provided: “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>16</sup> Footnote 8 stated that the “conditions and procedures relating to such injunction will be left to each Party’s legal system.”<sup>17</sup> Similarly, bracketed Article 2.5.X 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>18</sup> The parties left undecided whether the provision of injunctions against intermediaries would be mandatory

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European Union regarding the repeated seizure of generic drugs originating in India); *see also India, Brazil Raise Dispute Over EU Drug Seizures*, SUNS, May 17, 2010, available at <http://www.twinside.org.sg/title2/wto.info/2010/twninfo100509.htm>; Kaitlin Mara, *Consultations on WTO Drug Transit Case Continue*, INTELL. PROP. WATCH (Sept. 16, 2010, 7:23 PM), <http://www.ip-watch.org/weblog/2010/09/16/consultations-on-wtocase-on-drugs-in-transit-continue/>; C.H. Unnikrishnan, *India May Move WTO as It Seeks to Resolve EU Dispute*, LIVEMINT (Oct. 11, 2010, 10:54 PM), [http://www.livemint.com/2010/10/1122\\_5420/India-may-move-WTO-as-it-seeks.html](http://www.livemint.com/2010/10/1122_5420/India-may-move-WTO-as-it-seeks.html).

15. *See* ACTA Draft—Apr. 21, 2010, *supra* note 10, art. 2.1 (containing alternative coverage proposals revealing a disagreement over whether the section should apply to all intellectual property rights, or only copyrights and related rights and trademarks).

16. *Id.* art. 2.X.2.

17. *Id.* art. 2.X n.8.

18. *Id.* art. 2.5.X.

or permissive. In either event, there would have been an *in terrorem* effect. A related concept to intermediary enforcement 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>19</sup> Enforcement against intermediaries 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>20</sup>

The April Predecisional Draft left undefined the key operative term, “intermediaries,” as well as the alternative term, “infringing intermediary.” Likewise, what constituted “services” used by another to infringe an IP right was also unclear. Previously, the concept “intermediary services” had been analyzed most closely with respect to internet service providers (“ISPs”).<sup>21</sup> In those circumstances, an ISP that merely provided facilities used by others for infringement, i.e. to download a digital copy of a song, book or movie, might be

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19. *Id.* art. 2.15.2.

20. *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 and 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].

*Id.*

21. *ACTA Ultra-Lite: The U.S. Cave on the Internet Chapter Complete*, MICHAEL GEIST BLOG (Oct. 6, 2010), <http://www.michaelgeist.ca/content/view/5352/125/> (noting these concerns have not been completely eliminated in the new ACTA text in part because the United States, who was initially in favor of tough liability provisions for intermediaries, decided only recently to “cave” on their insistence of such provisions).

interdicted. Given the lack of definition, access-to-knowledge activists were concerned 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. However, their application to mail or telecommunications providers had been deemed unlikely.<sup>22</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 over the impact of intermediary enforcement on access to medicines and because of a lack of clarity about the territorial reach of injunctive powers,<sup>23</sup> the parties dropped the intermediary language in the first quasi-official text, the Consolidated Text—Anti-Counterfeiting Trade Agreement, Informal Predecisional/ Deliberative Draft, dated October 2, 2010,<sup>24</sup> and instead introduced the concept of third-party enforcement in its place. Pursuant to the revised Civil Enforcement—Provisional Measures section:

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22. See Kimberlee Weatherall, *The Anti-Counterfeiting Trade Agreement: Analysis of the January Consolidated Text 18* (Apr. 2010), available at <http://works.bepress.com/cgi/viewcontent.cgi?article=1019&context=kimweatherall> (suggesting that it would be utterly unprecedented to apply the terms “intermediaries” or “infringing intermediaries” to mail service and telecommunications companies).

23. See *Text of Urgent ACTA Communique: International Experts Find that Pending Anti-Counterfeiting Trade Agreement Threatens Public Interests*, AM. U. WASH. C. L. PROGRAM ON INFO. JUST. & INTELL. PROP. (Jun. 23, 2010), <http://www.wcl.american.edu/pijip/go/acta-communique> (identifying the threat to access to medicines by the intermediary liability language of the April Predecisional Draft of ACTA, which included expanding the scope of the agreement to include patents and limiting key flexibilities on injunctions); see also *ACTA - People Before Profits!*, AVAAZ, <http://www.avaaz.org/en/acta> (last visited Mar. 1, 2011) (calling for transparency in the ACTA negotiations spurred by mounting concern over denial of access to life-saving generic medicines); *Berkeley Declaration on Intellectual Property Enforcement and Access to Medicines*, BERKELEY L. SCH. (Jul. 15, 2010), [http://www.law.berkeley.edu/files/Berkeley\\_Declaration.pdf](http://www.law.berkeley.edu/files/Berkeley_Declaration.pdf) (discussing the negative impact ACTA would have on the supply of generic medicines and emphasizing that restricting generic medicines disrupts competition and makes it difficult for those with limited resources to access important medicines).

24. ACTA Draft—Oct. 2, 2010, *supra* note 1.

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>25</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>26</sup>

This language concerning third-party enforcement was present in the penultimate draft<sup>27</sup> and final ACTA text.<sup>28</sup>

Adoption of third-party enforcement exceeds TRIPS protocol, or is “TRIPS-plus,” because no comparable provisions in TRIPS addresses injunctions for established violations and provisional measures for threatened infringements.<sup>29</sup> Under TRIPS Article 44, members are not obligated to allow for injunctions against persons who acquire or order protected subject matter without having known or having had reason to know that they were dealing in infringing products.<sup>30</sup> However, there is an obligation under TRIPS Article 47 to provide information about “the identity of third persons involved in the production and distribution of the infringing goods or services and of their channels of distribution.”<sup>31</sup> Article 50 permits provisional measures to prevent the infringement of IP rights and to

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25. *Id.* art. 2.5(1)(a) (emphasis added).

26. *Id.* art. 2.X.1 (emphasis added).

27. ACTA Draft—Nov. 15, 2010, *supra* note 1, arts. 2.5:1(a), 2.X.1.

28. ACTA Text—Dec. 3, 2010, *supra* note 1, arts. 12:1(a), 8:1.

29. *See* TRIPS arts. 44, 50.

30. *See id.* art. 44.1 (“Members are not obligated to accord such authority in respect of protected subject matter acquired or ordered by a person prior to knowing or having reasonable grounds to know that dealing in such subject matter would entail the infringement of an intellectual property right.”).

31. *Id.* art. 47.

prevent the entry of infringing products, but like Article 44, it does not directly address enforcement against third parties.<sup>32</sup>

The necessity of having personal and territorial jurisdiction over a third party is at least referenced by the final ACTA text,<sup>33</sup> but ACTA introduced an additional confusing phrase—“entering into the channels of commerce.” TRIPS had previously referenced “channels of commerce” in its enforcement provisions, but clarified the concept considerably by limiting it to goods that had entered commercial channels within the territory of the enforcing country.<sup>34</sup> By now extending this concept beyond such territory, ACTA is not only TRIPS-plus, but it also introduces substantial ambiguity about the length, depth, and width of the channels of commerce.<sup>35</sup>

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32. See *id.* art. 50 (failing to directly address third parties in the “Provisional Measures” article).

33. See ACTA Text—Dec. 3, 2010, *supra* note 1, arts. 12:1(a). Injunctions are usually limited in their application to activities occurring within the geographic territory of the issuing jurisdiction, but jurisdiction sometimes extends to extraterritorial activities that adversely impact in-territory interests. Under a strict territorial rule, to enjoin third-party enablement of IP infringement in India, first the third party would have to be facilitating an infringement of a territorial IP right in India, 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. See AM. L. INST., INTELLECTUAL PROPERTY PRINCIPLES GOVERNING JURISDICTION, CHOICE OF LAW, AND JUDGMENTS IN TRANSNATIONAL DISPUTES (2008). A full discussion of extraterritorial jurisdiction is clearly beyond the scope of this short article, but for a discussion of some of the relevant principles, see generally *id.*

34. See TRIPS art. 44(1) (“The judicial authorities shall have the authority to order a party to desist from an infringement . . . to prevent the entry into the channels of commerce in their jurisdiction of imported goods that involve the infringement of an intellectual property right, immediately after customs clearance of such goods.”).

The judicial authorities shall have the authority to order prompt and effective provisional measures: (a) to prevent an infringement of any intellectual property right from occurring, and in particular to prevent the entry into the channels of commerce in their jurisdiction of goods, including imported goods immediately after customs clearance.

*Id.* art. 50(1)(a).

35. See *infra* Part II (describing the risk faced by distributors and transporters of generic medicine due to the ambiguity of ACTA’s third-party enforcement

An additional incoherence in the ACTA text is that provisional measures can be used to address any IP infringement but 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 do so.<sup>36</sup>

In service of third-party enforcement, all the relevant drafts of ACTA have required production of information “regarding any person involved in any aspect of the infringement . . . and regarding the means of production or the channels of distribution of the infringing or allegedly infringing goods or services.”<sup>37</sup> This language is in substantial conformity with TRIPS.<sup>38</sup> With respect to criminal enforcement, the parties modified the April Predecisional Draft provision to exclude incitement and instead require that each “[p]arty shall ensure that criminal liability for aiding and abetting is available under its law.”<sup>39</sup>

Although the final ACTA text clearly elected to focus IP enforcement on third parties rather than intermediary service providers, the next section addresses both concepts because of the dangers each poses to access to medicines.

## II. APPLYING INTERMEDIARY AND NOW THIRD-PARTY ENFORCEMENT TO PHARMACEUTICALS

In the context of access to medicines, the concept “intermediary services” may be quite ominous. Services are obviously provided by ISPs—allowing suppliers to market medicines online—and, in the pharmaceutical context, by shipping agents.<sup>40</sup> However, lawyers and accountants, communications service providers, and factory workers

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concept).

36. ACTA Text—Dec. 3, 2010, *supra* note 1, arts. 8, 12 (providing, in Article 12, that provisional measures may be taken against a party or third party to prevent an infringement of any intellectual property right, including to prevent goods from entering channels of commerce, while Article 8 provides for final injunctions against any goods that infringe upon intellectual property rights from entering into the channels of commerce).

37. *E.g., id.* art. 11.

38. *See* TRIPS art. 47 (allowing judicial authorities “to order the infringer to inform the right holder of the identity of third persons involved in the production and distribution of infringing goods or services”).

39. ACTA Text—Dec. 3, 2010, *supra* note 1, art. 23.4.

also supply services. Although one does not usually consider suppliers of components—for example, API and inert ingredient suppliers—to be providing a “service,” if components are deemed to be services, then all medicine component suppliers could be deemed “intermediaries” who contributed services instantiated in the manufacture and distribution of an IP-infringing generic medicine, and would therefore be subject to an injunction and perhaps even an order of destruction.<sup>41</sup>

Perhaps more ominously, many others who helped fund or facilitate purchases of generic drugs as they moved through the stream of international commerce from producer to consumer could face intermediary liability. For example, the Global Fund solicits and funds country-led proposals for funding priority disease prevention, treatment, and care.<sup>42</sup> More to the point, the Global Fund now provides a voluntary pooled-procurement service for medicines<sup>43</sup> and

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40. 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*, BARDEHLE PAGENBERG IP REP. (Düsseldorf, Ger.), 2010/I, at 6, available at [http://www.bardehle.com/uploads/files/IP\\_Report\\_2010\\_I.pdf](http://www.bardehle.com/uploads/files/IP_Report_2010_I.pdf) (summarizing a German Court ruling granting injunctive relief against a shipping agent who delivered allegedly patent infringing MP3 players); see also Trade Enforcement Act of 2009, S. 1466, 111th Cong. § 223(2)(C)-(D) (2009) (providing for disclosure of identities and contact information of parties involved in shipments of infringing goods); 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); ACTA Draft—Apr. 21, 2010, *supra* note 10, art. 2.4 (allowing intermediary liability to extend to shippers by including a direct reference to distribution and channels of distribution).

41. See ACTA Text—Dec. 3, 2010, *supra* note 1, art. 10(2) (arguably permitting the destruction of APIs used in the “manufacture” of “infringing” generic medicines).

Each Party shall further provide that its judicial authorities have the authority to order that materials and implements, the predominant use of which has been in the manufacture or creation of such infringing goods, be, without undue delay and without compensation of any sort, destroyed or disposed of outside the channels of commerce in such a manner as to minimize the risks of further infringements.

*Id.*

42. See *About the Global Fund*, GLOBAL FUND, <http://www.theglobalfund.org/en/about/> (last visited Mar. 1, 2011) (describing the organization’s mission of preventing and treating diseases such as HIV/AIDS, tuberculosis, and malaria).

43. See *E.D. Report Provides Updates on CCMs, Round 8 Grants, Other Topics*, GLOBAL FUND OBSERVER (Aidspan, Nairobi, Kenya), Jun. 24, 2010, at 13-

maintains tight control over purchases of particular tuberculosis and malaria medicines.<sup>44</sup> Will the Global Fund—and similar funding/facilitating services such as those offered by UNITAID,<sup>45</sup> the Clinton Health Access Initiative,<sup>46</sup> SCMS,<sup>47</sup> IDA Foundation,<sup>48</sup> *Médecins Sans Frontières*,<sup>49</sup> and even UNICEF<sup>50</sup>—fear that their

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14, available at <http://www.aidsplan.org/documents/gfo/GFO-Issue-127.pdf>.

[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.

*Id.*

44. See THE GLOBAL FUND, GUIDE TO THE GLOBAL FUND'S POLICIES ON PROCUREMENT AND SUPPLY MANAGEMENT 12 (2009), available at [http://www.theglobalfund.org/documents/psm/pp\\_guidelines\\_procurement\\_supply\\_management\\_en.pdf](http://www.theglobalfund.org/documents/psm/pp_guidelines_procurement_supply_management_en.pdf) (“All procurement of pharmaceutical products to treat multidrug resistant TB (tuberculosis) must be conducted through the Green Light Committee . . . .”); see also *Affordable Medicines Facility - malaria (AMFm)*, GLOBAL FUND, <http://www.theglobalfund.org/en/amfm/> (last visited Mar. 1, 2011) (describing the Affordable Medicines Facility – malaria, whose mission is to expand access to effective malaria treatment through innovative financing techniques that include tapping the public sector, private sector, and NGO's).

45. See UNITAID, UNITAID CONST. § 1 (2007), 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) (relating that as part of the WHO, UNITAID's express mission is to increase access to HIV/AIDS, tuberculosis, and malaria medicines by leveraging price reductions for unaffordable treatments).

46. See *Clinton Health Access Initiative - What We Do*, CLINTON FOUND., <http://www.clintonfoundation.org/what-we-do/clinton-health-access-initiative> (last visited Mar. 1, 2011) (summarizing the goals and purpose of the Clinton Health Access Initiative, which include strengthening integrated health systems and expanding access to treatment for diseases such as HIV/AIDS, malaria, and tuberculosis).

47. See *About Us*, SUPPLY CHAIN MGMT. SYS., <http://scms.pfscm.org/scms/about> (last visited Mar. 1, 2011) (recounting the mission and purpose of the Supply Chain Management System, which includes reducing the costs of essential medicines by encouraging its clients to buy in bulk and establishing long term contracts with manufactures).

48. See IDA FOUNDATION, <http://ida.nl/> (last visited Mar. 1, 2011) (describing the mission and purpose of the IDA Foundation, which include utilizing its resources to improve access to high quality medicines).

49. See *Access to Essential Medicines: Ten Stories that Mattered in 2010*, MÉDECINS SANS FRONTIÈRES/DOCTORS WITHOUT BORDERS (Dec. 29, 2010), <http://www.doctorswithoutborders.org/publications/article.cmf?id=4936&cat=special-report> (outlining *Médecins Sans Frontières'* drug procurement activities and vaccination campaigns).

50. See *Supplies and Logistics*, UNICEF, <http://www.unicef.org/supply/index>

access-to-medicines resources and activities will be 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>51</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 infringement?<sup>52</sup>

Unfortunately, the switch to third-party enforcement, retained in the latest ACTA text, does little or nothing to allay the potential 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.<sup>53</sup> One may still seek provisional orders 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.<sup>54</sup> Furthermore, the state may still impose criminal sanctions against those who aid and abet criminal infringement activities.<sup>55</sup>

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.html (last updated Nov. 8, 2010) (describing UNICEF's procurement of \$1.75 billion worth of supplies from suppliers all over the world as an example of it fulfilling its mission to ensure quality supplies reach children and their families).

51. *Cf.* THE GLOBAL FUND, *supra* note 44, at 12 (detailing The Global Fund's current requirements that recipients comply with "the policies of other international funding sources" with regard to procurement of pharmaceutical products). Ambiguity remains regarding possible new duties of the Global Fund to double-check and confirm the intellectual property status of medicines purchases it finances under international law (TRIPS Agreement), the law of the country of use, and the law of every transit country as a result of intermediary enforcement concerns.

52. *See Effective Medicines Regulation: Ensuring Safety, Efficacy, and Quality*, POLICY PERSPECTIVES ON MEDICINES (World Health Org., Geneva, Switz), Nov. 2003, available at <http://www.who.int/medicinedocs/pdf/s4921e/s4921e.pdf> (creating guidelines for drug regulatory authorities to assess medicines for quality, safety, and efficacy and approve the medicine for marketing within a country). By doing so, drug regulatory authorities would arguably enable the lawful distribution and sale of alleged IP infringing medicines and thus be subject to intermediary enforcement.

53. ACTA Text—Dec. 3, 2010, *supra* note 1, art. 11.

54. *Id.* arts. 8, 12.

55. *See id.* art. 23.4 (allowing for criminal liability of those who aid and abet infringement activities).

In particular, many uncertainties exist in the meaning and scope of application of these provisions with respect to the concept of entrance into the channels of commerce. 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, thereby placing these products squarely in the middle of channels of commerce where territorial jurisdiction surely applies. Additionally, component suppliers might also be liable under the provisional measures provision since enjoining them as third parties could arguably prevent the offending product from being made in the first place.<sup>56</sup> Similarly, it is conceivable, though perhaps not as likely, that other enablers of commercialization, including procurement agents like *Médecins Sans Frontières* and the International Dispensary Association; funders like PEPFAR, the Global Fund, and UNITAID; and even drug regulatory authorities could also be temporarily enjoined to prevent the commercialization and distribution of alleged IP infringing products.<sup>57</sup> Whether criminal “aiding and abetting” extends to suppliers of subsidiary materials and other enablers, who thereby contribute to either the production or commercialization of the offending products, is perhaps less clear, but the possibility of criminal liability<sup>58</sup> 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

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56. *See id.* art. 12.1 (“Each Party shall provide that its judicial authorities have the authority to order prompt and effective provisional measures . . . against a third party . . . to prevent an infringement of any intellectual property right from occurring, and in particular, to prevent goods that involve the infringement of an intellectual property right from entering into the channels of commerce . . .”).

57. *See id.* Third-party enforcement against these parties is less likely because their role in enabling an IP infringing product to enter the channels of commerce is much less direct than that of component suppliers, manufacturers, or distributors. Nonetheless, the ultimate commercialization and movement of the product would not occur were it not for their activities. A second reason that enforcement against these parties is less certain is that jurisdictional reach to extra-territorial activities is much less certain.

58. *See id.* art. 23.4 (authorizing criminal liability of those who aid and abet infringement activities).

trademark.<sup>59</sup> In these circumstances and under TRIPS and conforming national 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.<sup>60</sup> However, imposing a second tier of liability on third-party suppliers and distributors who often lack knowledge of the IP status of the product at issue is an undesirable outcome. This second tier of liability would clog the channels of commerce by requiring 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.

Certainly ACTA's impact on access to medicines will be greatest if its civil enforcement measures are used with respect to alleged patent infringement. Health advocates therefore scored a victory when the parties to the ACTA draft amended the border measures provision to totally exclude patents and protection of undisclosed information.<sup>61</sup> Unfortunately, this exclusion does not prevent ACTA members from unilaterally adopting patent-related border measures such as those currently codified in EC 1383/2003.<sup>62</sup> And in contrast to ACTA's border measures section, the civil enforcement section stipulates that "[a] Party may exclude patents and protection of undisclosed information from the scope of this [civil enforcement] Section."<sup>63</sup> This permission to exclude leaves patents within ACTA's

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59. See generally Letter from Peter Maybarduk, Staff Attorney, Essential Action, to Consultations and Liaison Division, Anti-Counterfeiting Trade Agreement, Foreign Affairs and International Trade Canada 6 (July 2, 2009), available at [http://www.whitehouse.gov/sites/default/files/omb/IPEC/frn\\_comments/EssentialAction.pdf](http://www.whitehouse.gov/sites/default/files/omb/IPEC/frn_comments/EssentialAction.pdf) (explaining that deliberately mislabeled medicines are within a subset of trademark infringing medicines which pose a risk to public health).

60. See TRIPS pt. III, § 2 (outlining specific civil and administrative procedures and remedies available to the IP right holder in a member's jurisdiction).

61. See ACTA Text—Dec. 3, 2010, *supra* note 1, art. 13 n.6 (excluding patents from the scope of Article 13).

62. See Council Regulation 1383/2003, *supra* note 12 (authorizing the detention of goods suspected of infringement on IP rights); *supra* notes 11-12 and accompanying text.

63. See ACTA Text—Dec. 3, 2010, *supra* note 1, art. 6-7 n.2 (updating the text from previous drafts, which read: "For the purpose of this Agreement, Parties agree that patents do not fall within the scope of this Section").

mandatory civil enforcement rules unless a country actively chooses to exclude. This presumptive inclusion could exert subtle pressure on countries to include protection for patents and undisclosed data. The presumption could also be the basis of pressure by powerful trade partners for civil enforcement measures that extend to patents and thus more directly threaten trade in generic medicines.

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>64</sup> Patent-related seizures had previously been made based on the in-country manufacturing fiction.<sup>65</sup> Obviously these seizures could have implicated third parties had ACTA's border measures provision not been changed to exclude patents.<sup>66</sup> Although trademark-related seizures have been fewer,<sup>67</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. Likewise, 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>68</sup> the trade dress of a branded and generic medicine

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64. *See id.* art. 13, n.6.

65. *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 where AIDS medicines purchased by UNITAID were being shipped from India to Nigeria).

66. ACTA Text—Dec. 3, 2010, *supra* note 1, art. 13 n.6.

67. *See, e.g.*, Press Release, Health Action Int'l, Another Seizure of Generic Medicines Destined for a Developing Country, This Time in Frankfurt (Jun. 5, 2009), <http://www.ip-watch.org/weblog/wp-content/uploads/2009/06/june-5-press-release-frankfurt-seizure.pdf> (recounting an in-transit seizure by German customs officials of generic Amoxicillin, en route from India to the Republic of Vanuatu, because of alleged trademark confusion with GlaxoSmithKline's off-patent brand name medicine "Amoxil").

68. *See generally* FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY:

might also be appropriately similar but still trade-dress confusing.<sup>69</sup> Once again, third parties might be held liable even under border measures limited to trademark and copyright violations. Moreover, in the unlikely event the trademark issue rose to the level of willful trademark counterfeiting on a commercial scale, actions of third-party suppliers and distributors could constitute criminal aiding and abetting. An innocent supplier for a producer, who later turned out to be a willful counterfeiter, could suddenly be deemed a criminal offender under Article 23.4 of ACTA.<sup>70</sup>

### III. ACTA NEGOTIATORS ARE PURSUING PHARMA'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>71</sup> However, the analysis above shows otherwise. Underlying health advocates' fears, the Pharmaceutical Research and

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STATISTICAL APPROACHES TO ESTABLISHING BIOEQUIVALENCE 2-4 (2001), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070244.pdf>. 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 study, involving a relatively small number of human subjects, instead of the expense and delay of duplicative Phase I-III clinical trials. *Id.* 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.

69. See Sean Flynn, *Note on ACTA and Access to Medicines*, AM. U. WASH. C. L. PROGRAM ON INFO. JUST. & INTELL. PROP., <http://www.wcl.american.edu/pijip/go/blog-post/note-on-acta-and-access-to-medicines> (last visited Mar. 1, 2011) (noting trademark confusion can occur when generic drugs are required to make their labeling similar to brand name drugs).

70. See ACTA Text—Dec. 3, 2010, *supra* note 1, art. 23.4 (stating each party shall ensure that criminal liability for aiding and abetting exists for certain instances of trademark counterfeiting).

71. Press Release, Eur. Comm'n Directorate Gen. for Trade, Anti-Counterfeiting Trade Agreement: European Commission Welcomes Release of Negotiation Documents (Apr. 21, 2010), <http://trade.ec.europa.eu/doclib/press/index.cfm?id=552>.

Manufacturers of America (“PhRMA”) advocates an even more extreme and precisely defined application. In PhRMA’s comments to the USTR on ACTA in 2008, PhRMA suggested that the Agreement should 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 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*

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*distribution of counterfeit products.*<sup>72</sup>

Equally troubling is the fact that the U.S. and E.C. will not stop with ACTA on their press for third-party enforcement; even before ACTA, they enacted provisions requiring enforcement measures against third parties. For example, in the EU/Colombia/Peru Economic Partnership Agreement,<sup>73</sup> there is an article on provisional and precautionary measures, Article 232, that states: “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>74</sup> Even more problematic is Article 234’s footnote 64, which provides that injunctions may be applied “against those whose services have been used to infringe intellectual property rights to the extent they have been involved in the process.”<sup>75</sup> The meaning of “involved in the process” is remarkably imprecise. Pursuant to the preceding analysis, does it mean that an NGO buying 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?

## 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. Their tools of preference include broad inclusion of IP rights, border/in-transit measures, and ubiquitous injunctions that might interfere with government use licenses and judicially-granted royalty schemes. Yet,

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72. James Love, *PhRMA Comments on ACTA: ISP Liability, Parallel Trade and Generic APIs*, KNOWLEDGE ECOLOGY INT’L (Jul. 10, 2008, 10:00 PM), <http://keionline.org/node/73>.

73. Trade Agreement Between the European Union [and its Member States] and Colombia and Peru, art. 232, *initialed* Mar. 23-24, 2011, *available at* <http://trade.ec.europa.eu/doclib/press/index.cfm?id=691> (follow “Preamble and text of the agreement” hyperlink).

74. *Id.* art. 232 (emphasis added). This article could potentially be used against NGOs or international medicines programs 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.” *Id.* States therefore preserve their margin of maneuver.

75. *See id.* art. 234 n.64.

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. Rather, 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 too late to stop the ACTA juggernaut, which has reached its final stages,<sup>76</sup> residual opportunities exist 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 exclude its application to patents and undisclosed data, to corral its interpretation to minimize the reach of third-party enforcement, to narrowly construe its jurisdictional grant, 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. Advocates 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.

However, the risk of intermediary service provider and third-party enforcement efforts is not limited to ACTA itself. The E.C. is on record that it hopes that ACTA will be adopted by other countries "facing the same counterfeiting and piracy problems."<sup>77</sup> Even more ominously, although the mandatory application of enhanced enforcement measures against patent- and data-infringing products

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76. See *ACTA Countries Finalize Agreement, Adopt U.S.-EU Compromise*, 28 INSIDE U.S. TRADE, Nov. 19, 2010, available at 2010 WLNR 23073528 (confirming ACTA members have finalized the ACTA text and had resolved all left over issues from the September round of negotiations); *EU Parliament ACTA Resolution Opens Doors to Final Approval*, 28 INSIDE U.S. TRADE, Dec. 3, 2010, available at 2010 WLNR 24009637 (reporting the passage of the non-binding resolution by a 331-294 vote of the European Union parliamentarians).

77. *Intellectual Property: Anti-Counterfeiting*, EUR. COMMISSION, <http://ec.europa.eu/trade/creating-opportunities/trade-topics/intellectual-property/anti-counterfeiting/> (last visited Mar. 1, 2011).

was avoided in ACTA, PhRMA's intentions in this regard are clear. Likewise, in bilateral trade agreements and Special 301 Watch List annual reports, there remain many opportunities for the hydra-like reappearance of full-blown intermediary or third-party enforcement. Accordingly, advocates must maintain vigilance for a significant time to come if these enforcement-related dangers to access to legitimate generic medicines are to be avoided.