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### ACTA and Access to Medicines

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10-06-2011

## ACTA and Access to Medicines

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**Prepared at the request of:**



**The Greens | European Free Alliance**  
in the European Parliament



# ACTA AND ACCESS TO MEDICINES

*Sean Flynn with Bijan Madhani<sup>1</sup>*

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## INTRODUCTION AND EXECUTIVE SUMMARY

The Greens/EFA Internet Core Group in the European Parliament, and a collection of its individual members,<sup>2</sup> commissioned this analysis of potential impacts of the Anti-Counterfeiting Trade Agreement (ACTA)<sup>3</sup> on access to medicines in developing countries.”<sup>4</sup> On the whole, ACTA negotiators created an agreement that shifts international “hard law” rules and “soft law” encouragements toward making enforcement of intellectual property rights in courts, at borders, by the government and by private parties easier, less costly, and more “deterrent” in the level of penalties. In doing so, it increases the risks and consequences of wrongful searches, seizures, lawsuits and other enforcement actions for those relying on intellectual property limitations and exceptions to access markets, including the suppliers of legitimate generic medicines. This, in turn, is likely to make affordable medicines more scarce and dear in many countries.

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<sup>2</sup> The Members of Parliament include: Jan Albrecht, Germany; Eva Lichtenberger, Austria; Judith Sargentini, Netherlands; Carl Schlyter, Sweden; Karima Delli, France; Sandrine Bélier, France; Franziska Keller, Germany; Christian Engström, Sweden.

<sup>3</sup> Anti-Counterfeiting Trade Agreement, Dec. 3, 2010 [hereinafter ACTA Text–Dec. 3, 2010], *available at* <http://dfat.gov.au/trade/acta/Final-ACTA-text-following-legal-verification.pdf>.

<sup>4</sup> *Proposal for a Study: ACTA and its impact on the access to medicine*, ACT ON ACTA, [http://en.act-on-acta.eu/ACTA\\_and\\_its\\_impact\\_on\\_the\\_access\\_to\\_medicine](http://en.act-on-acta.eu/ACTA_and_its_impact_on_the_access_to_medicine).

The ACTA process and substance is counter to two sets of specific instructions contained in European Parliament resolutions and supported by international human rights law.

(1) First, the negotiation disregarded specific Parliament instructions stating that processes for international law making impacting access to medicines and other important social interests be open, transparent and participatory.

(2) Second, the substance of the Agreement violates Parliament demands that trade agreements in general, and ACTA specifically, not include “TRIPS-plus” measures that may restrict the global trade in affordable medicines. ACTA provisions that are TRIPS-plus and could restrict access to essential medicines in developing countries and elsewhere include:

- **Border measures requirements** that expand the scope of authorized seizures to any case where a border agent “suspects” a medicine’s label of being “confusingly similar” to a brand.
- **Injunction provisions** that require all ACTA members to put in place the basic legal elements that were used in the “Dutch seizures” cases in the EU, enabling authorities in one country issue injunctions preventing goods from entering commerce in a third country without that third country’s officials ever passing on whether the item would infringe its own laws.
- **Third-party liability rules** that increase risks of erroneous injunctions and seizures of property from distributors, shippers, procurement agents and component suppliers of any generic product suspected of having a “confusingly similar” label.
- **Damages provisions** that over-deter lawful conduct by encouraging determinations of damages in poorer countries based on the “market price” or “suggested retail price” of a branded product, even where that price is intentionally set at a level that excludes the great majority of a population from access to the product.
- **Information disclosure requirements** that could be used by right holders to discover details on distribution chains of generic companies and mount aggressive and expensive litigation against suppliers and intermediaries to deter generic entry into key markets.
- **Expansion of criminal liability** to cases where a supplier did not intentionally create or use the counterfeit label itself, thus raising the (over-)deterrent effect of trademark law for importers, including those of generic medicines.

- **Expansion of seizure and destruction rules** to require that, for example, absent “exceptional circumstances,” a medicine found to have a minor trademark infringement on a label be destroyed rather than re-labeled and re-sold.

Given these paramount procedural and substantive flaws, this opinion concludes that the EU Parliament should withhold consent to ACTA.

#### I. ACTA’S PROCESS DID NOT COMPLY WITH PARLIAMENT MANDATES ON TRANSPARENCY AND STAKEHOLDER PARTICIPATION

ACTA is a sweeping legal framework agreement, creating a minimum standards that require or prevent changes in domestic legislation that affect a broad range of public interests.<sup>5</sup> Unlike in multilateral institutions, including the World Intellectual Property Organization, where similar agreements are sometimes crafted, ACTA did not afford basic public participation resources. Ongoing releases of negotiation texts and background materials, institutionalized and regular briefings of civil society and the general public and public access to the negotiation venue were all absent.<sup>6</sup>

Open policy making process are needed to promote democratic legitimacy and respect for human rights,<sup>7</sup> as well as for the instrumental aim of promoting better policy outcomes more reflective of the fullest range of stakeholder interest. Recognizing these values and objectives, the European Parliament’s March 2010 resolution on ACTA contains at least nine specific demands for transparency and open process.<sup>8</sup> Each of these

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<sup>5</sup> See Sean Flynn, *ACTA’s Constitutional Problem: The Treaty is not a Treaty*, 26 AM. U. INT’L L. REV. 903, 908-912 (2011).

<sup>6</sup> See Jeremy Malcolm, *Public Interest Representation in Global IP Policy Institutions* 20-21 (Program on Info. Justice and Intellectual Prop. Working Paper No. 6, 2010), available at <http://digitalcommons.wcl.american.edu/research/9> (demonstrating that ACTA negotiations failed to satisfy best practices for transparency and public participation).

<sup>7</sup> See U.N. Special Rapporteur Anand Grover, *Promotion and Protection of All Human Rights, Civil, Political, Economic, Social, and Cultural Rights, Including the Right to Development: Rep. of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health*, ¶ 4, U.N. Doc. A/HRC/11/12 (Mar. 31, 2009) (describing human rights requirements to promote broad public participation in health policy making).

<sup>8</sup> See generally Eur. Parl. res. of 10 March 2010 on the transparency and state of play of the ACTA negotiations, P7\_TA(2010)0058 (2010), available at <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2010-0058+0+DOC+XML+V0//EN&language=EN>. See also Eur. Parl. res. on the Anti-Counterfeiting Trade Agreement (ACTA), B7-0617/2010 (2010), available at

demands and the response of the ACTA negotiation are detailed in the chart below. In short, ACTA's negotiating process violated every one of the EU Parliament's open process demands.

European Parliamentary Resolution March 2010	ACTA Process (post-resolution)
2. Expresses its concern over the lack of a transparent process in the conduct of the ACTA negotiations, a state of affairs at odds with the letter and spirit of the TFEU [Treaty on the Functioning of the European Union];	Process not dramatically improved. No Public hearings held on draft text. Public health representatives continue to be consulted only in closed-door sessions with no access to text.
[I]s deeply concerned that no legal base was established before the start of the ACTA negotiations and that parliamentary approval for the negotiating mandate was not sought;	No legal base established before conclusion of ACTA negotiations.
3. Calls on the Commission and the Council to grant public and parliamentary access to ACTA negotiation texts and summaries, in accordance with the Treaty and with Regulation (EC) No 1049/2001 of 30 May 2001 regarding public access to European Parliament, Council and Commission documents;	One public release of draft negotiating text in April 2010. <sup>9</sup> Parliament given ongoing access to negotiating drafts after April, but public is not given similar access.
4. Calls on the Commission and the Council to engage proactively with ACTA negotiation partners to rule out any further negotiations which are confidential as a matter of course and to inform Parliament fully and in a timely manner about its initiatives in this regard; expects the Commission to make proposals prior to the next negotiation round in New Zealand in April 2010, to demand that the issue of transparency is put on the agenda of that meeting and to refer the outcome of the negotiation round to Parliament immediately following its conclusion;	Whether the Commission in fact pressured other partners to increase transparency is unknown because all negotiation venues and positions remained secret through the finalization of text in December 2011. Rounds of negotiations continued to be held in locations that were undisclosed until hours before their formal start.
5. Stresses that, unless Parliament is immediately and fully informed at all stages of the negotiations, it reserves its right to take suitable action, including bringing a case before the Court of Justice in order to safeguard its prerogatives;	After the resolution, the European Parliament's International Trade Committee (INTA) was given access to negotiating text, but under rules prohibiting the sharing of text with uncleared constituents stakeholders.  The Commission is now being sued by one MEP for a failure to meet Parliament's demands. <sup>10</sup>

<http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+MOTION+B7-2010-0617+0+DOC+XML+V0//EN>; Eur. Parl. res. on ACTA – preparing for the consent procedure, B7-0619/2010 (2010), available at <http://www.europarl.europa.eu/sides/getDoc.do?type=MOTION&reference=B7-2010-0619&language=EN> (demonstrating that political groups Greens/EFA and ALDE tabled identical resolutions containing policies similar to the European Parliament Resolution).

<sup>9</sup> Anti-Counterfeiting Trade Agreement: PUBLIC Predecisional/Deliberative Draft, April 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) [hereinafter ACTA Text–Apr. 2010].

6. Deplores the calculated choice of the parties not to negotiate through well-established international bodies, such as WIPO and WTO, which have established frameworks for public information and consultation;	ACTA was not moved to a multilateral forum.
8. Welcomes affirmations by the Commission that any ACTA agreement will be limited to the enforcement of existing IPRs, with no prejudice for the development of substantive IP law in the European Union”	In the end, as discussed below, ACTA limits the ability to develop limitations and exceptions to intellectual property rights enforcement, thereby impacting the practical reach of intellectual property rights.
9. Calls on the Commission to continue the negotiations on ACTA and limit them to the existing European IPR enforcement system against counterfeiting;	EU academic analysis indicates that ACTA goes beyond the <i>acquis communautaire</i> . <sup>11</sup>
[C]onsiders that further ACTA negotiations should include a larger number of developing and emerging countries, with a view to reaching a possible multilateral level of negotiation;	No more developing countries are added to the negotiation. Despite the proclaimed intent to make ACTA a new <u>global</u> standard, <sup>12</sup> only two of the 37 negotiating countries, Morocco and Mexico, were developing countries.

## II. ACTA DOES NOT COMPLY WITH PARLIAMENT ORDERS TO EXCLUDE TRIPS-PLUS PROVISIONS ON MEDICINES

Following controversial interpretations of TRIPS requirements in a series of attempts to challenge facially compliant access to medicine policies in developing countries in the mid 1990s, a body of legal norms emerged that are critical of so-called “TRIPS-plus” measures that heighten intellectual property for medicines in developing countries beyond the plain

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<sup>10</sup> See generally Case T-301/10, In 't Veld v Comm'n, 2010 O.J. (C 260) 18-19 (Sept. 25, 2010), available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2010:260:0018:0019:EN:PDF>. See also Eur. Comm. for Trade Karel De Gucht, *Answer to a written question - ACTA — a law enforcement treaty?*, ¶5, E-8847/2010, (2010), available at <http://www.europarl.europa.eu/sides/getAllAnswers.do?reference=E-2010-8847&language=EN> (refusing to answer whether Commission has “compromised the rules and regulations on access to information and transparency in the European Union” because “this issue is currently the object of a court case lodged by an Member of the European Parliament against the Commission”).

<sup>11</sup> See *Opinion of European Academics on the Anti-Counterfeiting Trade Agreement*, Institute for Legal Informatics (2011), available at [http://www.iri.uni-hannover.de/tl\\_files/pdf/ACTA\\_opinion\\_200111\\_2.pdf](http://www.iri.uni-hannover.de/tl_files/pdf/ACTA_opinion_200111_2.pdf) [hereinafter *European Academics*] (finding that: “ACTA provisions are not entirely compatible with EU law and will directly or indirectly require additional action on the EU level,” and advising, “as long as significant deviations from the EU *acquis* or serious concerns on fundamental rights, data protection, and a fair balance of interests are not properly addressed, to withhold consent.”).

<sup>12</sup> See Office of the U.S. Trade Representative, 2008 Special 301 Report 4 (2008), available at [http://www.ustr.gov/sites/default/files/asset\\_upload\\_file553\\_14869.pdf](http://www.ustr.gov/sites/default/files/asset_upload_file553_14869.pdf) (explaining that ACTA is designed to ultimately create new “global” enforcement standards).

meaning of TRIPS minimum standards.<sup>13</sup> Implementing this trend toward protection of access to medicines in international trade policy, the European Parliament has repeatedly enjoined the Commission from negotiating agreements with developing countries containing TRIPS-plus provisions on medicines. Specifically:

- In 2007 the Parliament resolved that the Commission should not negotiate “pharmaceutical-related TRIPS-plus provisions affecting public health and access to medicines” in “future bilateral and regional agreements with developing countries.”<sup>14</sup>
- In March 2010, the Parliament specifically addressed the issue with respect to ACTA, resolving that “ACTA provisions, notably measures aimed at strengthening powers for cross-border inspection and seizure of goods, should not affect global access to legitimate, affordable and safe medicinal products – including innovative and generic products – on the pretext of combating counterfeiting.”<sup>15</sup>

ACTA does not comply with these mandates. The ACTA agreement itself has several developing country members. And the policies it implements, by raising border controls in “in-transit” and exporting countries regardless of the ultimate country of destination, can impact every developing country that relies on shipments from or through European

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<sup>13</sup> See Doha Declaration on TRIPS and Public Health, World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1, 41 I.L.M. 746 ¶4 (2002) [hereinafter Doha Declaration] (affirming that TRIPS “should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all,” and reaffirming “the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose”); U.N. Special Rapporteur Anand Grover, *Promotion and Protection of All Human Rights, Civil, Political, Economic, Social, and Cultural Rights, Including the Right to Development: Rep. of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health*, ¶ 108, U.N. Doc. A/HRC/11/12 (Mar. 31, 2009) (“Developing countries and LDCs should not introduce TRIPS-plus standards in their national laws. Developed countries should not encourage developing countries and LDCs to enter into TRIPS-plus FTAs and should be mindful of actions which may infringe upon the right to health.”).

<sup>14</sup> Eur. Parl. res. of 12 July 2007 on the TRIPS Agreement and access to medicines, P6\_TA(2007)0353, available at <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P6-TA-2007-0353+0+DOC+XML+V0//EN> (resolving further that “measures to tackle counterfeiting need to be . . . reinforcing the regulatory capacity of the national authorities [not] increasing levels of intellectual property protection.”).

<sup>15</sup> Eur. Parl. res. of 10 March 2010 on the transparency and state of play of the ACTA negotiations, P7\_TA(2010)0058 (2010), available at <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2010-0058+0+DOC+XML+V0//EN&language=EN>.

ports. In this context, ACTA contains over a dozen provisions that require or encourage member countries to raise intellectual property enforcement standards on medicines, including on those medicines ultimately destined for developing countries. These concerns are described in more detail below.

#### A. Border Measures

One of ACTA's most serious threats to access to medicines comes from the raising of TRIPS requirements for border seizures of suspected products. The border provisions were some of the most controversial aspects of ACTA. The controversies were triggered by a series of wrongful uses of border measures in the EU to detain lawful shipments of generics to and from developing countries, now generally referred to as the "Dutch Seizures."<sup>16</sup> In recognition of the abusive nature of the Dutch Seizure cases, negotiators exempted patents from application of the Border Measures sections.<sup>17</sup> But medicines are also subject to trademark rules and medicines were wrongfully detained elsewhere in Europe on trademark grounds.<sup>18</sup> ACTA's dramatic expansion of TRIPS border measure requirements, including requiring the authorization of seizures where border agents "suspect" a medicine's label of being "confusingly similar" to a brand, will increase the risk of seizures of legitimate medicines.<sup>19</sup> The lowering of

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<sup>16</sup> See Kimberlee Weatherall, Politics, *Compromise, Text and the Failures of the Anti-Counterfeiting Trade Agreement*, 33 SYDNEY L. REV. 229, 245 (2011); Intervention by India, TRIPS Council, Agenda item 'M' – Other Business – Public Health dimension of TRIPS Agreement 2 (Feb. 4, 2009), <http://ip-watch.org/weblog/wp-content/uploads/2009/03/intervention-by-india.doc>; Statement by Brazil, TRIPS Council, Agenda item 'M' – Other Business – Public Health dimension of TRIPS Agreement ¶15, 16 (Feb. 4, 2009), <http://ip-watch.org/weblog/wp-content/uploads/2009/03/intervention-by-brazil.pdf> (stating the importance of the TRIPS flexibilities for public health via their inclusion in the *Doha Declaration*, while noting that the actions of the Dutch authorities did not comport with those flexibilities).

<sup>17</sup> See ACTA Text–Dec. 3, 2010, *supra* note 3, art. 13 n.6 (stating "[t]he Parties agree that patents and protection of undisclosed information do not fall within the scope of this section").

<sup>18</sup> An example is a German case where drugs were seized for bearing the INN name (mandated for labels in most countries) that was thought to be "confusingly similar" to a brand name. See generally Press Release, Health Action International, *Another Seizure of Generic Medicines*, (June 5, 2009), available at <http://www.haiweb.org/19062009/5%20Jun%202009%20Press%20release%20Seizure%20of%20generic%20medicines%20in%20Frankfurt.pdf>.

<sup>19</sup> *Compare* Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, art. 58, 108 Stat. 4809, 1869 U.N.T.S. 299 [hereinafter TRIPS] (requiring authorization to seize suspected counterfeit trademark goods in response to *prima facie* evidence from the

minimum standards for procedural rights and evidence before seizures may also implicate international and European human rights norms governing fair trials and takings of property.<sup>20</sup>

### B. Injunctions And Provisional Measures

ACTA expands injunction and provisional measures requirements that could stop flows of legitimate medicines within and beyond member countries, even with no determination of an intellectual property violation.<sup>21</sup> Specifically:

- While TRIPS permits equitable relief solely with respect to goods entering the channels of commerce within a country’s jurisdictional territory,<sup>22</sup> ACTA expands injunction requirements to include the prevention of any alleged infringement, including infringements taking place wholly outside the ACTA member country.
- ACTA extends TRIPS requirements to authorize provisional measures from actual infringements to “suspect” goods,<sup>23</sup> thus lowering the evidentiary threshold under which medicines and other goods may be subject to provisional orders interrupting supply.
- ACTA’s injunction requirements apply to patents, unless expressly exempted by an individual country.<sup>24</sup>

right holder, and allowing, but not requiring, *ex officio* restraints of imports), with ACTA Text–Dec. 3, 2010, *supra* note 3, art. 13 n.6 (stating “[t]he Parties agree that patents and protection of undisclosed information do not fall within the scope of this section”); *id.* art. 16:1(a) (stating that Parties “shall adopt” procedures where its customs authorities suspend the release of suspect goods on their own initiative); *id.* art. 16:2 (omitting any reference to infringements of domestic or foreign intellectual property law);

<sup>20</sup> Compare TRIPS art. 58 (noting that competent authorities may act upon their own initiative in suspending the release of goods when they have acquired *prima facie* evidence of infringement), with ACTA Text–Dec. 3, 2010, *supra* note 3, arts. 16:1(a), 16:2(b), 17:1 (mentioning a *prima facie* evidentiary requirement for suspensions only in the case of requests by right holders, not when customs authorities act on their own).

<sup>21</sup> See ACTA Text–Dec. 3, 2010, *supra* note 3, art. 12:1(a) (stating that judicial authorities have the authority to order provisional measures to “prevent an infringement of any intellectual property right from occurring”).

<sup>22</sup> Compare TRIPS arts. 44.1, 50.1(a) (stating that judicial authorities have the authority to order injunctions and provisional measures to prevent infringing goods from entry into the channels of commerce “in their jurisdiction”), with ACTA Text–Dec. 3, 2010, *supra* note 3, arts. 8:1, 12:1(a) (including reference to the channels of commerce, but omitting the “in their jurisdiction” language).

<sup>23</sup> See ACTA Text–Dec. 3, 2010, *supra* note 3, art. 12:3 (“each Party shall provide that, in civil judicial proceedings, its judicial authorities have the authority to order the seizure or other taking into custody of suspect goods . . .”).

<sup>24</sup> See *id.* art. 7 n.2 (“A Party may exclude patents and protection of undisclosed information from the scope of this Section.”) (emphasis added).

Together, these expansions of authority require all member countries to put in place the basic legal elements similar to those used in the “Dutch seizures.” Specifically, they enable authorities in one country to issue injunctions preventing goods from entering commerce in a third country without that third country’s officials ever passing on whether the item would infringe its own laws. Because medicines contain trademarks as well as patents, merely eliminating all application of ACTA provisions to patents will not solve this problem.<sup>25</sup>

### *C. Third-Party Liability*

ACTA expands potential liability to third-parties that supply goods or services to medicines suppliers accused of infringing intellectual property rights. As discussed above, ACTA allows provisional measures (preliminary injunctions) against third parties to prevent an infringement from occurring by another party and allows injunctions against third parties to prevent goods that infringe an IP right from entering into the channels of commerce.<sup>26</sup>

The scope of third-parties that can be held liable is potentially very broad. In the pharmaceutical context, third parties potentially liable under ACTA standards could include distributors, shippers, procurement agents and component suppliers.<sup>27</sup> Third-party enforcement, including injunctions and other interruption of supplies based on a minimal level of suspicion, may deter various businesses in the supply chain from dealing in the trade of legitimate generic medicines.

### *D. Damages*

ACTA’s provisions on damages encourage courts to adopt punitive measures of damages that may over-deter generic companies from competing with brand holders, particularly in developing country markets. ACTA expands TRIPS requirements by delineating specific measures of damages that each member’s authorities “shall consider.”<sup>28</sup> The measures

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<sup>25</sup> See Directorate-General for External Policies, *The Anti-Counterfeiting Trade Agreement (ACTA): An Assessment*, 61, EXPO/B/INTA/FWC/2009-01/Lot7/12 (July 11, 2011) [hereinafter ACTA Assessment] (noting that trademarks are frequently litigated in the medicines market and that trademark concerns frequently hinder generic medicine market penetration)

<sup>26</sup> ACTA Text–Dec. 3, 2010, *supra* note 3, arts. 8:1, 12:1(a).

<sup>27</sup> Brook K. Baker, *ACTA: Risks of Third-Party Enforcement to Access to Medicines*, 26 AM. U. INT’L L. REV. 579, 581 (2011).

<sup>28</sup> Compare TRIPS art. 45 (suggesting methods of determining damages that judicial

suggested by ACTA, including lost profits and the “market price” or “suggested retail price” of a branded product,<sup>29</sup> are highly inappropriate for developing countries. This standard would apply to every trademark infringement action on a challenged label, and could apply as well in patent litigation. In a world where brand holders traditionally offer no discounts to developing countries for high priced medicines, setting damages for intellectual property violations based on these factors rewards exclusionary pricing and over-deters generic entry to the detriment of access to medicines concerns.

#### *E. Information Disclosure*

ACTA expands requirements to authorize disclosures of information to rights holders in ways that may deter companies from working with generic suppliers and may enable strategic litigation to create barriers to generic entry. ACTA’s TRIPS-plus requirements in this area include:

- Requiring disclosure of information about “alleged,” rather than proven, infringers;<sup>30</sup>
- Removing a TRIPS safeguard that countries need not grant information to rights holders if it “would be out of proportion to the seriousness of the infringement”;<sup>31</sup> and
- Extending the duty to disclose information to a much broader range of information, including that “regarding any person involved in any aspect of the infringement or alleged infringement,” and “regarding the means of production or the channels of distribution of the infringing or allegedly infringing goods or services.”<sup>32</sup>

In practical effect, the provisions could be used by right holders to discover details on distribution chains of generic companies and mount aggressive and expensive litigation against suppliers and intermediaries to deter generic entry into key markets.

#### *F. Criminal Offenses*

ACTA dramatically expands the scope of common trademark violations

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authorities may authorize), *with* ACTA Text–Dec. 3, 2010, *supra* note 2, arts. 9:3, 9:3(b) n.3 (including the TRIPS suggestions plus recommended formulas for calculating damages).

<sup>29</sup> See ACTA Text–Dec. 3, 2010, *supra* note 3, arts. 9:3(b) n.3.

<sup>30</sup> *Id.* art. 11.

<sup>31</sup> Compare TRIPS art. 47, *with* ACTA Text–Dec. 3, 2010, *supra* note 3, art. 11 (reducing the safeguard to a “justified request of the right holder”).

<sup>32</sup> ACTA Text–Dec. 3, 2010, *supra* note 3, art. 11.

that can be considered criminal, thus raising the risks for generic suppliers that rely on similar labeling to create consumer confidence and meet regulatory requirements. ACTA's definition of criminal offences for trademark infringement include the intentional importation and use of the *good* containing a counterfeited mark, rather than the act of counterfeiting itself.<sup>33</sup> One could thus be held liable under this standard by intentionally importing a good with a counterfeit label, even if that person did not intentionally create or use, or perhaps even know of, the counterfeit label itself. This could greatly expand the number of cases of trademark misuse that could be considered criminal, thus raising the (over-)deterrent effect of trademark law for importers of generic medicines and other goods.<sup>34</sup>

#### *G. Seizure And Destruction Of Goods*

ACTA requires that, "except in exceptional circumstances," all intellectual property infringing goods must be destroyed without compensation. This is a dramatic expansion of the TRIPS requirements for destruction of goods. ACTA could be interpreted to require that, for example, absent "exceptional circumstances," a medicine found to have a minor trademark infringement on a label be destroyed rather than re-labeled and re-sold. ACTA also expands criminal seizures from being a remedy for proven violations of criminal law to require seizures of "suspected" violations.<sup>35</sup> This expansion may have the effect of leading to more seizures of legitimate medicines, particularly when coupled with the expansion of criminal liability discussed above.

Each of these provisions is analyzed in more detail in the following Part, providing a section by section analysis of the ACTA text.

### III. SECTION BY SECTION ANALYSIS

This Part presents a section by section analysis of provisions in the ACTA agreement that may negatively impact access to medicines in developing countries. Each ACTA section identified is quoted in its applicable parts followed by a quotation of the provisions of TRIPS that bear on the same topic. An analysis section describes the ways in which the

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<sup>33</sup> Compare TRIPS art. 61 (providing for criminal procedures in the event of wilful trademark counterfeiting on a commercial scale), with ACTA Text–Dec. 3, 2010, *supra* note 3, art. 23:2 (adding the provision for criminal procedures in the event of willful *importation*) (emphasis added).

<sup>34</sup> See ACTA Assessment at 61.

<sup>35</sup> Compare TRIPS art. 61 (providing for criminal seizures in cases involving actual infringing goods), with ACTA Text–Dec. 3, 2010, *supra* note 3, art. 25.1 (discussing "suspect" goods and "alleged" offences).

ACTA text exceeds the minimum standards in the TRIPS agreement and may negatively impact access to medicines in developing countries.

A. *Chapter II, Section 2, fn. 2: CIVIL ENFORCEMENT (SCOPE OF PROVISIONS)*

**A Party may exclude patents and protection of undisclosed information from the scope of this Section.**

1. *Related TRIPS Provisions*

TRIPS Sec. 1, Art. 1(2) – Nature and Scope of Obligations

- For the purposes of this Agreement, the term "intellectual property" refers to all categories of intellectual property that are the subject of Sections 1 through 7 of Part II.

2. *Analysis*

Although TRIPS provisions cover a broad range of intellectual property rights, many of its enforcement and remedy provisions are limited to trademark counterfeiting and copyright piracy.<sup>36</sup> Public health advocates have been particularly concerned with new rules that would extend remedies and measures traditionally restricted to copyrights or trademark counterfeiting to patents. One key reason for concern is that patent violations are extremely technical and hard to detect. Extending enforcement measures that rely on non-expert determinations, remedies without full hearings, and extension of liability to third parties and intermediaries who may have no ability to detect patent law violations may over-deter business dealings with generic drug makers.

In early drafts of ACTA, there was no substantive discussion of the scope of the civil enforcement section.<sup>37</sup> There was first a suggestion to limit the scope to trademark counterfeiting and copyright piracy in an

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<sup>36</sup> See TRIPS art. 51 (only mentioning importation of counterfeit trademark or pirated copyright goods as subject to border measures).

<sup>37</sup> See Anti-Counterfeiting Trade Agreement: Informal Predecisional/Deliberative Draft, Jan. 18, 2010, art. 2.1, available at [http://www.laquadrature.net/files/201001\\_acta.pdf](http://www.laquadrature.net/files/201001_acta.pdf); ACTA Text–Apr. 2010, *supra* note 9 art. 2.1 (making no mention of the scope of intellectual property rights covered by the Article on civil enforcement measures).

August draft. But other parties, particularly the EU, promoted the use of ACTA to broaden the scope of international enforcement mandates to all intellectual property rights covered by TRIPS, including, especially, patents and geographic indicators.

The final draft of ACTA permits countries to exclude patents and undisclosed information from the scope of the civil enforcement section. This change from earlier leaked drafts significantly reduces some negative impacts on access to medicines.<sup>38</sup> However, it is important to note that the inclusion of patents and data protection within ACTA's enforcement mandates remains the default position. The provision that a country "may exclude" suggests that such exclusion should be the exception rather than the rule.<sup>39</sup> This language may thus encourage countries to apply the ACTA civil enforcement provisions to patents and data exclusivity, and could be used by trading partners for this purpose.<sup>40</sup> Allowing Parties to expand the focus of ACTA to patents or data protection can directly endanger the legitimate trade of generic products.<sup>41</sup>

*B. Chapter II, Section 2, Article 8, 1 – INJUNCTIONS*

**Each Party shall provide that, in civil judicial proceedings concerning the enforcement of intellectual property rights, its judicial authorities 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 goods that involve the infringement of an intellectual property right from entering into the channels of commerce.**

*1. Related TRIPS Provision*

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<sup>38</sup> See ACTA Assessment at 60.

<sup>39</sup> See Baker, *supra* note 27, at 594 (noting that the permissive nature of ACTA's exclusion of patents and data protection from the section on civil enforcement is ineffective unless a "a country actively chooses to exclude").

<sup>40</sup> See *id.* at 594 (remarking on the possibility of subtle pressure as a result of the presumptive inclusion of patents and data protection in the scope of civil enforcement, and more active pressure from influential trade partners with the aim of maintaining the inclusion).

<sup>41</sup> Public Comment, Generic Pharma. Assoc., Comments of the Generic Pharmaceutical Association on the Anti-Counterfeiting Trade Agreement 2 (Feb. 15, 2011), <http://www.regulations.gov/#!documentDetail;D=USTR-2010-0014-0113>.

TRIPS – Sec. 2, Art. 44(1) – Civil and Administrative Procedures and Remedies – Injunctions

- The judicial authorities shall have the authority to order a party to desist from an infringement, inter alia 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. Members are not obliged 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.

2. *Analysis*

ACTA expands injunction requirements for member countries in important respects. TRIPS requires that member countries have authority to prevent intellectual property infringing “imported” goods from “the channels of commerce in their jurisdiction.”<sup>42</sup> The provision is thus limited to goods entering the market of the country applying the procedure; it does not apply to exports or in-transit goods. In ACTA, these limitations are removed.<sup>43</sup> The words “imported” and “in their jurisdiction” are absent, leaving a duty to authorize injunctions to halt the flow of infringing goods into any commerce, whether or not such commerce is in the country’s jurisdiction.

Injunctions are a useful tool for reducing the prevalence of counterfeit goods in a market, but like all tools, they can be abused.<sup>44</sup> When applied to international trade, they can prevent market entry.<sup>45</sup> By mandating injunctions for goods not being imported into the country and not destined for that country’s markets, ACTA’s injunction provisions raise the possibility of aforementioned “Dutch seizure” type problems – i.e. where the authorities in one country issue injunctions preventing goods from entering commerce in a third country without that third country’s officials ever passing on whether the item would infringe its own laws.<sup>46</sup>

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<sup>42</sup> See TRIPS art. 44:1 (only mentioning importation of counterfeit trademark or pirated copyright goods as subject to border measures).

<sup>43</sup> See ACTA Text–Dec. 3, 2010, *supra* note 3, art. 8:1 (applying injunctive measures to all infringing goods that might enter into the channels of commerce, with no limitation to imports).

<sup>44</sup> See ACTA Assessment at 61.

<sup>45</sup> *Id.* at 60.

<sup>46</sup> See Weatherall, *supra* note 16, at 249 (explaining the danger of “in-transit” enforcement as the “extraterritorial application of the transit country’s” intellectual

The ACTA language also eliminates the second part of the TRIPS injunction language providing a safeguard not obliging members to authorize injunctions in the event that a person does not have “reasonable grounds to know that dealing in such subject matter would entail the infringement of an intellectual property right.”<sup>47</sup> Since TRIPS safeguards are included for other provisions of ACTA, the exclusion of an important safeguard here raises troubling interpretative questions about the negotiators’ intent.

Also of great concern is the extension of mandatory injunction authority against third parties. In the realm of the generics trade, these third-parties include active pharmaceutical ingredient (“API”) suppliers, which provide materials for the manufacture of pharmaceuticals, and transporters and registrants involved in the commercial and legal aspects of bringing generic pharmaceuticals to market.<sup>48</sup> The application of injunctive and provisional measures to third parties associated with drugs alleged to have infringed on a patent or trademark may deter their involvement in the generics trade.

*C. Chapter II, Section 2, Article 9, 1 – DAMAGES*

**Each Party shall provide that, in civil judicial proceedings concerning the enforcement of intellectual property rights, its judicial authorities have the authority to order the infringer who, knowingly or with reasonable grounds to know, engaged in infringing activity to pay the right holder damages adequate to compensate for the injury the right holder has suffered as a result of the infringement. In determining the amount of damages for infringement of intellectual property rights, a Party’s judicial authorities shall have the authority to consider, inter alia, any legitimate measure of value the right holder submits, which may include lost profits, the value of the infringed goods or services measured by the market price, or the suggested retail price.**

*1. Related TRIPS Provisions*

TRIPS Sec. 2, Art. 45(1) – Civil and Administrative Procedures and Remedies – Damages

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property rights).

<sup>47</sup> See TRIPS art. 44:1.

<sup>48</sup> Baker, *supra* note 27, at 581.

- The judicial authorities shall have the authority to order the infringer to pay the right holder damages adequate to compensate for the injury the right holder has suffered because of an infringement of that person's intellectual property right by an infringer who knowingly, or with reasonable grounds to know, engaged in infringing activity.

## 2. Analysis

The ACTA provision on damages expands TRIPS requirements by delineating specific measures of damages that each member's authorities "shall consider."<sup>49</sup> The measures suggested by ACTA, including lost profits of the rights holder and the "market price" or "suggested retail price" "submitted by the right holder," are highly inappropriate for developing countries as they reinforce exclusionary pricing incentives.

It is recognized that intellectual property monopolies on needed medicines in middle-income countries promote profit-maximizing pricing to the elite segment of the population (e.g. top 10% or so of the economy).<sup>50</sup> To promote access to affordable medications, developing countries must adopt policies that require or incentivize intellectual property holders to allow competition or set prices much lower than the profit maximizing level.<sup>51</sup> Setting damages for infringements of patents or other intellectual property on medicines in developing countries at "lost profit" or the retail price demanded by the supplier works directly counter to this essential public health policy. Such measures would routinely overcompensate brand name drug suppliers for socially harmful pricing strategies and over-deter generics from legitimately entering markets.

This provision can be contrasted with measures of damages that would flow from access to medicines concerns and human rights. For example, many patent laws, especially in developing countries, require rights holders to work the invention by serving the entire market on reasonable terms.<sup>52</sup>

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<sup>49</sup> Compare TRIPS art. 45 (suggesting methods of determining damages that judicial authorities may authorize), with ACTA Text–Dec. 3, 2010, *supra* note 3, arts. 9:3, 9:3(b) n.3 (including the TRIPS suggestions plus recommended formulas for calculating damages).

<sup>50</sup> See Sean Flynn et al., *An Economic Justification of Open Access to Essential Medicine Patents in Developing Countries*, 37 J.L. MED. & ETHICS 184, 190 (2009) (indicating that a drug monopolist in developing with high levels of inequality will maximize revenue by selling at a high price with only the rich able to pay).

<sup>51</sup> See *id.* at 191 (demonstrating that the grant of open licenses on patents for essential medicines to permit competition allows markets to decrease prices toward the marginal cost of producing the drugs).

<sup>52</sup> See *id.* at 192 (describing the order by the South African Competition Commission

An incentive to meet working requirements could be furthered by setting infringement damages at very low levels where the infringer supplies markets left unserved by the intellectual property holder. Such a rule would reduce risk and promote entry for generic producers seeking to serve poor communities and severe needs. ACTA works counter to this goal.

*D. Chapter II, Section 2, Article 9, 2 – DAMAGES*

**At least in cases of copyright or related rights infringement and trademark counterfeiting, each Party shall provide that, in civil judicial proceedings, its judicial authorities have the authority to order the infringer to pay the right holder the infringer's profits that are attributable to the infringement. A Party may presume those profits to be the amount of damages referred to in paragraph 1.**

*1. Related TRIPS Provisions*

TRIPS Part III, Sec. 2, Art. 45(2) – Civil and Administrative Procedures and Remedies – Damages

- The judicial authorities shall also have the authority to order the infringer to pay the right holder expenses, which may include appropriate attorney's fees. In appropriate cases, Members may authorize the judicial authorities to order recovery of profits and/or payment of pre-established damages even where the infringer did not knowingly, or with reasonable grounds to know, engage in infringing activity.

*2. Analysis*

ACTA removes the internal safeguard from the TRIPS requirement on restitution of profits that such awards only be in “appropriate cases.”<sup>53</sup> It is unclear how the removal of this internal safeguard will be interpreted. One possibility is that it could prohibit appropriate exceptions to damages measures, such as the standard discussed above making damages

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that authorized any person seeking to manufacture generic versions of certain patented medicines in exchange for a “reasonable royalty”) (quoting Media Release, South Africa Competition Commission, Competition Commission Finds Pharmaceutical Firms in Contravention of the Competition Act (October 16, 2003), <http://www.wcl.american.edu/pijip/documents/MediaRelease.doc>).

<sup>53</sup> Compare TRIPS art. 45, with ACTA Text–Dec. 3, 2010, *supra* note 3, art. 9(2).

determinations in reference to whether the infringer is supplying markets left unserved by the infringer. This section also appears intended to expand the use of damage measures in Article 9(2), identified as problematic for access to medicines concerns above.

*E. Chapter II, Section 2, Article 9, 3(b), fn. 3: DAMAGES*

**The presumptions referred to in subparagraph 3(b) may include a presumption that the amount of damages is: (i) the quantity of the goods infringing the right holder’s intellectual property right in question and actually assigned to third persons, multiplied by the amount of profit per unit of goods which would have been sold by the right holder if there had not been the act of infringement; or (ii) a reasonable royalty; or (iii) a lump sum on the basis of elements such as at least the amount of royalties or fees which would have been due if the infringer had requested authorization to use the intellectual property right in question.**

*1. Related TRIPS Provisions*

TRIPS Sec. 2, Art. 45(2) – Civil and Administrative Procedures and Remedies – Damages

- The judicial authorities shall also have the authority to order the infringer to pay the right holder expenses, which may include appropriate attorney's fees. In appropriate cases, Members may authorize the judicial authorities to order recovery of profits and/or payment of pre-established damages even where the infringer did not knowingly, or with reasonable grounds to know, engage in infringing activity.

*2. Analysis*

ACTA encourages damages to be calculated based on “the quantity of the goods infringing the right holder’s intellectual property right . . . multiplied by the amount of profit per unit of goods which would have been sold by the right holder . . .”<sup>54</sup> This could be a very invidious standard in many access to medicines cases. For example, pharmaceutical companies might serve high-risk/low-income countries – e.g. those with a GDP per

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<sup>54</sup> ACTA Text–Dec. 3, 2010, *supra* note 3, art. 9:3(b) n.3.

capita below one dollar a day and an AIDS rate of 20 percent of the adult population – with a branded AIDS drug at a price of \$12,000 per year. If an Indian supplier entered such a market and offered a generic drug at a price of less than \$90 a year, but did so with a label that was found to have technically infringed on the trademark of the rights owner, what amount damages should be awarded? Multiplying the number of highly demanded generic units by the branded drug’s asking price would result in a damage award higher than the company could have ever received through marketing its own product. Such exorbitant damage awards go beyond mere deterrence of technical infringement and can instead prevent a generic manufacturer from entering an at-risk market entirely.

It is noteworthy that the options for damage calculations include one that is fairly protective of access to medicines concerns. A damage calculation based on “(ii) a reasonable royalty”<sup>55</sup> linked to a percentage of the generic price can avoid the problems identified with retail or “market” price valuations. In the case above, the damage award here would be a reasonable percentage of the \$90 generic price, rather the difference between the \$90 sale and the \$12,000 expectation of the brand supplier. However, the fact that a legitimate generics manufacturer might be subject to trademark counterfeiting damages in the first place remains the area of greatest concern.

As in other areas of ACTA, the problem is not that this provision mandates the worst possible practices, but it does appear to encourage them. If the agreement is adopted, it will be important for technical assistance to be directed at explaining the full range of interpretive options available and encouraging developing countries to adopt those most protective of access to medicine concerns.

*F. Chapter II, Section 2, Article 11 – INFORMATION RELATED TO INFRINGEMENT*

**Without prejudice to its law governing privilege, 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, its judicial authorities have the authority, upon a justified request of the right holder, to order the infringer or, in the alternative, the alleged infringer, to provide to the right holder or to the judicial authorities, at least for the purpose of**

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<sup>55</sup> *Id.*

**collecting evidence, relevant information as provided for in its applicable laws and regulations that the infringer or alleged infringer possesses or controls. Such information may include information regarding any person involved in any aspect of the infringement or alleged infringement and regarding the means of production or the channels of distribution of the infringing or allegedly infringing goods or services, including the identification of third persons alleged to be involved in the production and distribution of such goods or services and of their channels of distribution.**

### 1. *Related TRIPS Provisions*

TRIPS Sec. 2, Art. 47 – Civil and Administrative Procedures and Remedies  
– Right of Information

- Members may provide that the judicial authorities shall have the authority, unless this would be out of proportion to the seriousness of the infringement, to order the infringer to inform the right holder of the identity of third persons involved in the production and distribution of the infringing goods or services and of their channels of distribution.

### 2. *Analysis*

ACTA dramatically expands requirements to authorize disclosure to rights holders of information on alleged infringers. The ACTA language repeats the TRIPS requirement that members have a mechanism to order proven infringers to turn over information to “identity of third persons involved in the production and distribution of the infringing goods or services.”<sup>56</sup> But ACTA expands this duty to:

- include “alleged” infringers,<sup>57</sup>
- remove the internal safeguard that countries need not grant such authority if it “would be out of proportion to the seriousness of the infringement,”<sup>58</sup>
- extend to a much broader range of information, including that “regarding any person involved in any aspect of the infringement or

<sup>56</sup> See TRIPS art. 47; ACTA Text–Dec. 3, 2010, *supra* note 3, art. 11.

<sup>57</sup> ACTA Text–Dec. 3, 2010, *supra* note 3, art. 11.

<sup>58</sup> Compare TRIPS art. 47, with ACTA Text–Dec. 3, 2010, *supra* note 3, art. 11 (reducing the safeguard to a “justified request of the right holder”).

alleged infringement,” and “regarding the means of production or the channels of distribution of the infringing or allegedly infringing goods or services”<sup>59</sup>

In deference to the privacy protections existing in some countries, ACTA makes this provision subject to members’ “law governing privilege, the protection of confidentiality of information sources, or the processing of personal data.”<sup>60</sup> But for countries without such protections, invasions of privacy and business confidentiality could be particularly invidious in the implementation of this section.

In practical effect, the provision could be used by right holders to discover details on distribution chains of generic companies and mount aggressive and expensive litigation against suppliers and intermediaries that deal with generic producers of allegedly infringing products. Applied to patents, the provision could be particularly troublesome since the actual determination of patent infringement is quite technical. But even applied to trademark infringement this provision is very concerning, since generic products often use labels, colors and other identifiers that are somewhat similar to brand products – to create consumer comfort with brand switching and maintain bioequivalence – while attempting to steer free of trademark violations. In this context, a great range of generic products could be subject to colorable allegations of trademark infringement even if the end products do not actually infringe.<sup>61</sup> Beyond expensive litigation, the information provisions could lead to harassment of members of their competitor’s distribution chains by right holders. These provisions, in conjunction with those concerning third-party enforcement, can allow for the destruction of generic medicines found to be infringing on a trademark (or patent if a regime permits). Intermediaries might also be subject to heightened threats of injunctions, provisional measures, and criminal sanctions.<sup>62</sup>

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<sup>59</sup> ACTA Text–Dec. 3, 2010, *supra* note 3, art. 11.

<sup>60</sup> *Id.*

<sup>61</sup> See generally Sean Flynn, *Counterfeit Versus “Confusingly Similar” Products*, PIJIP BLOG (May 7, 2010), <http://www.wcl.american.edu/pijip/go/pijip05072010> (analyzing the ambiguity present in determining whether a good is confusingly similar, counterfeit, or neither).

<sup>62</sup> See Baker, *supra* note 27, at 595 (explaining how an innocent third party supplier or distributor could be subject to criminal sanctions as a result of ACTA’s aiding and abetting provision).

## G. Chapter II, Section 2, Article 12, 1(a) – PROVISIONAL MEASURES

**Each Party shall provide that its judicial authorities have the authority to order prompt and effective provisional measures:**

- (a) against a party or, where appropriate, a third party over whom the relevant judicial authority exercises jurisdiction, 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;**

## 1. Related TRIPS Provisions

## TRIPS Sec. 3, Art. 50(1) – Provisional Measures

- 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; (b) to preserve relevant evidence in regard to the alleged infringement.

## 2. Analysis

ACTA and TRIPS both provide for provisional measures, but ACTA expands the obligation by requiring authorities to apply provisional measures against third parties where appropriate.<sup>63</sup> ACTA also eliminates the internal qualifier that provisional measures enjoining entry into streams of commerce be limited to such commerce “in their jurisdiction.”<sup>64</sup> Like Article 8, Injunctions, above, this expansion raises the possibility of “Dutch seizure” type actions of one country to halt the shipments of medicines or other goods to a third country, even with no determination that the good would violate the intellectual property laws in that third country. A single

<sup>63</sup> Compare TRIPS art. 50:1, with ACTA Text–Dec. 3, 2010, *supra* note 3, art. 12:1(a) (expanding the reach of provisional measures to third parties).

<sup>64</sup> Compare TRIPS art. 50.1(a) (stating that judicial authorities have the authority to order provisional measures to prevent infringing goods from entry into the channels of commerce “in their jurisdiction”), with ACTA Text–Dec. 3, 2010, *supra* note 3, art. 12:1(a) (including reference to the channels of commerce, but omitting the “in their jurisdiction” language).

intermediary in a generics chain can have infringement alleged and related third parties can have provisional measures enacted against them. These provisional measures might require generic industry intermediaries, including active pharmaceutical ingredient manufacturers and shippers, to cease business with generics firms to prevent “future” infringement – something that might cause irreparable harm to the generics market.<sup>65</sup>

The ACTA text fails to incorporate other sections of TRIPS Article 50 that reflect a more balanced concern for those subject to seizures. ACTA fails to incorporate, for example, Article 50(6) requiring provisional measures to be revoked “if proceedings leading to a decision on the merits of the case are not initiated within a reasonable period,” or 50(7) mandating “appropriate compensation” to the defendant of baseless suits “for any injury caused by these measures.”

As in other areas of ACTA, the scope of the provision applying “at least” to trademark and copyright issues suggests a preference default for applying the standards to patents and other disparate intellectual property doctrines as well. As discussed throughout this report, the application of remedies and injunctions to patent issues without adequate hearings and expert inquiry is inadvisable and should not be promoted even through soft-law encouragements.

#### *H. Chapter II, Section 2, Article 12, 3 – PROVISIONAL MEASURES*

**At least in cases of copyright or related rights infringement and trademark counterfeiting, each Party shall provide that, in civil judicial proceedings, its judicial authorities have the authority to order the seizure or other taking into custody of suspect goods, and of materials and implements relevant to the act of infringement, and, at least for trademark counterfeiting, documentary evidence, either originals or copies thereof, relevant to the infringement.**

#### *1. Related TRIPS Provisions*

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<sup>65</sup> See Baker, *supra* note 27, at 581 (predicting that necessary API suppliers, shippers, and funders could be deterred from involvement with generic producers); Peter Maybarduk, *ACTA and Public Health* 10 (Prog. on Info. Justice and Intellectual Prop. Working Paper No. 9, 2010), available at <http://digitalcommons.wcl.american.edu/research/9/> (describing the chilling effect the uncertain reach of injunctive measures could have on the generics market).

TRIPS Part III, Sec. 3, Art. 50(1)

- 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; (b) to preserve relevant evidence in regard to the alleged infringement.

## 2. Analysis

The final draft expands on TRIPS art. 50 to explicitly mandate authorization of seizures of “suspect” goods in the copyright/trademark-counterfeiting context during civil judicial proceedings.<sup>66</sup> Under this new standard, all goods suspected of infringement are subject to seizure in addition to the implements of their creation during proceedings on the merits. As a result, shipments of generic medicine related to those alleged to have infringed can be seized or their manufacture prevented with the seizure of necessary manufacturing apparatus. There is no restriction in this provision that goods seized be destined for a market within the jurisdiction of the enforcing country. Thus, this provision may be used to promote “Dutch seizure” type actions of one country to halt the shipments of medicines or other goods to a third country, even with no determination that the good would violate the intellectual property laws in that third country.

### 1. Chapter II, Section 3, Article 13, fn. 6, SCOPE OF BORDER MEASURES

**The Parties agree that patents and protection of undisclosed information do not fall within the scope of this Section.**

### 1. Related TRIPS Provisions

TRIPS Part III, Sec. 4, Art. 51 – SPECIAL REQUIREMENTS RELATED TO BORDER MEASURES – SUSPENSION OF RELEASE BY CUSTOMS AUTHORITIES [No limitations as to the scope of border measures.]

<sup>66</sup> Compare TRIPS art. 50:1, with ACTA Text–Dec. 3, 2010, *supra* note 3, art. 12:3 (“[E]ach Party shall provide that, in civil judicial proceedings, its judicial authorities have the authority to order the seizure or other taking into custody of suspect goods . . .”).

- Members shall, in conformity with the provisions set out below, adopt procedures to enable a right holder, who has valid grounds for suspecting that the importation of counterfeit trademark or pirated copyright goods may take place, to lodge an application in writing with competent authorities, administrative or judicial, for the suspension by the customs authorities of the release into free circulation of such goods. Members may enable such an application to be made in respect of goods which involve other infringements of intellectual property rights, provided that the requirements of this Section are met. Members may also provide for corresponding procedures concerning the suspension by the customs authorities of the release of infringing goods destined for exportation from their territories.

## 2. Analysis

Border measures are methods by which customs authorities of member nations can seize goods suspected of infringement of intellectual property rights.<sup>67</sup> In an effort to stave off complaints about ACTA from public health advocates, ACTA's provisions on border measures have been made inapplicable to patents.<sup>68</sup> This is a positive, but unfortunately limited change.<sup>69</sup> ACTA still contains a dramatic expansion of border measures requirements to all intellectual property rights in TRIPS not within this narrow exception.

ACTA's expansion of border measures beyond "counterfeit trademark or pirated copyright goods" will notably include requirements that countries authorize seizures of suspected "confusingly similar" trademarks.<sup>70</sup> "The inclusion of civil trademark claims in ACTA's border measures creates

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<sup>67</sup> See Weatherall, *supra* note 16, at 244 (defining border measures as "procedures for the detention, by customs authorities, of goods suspected of infringing intellectual property rights . . .").

<sup>68</sup> See ACTA Text–Dec. 3, 2010, *supra* note 3, art. 13 n.6 (stating "[t]he Parties agree that patents and protection of undisclosed information do not fall within the scope of this section").

<sup>69</sup> The language of exclusion of patents in the Border Measures chapter is stronger than in Civil Enforcement. Compare ACTA Text–Dec. 3, 2010, *supra* note 3, art. 7 n.2 (members "may exclude"), with *id.* art. 13 n.6 ("patents . . . do not fall within the scope" of border measures). *But cf.* Baker, *supra* note 27, at 593 (citing Council Regulation 1383/2003, 2003 O.J. (L 196) 7 (EC)) ("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>70</sup> See ACTA Assessment at 62 (noting that ACTA's treatment of similar or confusing trademarks could lead to issues with the generic trade).

risks for access to medicines similar to those raised by patents.”<sup>71</sup>

Unlike counterfeiting, in which trademarks must be willfully identical to the original mark, determination of infringing marks under the confusingly similar doctrine are quite fact and law intensive. And there is existing evidence of the wrongful use of this standard to delay shipments of needed medicines in Europe. German authorities used this ground to wrongfully halt a generic shipment of amoxicillin, the INN name, because the officials reasoned that it was confusingly similar to a trademarked name: “Amoxil.”<sup>72</sup> ACTA exports the doctrinal basis of these EU seizures to all member countries, raising the risk of similar seizures of legitimate generic medicines elsewhere.<sup>73</sup>

Aggressive enforcement of a right to preempt “similar” marks can also conflict with public health policy.<sup>74</sup> Such policy may promote the use of similar colors, shapes and names for branded and generic registered medicines to promote generic substitution and avoid patient confusion and prescription errors.<sup>75</sup>

*J. Chapter II, Section 3, Article 16 – BORDER MEASURES*

**1. Each Party shall adopt or maintain procedures with respect to import and export shipments under which:**

- (a) its customs authorities may act upon their own initiative to suspend the release of suspect goods; and**
- (b) where appropriate, a right holder may request its competent authorities to suspend the release of suspect goods.**

**2. A Party may adopt or maintain procedures with respect to suspect in-transit goods or in other situations where the goods are under customs control under which:**

- (a) its customs authorities may act upon their own initiative to suspend the release of, or to detain, suspect goods; and**
- (b) where appropriate, a right holder may request its**

<sup>71</sup> Maybarduk, *supra* note 65, at 27.

<sup>72</sup> See Press Release, Health Action International, *supra* note 18.

<sup>73</sup> See ACTA Assessment at 62.

<sup>74</sup> See *id.* at 61.

<sup>75</sup> See generally Flynn, *Confusingly Similar*, *supra* note 61.

**competent authorities to suspend the release of, or to detain, suspect goods.**

### 1. Related TRIPS Provisions

TRIPS Sec. 4, Art. 58 – Special Requirements Related to Border Measures– Ex Officio Action

- Where Members require competent authorities to act upon their own initiative and to suspend the release of goods in respect of which they have acquired *prima facie* evidence that an intellectual property right is being infringed: (a) the competent authorities may at any time seek from the right holder any information that may assist them to exercise these powers; (b) the importer and the right holder shall be promptly notified of the suspension. Where the importer has lodged an appeal against the suspension with the competent authorities, the suspension shall be subject to the conditions, *mutatis mutandis*, set out at Article 55; (c) Members shall only exempt both public authorities and officials from liability to appropriate remedial measures where actions are taken or intended in good faith.

fn. 13

- It is understood that there shall be no obligation to apply such procedures to imports of goods put on the market in another country by or with the consent of the right holder, or to goods in transit.

### 2. Analysis

There is no requirement in TRIPS that members grant *ex officio* border seizure authority.<sup>76</sup> Where members do give such authorization for imported goods, such seizures require *prima facie* evidence, must be followed by prompt notification of the importer, and, by referencing Art. 55, must be released within 10 working days if the right holder does not initiate a proceeding on the merits.<sup>77</sup> There is “no obligation to apply” TRIPS border provisions to in-transit procedures.<sup>78</sup>

ACTA escalates border seizure requirements while reducing safeguards. ACTA mandates *ex officio* seizures, extends the scope of requirements to include exports, and makes no mention of a *prima facie* evidence

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<sup>76</sup> See TRIPS art. 58 (addressing Member states where competent authorities are required to act upon their own initiative to suspend the release of suspect goods).

<sup>77</sup> *Id.* arts. 58, 54, 55.

<sup>78</sup> *Id.* art. 51 n.13.

requirement or limited duration of the suspension pending a determination on the merits.<sup>79</sup> ACTA leaves the application of border seizure measures to in-transit shipments permissible, but does so with language encourages the practice.<sup>80</sup>

These provisions raise the potential for abuse and wrongful detention of legitimate products. Infringement claims based on similar marks, trademark dilution, unfair advantage or damage to reputation are fertile ground for abuse of in-transit enforcement measures.<sup>81</sup> Rights holders might use border measures to harass competitors producing legitimate generic pharmaceuticals, relying on unprepared and unqualified customs authorities to determine whether rights holder claims are reasonable or unfounded.<sup>82</sup> In-transit enforcement further complicates the potential for abuse or mistake.<sup>83</sup>

*K. Chapter II, Section 3, Article 17, 1 – APPLICATION BY THE RIGHT HOLDER*

**Each Party shall provide that its competent authorities require a right holder that requests the procedures described in subparagraphs 1(b) and 2(b) of Article 16 (Border Measures) to provide adequate evidence to satisfy the competent authorities that, under the law of the Party providing the procedures, there is prima facie an infringement of the right holder's intellectual property right, and to supply sufficient information that may reasonably be expected to be within the right holder's knowledge to make the suspect goods reasonably recognizable by the competent authorities. The requirement to provide sufficient information shall not unreasonably deter recourse to the procedures described in subparagraphs 1(b) and 2(b) of Article 16 (Border Measures).**

<sup>79</sup> See ACTA Text–Dec. 3, 2010, *supra* note 3, art. 16:1 (stating that Parties “shall adopt” measures where customs authorities may act on their own initiative to seize goods without any reference to evidence requirements or a duration of the seizure).

<sup>80</sup> See *id.* art. 16:2 (stating that Parties “may adopt” procedures as opposed to having no obligation).

<sup>81</sup> See ACTA Assessment at 61.

<sup>82</sup> Maybarduk, *supra* note 65, at 17.

<sup>83</sup> See Weatherall, *supra* note 16, at 249 (“(1) the law of the country in which the customs procedure is invoked; (2) the law of the origin country; (3) the law of the destination country; or (4) by some combination (requiring, for example, infringement according to local and foreign law) . . .”).

### 1. Related TRIPS Provisions

#### TRIPS Sec. 4, Art. 52 – Special Requirements Related to Border Measures – Application

- Any right holder initiating the procedures under Article 51 shall be required to provide adequate evidence to satisfy the competent authorities that, under the laws of the country of importation, there is prima facie an infringement of the right holder’s intellectual property right and to supply a sufficiently detailed description of the goods to make them readily recognizable by the customs authorities. The competent authorities shall inform the applicant within a reasonable period whether they have accepted the application and, where determined by the competent authorities, the period for which the customs authorities will take action.

### 2. Analysis

ACTA puts in place a streamlined system of border control that caters to rights holders while offering minimal safeguards or recourse for the wrongly accused. ACTA allows countries to rely on customs officials to perform complex adjudications on IPR issues at the border, rather than requiring judicial review,<sup>84</sup> and adds to TRIPS requirements a duty to ensure that evidence requirements for suspensions “shall not unreasonably deter recourse to the procedures.”<sup>85</sup> On the other side, ACTA fails to mention any concrete duration or required action for continued suspension,<sup>86</sup> omits requirements to indemnify importers for wrongful

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<sup>84</sup> ACTA defines “competent authorities” as including the “appropriate judicial, administrative, or law enforcement authorities . . .” ACTA Text–Dec. 3, 2010, *supra* note 3, art. 5(c). Given that “judicial authorities” are specifically mentioned throughout the earlier sections on provisional measures, it is striking that Parties are instead encouraged to use “competent authorities” with respect to border measures. *See id.* art. 19 (requiring that parties adopt procedures for its competent authorities to determine whether an infringement has occurred).

<sup>85</sup> ACTA Text–Dec. 3, 2010, *supra* note 3, art. 17:1. TRIPS contains similar safeguard language for rights holders in other provisions. *See* TRIPS arts. 54-56 (providing for safeguards for the importer, including prompt notice of seizure, a ten working day period for rights holders to begin proceedings on the merits and subsequent review, and the power for authorities to order rights holders to indemnify importers following wrongful or poorly conducted detention).

<sup>86</sup> ACTA does not repeat the TRIPS provision for the release of suspect goods if a proceeding on the merits has not been initiated within ten working days. Art. 19.

detention,<sup>87</sup> and fails to require notice to importers whose goods have been seized.<sup>88</sup>

Legitimate generic medicines have already been shown to be vulnerable to overzealous customs authorities and overbroad infringement definitions,<sup>89</sup> and ACTA's distinctly pro-rights holder border measure procedures exacerbate that danger. Generic medicines can be detained for a "reasonable" period at the request of rights holders with minimal evidence, by customs authorities with little experience in complex issues of trademark infringement. As ACTA has no requirement for notifying the manufacturers or importers, those subject to seizures will be less able to challenge wrongful detentions of legitimate generics. ACTA's additional failure to insist on adjudication on the merits by judicial authorities could result in countries with less means allowing border authorities to make determinations as to trademark infringement for those generics. These factors combined can delay or preclude the arrival of necessary drugs in countries with a serious need for affordable treatments.

*L. Chapter II, Section 3, Article 17, 2 – MULTIPLE SHIPMENTS*

**Each Party shall provide for applications to suspend the release of, or to detain, any suspect goods [7] under customs control in its territory. A Party may provide for such applications to apply to multiple shipments. A Party may provide that, at the request of the right holder, the application to suspend the release of, or to detain, suspect goods may apply to selected points of entry and exit under customs control.**

*1. Related TRIPS Provisions*

TRIPS Sec. 4 Article 51 – Special Requirements Related to Border Measures – Suspension of Release by Customs Authorities

- Members shall, in conformity with the provisions set out below, adopt procedures [13] to enable a right holder, who has valid

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<sup>87</sup> See *id.* art. 17:4, 18, 20 (making no mention of indemnification of the defendant in the event of a faulty claim, despite mentioning abuse of procedures, assurance for the defendant, and remedies).

<sup>88</sup> See *id.* art. 17:3 (ensuring that the competent authorities inform the applicant of the status of the application, without giving consideration to the defendant whose goods are seized).

<sup>89</sup> See *supra* note 16.

grounds for suspecting that the importation of counterfeit trademark or pirated copyright goods [14] may take place, to lodge an application in writing with competent authorities, administrative or judicial, for the suspension by the customs authorities of the release into free circulation of such goods. Members may enable such an application to be made in respect of goods which involve other infringements of intellectual property rights, provided that the requirements of this Section are met. Members may also provide for corresponding procedures concerning the suspension by the customs authorities of the release of infringing goods destined for exportation from their territories.

## 2. *Analysis*

ACTA expands on TRIPS border measures by authorizing applications by rights holders for seizure of multiple shipments.<sup>90</sup> This does not appear to be a change in the underlying legal landscape – TRIPS did not prohibit such applications and ACTA is permissive in this regard. But including the concept in ACTA may encourage more countries to adopt procedures applicable to multiple shipments. The potential problem for access to medicines concerns is the increased risk of arbitrary seizures of products that may follow from broad authorizations of border interdiction.

### *M. Chapter II, Section 3, Article 20, 1 – DESTRUCTION OF GOODS*

**Each Party shall provide that its competent authorities have the authority to order the destruction of goods following a determination referred to in Article 19 (Determination as to Infringement) that the goods are infringing. In cases where such goods are not destroyed, each Party shall ensure that, except in exceptional circumstances, such goods are disposed of outside the channels of commerce in such a manner as to avoid any harm to the right holder.**

#### 1. *Related TRIPS Provisions*

TRIPS Sec. 4, Art. 46. Other Remedies

- In order to create an effective deterrent to infringement, the judicial authorities shall have the authority to order that goods that they have

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<sup>90</sup> See ACTA Text–Dec. 3, 2010, *supra* note 3, art. 17:2.

found to be infringing be, without compensation of any sort, disposed of outside the channels of commerce in such a manner as to avoid any harm caused to the right holder, or, unless this would be contrary to existing constitutional requirements, destroyed. The judicial authorities shall also have the authority to order that materials and implements the predominant use of which has been in the creation of the infringing goods be, without compensation of any sort, disposed of outside the channels of commerce in such a manner as to minimize the risks of further infringements. In considering such requests, the need for proportionality between the seriousness of the infringement and the remedies ordered as well as the interests of third parties shall be taken into account. In regard to counterfeit trademark goods, the simple removal of the trademark unlawfully affixed shall not be sufficient, other than in exceptional cases, to permit release of the goods into the channels of commerce.

## 2. Analysis

ACTA requires that, “except in exceptional circumstances,” all infringing goods be “disposed of outside the channels of commerce.”<sup>91</sup> The language in ACTA removes a key TRIPS safeguard, that “[i]n considering such requests, the need for proportionality between the seriousness of the infringement and the remedies ordered as well as the interests of third parties shall be taken into account.” ACTA could be interpreted to require that, for example, absent “exceptional circumstances,” a medicine found to have a minor trademark infringement on a label be destroyed rather than re-labeled and re-sold. ACTA also removes mention of a safeguard for the accused present in TRIPS art. 59: the “right of the defendant to seek review by judicial authority” of any decision to dispose of infringing goods.<sup>92</sup>

## N. Chapter II, Section 3, Article 22(a) – DISCLOSURE OF INFORMATION

**a Party may authorize its competent authorities to provide a right holder with information about specific shipments of goods, including the description and quantity of the goods, to assist in the detection of infringing goods;**

<sup>91</sup> See ACTA Text–Dec. 3, 2010, *supra* note 3, art. 25:3.

<sup>92</sup> Compare TRIPS art. 59, with ACTA Text–Dec. 3, 2010, *supra* note 3, arts. 19, 25:3 (failing to mention mechanisms for the appeal or review of determinations of infringement and resulting orders of destruction).



### 1. *Related TRIPS Provisions*

#### TRIPS Sec. 4, Art. 57 – Special Requirements Related to Border Measures – Right of Inspection and Information

- Without prejudice to the protection of confidential information, Members shall provide the competent authorities the authority to give the right holder sufficient opportunity to have any goods detained by the customs authorities inspected in order to substantiate the right holder’s claims. The competent authorities shall also have authority to give the importer an equivalent opportunity to have any such goods inspected. Where a positive determination has been made on the merits of a case, Members may provide the competent authorities the authority to inform the right holder of the names and addresses of the consignor, the importer and the consignee and of the quantity of the goods in question.

### 2. *Analysis*

TRIPS requires member countries to have the authority “to give the right holder sufficient opportunity to have any goods detained by the customs authorities inspected” to substantiate any claims of infringement.<sup>93</sup> TRIPS includes a balancing provision giving the importer this same opportunity.<sup>94</sup> ACTA adds that members “may . . . provide a right holder with information about specific shipments of goods.”<sup>95</sup> There is nothing in TRIPS that would appear counter to such authorization within a member state and therefore this section does not appear to alter the legal background rules. Nonetheless, its inclusion in ACTA may encourage countries to grant such authorization. The new ACTA provision is notably one-sided – it includes an information right for the rights holder, but no comparable right or protection for the importer. This provision lends itself to abuse, as rights holders can seek out legitimate or technically infringing shipments of necessary generics and request for the detention of all of these shipments by the low evidentiary standard set out in Article 17.

### *O. Chapter II, Section 4, Article 23 – CRIMINAL OFFENCES*

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<sup>93</sup> TRIPS art. 57.

<sup>94</sup> *Id.*

<sup>95</sup> ACTA Text–Dec. 3, 2010, *supra* note 3, art. 22(a).

**1. Each Party shall provide for criminal procedures and penalties to be applied at least in cases of wilful trademark counterfeiting or copyright or related rights piracy on a commercial scale.<sup>[9]</sup> For the purposes of this Section, acts carried out on a commercial scale include at least those carried out as commercial activities for direct or indirect economic or commercial advantage.**

<sup>[fn 9]</sup> Each Party shall treat wilful importation or exportation of counterfeit trademark goods or pirated copyright goods on a commercial scale as unlawful activities subject to criminal penalties under this Article. A Party may comply with its obligation relating to importation and exportation of counterfeit trademark goods or pirated copyright goods by providing for distribution, sale or offer for sale of such goods on a commercial scale as unlawful activities subject to criminal penalties.

**2. Each Party shall provide for criminal procedures and penalties to be applied in cases of wilful importation and domestic use, in the course of trade and on a commercial scale, of labels or packaging:**

**(a) to which a mark has been applied without authorization which is identical to, or cannot be distinguished from, a trademark registered in its territory; and**

**b) which are intended to be used in the course of trade on goods or in relation to services which are identical to goods or services for which such trademark is registered.**

### *1. Related TRIPS Provisions*

#### TRIPS Sec. 5, Art. 61 – Criminal Procedures

- Members shall provide for criminal procedures and penalties to be applied at least in cases of wilful trademark counterfeiting or copyright piracy on a commercial scale. Remedies available shall include imprisonment and/or monetary fines sufficient to provide a deterrent, consistently with the level of penalties applied for crimes of a corresponding gravity. In appropriate cases, remedies available shall also include the seizure, forfeiture and destruction of the infringing goods and of any materials and implements the

predominant use of which has been in the commission of the offence. Members may provide for criminal procedures and penalties to be applied in other cases of infringement of intellectual property rights, in particular where they are committed wilfully and on a commercial scale.

## 2. Analysis

ACTA expands the definition of criminal offences for trademark infringement by shifting the intent standard. The TRIPS criminal standard for trademark was limited to “willful trademark counterfeiting.”<sup>96</sup> The most logical reading of TRIPS is that the intent modifies counterfeiting – i.e. criminal counterfeiting is the intentional creation or use of an unauthorized identical mark. ACTA shifts the intent standard from the use of the mark to the act of importation and use of the *good*. At least in plain language terms, one could meet the ACTA definition of a crime by intentionally importing a good with a counterfeit label, even if that person did not intentionally create or use the counterfeit label itself; indeed even if it was unknown that the label was counterfeit.<sup>97</sup> This has the potential to greatly expand the number of cases of trademark misuse that could be considered criminal, including the use and trade in parallel imported goods.

The potential extension of ACTA to the regulation of parallel imports puts it at odds with the European Parliament’s resolution on the proposed “directive on criminal measures aimed at ensuring the enforcement of intellectual property rights” (“IPRED2”). Under that resolution, member states are prohibited from applying criminal sanctions to cases of the “parallel importation of original goods which have been marketed with the agreement of the right-holder in a country outside the European Union.”<sup>98</sup> Parallel imports by definition carry the exact labeling as the original good. If the rights holder succeeds in declaring the labels on such goods to be counterfeit by virtue of their use in parallel imports without authorization of the right holder, then the standard for criminalization under ACTA could be met even without any intent to make or use the counterfeit label. The intent to import the good would be sufficient to meet the criminality

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<sup>96</sup> TRIPS art. 61.

<sup>97</sup> See ACTA Assessment at 62 (discussing the potential issues from confusingly similar trademarks).

<sup>98</sup> European Parliament legislative resolution of 25 April 2007 on the amended proposal for a directive of the European Parliament and of the Council on criminal measures aimed at ensuring the enforcement of intellectual property rights, P6\_TA(2007)0145, available at <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P6-TA-2007-0145+0+DOC+XML+V0//EN&language=EN#BKMD-12>

requirement.<sup>99</sup> ACTA's Article on criminal measures for counterfeiting can be interpreted in a similar vein, as they extend to cases of counterfeiting on a commercial scale.<sup>100</sup> This includes commercial activities carried out for indirect commercial benefit.<sup>101</sup> The European Parliament's position is that acts performed by private and not-for-profit purposes should be excluded from the scope of enforcement directives in the European Union, particularly IPRED2.<sup>102</sup> ACTA would seem to contradict that position.

The resulting effect of both of these criminal offence provisions could be the application of criminal measures for individuals or groups seeking to save money by parallel importing of medicines. In the trademark infringement case, criminal sanctions could result if the medicine labels are unlicensed in the country of import. In the aforementioned example involving counterfeit labels, criminal sanctions could attach because the importers indirectly benefitted commercially – they paid less for the imported drugs. No matter the textual basis for the alleged crime, the result remains the same – that innocent parties seeking affordable medicines are potentially subject to costly criminal prosecution.

The impact may extend to third parties who supply or work with generic producers, thanks to a provision that ensures criminal liability for “aiding and abetting.”<sup>103</sup> “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>104</sup> Like the third party enforcement provisions present in other portions of ACTA, this provision could deter involvement in generic manufacturing by necessary partners, raise prices, and hinder accessibility worldwide.

*P. Chapter II, Section 4, Article 25, 1 – SEIZURE, FORFEITURE, AND DESTRUCTION*

**With respect to the offences specified in paragraphs 1, 2, 3, and 4 of Article 23 (Criminal Offences) for which a Party provides criminal procedures and penalties, that Party shall provide that its competent authorities have the authority to order the seizure of suspected counterfeit trademark goods or pirated copyright goods,**

<sup>99</sup> See European Academics, *supra* note 11, ¶8.

<sup>100</sup> See ACTA Text–Dec. 3, 2010, *supra* note 3, art. 23:1.

<sup>101</sup> *Id.*

<sup>102</sup> See ACTA Assessment at 62 (discussing the potential issues from confusingly similar trademarks).

<sup>103</sup> See ACTA Text–Dec. 3, 2010, *supra* note 3, art. 23:4.

<sup>104</sup> Baker, *supra* note 27, at 595.

**any related materials and implements used in the commission of the alleged offence, documentary evidence relevant to the alleged offence, and the assets derived from, or obtained directly or indirectly through, the alleged infringing activity.**

1. *Related TRIPS Provisions*

TRIPS Part III, Sec. 5, Art. 51

- Members shall provide for criminal procedures and penalties to be applied at least in cases of wilful trademark counterfeiting or copyright piracy on a commercial scale. Remedies available shall include imprisonment and/or monetary fines sufficient to provide a deterrent, consistently with the level of penalties applied for crimes of a corresponding gravity. In appropriate cases, remedies available shall also include the seizure, forfeiture and destruction of the infringing goods and of any materials and implements the predominant use of which has been in the commission of the offence. Members may provide for criminal procedures and penalties to be applied in other cases of infringement of intellectual property rights, in particular where they are committed wilfully and on a commercial scale.

2. *Analysis*

ACTA alters the TRIPS standard by making criminal seizures of property a remedy for “suspected” violations, instead of proven infringements.<sup>105</sup> This expansion may have the effect of leading to more criminal seizures of legitimate medicines, particularly when coupled with the expansion of criminal liability discussed above.

*Q. Chapter II, Section 4, Article 25, 2 – SEIZURE, FORFEITURE, AND DESTRUCTION*

**Where a Party requires the identification of items subject to seizure as a prerequisite for issuing an order referred to in paragraph 1, that Party shall not require the items to be described in greater detail than necessary to identify them for**

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<sup>105</sup> See ACTA Text–Dec. 3, 2010, *supra* note 3, art. 25:1 (describing the applicability of the provision on seizure to “suspect counterfeit trademark goods” and referring to “alleged” offences).

<b>the purpose of seizure.</b>
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1. *Related TRIPS Provisions*

[N/A]

2. *Analysis*

In order to obtain a seizure of goods for merely being “suspected” of a criminal violation, ACTA imposes a relatively low standard of proof – ensuring that a country “shall not require the items to be described in greater detail than necessary to identify them for the purpose of seizure.”<sup>106</sup> This heightened concern for burdens on right holders requesting criminal seizures of property conflicts with civil and human rights that demand high evidentiary thresholds for criminal seizures. There is no mention here of safeguards for the rights and interests of importers – an imbalance that may lead to more unjustified criminal seizures of medicines in ACTA countries.

#### CONCLUSION

ACTA proposes to require a broad range of TRIPS-plus measures on intellectual property enforcement that will predictably lead to increased burdens on the cross-border trade of medicines to and from developing countries. The agreement was negotiated behind closed doors within minimum input from public health and other public interest representatives. These substance and procedural flaws in the agreement violate specific commands in multiple EU Parliament resolutions.

Taking into account the analysis above, including of the human rights obligations and international policy commitments of the EU Parliament, this opinion advises that the EU Parliament withhold consent to the ACTA agreement. Parliament should instead reassert the demands of its March 10, 2010, resolution that international intellectual property policy be committed to “well-established international bodies, such as WIPO and WTO, which have established frameworks for public information and consultation” and that any agreements resulting from such process not include TRIPs-plus measures that raise barriers to cross-border trade in or access to affordable medications.

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<sup>106</sup> ACTA Text–Dec. 3, 2010, *supra* note 3, art. 25:2.

