



## A BLANK CHEQUE FOR ABUSE

### The Anti-Counterfeiting Trade Agreement (ACTA) and its Impact on Access to Medicines

*Eight countries - Australia, Canada, Japan, Morocco, New Zealand, Singapore, South Korea and the United States – signed ACTA on 1<sup>st</sup> October 2011. The European Union and 22 of its Member States signed on 26<sup>th</sup> January 2012. Five EU Member States- Cyprus, Estonia, Germany, Netherlands and Slovakia - have not yet signed the agreement. For the agreement to become legally binding on a party it must first be signed and then ratified by that party. Within the EU, the agreement must be separately ratified by the European Parliament, individual Member States and the EU Council- this has not yet happened.<sup>1</sup>*

As a treatment provider, Médecins Sans Frontières (MSF) is deeply concerned about the impact of the enforcement agenda on the production and supply of affordable, legitimate medicines. **We urge contracting States not to sign or ratify ACTA unless all concerns related to access to medicines are fully addressed.**

#### The context

→ **MSF relies primarily on generic medicines procured internationally.** So too do the major procurers of AIDS medicines worldwide - the Global Fund and PEPFAR.<sup>2</sup> Many developing countries have no domestic pharmaceutical manufacturing capacity and governments and patients rely on imported generic medicines. Generic competition is the main driver of pharmaceutical price reductions.

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→ **It is a public health necessity that the trade in affordable and legitimate medicines functions smoothly and without undue burdens.** If a patient misses a lifesaving drug, even due to temporary delays, there can be potentially life-threatening health repercussions.

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→ **MSF has been increasingly concerned by the proliferation of enforcement measures that harm access to medicines** and which have been pushed in a number of different forms– as a part of free trade agreements, international treaties, domestic legislation and customs regulations.

ACTA is a part of this trend, and is the result of the intellectual property enforcement agenda advanced by rich countries, outside of multilateral norm-setting institutions.<sup>3</sup> The enforcement agenda blurs crucial distinctions between types of IP rights and provides excessive punishment, increasing the likelihood that wrongful searches, seizures and legal actions against legitimate suppliers of generic medicines will be carried out. As well it widens the scope of actors that could have penalties brought against them, so that the whole medicines supply chain becomes affected.

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→ **Overbroad enforcement measures can threaten access to medicines.** The impact of this has already been documented, for example in relation to the 2008 Anti-Counterfeit Act in Kenya<sup>4</sup> which is currently being by challenged people living with HIV.

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→ **International trade rules are clear on a countries' right to protect public health and in particular promote access to medicines for all.** The TRIPS Agreement is the major international agreement governing trade and intellectual property. The Doha Declaration, signed by all members of the World Trade Organization, affirms that TRIPS can and should be interpreted and implemented in a manner supportive of their right to promote public health. This includes in relation to intellectual property enforcement measures, such as the ones contained in ACTA.

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→ **The TRIPS Agreement already requires countries to introduce enforcement rules.** But crucially, the Agreement sets minimal rules. It does not require countries to go beyond this and adopt more restrictive measures that are known as 'TRIPS-plus'. ACTA contains TRIPS-plus measures, and does not contain sufficient safeguards to protect public health and access to medicines.

## **The impact of ACTA on access to medicines**

Although a number of provisions that were harmful to access to medicines in developing countries were removed during the negotiations, the final text remains problematic.

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→ **While it is claimed that ACTA will protect against falsified medicines by allowing countries and companies to take strong measures in trademark disputes, this may in fact impede access to genuine generic medicines.**

There are several issues here. First, not all trademark disputes amount to a public health problem. Only 'wilful trademark counterfeiting on a commercial-scale'<sup>5</sup> - a form of fraud with a deliberate intention to exactly copy a product's branding - presents a legitimate public health concern. The World Trade Organization itself distinguishes between 'trademark counterfeiting' and 'trademark infringement'. This means that trademark infringement disputes that companies may have over similar names or packaging by competitors cannot be considered as trademark counterfeiting.<sup>6</sup>

But ACTA blurs this distinction. This means it would require countries to impose stringent intellectual property (IP) enforcement measures for civil trademark confusion disputes.<sup>7</sup> Worryingly, disputes over allegations of similar sounding names or packaging are common in the medicines field, as companies will often choose brand names for medicines that sound inevitably similar, in that they are derived from the drug's international non-proprietary name (INN). Similar names and packaging are often even desirable to demonstrate medical equivalency, but they do not mean that the medicines are unsafe or indeed that there has been a trademark infringement.

ACTA even extends enforcement to patent challenges.<sup>8</sup> These IP infringements are generally commercial disputes where no inherent public health concerns exist. While patents and protection of undisclosed information are explicitly excluded from the border measures and criminal enforcement sections of the agreement—significantly reducing the negative effects on access to medicines,<sup>9</sup> a number of provisions apply to patents and data protection as the default position, with the precision that signatories to ACTA 'may exclude' them. As has been noted,<sup>10</sup> this suggests that such exclusion should be the exception and not the norm, and it is highly likely that such distinctions will be blurred in the course of negotiations with developing countries.

Lastly, ACTA's civil enforcement section may also allow expanded enforcement efforts based on fictional patent claims.<sup>11</sup> These efforts favour rights holders and contain few if any safeguards for defendants or third parties.

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**→ ACTA puts third parties that use medicines at the heart of an enforcement dispute—like distributors and even non-governmental organisations like MSF, or public health authorities—at risk of severe penalties.**

ACTA contains a number of provisions, which would expose third parties to the risk of enforcement in relation to allegations of trademark infringement and potentially patents infringements. Third parties are at risk of injunctions,<sup>12</sup> provisional measures,<sup>13</sup> and even criminal penalties, including imprisonment and severe economic losses.<sup>14</sup> This could implicate, for example, suppliers of active pharmaceutical ingredients (API) used for producing generic medicines; distributors and retailers who stock generic medicines; NGOs, such as MSF, who provide treatment; funders who support health programs; and drug regulatory authorities who examine medicines. These measures include powers for judicial authorities to issue orders against third parties to prevent suspected but not yet proved infringement.

These provisional measures would take immediate effect, and even if a court later found that there was in fact no infringement, the negative consequences for access to medicines will not be reversible. For example, an API manufacturer could be stopped from supplying a drug manufacturer; and medicines purchasers, like MSF, could be prevented from continuing to purchase or distribute the medicines.

All of these measures are TRIPS-plus and have potentially far-reaching consequences. They could act as a significant deterrent to anyone involved in the production, sale and distribution of affordable generic medicines. From the perspective of patients and access to medicines, this chilling effect on the entire production and supply system of generic medicines is of grave concern as it could limit the availability of affordable generic medicines in pharmacies or through treatment programmes.

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**→ ACTA allows the border detention of in-transit medicines destined for developing countries, which will interfere with the trade in legitimate medicines, and leaves trade in generic medicines open to disruption.**

While the border measures section of ACTA no longer includes patents, it still includes civil trademark infringement.<sup>15</sup> This means a customs official could decide to detain and even destroy an allegedly infringing good - *without any court oversight or even notification to the rights holder or the generic company alleged to have violated the trademark* - on the basis of the customs official's own view on whether the goods in question infringe a commercial trademark.<sup>16</sup>

The risks to access to medicines of such overbroad provisions have been recently highlighted when medicines were detained in Germany based on the wrong assumption that a generic medicine, using the required international non-proprietary name (INN) 'amoxicillin' to describe the contents, infringed GSK's trademark on the brand name Amoxil (which besides is itself a use of the INN). At the core of this detention was an expansive EU customs regulation designed to expand the enforcement of IP rights<sup>17</sup> that led to many other detentions of medicines in transit between developing countries which were not IP-protected in the source or destination countries.<sup>18</sup>

Under ACTA, too, even legitimate medicines just transiting through an ACTA member country could be temporarily or permanently seized.<sup>19</sup> *Ex officio* mechanisms without judicial review—and allowing the detention, seizure, and even destruction of goods—are susceptible to over-enforcement.<sup>20</sup> Civil trademark infringement is a very grey area of fact and degree that requires judicial oversight to resolve. It is not appropriate for untrained border guards acting *ex officio* to make determinations that courts are best suited to make - particularly in cases where the result of these determinations would be the denial of medicines to patients.

Rights holders could also use border measures as a commercial tactic to delay or destroy rivals' goods on a mere allegation of similar names, without a health threat, before a court hearing to determine whether their claim is in fact valid.

ACTA expands also the TRIPS requirement on border measures for import to cover export as well.<sup>21</sup> For countries which are exporters of generic medicines for the developing world, the application of border measures to exports threatens to disrupt the lifeline for patients.

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**→ ACTA undermines the role of the judiciary in protecting the right to health and balance private intellectual property rights with the larger public interest.**

ACTA allows for extra-judicial processes and fundamentally changes how courts and judges approach cases involving IP disputes. ACTA would limit due process for IP challenges by permitting the seizure and destruction of medicines without even advising the owner, or providing the owner the opportunity to respond, or mandating judicial oversight.<sup>22</sup> Such *ex parte* measures are manifestly susceptible to abuse.

Even where judicial process is outlined, the balance lies heavily in favour of the rights holder alleging infringement.<sup>23</sup> Under ACTA, judges have limited power to balance health

issues against the interests of private companies. Yet, many countries place the right to health above private IP rights.<sup>24</sup> This is explicitly recognised in the TRIPS Agreement where the judiciary is given the full scope to determine the appropriate remedy particularly where public interest is involved.

A court may decide for example on public health grounds that a commercial dispute should be resolved in the short term not by an injunction - which would stop the rival medicines being produced and could deprive patients of cheaper or adapted formulations - but by a requirement to monitor sales or pay royalties, the amount of which would be finalised when the court determines whether an infringement has in fact taken place. Or, as in the US, that royalties should be given instead of a permanent injunction on the basis of the public interest in having competition in medical devices.<sup>25</sup>

But ACTA requires injunctions to stop the distribution of goods even at the early stage of an infringement allegation - except where a national law prohibits it - and in some cases calls for the destruction of infringing goods.<sup>26</sup> In practical terms, this could mean effective and safe medicines are stopped from being produced or destroyed to protect company profits.

Further, unlike TRIPS, ACTA does not require judicial authorities to consider proportionality between the seriousness of the infringement and the interests of third parties when deciding what remedies to grant.

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**→ ACTA acts as a deterrent to the production and trade in generic medicines, as it provides for excessive punishment, shifts the risks entirely on to the generic manufacturer, and grants few protections against abuse.**

ACTA is imbalanced. On a mere allegation and not proof, *including allegation brought by a competitor*, generic suppliers allegedly infringing a trademark and potentially a patent may face the delay or destruction of goods, disproportionate damages, potential bankruptcy, and in some cases, even criminal proceedings.<sup>27</sup>

The severe punishment for infringement obstructs and deters legitimate generic competition by dramatically altering the risks faced by generic medicines manufacturers, intermediaries and third parties. By generally focusing on harsh remedies before infringement has been proven, ACTA seeks to shift the risk on to the generic manufacturers rather than waiting until the IP holder has proved its case. The possibility of issuing injunctions and seizing medicines on a mere suspicion of infringement is extremely problematic and goes beyond what is required under the TRIPS Agreement. This will have a chilling effect on the manufacturers of generic medicines.

Further, ACTA provides great incentives for abuse because of the greater access to information and the potential for competitive advantage, coupled with limited liability for abuse. There are few penalties for false accusations, and few protections for the alleged infringer.<sup>28</sup>

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**→ ACTA is a cynical exploitation of concerns around unsafe medicines and is not a legitimate response to the problem of falsified medicines.**

The spectre of harmful fake medicines is a concern that continues to be used to justify ACTA. Yet ACTA is not designed to deal with fraudulent, unsafe, and ineffective medicines; its purpose is to protect the commercial interest of companies that hold IP rights. There is one small area of overlap with fraudulent medicines, but even then the measures proposed would pose greater harm to access to legitimate generic medicines than they would act as a safeguard against fake medicines.

ACTA proponents consistently exploit public health concerns to advance business interests, in part by conflating profit-maximizing IP issues with true public health problems. The cynical use of public health concerns undermines faith in the commitment of proponents to tackle public health issues seriously. Further, because ACTA would inhibit generic competition, raise medicine prices and decrease the availability of generic medicines, it actually incentivizes the introduction of unsafe medicines to meet the demand from patients who have been cut off from access to safe, effective and affordable generic medicines due to over zealous IP enforcement measures. The WHO has recognized that high drug prices are a cause of counterfeit medicines: patients demand low-cost alternatives, and counterfeiters respond.<sup>29</sup>

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**→ ACTA will undermine the ability of developing country governments to apply the Doha Declaration to protect public health.**

ACTA is intended and structured as a norm-setting tool. In addition to being applicable to the negotiating parties, it is expected that other countries, including developing countries, will be pressured to become party to the agreement, mostly as a result of trade pressures.<sup>30</sup>

If enacted, it will minimize the flexibilities countries have under the TRIPS Agreement and the Doha Declaration 2001 to incorporate appropriate public health measures and balances in their laws.

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**→ ACTA has been negotiated in secret with little room for public engagement.**

Despite its anticipated far-reaching effects, over three years of secret negotiations, an official version of the negotiation text was only released once, in April 2010, after the text was leaked and the European Parliament criticized the secret negotiations.<sup>31</sup> Its application to countries with key trading ports means its impact will be felt even by countries not party to the treaty, if medicines are seized or detained in IP enforcement disputes.

It is also a blank cheque for the future. ACTA aims to institutionalize the ambitious norm-setting and secrecy on which it was founded. In a move that would circumvent open debate and due scrutiny: the agreement proposes an annual meeting of signatories where amendments to the Treaty can be negotiated.<sup>32</sup> Even some of the most contentious issues that have been removed during the negotiations could, within a year, be back in the text once ACTA is out of the public spotlight. Any future changes to ACTA must be subject to public scrutiny by all stakeholders and must receive parliamentary approval.

## **Conclusions and recommendations**

→ **ACTA is flawed, with fatal consequences on access to medicines:** ACTA locks in the most controversial aspects of US and EU intellectual property enforcement laws, and has insufficient safeguards to prevent abuse and protect the public.

→ **ACTA does nothing to address the problem of poor quality and unsafe medicines:** ACTA is an inappropriate and ineffective response with counterproductive consequences for developing countries.

→ **ACTA undermines existing international declarations to protect public health:** ACTA circumvents the Doha Declaration by restricting the right of countries to act in favour of access to medicines, imposes TRIPS-plus measures, and is not an appropriate standard for developing countries.

→ **ACTA should:**

- Not be signed and ratified by contracting States unless all concerns related to access to medicines are fully addressed.
- Only be applicable to wilful copyright and trademark counterfeiting on a commercial scale. It should exclude both patents and civil trademark infringement from the scope of the agreement.
- Not establish third party or aiding and abetting liability.
- Not include TRIPS-plus measures on civil and criminal enforcement mechanisms.
- Include protections against abuse, including judicial review, penalties for abusive litigation and baseless allegations, access to information for the alleged infringer, and the obligation to consider proportionality and the public interests in setting the remedy.
- Ensure that any institutional structure established through ACTA be open and transparent. It should not have the authority to amend ACTA without public scrutiny and approval from elected democratic bodies.

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<sup>1</sup> <http://ec.europa.eu/trade/creating-opportunities/trade-topics/intellectual-property/anti-counterfeiting/>

<sup>2</sup> PEPFAR has increasingly relied on generic medicines. In 2008 the proportion of generic medicines procured through PEPFAR approached 90%. From 2005-2008, PEPFAR estimated savings of \$325 million due to the purchase of generic medicines. Charles Holmes, *et al.*, Use of Generic Antiretroviral Agents and Cost Savings in PEPFAR Treatment Programs, *JAMA*. 2010;304(3):313-20.

<sup>3</sup> US and Japan initiated ACTA in 2006. ACTA is being negotiated by the US, EU and 27 member states, Japan, Canada, Australia, Mexico, Morocco, New Zealand, South Korea, Singapore, and Switzerland.

<sup>4</sup> 'FATAL FLAWS: How Kenya's 2008 Anti-Counterfeit Act could endanger access to medicines' A Médecins Sans Frontières briefing document (March 2010)  
[http://www.msfaccess.org/sites/default/files/MSF\\_assets/Access/Docs/ACCESS\\_briefing\\_FatalFlaws\\_Kenya\\_ENG\\_2010.pdf](http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_briefing_FatalFlaws_Kenya_ENG_2010.pdf)

<sup>5</sup> TRIPS Ch. III, Sec. 5, Art. 61.

<sup>6</sup> Originator pharmaceutical companies are increasingly seeking protection on various non-functional aspects of medicines, such as pill colour and shape, civil disputes over such matters will continue to arise. Regardless of whether similarly-named, coloured or shaped generic versions of medicines are ultimately found to infringe a valid trademark in civil litigation proceedings (and companies have the right to pursue these problems in the court), they need not, and indeed should not, be confused with counterfeit medicines. Adopting an overly-broad definition that would consider similarly named, coloured or shaped medicines to be counterfeit would likely hinder access to legitimate, safe, effective and affordable generic medicines

<sup>7</sup> ACTA Ch. II, Sec. 2, 3. Civil trademark disputes occur where one company accuses a competitor of having a trademark or packaging too similar to its own trademark. This has nothing to do with a deliberate intention to deceive with a fake medicine, and must be distinguished from the fight against counterfeit medicines. Civil trademark disputes will likely remain a common occurrence in the pharmaceutical field as companies will often choose brand names for medicines that sound inevitably similar, in that they are derived from the drug's international non-proprietary name (INN).

<sup>8</sup> ACTA Ch. II, Sec. 2. Footnote 2 provides that a Party *may* exclude patents and protection of undisclosed information from the scope of section dealing Civil Enforcement. This language is problematic as it only allows a Member State to exclude patents if it wants to do so. Otherwise, patents are included in the scope by default.

<sup>9</sup> ACTA Ch. II, Sec. 3, Art. 13, fn. 6 ("The Parties agree that patents and protection of undisclosed information do not fall within the scope of this Section."); Ch. II, Sec. 4, Art. 23 ("Each Party shall provide for criminal procedures and

penalties to be applied at least in cases of willful trademark counterfeiting or copyright or related rights piracy on a commercial scale.”).

<sup>10</sup> Sean Flynn and Bijan Madhani, *ACTA and Access to Medicines*, (10 June 2011) 13 at <http://goo.gl/Ge9VI>

<sup>11</sup> ACTA Ch. II, Section 2, Art. 8.1 and 12.1 dealing with injunctions and provisional measures. The risk that ACTA’s civil enforcement provisions will extend to all IP rights, including patents, still exists. If so, even though border agents will not be able to act unilaterally or at the immediate behest of drug companies to seize in-transit medicines, the patent holder will be able to go to court and seek the seizure and destruction of generic medicines based on a so-called manufacturing fiction. Under this fiction, even though the generic medicine is not patent protected in the country of manufacture or in the country of importation and use and even though the medicine is not commercialized in the transit territory, the courts apply a fiction that the medicine should be treated as if it had been manufactured in the transit country. This is the fiction still allowed under EU law and applied in the Netherlands, Germany, and France to intercept multiple shipments of Indian medicines destined for Latin America and Africa.

<sup>12</sup> ACTA Ch. II, Sec. 2, Art. 8.1: Injunctions.

<sup>13</sup> ACTA Ch. II, Sec. 2, Art. 12.1 (a).

<sup>14</sup> ACTA creates a third party aiding and abetting criminal liability: third parties can face criminal measures including prison terms and high monetary fines; the seizure, forfeiture, and/or destruction of goods and/or “any related materials and implements used in the commission of the alleged offense”. TRIPS includes no aiding and abetting liability in its criminal enforcement provision. Compare TRIPS Ch. III, Sec. 5, Art. 61 with ACTA Ch. II, Sec. 4, Arts. 23.4, Art. 25.1.

<sup>15</sup> ACTA Ch. II, Sec. 3, Art. 13: Scope of the Border Measures.

<sup>16</sup> ACTA Ch. II, Sec. 3, Art. 20. Destruction is available as a remedy, and through “competent authorities,” without specification of judicial oversight. This is a significant expansion from TRIPS. Under TRIPS, *ex officio* action is *permissible* to seek information from the right holder, promptly notify both parties, and order the destruction or disposal of infringing goods *with judicial review*. TRIPS III, Sec. 4, Arts. 58-59.

<sup>17</sup> EU Reg. 1383/2003. This Regulation is currently being amended and a proposed Regulation is released to discussion and consultation. Though some safeguard provisions are added in the proposed Regulation but it is still problematic and enables Custom authorities to detain generic drugs in transit.

<sup>18</sup> Among other seizures, European customs authorities seized a blood pressure drug in transit to Brazil; and AIDS drugs en route to Nigeria—and purchased by the Clinton Initiative relying on funds from the international entity, UNITAID.

<sup>19</sup> ACTA Ch. II, Sec. 3, Art. 16 (Border Measures). Though the in transit seizures provision is permissive and not mandatory (A Party may adopt or maintain procedures with respect to suspect in-transit goods), but it would effectively grant a right to exclude a developing country from receiving medicines produced in another developing country—only because the medicines must travel through one of the ACTA member countries. This provision also further defines a norm that was explicitly left out of TRIPS..

Further, the definition of counterfeit trademark goods in ACTA differs from TRIPS in one essential respect: the infringement is asserted in the country where invoked rather than the country of importation. This is a remarkable expansion of TRIPS: goods never intended to enter into a country, and only transiting through, could under ACTA be subject to infringement challenges in the transit country. ACTA Sec. 2, Art. 5(d): Definitions (definition of counterfeit trademark goods).

<sup>20</sup> Increased power is handed to customs officials based on information provided by a company, including a company trying to deter its competitors. See ACTA Sec. 3, Art. 17. No notification to the goods-holder is required (compare ACTA Sec. 3, Art. 17 with TRIPS Ch. III, Sec. 4, Art. 54); eliminating judicial review (compare ACTA Sec. 3, Art. 17 with TRIPS Ch. III, Sec. 4, Art. 59); ACTA allows for a detention of goods with no defined time limit (compare ACTA Ch. II, Sec. 3, Art.19 with TRIPS CH III, Section 4, Art.55 ); and lacks any safeguards of inspection, indemnification, or judicial review, even prior to the destruction of goods. ACTA Ch. II, Sec. 3, Art. 17..

<sup>21</sup> ACTA Ch. II, Sec. 3, Art. 16 (Each Party shall adopt or maintain procedures with respect to import and export Shipments)

<sup>22</sup> ACTA Ch. II, Sec. 3, Art. 17.3. ACTA requires that the competent authorities inform the applicant of the status of the application, without giving consideration to the defendant whose goods are seized. Compare this with Article 58 of the TRIPS Agreement which provides that “the importer and the right holder shall be promptly notified of the suspension.”

<sup>23</sup> E.g., ACTA Ch. II, Sec. 2, Art. 10.2. Similar provision is provided in Border Measures Section (ACTA Ch. II, Sec. 2, Art. 20) Under ACTA, judges have the authority to order the destruction of infringing goods, and materials and implements predominantly used for the manufacture of the infringing goods – but without the TRIPS limitation that judges also consider the “proportionality” of the offense relative to the remedy, and the “interests of third parties.” Compare ACTA Ch. II, Sec. 2, Art. 10.2 with TRIPS Ch. III, Sec. 2, Art. 46.

<sup>24</sup> For example Indian courts distinguish drugs from other cases of IP infringement. Medicines are different: courts have to tread with care and ensure there is no violation of the Indian Constitution’s guarantee to the right to life when considering remedies. *F. Hoffmann-La Roche Ltd. & Anr. v. Cipla Limited*, I.A 642/2008 IN CS (OS) 89/2008, Delhi High Court, Order dated 19 March 2008

<sup>25</sup> *eBay Inc v. MercExchange, L.L.C.*, 547 U.S. 388 (2006) ((permitting the denial of a permanent injunction if the public interest would be disserved). In a recent case, *Bard Peripheral Vascular, Inc. v. W.L. Gore & Associates, Inc.*, 2010-1510 (Fed. Cir. February 10), the majority agreed with the district court that “it was in the public interest to allow competition in the medical device arena.”

<sup>26</sup> ACTA Ch. II, Sec. 2, Art. 8. A limitation is also provided that: “where these remedies are inconsistent with a Party’s law, declaratory judgments and adequate compensation shall be available.” ACTA Ch. II, Sec. 2, Art. 8.2.

<sup>27</sup> ACTA requires high penalties for alleged infringers that are beyond those required under TRIPS. These TRIPS-plus civil enforcement penalties include injunctions, with limited exceptions, and even if the infringer had no prior

knowledge or the infringement was inadvertent, ACTA Ch. II, Sec. 2, Art. 8, *compare with* TRIPS Ch. III, Sec. 2, Art. 44.1; excessive damages, allowing the consideration of “any legitimate measure of value”, ACTA Ch. II, Sec. 2, Art. 9.1 and mandating judicial authority to order the payment of “profits”, Ch. II, Sec. 2, Art. 9.1, and legal expenses, ACTA Ch. II, Sec. 2, Art. 9.5; the removal and destruction of goods, and even of manufacturing plants, at the infringer’s expense, ACTA Ch. II, Sec. 2, Art. 10.2 and 10.3, without the TRIPS limitation for consideration of “proportionality” and the “interests of third parties”, TRIPS Ch. III, Sec. 2, Art. 46; the exposure of significant information, ACTA Ch. II, Sec. 2, Art. 11, where TRIPS limited this to the identification of third parties and further required that proportionality be considered, TRIPS Ch. III, Sec. 2, Art. 47. ACTA would allow for the seizure of goods even before the initiation of proceedings, and even without notification to the owner. See ACTA provisions on Provisional Measures and Border Measures. This is also TRIPS-plus.

TRIPS-plus border measures likewise shift the balance. With regard to border measures, TRIPS limits seizures of exports, TRIPS Ch. III, Sec. 4, Art. 51, and goods in transit, TRIPS Ch. III, Sec. 4, Art. 51, note 13; sets a maximum term for the withholding of allegedly infringing goods of 10-20 days, TRIPS Ch. III, Sec. 4, Art. 55; provides for an equivalent opportunity for the *importer* to inspect, TRIPS Ch. III, Sec. 4, Art. 57; provides for indemnification in the case of wrongful suspension, TRIPS Ch. III, Sec. 4, Art. 56; and requires the right of judicial review prior to the destruction of goods as a remedy, TRIPS Ch. III, Sec. 4, Art. 59. None of these limitations exist within ACTA: ACTA requires border measures for exports, ACTA Ch. II, Sec. 3, Art. 2.X.1, and allows them for goods in transit, ACTA Ch. II, Sec. 3, Art. 2.X.2; sets no maximum term for detention, requiring only that the detention is “reasonable”, ACTA Ch. II, Sec. 3, Art. 2.10; and lacks any safeguards of inspection, indemnification, and judicial review prior to destruction. ACTA Ch. II, Sec. 3. ACTA even allows customs authorities to act at the behest of a right-holder to detain allegedly infringing goods *with no obligation to even inform the alleged infringer*. Compare ACTA Ch. II, Sec. 3 with TRIPS Ch. III, Sec. 4, Art. 54.

With regard to criminal enforcement, TRIPS does not extend criminal enforcement measures to those found to be aiding and abetting infringement. ACTA does create this third party criminal liability with potentially far-reaching consequences: third parties can face criminal measures including prison terms and high monetary fines; the seizure, forfeiture, and/or destruction of goods and/or “any related materials and implements used in the commission of the alleged offense”. Compare TRIPS Ch. III, Sec. 5, Art. 61 with ACTA Ch. II, Sec. 4, Arts. 2.14.4, 2.15, 2.16.

<sup>28</sup> TRIPS includes provisions to protect against abuse that are notably absent within ACTA. These include provisions within TRIPS to indemnify the defendant for civil enforcement or border measures taken. TRIPS Ch. III, Sec. 2, Art. 48.1 (the ability of judicial authorities to order “a party wrongfully enjoined or restrained adequate compensation for the injury suffered” and legal fees); TRIPS Ch. III, Sec. 4, Art. 56 (“appropriate compensation for any injury caused to them through the wrongful detention of goods or through the detention of goods released”). No comparable provisions exist within ACTA. Strikingly, where TRIPS provides for indemnification of the importer and owner in the case of wrongful detention, TRIPS Ch. III, Sec. 4, Art. 56, ACTA only requires that an application be denied, suspended, or voided where a rights-holder has abused the process, ACTA Ch. I, Sec. 3, 17.4. This is essentially no punishment at all for an abuse of the system despite harmful consequences.

Further, TRIPS recognizes the right of all parties to judicial review, TRIPS Ch. III, Sec. 1, Art. 41.4, and access to information, TRIPS III, Sec. 2, Arts. 41.3, 42, 43. Under ACTA, customs authorities can act at the behest of a right-holder to detain allegedly infringing goods *with no obligation to inform the alleged infringer*. Compare ACTA Ch. II, Sec. 3 with TRIPS Ch. III, Sec. 4, Art. 54.

<sup>29</sup> World Health Organization (WHO), Regional Office for South-East Asia (SEARO), Legal Aspects of Defining “Counterfeit Medicines”: A Discussion Paper (2009), 2.

<sup>30</sup> Susan K. Sell, ‘TRIPS was never enough: Vertical Forum Shifting, FTAs, ACTA, and TPP’ at <http://infojustice.org/download/gcongress/dii/Sell%20-%20TRIPS%20Was%20Never%20Enough%20-%20June%202011.pdf>

<sup>31</sup> European Parliament resolution of 10 March 2010 on the transparency and state of play of the ACTA negotiations at <http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P7-TA-2010-0058&language=EN>

<sup>32</sup> ACTA Ch. VI, Art. 42