CAMPAIGN FOR ACCESS TO ESSENTIAL MEDICINES

MEDECINS SANS FRONTIERES

THE SECRET TREATY

Anti-Counterfeiting Trade Agreement (ACTA) and Its Impact on Access to Medicines

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. MSF relies primarily on generic medicines procured internationally. So too do the major procurers of AIDS medicines worldwide—the Global Fund and PEPFAR.[i] 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.

ACTA is part of the enforcement agenda advanced by rich countries outside of multilateral norm-setting institutions.[ii] ACTA would impose limits on price-reducing generic competition and jeopardize the free flow of legitimate medicines across borders. These enforcement efforts enhance the rights of pharmaceutical companies at the expense of poor patients.

- **ACTA's scope is overbroad and will harm access to medicines. The name of the treaty is misleading: it does not just seek to cover anti-counterfeiting.** Counterfeit challenges should be limited to trademark violations where there is a deliberate attempt to deceive.[iii] ACTA blurs these distinctions. *First,* it would require countries to impose stringent IP enforcement measures for civil trademark confusion disputes.[iv] But disputes over allegations of similar sounding names or packaging are common in the medicines field: similar names and packaging are often even desirable to demonstrate medical equivalency, but they do not mean that the medicines are unsafe. *Second*, ACTA also applies to patent challenges.[v] These IP infringements are generally commercial disputes where no inherent public health concerns exist. While patents are excluded from the border measures and criminal enforcement sections of the agreement[vi], only the United States pointedly aims to exclude patents from the entire scope of the agreement—Europe and Japan want the civil enforcement provisions to apply to patents.[vii] *Lastly*, ACTA's civil enforcement section may also allow enforcement efforts based on fictional patent claims.[viii]

  There is no place for patents or civil trademark infringement in a genuine anti-counterfeiting treaty. It is claimed that ACTA will protect public health against fake medicines. The TRIPS[ix] definition of counterfeit only relates to trademark infringement.[x] In medicines that would mean disputes over the use of brand names or other labelling or sometimes the shape of color of a pill. But not all such trademark disputes amount to a public health problem. Only 'wilful commercial-scale trademark counterfeiting'[xi]—a form of fraud with a deliberate intention to exactly copy a product's branding—presents a legitimate public health concern. These are unregulated and intended to defraud the consumer.

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- **ACTA would still allow the border detention of in-transit medicines destined for developing countries.** Despite assurances to the contrary from negotiators, ACTA would increase border searches and interfere with the transit of legitimate medicines. While the border measures section no longer includes patents, it still includes civil trademark infringement.[xii] This means a customs official could decide to detain and even destrroy an allegedly infringing good without any court oversight or even notification to the rights holder—on the basis of the customs official's own view on whether the goods in question infringe a commercial trademark.[xiii] 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, which used the brand name Amoxil,itself a use of the INN. At the core of this detention was an expansive EU customs regulation designed to protect IP rights[xiv] that led to many other detentions of medicines in transit between developing countries which were not IP-protected in the source or destination countries.[xv] Under ACTA, too, even legitimate medicines

just transiting through an ACTA member country could be temporarily or permanently seized.[xvi] *Ex officio* mechanisms without judicial review—and allowing the detention, seizure, and even destruction of goods—are susceptible to over-enforcement.[xvii] Mere trademark violation is a very grey area of fact and degree that needs litigation. It is not appropriate for untrained border guards acting *ex officio*. Rightsholders 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 undermines the role of the judiciary in protecting the right to health.** ACTA undermines the courts by allowing extra-legal processes. ACTA would limit due process for IP challenges by permitting the seizure and destruction of medicines without even advising the owner, providing the owner the opportunity to respond, or mandating judicial oversight.[xviii] Such *ex parte* measures are manifestly susceptible to abuse.

  Even where judicial process is outlined, the balance lies heavily in favor of the rightsholder alleging infringement. Under ACTA, judges have limited power to balance health issues against the interests of private companies.[xix] Yet, many countries place the right to health above private IP rights.[xx] Sometimes the court will decide 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 finalized when the court determines whether an infringement has in fact taken place.

  But ACTA requires injunctions to stop the distribution of goods even at the early stage of an infringement challenge—except where a national law prohibits it—and in some cases calls for the destruction of infringing goods.[xxi] 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 never requires judicial authorities to consider proportionality and the interests of third parties in fashioning certain remedies.

- **ACTA is imbalanced: it provides excessive punishment, and grants few protections against abuse.** The severe punishment for infringement contained in ACTA obstructs and deters legitimate generic competition by dramatically altering the risks faced by generic medicines manufacturers and intermediaries. On a mere allegation and not proof, including by a competitor, generic suppliers allegedly infringing a patent or a trademark may face the delay or destruction of goods, disproportionate damages, potential bankruptcy, and in some cases, even criminal proceedings.[xxii] The punishment is excessive and deters the production and sale 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 the limited liability for abuse. There are few penalties for false accusations, and few protections for the alleged infringer.[xxiii]

- **ACTA puts third parties—like distributors and even non-governmental organizations or public health authorities—at risk of severe penalties.** Third parties are at risk of injunctions[xxiv], provisional measures,[xxv] and even criminal penalties, including imprisonment and severe economic losses.[xxvi] All of these are TRIPS-plus and with potentially far-reaching consequences. This could implicate, for example, suppliers of active pharmaceutical ingredients 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. This could act as a significant deterrent to anyone involved in the production, sale and distribution of affordable generic medicines.

- **ACTA is not a legitimate response to unsafe medicines.** The specter of harmful fake medicines is a concerns 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 and raise drug prices, it actually incentivizes the introduction of trademark-infringing counterfeit medicines. The WHO has recognized that high drug prices are a cause of counterfeit medicines: patients demand low-cost alternatives, and counterfeiters respond.[xxvii]

- **ACTA is intended to apply to developing countries but contains insufficient safeguards.** ACTA is intended and structured as a norm-setting tool. In addition to being applicable soon after its finalization by the negotiating parties, it is structured and expected that other countries, including developing countries, will become party to the agreement, mostly as a result of trade pressures. If enacted, it will minimize the flexibilities countries have to incorporate appropriate public health measures and balances in their laws.

- **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. The near-final text has now been released—and it is TRIPS-plus and does not respect the rights of developing countries to protect the health of their populations and ensure access to medicines.

- **ACTA is a blank check 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. 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.[xxviii]

Patients must come first!

- ACTA is fatally flawed. ACTA locks in the most controversial aspects on US and EU IP enforcement laws, and has insufficient safeguards to prevent abuse and protect the public. For the problem of poor quality and unsafe medicines, ACTA is an inappropriate and ineffective response with counterproductive consequences.

- If ACTA is finalized, significant changes are necessary.
  (1) ACTA should only be applicable to willful copyright and trademark infringement on a commercial scale. It should exclude both patents and civil trademark infringement from the scope of the agreement.
  (2) Civil and criminal enforcement mechanisms should not be TRIPS-plus.
  (3) Protections against abuse must exist, including judicial review, access to information for the alleged infringer, and the obligation to consider proportionality and the public interests in setting the remedy.
  (4) ACTA should not establish TRIPS-plus third party or aiding and abetting liability.
  (5) Any institutional structure established should be open and transparent. It should not have the authority to amend ACTA without public scrutiny and approval from democratic bodies, such as Parliament or Congress.

[i] 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.

[ii] 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.

[iii] *See* World Health Organization (WHO), Regional Office for South-East Asia (SEARO), Legal Aspects of Defining "Counterfeit Medicines": A Discussion Paper (2009).

[iv] 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).

[v] ACTA Ch. II, Sec. 2. Footnote 2 of the current draft suggests that the US is the only negotiating party that is attempting to exclude patents from the scope of civil enforcement section of the agreement.

[vi] ACTA Ch. II, Sec. 3, fn. 6 ("Parties agree that patents do not fall within the scope of [the border measures] Section."); Ch. II, Sec. 4, Art. 2.14.1 ("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.").

[vii] ACTA Ch. II, Sec. 2 fn. 2.

[viii] 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. These seizures are now the subject of a WTO complaint by India and Brazil against the EU.

[ix] World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property.

[x] TRIPS Ch. III, Sec. 4 Art. 51, fn. 14(a).

[xi] TRIPS Ch. III, Sec. 5, Art. 61.

[xii] ACTA Ch. II, Sec. 3, Art. 2.X: Scope of the Border Measures.

[xiii] 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.

[xiv] EU Reg. 1383/2003 is reportedly being reviewed for revision, including regarding the issue of scope.

[xv] 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.

[xvi] In the current text, the in transit seizures provision is permissive and not mandatory, 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. ACTA Ch. II, Sec. 3, Art. 2.X.2. See TRIPS Ch. III, Sec. 4, Art. 51, note 13.

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 Ch. I, Sec. B, Art. 1.X: Definitions (definition of counterfeit trademark goods).

[xvii] Increased power is handed to customs officials based on information provided by a company, including a company trying to deter its competitors. ACTA Ch. II, Sec. 3. No notification to the goods-holder is required (compare ACTA Ch. II, Sec. 3 with TRIPS Ch. III, Sec. 4, Art. 54); judicial review is extraordinarily limited (compare ACTA Ch. II, Sec. 3 with TRIPS Ch. III, Sec. 4, Art. 59); ACTA allows for a detention of goods with no defined time limit (ACTA Ch. II, Sec. 3, Art. 2.10); and lacks any safeguards of inspection, indemnification, or judicial review, even prior to the destruction of goods. ACTA Ch. II, Sec. 3, Art. 2.11.1.

[xviii] ACTA Ch. II, Sec. 3, Art. 2.11.1.

[xix] E.g., ACTA Ch. II, Sec. 2, Art. 2.3. 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. 2.3 with TRIPS Ch. III, Sec. 2, Art. 46.

[xx] 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

[xxi] ACTA Ch. II, Sec. 2, Art. 2.X: Injunctions. In an improvement over previously leaked texts, the current draft text provides a limitation: "where these remedies are inconsistent with a Party's law, declaratory judgments and adequate compensation shall be available." ACTA Ch. II, Sec. 2, Art. 2.X.2.

[xxii] 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. 2.X, *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. 2.2.1, and mandating judicial authority to order the payment of "profits", Ch. II, Sec. 2, Art. 2.2.2, and legal expenses, ACTA Ch. II, Sec. 2, Art. 2.2.5; the removal and destruction of goods, and even of manufacturing plants, at the infringer's expense, ACTA Ch. II, Sec. 2, Art. 2.3, 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. 2.4, 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. ACTA Ch. II, Sec. 2, Arts. 2.5.2, 2.5.3. 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.

[xxiii] 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, 2.X.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.

[xxiv] Ch. II, Sec. 2, Art. 2.X.1: Injunctions.

[xxv] Ch. II, Sec. 2, Art. 2.5.1(a).

[xxvi] 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. 2. 14.4, 2.15, 2.16.

[xxvii] World Health Organization (WHO), Regional Office for South-East Asia (SEARO), Legal Aspects of Defining "Counterfeit Medicines": A Discussion Paper (2009), 2.

[xxviii] ACTA Ch. V, Art. 6.4: Amendments, Arts. 5.1.2. 5.1.4.