Essential Action
P.O. Box 19405
Washington, D.C. 20036

July 2, 2009

Consultations and Liaison Division (BSL)
Anti-Counterfeiting Trade Agreement (ACTA)
Foreign Affairs and International Trade Canada
Lester B. Pearson Building
125 Sussex Drive
Ottawa, Ontario
K1A 0G2

Re: Comments of Essential Action on the Proposal for an Anti-Counterfeiting Trade Agreement

Dear Consultation and Liaisons Division,

Essential Action submits the following comments concerning the proposed Anti-Counterfeiting Trade Agreement (ACTA).

Essential Action is a project of Essential Information, a non-profit organization based in Washington, D.C. We are concerned with protecting the public domain and the information commons. A key organizational area of focus is promoting global access to medicines. While we recognize the proposed treaty implicates many other important issues, our comments focus on the public health priority of ensuring access to safe and affordable medicines to people around the world, regardless of income or wealth.

Transparency and stakeholder participation

As a threshold matter, we note ACTA's draft text has not been made public, and the publicly available materials regarding ACTA's proposed subject areas are still thin and too general. This lack of transparency and specificity makes meaningful public consultation difficult, and diminishes the public legitimacy of the proposed agreement.

This is especially true in light of ACTA's misleading name. While titularly an "anti-counterfeiting" agreement, ACTA in fact seeks to "*Establish, among nations committed to strong IPR [intellectual property rights] protection, a common standard for IPR enforcement to combat global infringements of IPR, particularly in the context of counterfeiting and piracy."*

In the public mind and conventional use, the term "counterfeiting" evokes a very different set of concerns – public concerns, including, for example, the safety of

consumer goods – than those that can be most effectively and appropriately addressed though the enforcement of private rights, including patents, trademarks and copyrights. ACTA may therefore fail to deliver on the public promise its name implies. Simultaneously, ACTA may confer new protections to private rights holders that could, in fact, come at a public cost. The secrecy of the agreement's text amplifies this problem of public misrepresentation.

We understand that Canada has stated, at least informally, that it favors making the draft ACTA text publicly available. We request Canada formally and publicly ask its ACTA negotiating partners to disclose the draft text. Such a request would help overcome the problem of negotiating partners insisting they cannot make the text public because they have promised other negotiating countries that it would remain secret. We further request negotiations be placed on hold until a draft text is released.

Additionally, we request Canada formally and publicly support Brazil's participation as a Party to ACTA, and urge ACTA negotiating parties to open the negotiations to interested developing countries. As we detail below, ACTA rules will likely have significant impact on access to medicines in developing countries, because they may interfere with the legitimate trade in generic medicines, while those medicines are in transit in ACTA countries. Even more importantly, ACTA rules may affect developing countries through its potentially harmful impact on the global supply of legitimate generic medicines.

ACTA's potential public costs

Approaching anti-counterfeiting policy through private rights enforcement comes with several potential, and potentially serious, public costs.

Global access to medicines depends in large part on market competition reducing prices over time, to levels where government treatment programs can scale-up coverage. Over the last ten years, global competition and generic medicines have produced a revolution in HIV/AIDS treatment, for example, reducing prices from $10,000 to near $100 per person per year, and enabling more than three million people to access lifesaving antiretroviral therapy.

The ACTA Key Elements Under Discussion[1] concerning injunctions, border measures, criminal penalties and enforcement practices suggest the Agreement may facilitate policies that obstruct and deter legitimate generic competition. For example, in several recent incidents, customs authorities in Europe have wrongly detained generic medicines in transit to developing countries, on suspicion of patent or trademark infringement. The medicines were in transit, and did not jeopardize private rights in the country through which they passed. But their detention did disrupt drug procurement in destination countries where, in at least some cases, the medicines were not even on patent. Problems

[1] "The Anti-Counterfeiting Trade Agreement – Summary of Key Elements Under Discussion," April 6, 2009, *available at*: http://www.international.gc.ca/trade-agreements-accords-commerciaux/fo/intellect_property.aspx?lang=en&menu_id=7&menu.

already evident in the European Union could be considerably worsened by ACTA proposals – both binding standards as well as non-binding norms – enabling abuse by rights holders, and chilling investments in the generics trade over time, particularly if appropriate safeguards are not put into place.

Many of the Key Elements Under Discussion could enable policies restricting the availability and free movement of generic medicines.

- ACTA could legitimize seizing in-transit medicines for alleged rights infringements in the transit country, even though such infringements in no way threaten the rights holder's protected market, because they are merely passing through.

- ACTA may grant customs officials broad authority to seize medicines *ex officio* – on their own authority – even though customs officials are poorly suited to analyze issues related to intellectual property infringements.

- ACTA may grant rights holders broad authority to trigger detentions, and to keep allegedly infringing goods out of circulation, proposals that clearly open the door to spurious infringement claims and abuse.

ACTA may also pile on deterrents against shipping generic medicines that could infringe a trademark or patent in a transit country, even when the products infringe no rights in their port of origin or destination.

- For example, the Elements Under Discussion contemplate assigning storage fees for detained medicines and legal fees to the alleged infringer.

- It is possible little evidence will be required to trigger detentions, or to support them after the fact.

- ACTA seeks to facilitate the development of public international enforcement networks for private right monopolies, consisting in part of law enforcement officials across the globe who may advise and prepare their colleagues in other countries to stop incoming shipments of generic medicines.

More broadly, ACTA contemplates enforcement norms of exceptional reach that would alter existing balances of rights and liability.

- Under the World Trade Organization's Agreement on Trade Related Aspects of Intellectual Property (TRIPS) Article 44.2, countries are not required to make injunctive relief – legal orders to stop rights infringement – available in all circumstances, because other important national interests, such as keeping health products on the market, could be compromised. (Rights holders can still sue for money damages.) Leaked ACTA draft texts suggest the Agreement may eliminate

this important flexibility. Among other harmful effects, this could enable many more detentions and seizures of generic medicines.

- ACTA could legitimize norms favoring widely available injunctive relief for alleged patent infringement, including detentions and seizures of medicines, even though patent status is not reasonably related to drug quality concerns (described in the next section), and generics do not mislead consumers.

- Criminal penalties and damages could be applied too broadly and bluntly, intimidating generics manufacturers (particularly in light of customs officials' inaccurate infringement assessments, and defendants' limited recourse to counter infringement claims) and chilling the trade.

Perhaps even more concerning, Article 2.4 of a leaked ACTA draft text states each Party shall provide judges the authority to order alleged infringers to identify third persons in the production chain, such as manufacturers of active pharmaceutical ingredients (APIs) that contract with generics firms. It is possible liability could attach to such contractors, as well (for example, if they knew or had reason to know the medicines might infringe a patent or trademark, somewhere in the world, even at some point of transit). Under such rules, API manufacturers might reason that contracting with generics firms has become too financially risky, and leads to undue invasive scrutiny of their business, and the supply of APIs to generics could dry up. This would undermine generic medicines worldwide.

Perhaps less severe versions of some of these Elements are under consideration. But any of these Elements could obstruct generic competition. Taken together, they would enact a very dangerous and poorly conceived enforcement environment, posing a deeply serious threat to global access to medicines.

Notably, the Elements Under Discussion do not adequately contemplate important safeguards. These should include, at a minimum and among others, explicitly rejecting patent infringement as a detention trigger, excluding all in-transit medicines from rights-based detentions, adequate procedural protections and provisions for the rights of alleged infringers to be heard, and robust anti-abuse and liability provisions adequate to deter wrongful detentions.

Essential Action is very concerned with the Elements Under Discussion, and urges a deeper analysis and public consultation process regarding their likely effects on global access to medicines.

ACTA may impose another quite literal cost on the public. Although public laws provide for patent, trademark and copyright protection, it is generally the responsibility of private parties to identify alleged infringements and bring suit. The broad enforcement measures contemplated in ACTA shift the burden of private rights enforcement to the public. This capture of public means for private ends is not only tangential to the legitimate public goals of protecting consumers from unsafe and ineffective products, it may also come at

significant financial cost to taxpayers, and divert considerable law enforcement resources from other priorities. A shift in enforcement responsibility implies a change in the very nature of these private rights. It is a potentially major policy shift that should, at a minimum, be subject to serious deliberation in the legislatures of the ACTA Parties.

A third possible public cost relates to innovation incentives and barriers to product development. As Knowledge Ecology International points out,[2] damages rules that enable dramatically increased penalties for infringement and increased availability of injunctive relief, both contemplated in the Elements Under Discussion, could actually hurt innovation, rather than help it. This is because companies developing complex, patent-rich technologies or copyrightable software sometimes infringe, willfully or unwillfully, intellectual property rights in the process. High rents and absolute bars on infringement can make it much more costly, or legally impermissible, to bring these products to market. But sometimes, it is important that infringing technologies reach market. For example, developers of new drug diagnostics might overlook a claimed patent or fail to reach a licensing agreement with a patent holder. Injunctions or excessive damages could keep such critical new technologies off the market, or (perhaps more likely) make them more expensive for consumers. Health technologies, especially those developed to treat diseases endemic in poorer countries, are very cost sensitive. If a technology is not cost effective for under-resourced health programs, it might never reach the people it was designed to serve.

ACTA's present inadequacy to address public safety

First among the public benefits ACTA advertises in its materials is protecting public health and safety from dangerous counterfeit goods. But intellectual property enforcement is a crude, overly broad and under effective tool for protecting these interests. There are more effective and narrowly tailored policies that could be put in place to protect the public from dangerous goods, including substandard medicines – without risking anti-competitive effects.

The Elements Under Discussion do not exclude patent infringement from ACTA's broad reach. But patent infringement analysis is not reasonably related to counterfeiting or drug quality concerns. The required analyses are entirely separate; one pertaining to alleged use of claimed proprietary inventions, the others to deliberate mislabeling and detailed assessments of drug safety and efficacy. Even a proven patent infringement is no basis for classifying a medicine (or any other product) as counterfeit, under either the TRIPS or World Health Organization definition. Generics are not categorically less safe than branded medicines. Rather than protecting public health, targeting generics through overly aggressive patent enforcement measures, especially without adequate anti-abuse provisions, obstructs competition and could jeopardize access to medicines.

[2] "Damages, Injunctions and Transparency Key Issues in ACTA Negotiations," James Love, Knowledge Ecology International, June 15, 2009, *available at*: http://www.keionline.org/blogs/2009/06/15/thoughts-acta-negotiations/.

In intellectual property usage, the term counterfeit, as regards medicine, correctly applies only to trademark infringement. But even in the trademark context, only a subset of infringing medicines (or other goods) pose a risk to public health. These include deliberately mislabeled medicines, which fraudulently misrepresent their source or ingredients to consumers. Generic medicines (or other goods) unintentionally bearing symbols or words that could be confused with trademarks cannot be said to pose such a categorical risk.

For this reason, trademark analysis and trademark enforcement is not necessary, and probably not even beneficial, to protecting the drug supply, given that there are better available alternative policies. A better policy would specifically target fraudulent and deliberately mislabeled drugs – irrespective of trademark or any other intellectual property issues. This is indeed a serious public priority.

The possibility of catching some intentionally mislabeled medicines in trademark's large net may not justify the risk overbroad enforcement policies could pose for access to medicines, given, again, there are more rational and narrowly tailored alternatives. Further, the evidence shows that customs officials overzealously detain medicines that do not, in the end analysis, infringe trademarks. Thus, trademark's net is probably even larger and less precise in practice than it is in theory. This means an even greater risk to access to medicines. These matters require much more attention and analysis than they have received, before enshrining overreaching enforcement measures in a new global treaty.

Public policy could better protect public health by focusing on mislabeled medicines, rather than intellectual property. For example, countries could require companies to disclose any information they have about potentially dangerous mislabeled medicines on the market. Private companies often have the first or most complete accounts of deliberately mislabeled products, but do not always share what they know.

For example, the Pharmaceutical Security Institute (PSI), formed by fourteen pharmaceutical companies in 2002, recorded 76 cases of counterfeiting in 2004. The U.S. FDA only knew of 58.[3] Some consider PSI's counterfeiting database the world's best, yet it "is not accessible to the WHO, health authorities or the public."[4]

There are at least two existing proposals for statutory disclosure requirements. Cockburn *et al.* propose a model based on the United Kingdom Civil Aviation Authority's reporting requirements for suspected unapproved aircraft parts.[5] Companies would be required to

[3] "Counterfeit medicines – What are the problems?" Pharma-Brief Special, BUKO Pharma-Kampagne, a member of Health Action International (2007) at 5.

[4] "The global threat of counterfeit drugs: why industry and governments must communicate the dangers." Robert Cockburn, Paul N. Newton, E. Kyerematen Agyarko, Dora Akunyili, Nicholas J. White, Public Library of Science (PLoS) Medicine, April 2005, Volume 2, Issue 4, at 305.

[5] PLoS, *supra* at 307.

report suspected deliberately mislabeled medicines to regulatory agencies. The agency would then take responsibility for confirming the report and deciding whether and when to alert law enforcement and the public. Meanwhile, U.S. legislation introduced by Representative Steve Israel proposed requiring drug companies to notify the FDA within two days of learning of a counterfeit threat.[6] Countries could also commit to sharing such information. Again, disclosure and notification requirements should include appropriate anti-abuse provisions.

Other policy priorities for combating dangerous fake medicines should include strengthening drug regulatory authorities and consumer protection agencies and developing reliable, impartial empirical data on the extent of the medical counterfeiting problem (very little empirical data currently exists), as well as promoting robust legitimate competition to lower prices. There is broad consensus that high prices of some goods drive both supply and demand in counterfeits markets. For example, according to the World Health Organization, "When the prices of medicines become excessively high and unaffordable, patients tend to look for cheaper sources. Such situation [sic] encourages counterfeiters to produce cheaper counterfeit drugs. … When price differences exist between identical products, patients and consumers go for the cheaper ones. This creates a greater incentive for counterfeiters to supply cheap counterfeit medicines." [7]

Principles; Analysis of ACTA costs and benefits

Under the present Elements of Discussion, the Anti-Counterfeiting Trade Agreement could jeopardize access to medicines, through potential anti-competitive effects, the obstruction of the generics trade, and a high likelihood of abuse by rights holders. At the same time, its method of protecting public safety – aggressive public enforcement of private intellectual property rights – is both over and under inclusive, and may capture some deliberately mislabeled or substandard medicines only incidentally, while aiming to protect pharmaceutical monopolies. Further, ACTA appears to come at significant financial cost to taxpayers, who will be asked to bear the burden of this monopoly enforcement.

There is a critical public interest at stake in the efficient and secure international passage of lifesaving generic medicines. Delays in medicine shipments – to say nothing of their permanent seizure and destruction – jeopardize the health of people awaiting the medicines, primarily in the developing world. Improper seizures of generics put the business model for generic medicines at risk – with potentially serious consequences for access to medicines around the globe.

---

[6] H.R. 2345, 109th Congress.

[7] "What encourages counterfeiting of drugs?" World Health Organization Counterfeits FAQ, available at: http://www.who.int/medicines/services/counterfeit/faqs/16/en/index.html.

Essential Action urges, at a minimum, the following principles for any enforcement policies that could affect the international medicines trade:

- All border measure policies must include robust anti-abuse provisions, including strong liability provisions adequate to deter wrongful detentions.

- Rights enforcement policies must include robust procedural safeguards and evidentiary standards to protect medicines manufacturers from costly rights enforcement errors.

- Rights enforcement policies must not compromise generic medicine supply chains.

- Detentions of in-transit medicines should be triggered only by case-specific, legitimate public health concerns – not by private rights.

- Patent status is clearly an improper proxy for drug quality or counterfeiting concerns. Patent status should have no role in decisions to detain or seize medicines, whether in-transit or at their point of destination.

- Trademark violation is not a valid ground for detaining in-transit medicines. Rather, in-transit medicines should only be detained on reasonable, case-specific and good faith belief of public endangerment or fraudulent labeling (the medicines' packaging deliberately misrepresents identity, source or contents).

Thank you for this opportunity to provide comments. Essential Action is available to discuss any of the aforementioned points in further detail.

Sincerely,

Peter Maybarduk
Staff Attorney
Essential Action

www.essentialaction.org/access
peter.maybarduk@essentialinformation.org

Public Citizen Recommended Guidelines for U.S. Government Provision of Technical Assistance in Matters Concerning Intellectual Property Rights

* TA provision must acknowledge that there are multiple legitimate options for IP policymaking, and that reflecting their particular situations, developing nations may have different priorities and appropriately choose different policy options than those adopted by the United States.

* TA provision must present developing countries with information on flexibilities available under international IP rules such as those in the TRIPS Agreement, and present specific policy options to utilize the flexibilities.

* TA provision relating to patents and related IP matters must explain the Doha Declaration on the TRIPS Agreement and Public Health, the safeguards it reiterates, and be informed by its commitment that the agreement should be "implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all."

* TA providing agencies should maintain and publish on the Internet a roster of persons or institutions they rely on for TA provision. The roster should include their areas of expertise and all relevant affiliations. TA providing agencies should also publish on the Internet a description of each TA provided, and the person(s) or institutions providing the TA.

* All materials presented and prepared in the course of the technical assistance provision should be published on the website of the TA provider.

* All materials produced as part of technical assistance (e.g., draft legislation) should be published on the website of the TA provider.

* TA providers should develop, publish and enforce rules governing conflicts of interest.

Contact: Robert Weissman, President, rweissman@citizen.org or Peter Maybarduk, Access to Medicines Program Director, pmaybarduk@citizen.org

essential action
Access to Medicines Project
P.O. Box 19405, Washington, DC, USA 20036
(202) 387-8030 • www.essentialaction.org/access/

Ensuring Effective Biogenerics Legislation: Timely Patent Dispute Resolution and Patent Disclosure

Providing timely access to affordable, safe and effective products should be the central purpose of U.S. legislation that introduces a regulatory pathway for the approval of generic substitutes for biologic pharmaceuticals (also known as "biotech drugs"). Provisions that extend the monopoly protection period of brand-name companies, making it unreasonably difficult to sell affordable biogenerics to patients as soon as possible after patent expiration, would defeat the purpose of the new rules.

To meet these objectives, U.S. biogenerics legislation should include provisions that encourage rapid resolution of patent disputes. Requiring brand-name companies to disclose all relevant patents is one key element to ensure potential generic competitors have sufficient information to make an informed assessment of the potential barriers to competition. Several of the biogenerics proposals under consideration by Congress do not require such disclosure as part of the proposed patent dispute resolution system, or do not contain any provisions governing patent dispute resolution related to biogenerics. Essential Action recommends that biogenerics legislation should incorporate the four principles outlined below.

1. Patent Disclosure Should Be Mandatory

The patent system is premised on public disclosure. Not only is the basic fact of a patent claim supposed to be public knowledge, but the very provision of a patent is supposed to embody a trade-off whereby the means to make the underlying invention is publicized in exchange for grant of the patent monopoly. Moreover, to perform their property-delineating function effectively, patents must provide effective notice to the public and potential industry competitors.

Given the essential public component and notice functions of the patent system, there is no legitimate public policy rationale in patent claims on medicines being treated as proprietary or subjected to industry gamesmanship.

Routine patent disclosure should therefore be the norm for medicines. For conventional drugs registered under the Food, Drug and Cosmetic Act, this routine disclosure is achieved through Orange Book listings. This is a problematic approach because of the patent linkage system associated with the Orange Book, but it does at least achieve the disclosure objective. We believe a sound public policy approach would require disclosure of claimed patents as a condition of enforcement, and believe this regime should be adopted for biologics registered under the Public Health Service Act.

Thus, initial registrants should be required at the time of application to indicate any granted or filed patents that they believe apply to the biologic for which they seek marketing approval. This should include both patents granted to the registrant or which have been licensed to them. They should be required to update this list for any new patent filings, within a statutorily defined period, perhaps 30 days. Failure to disclose should forfeit the right to enforce.

2. The Patent Resolution Process Should Be Available at Any Point After Initial Registration

Given the centrality of patents to pharmaceutical manufacture, and the considerable up-front costs of undertaking tests to determine generic substitutability (or comparability, or therapeutic equivalence, or similarity), it is often impractical for generic manufacturers to introduce a product onto the market without ascertaining that they can do so without infringing the patents held or licensed by the registrant of the reference product. For biologics, the expected greater cost of achieving and demonstrating substitutability, comparability, equivalence, or similarity will likely deter in many cases pre-marketing investments unless there is certainty about the patent landscape. It is thus vital that there be a system for pre-marketing resolution of the validity and applicability of reference product patents to a subsequent generic or similar product.

The objective of such a system should be to clear patent claims so that a) invalid patents do not delay investment in, or introduction of, generic or similar products; b) non-applicable patents do not delay investment in, or introduction of, generic or similar products; and c) all potential patent claims are resolved in advance of any applicable marketing exclusivities.

The originators have a legitimate interest in protecting and enforcing their patents. They do not have a legitimate interest in enforcing invalid patents, however, or delaying second entrant entry by brandishing patents that do not apply to the second entrant's product.

Delays in starting the process of pre-marketing patent resolution serve only to enable invalid or non-applicable patents to delay second entrant investment or marketing. If a pre-marketing patent resolution process leads to a finding that a patent is valid and/or applicable to a second entrant, then the originator will be able to obtain full protection for that patent, no matter when the process is originated.

We thus believe that potential second entrants should be free to initiate patent resolution processes at any point following approval of an originator product.

With such a system, there may be cases in which a second entrant initiating a patent resolution process does so before developing its process to make its version of the reference product. In such a case, it might not be able to obtain clarity on process patents. This would be a risk borne by the second entrant. It would retain the right to initiate a patent resolution process for potentially applicable process patents at a later date.

3. The Second Entrant Should Not Be Required to Share Confidential Information During the Administrative Process

Some legislative proposals for early patent resolution require the second entrant to share confidential information with the maker of the reference product. Statutory promises of protection notwithstanding, it is hard to imagine such information remaining confidential and not being shared with scientists employed by the originator company. Such a requirement to share confidential information is notably discordant with the confidentiality protections afforded to originators.

Second entrants should not be required to share confidential information with reference product makers, at least until a court proceeding is underway.

This problem can be avoided by placing responsibility for initiating a patent resolution process on to the second entrant. If the second entrant identifies claimed patents that it believes to be invalid or not

to cover its product, then those disputes can be litigated or resolved through an appropriate process, without any pre-screening of second entrant confidential information by the originator.

The originator company would reserve the right to enforce at a later date any patent not addressed through the pre-marketing patent resolution process.

4. Second Entrants Should Have the Right to Opt Out of the Early Patent Resolution System

Second entrants should reserve the right to bypass the early patent resolution system. It is especially important to preserve this right if the early patent resolution system requires the second entrant to share confidential information.

There is no diminution of the patent holders' rights if a second entrant chooses to bypass a pre-marketing patent resolution process.

Because there are significant business risks in doing so, it is unlikely that most second entrants would exercise this option. But it should remain open. It may be the preferred choice for second entrants in particular cases, or because the pre-marketing patent resolution process evolves in such a fashion as to constitute a barrier to investment and marketing.

For more information contact:

Sarah Rimmington, Attorney
Essential Action, Access to Medicines Project
(202) 387-8030
srimmington@essentialinformation.org