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March 28, 2010

Re: FR Doc. 2010-3539
Coordination and Strategic Planning of the Federal Effort Against Intellectual Property Infringement: Request of the Intellectual Property Enforcement Coordinator for Public Comments Regarding the Joint Strategic Plan

Dear Ms. Espinel,

Public Citizen submits the following comments concerning the Joint Strategic Plan on intellectual property enforcement.[1] Pursuant to the Office of the Intellectual Property Enforcement Coordinator's (IPEC) Federal Register notice, we "provide specific recommendations … regarding the objectives and content of the Joint Strategic Plan and other specific recommendations for improving the Government's intellectual property enforcement efforts." We note IPEC's particular interest in threats to public health and safety, and we provide analysis and principles we hope will help guide this concern. While we recognize many important interests may be implicated by the Plan, our comments focus most specifically on protecting global access to safe, effective and affordable medicines, and related consumer interests.

With 150,000 members and supporters, Public Citizen is a national, 501(c)3 and (c)4 nonprofit consumer advocacy organization founded in 1971 to represent consumer interests in Congress, the executive branch and the courts. Key areas of organizational focus include consumer safety, pharmaceutical drug quality, public health, and access to medicines.

[1] IPEC's Federal register notice 2010-3539 states, "The [PRO IP Act of 2008] requires the [Intellectual Property Enforcement Coordinator] to chair an interagency intellectual property enforcement advisory committee in order to develop an Administration strategy for enforcement against intellectual property infringement: The Joint Strategic Plan."

Summary

Public Citizen believes intellectual property enforcement is a poor framework for protecting public health and safety. More direct, effective and precise mechanisms should be used, and often are used, to guide U.S. and other governments' efforts to protect consumers from unsafe products, including potentially dangerous medicines that misrepresent their source. Public Citizen is concerned that treating exclusive commercial rights as a proxy for a public safety regime could divert attention and resources away from rational, priority safety and consumer protection measures available to public agencies.

Further, without adequate safeguards, imprecise or overreaching intellectual property enforcement measures could threaten and chill legitimate competition, endangering, among other key consumer interests, global access to medicines.

If the Joint Strategic Plan is not carefully conceived, the public health costs of enforcement measures could outweigh the benefits. Because the relationships between competition, public health and particular proposed interagency intellectual property enforcement measures have not been adequately examined, and because the Joint Strategic Plan implicates broad public and consumer interests, the Office of the Intellectual Property Enforcement Coordinator should host public meetings toward designing a tailored and appropriate policy – before commencing efforts to intensify intellectual property enforcement for the purported purpose of protecting public health.

We are also concerned that IPEC's Federal Register notice seems to reflect primarily the priorities of rights holder industries. We propose IPEC convene a consumer protection advisory committee, to represent public interests including competition, access, health and safety.

In our comments, we will:

- Introduce the essential role of competition and the generics trade in promoting global access to safe, effective and affordable medicines;

- Review the risks to access to medicines that overreaching intellectual property enforcement measures can pose, and how the Joint Strategic Plan can take these risks into account;

- Outline why intellectual property enforcement is an indirect and inadequate framework for protecting public health and safety from dangerous products;

- Propose rational alternatives and appropriate foundations for interagency action;

- Conclude with recommended principles to help avert abuses and anti-competitive effects in the enforcement of copyright, patents and trademarks, to inform the content and objectives of the Joint Strategic Plan.

The role of generic competition in promoting global access to medicines

Improving global access to medicines depends in large part on market competition reducing prices over time, to levels where governments and international agency treatment programs can scale-up coverage. For example, over the last ten years, global competition and generic medicines have produced a revolution in HIV/AIDS treatment, reducing prices from $10,000 to $100 per person per year, and enabling more than four million people worldwide to access lifesaving antiretroviral therapy. Competition remains every bit as vital today to improve broad access to new drugs, including among many others expensive second and third-line HIV/AIDS treatments.

Risks of overreaching intellectual property enforcement to access to medicines

Measures that limit competition may therefore limit access to medicines. Public Citizen is particularly concerned about recent trends in intellectual property enforcement toward measures that may:

- Restrict availability and free movement of generic medicines;

- Create uncertainty and impose excessively high costs on generics firms, chilling the trade.

We detail some of our very specific concerns in Appendix A, attached.[2] Appendix A analyzes particular leaked model provisions of the proposed Anti-Counterfeiting Trade Agreement, which is widely understood to be one of several templates under serious consideration for heightened intellectual property enforcement efforts in the United States and beyond.

Briefly, these provisions include proposals by Parties to ACTA to:

- Allow border measures that seize lawfully produced generic medicines that are being transshipped to where they may be lawfully consumed,

- Impose robust penalties and litigation and storage fees on alleged infringers, potentially without procedural or monetary safeguards or anti-abuse provisions adequate to deter frivolous or harassing enforcement efforts by rights holders,

- Establish new agreements on damages and injunctive relief that could hinder both innovation and the manufacture and distribution of lawful generic equivalents,

[2] Appendix A, *"Comments of Essential Action on the Proposal for an Anti-Counterfeiting Trade Agreement."*

- Impose liability for active ingredient manufacturers that may threaten the generics supply chain.

- Establish criminal penalties for non-counterfeiting cases of trademark infringement,[3] potentially chilling the legitimate generics trade (this is discussed further in the next section).

Analogues to some of these provisions have appeared in other proposed laws and enforcement measures in the United States and elsewhere.

Generics firms are often smaller than patent-based pharmaceutical firms, and operate on lower margins of return. Public Citizen is concerned these provisions jeopardize not only particular shipments of generic medicines, but the business model for the relatively small-scale generics industry, and the access to medicines interests that rely on it.

We request that the public be given the opportunity to consult and comment on proposed elements of the Joint Strategic Plan as it is developed, in order to protect the access to medicines interests at stake.

Recent specific examples of enforcement measures that have jeopardized health include, among others, the seizures of licensed generics in Europe, summarized in part here by Kevin Outterson of Boston University School of Law:

> Recent seizures of generic medication by Dutch customs officials highlight the danger from over zealous border protection regimes based on intellectual property. Brazilian officials have identified over a dozen incidents where authorities have confiscated generic drugs in transit passing through Dutch ports in 2008 (Statement by Brazil 2009; KEI 2009). Most notably, in November of 2008, AIDS medications purchased by The Clinton Foundation through UNITAID were confiscated on the grounds that the shipments contained "counterfeit" goods, when in fact there was neither misrepresentation as to source nor patent infringement (Pandeya 2009). These drugs were manufactured in India and en route to Nigeria where they would have been able to treat 166 HIV positive individuals for three months (Pandeya 2009; HAI et al. 2009). These generic drugs are legitimate products, prequalified by the WHO, and fully compliant with patent and trademark laws in India, Nigeria, and under TRIPS (UNITAID 2009). A Dutch patent holder instigated the seizure, even though the drugs were not being marketed in Europe but merely being transshipped through Schipol airport on their way to Nigeria. This action has been strongly condemned (HAI et al. 2009; UNITAID 2009). As one Health Action International official said, "[t]his is a grave situation. If the shipment is not allowed to pass, HIV positive Nigerians will miss out on critical treatment. We're concerned about

[3] Japan and New Zealand propose criminalizing non-counterfeiting, "likelihood of confusion" trademark violations in Section 3, Article 2.14 (1) of the latest leaked ACTA text.

> what appears to be confusion between counterfeit medicines that kill people and generic medicines that save lives" (HAI et al. 2009).[4]

Although these medicines were seized abroad, and U.S. officials have stated the United States protocol is different, it is important to note the proposed U.S. interagency intellectual property enforcement effort contemplates considerable international cooperation, as well as the provision of technical assistance.[5] U.S. interagency norms will carry influence in many parts of the world, and U.S. resources may be broadly applied. What standards regarding generic medicines will the United States support or accept in its joint enforcement programs?

Seizures of licensed generics based on allegations of likelihood-of-confusion trademark misappropriation may also impose anti-competitive effects without public health benefit. We discuss this further in the next section.

Worldwide, many proposed enforcement measures to date do not contemplate important safeguards. These should include, at a minimum and among others, explicitly rejecting patent infringement or non-counterfeiting trademark similarity as medicines detention triggers, adequate procedural protections and provisions for the rights of alleged infringers to be heard, and robust anti-abuse and liability provisions adequate to deter rightsholders from triggering frivolous, harassing, or otherwise wrongful detentions.

Public Citizen recommends that the Joint Strategic Plan, in addition to considering the legitimate interests of copyright, trademark and patent holders, also consider the legitimate interests of licensed businesses attempting to compete in the global market. The objectives of the Joint Strategic Plan as listed in the Federal Register include at least nine separate explicit references to stopping infringement and protecting rights holder interests, one reference to "U.S. persons otherwise harmed by infringements in other countries," but no references to protecting the interests of competition or the rights of persons accused of infringement. At least fifteen of IPEC's twenty suggested Supplemental Comment Topics solicit suggestions specifically to reduce IP infringement, but again none request input on ensuring adequate process to protect legitimate competition.

The Joint Strategic Plan should add to its objectives the principles of non-interference with legitimate commerce and accuracy (limiting the frequency and scope of enforcement actions that ultimately prove to have targeted non-infringing products). IPEC should actively seek input and best practices on safeguarding competition under intellectual property enforcement measures. Public Citizen urges a deeper analysis and public

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[4] Kevin Outterson, "Import Safety Rules And Generic Drug Markets," in Import Safety: Regulatory Governance in the Global Economy (Cary Coglianese, Adam Finkel, & David Zaring, eds., 2009) (The University of Pennsylvania Press) (http://ssrn.com/author=340746).

[5] *See, e.g.*, FR Doc. 2010-3539 Numbers 11-13. Public Citizen provides recommended guidelines for the provision of technical assistance in intellectual property issues, *attached* as Appendix B.

consultation process regarding specific proposed enforcement protocols and their potential effects on competition and global access to medicines.

There is another public cost to consider. Although public laws provide for patent, trademark and copyright protection, it is most generally and historically the responsibility of private parties to identify alleged infringements in the market and bring suit. The proposed interagency effort and other new intellectual property enforcement measures considerably shift the burden of private rights enforcement to the public. This comes at financial cost to taxpayers, and may divert law enforcement resources from other priorities. This is a serious concern in the United States, but even more so in the developing countries to which IPEC will be devoting attention.

Significant shifts in enforcement responsibility and enforcement mechanisms could imply a change in the very nature of these private commercial rights. This is a significant policy development and public expense that should be subject to greater public input and deliberation, to ensure consumer interests are protected as well.

To the extent the enforcement effort intends to serve both commercial and health and safety interests, there is a risk it could operate at cross purposes. As regards public safety, resources could be more effectively and efficiently invested in continuing interagency and global efforts that directly apply health, safety and consumer protection standards and policy tools, such as pharmacovigilance, rather than the indirect and insufficient framework of intellectual property. Meanwhile, some intellectual property enforcement measures could import new public health risks by jeopardizing competition. Again, the Joint Strategic Plan should adopt safeguards and consult consumer groups to ensure the interests of health, safety, competition and access are protected.

Inadequacy of an IP enforcement framework to protect public health & safety

Intellectual property enforcement is an overly broad, under effective and duplicative tool for protecting the critical interests of consumer health and safety. There are more effective and narrowly tailored policies that should be applied to protect the public from dangerous goods, including adulterated, mislabeled, and substandard medicines – without risking anti-competitive effects.

Patents

Patent infringement analysis is not reasonably related to trademark counterfeiting, fraudulent misrepresentation of source, health or safety. The required analyses are entirely separate. Patents pertain to alleged use of claimed proprietary inventions, the others to marks, deliberate mislabeling or detailed assessments of drug safety and efficacy. Even a proven patent infringement is no basis whatsoever for classifying a medicine (or any other product) as counterfeit, under either the World Trade

Organization[6] or World Health Organization[7] definition. Indeed, patent infringement cases allege putting the patented technology to use. In almost all cases, the alleged infringer is attempting to manufacture or market a legitimate medicine. Rather than protecting public health, imprecise or overly aggressive patent enforcement measures could obstruct competition and jeopardize access to medicines.

Copyright

Copyright is not reasonably related to health or safety.

Trademark

In intellectual property usage, the term "counterfeit" applies correctly to a subset of trademark infringement. 18 U.S.C. § 2320 defines a counterfeit mark as a "spurious mark ... that is identical with, or substantially indistinguishable from, a mark registered on the principal register in the United States Patent and Trademark Office and in use, whether or not the defendant knew such mark was so registered."[8] This is similar in principle to the World Trade Organization definition.

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[6] Under the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights, Article 51 *at* footnote 14, "counterfeit trademark goods shall mean any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation".

[7] The World Health Organization defines a counterfeit as "a medicine, which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging."

[8] 18 U.S.C. § 2320(e):

> 1) the term "counterfeit mark" means--
>
> (A) a spurious mark--
>
> (i) that is used in connection with trafficking in any goods, services, labels, patches, stickers, wrappers, badges, emblems, medallions, charms, boxes, containers, cans, cases, hangtags, documentation, or packaging of any type or nature;
>
> (ii) that is identical with, or substantially indistinguishable from, a mark registered on the principal register in the United States Patent and Trademark Office and in use, whether or not the defendant knew such mark was so registered;
>
> (iii) that is applied to or used in connection with the goods or services for which the mark is registered with the United States Patent and Trademark Office, or is applied to or consists of a label, patch, sticker, wrapper, badge, emblem, medallion, charm, box, container, can, case, hangtag, documentation, or packaging of any type or nature that is designed, marketed, or otherwise intended to be used on or in connection with the goods or services for which the mark is registered in the United States Patent and Trademark Office; and

A trademark counterfeit is distinct from a case in which one product's commercial design or packaging may suggest a "likelihood of confusion" with an established trademark. For example, pharmaceutical firms sometimes give their products commercial names derived in part from an active ingredient's international nonproprietary name (INN). Products based on the same active ingredient may therefore bear similar names. Generic medicines also sometimes feature packaging with similar qualities to established marks, specifically because the products are bioequivalent, and designed for consumers' interchangeable use – as evidenced in the aisles of most American drug stores. Either of these cases could form the basis of a civil trademark infringement claim, and trademark owners have a legitimate commercial interest in defending their marks. But neither would be properly termed a case of "counterfeiting."

It is important intellectual property enforcement measures reflect this distinction. Even in the trademark context, only a subset of potentially infringing medicines (or other goods) poses a risk to public health. These include deliberately mislabeled or fraudulently packaged medicines, which fraudulently misrepresent their source or ingredients to consumers. Hence the TRIPS standard for criminal trademark infringement – willful trademark counterfeiting on a commercial scale – is a category that rightly triggers public health concern.[9] It is generally appropriate that public authorities intervene in such circumstances.

But generic medicines (or other goods) that correctly describe their source and ingredients, yet bear symbols or words that could be confused with trademarks, cannot be

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(iv) the use of which is likely to cause confusion, to cause mistake, or to deceive;

[9] But there could also be reason to distinguish between cases of willful trademark counterfeiting and cases of counterfeiting where no intent to fraudulently misrepresent source is evident. Note the TRIPS definition of counterfeiting does not require a showing of intent (it is arguable the U.S. statutory definition does, in its use of the word "spurious"). The "substantially indistinguishable mark" counterfeiting standard could also be different in some limited cases than a standard of fraudulent misrepresentation of source. Perhaps one firm could use a packaging design nearly identical to an established design, but employ a different name. This could amount to "substantially indistinguishable" use of a mark classifying the product as counterfeit, but it might still represent more an effort to indicate similarity (or bioequivalence) to the first product than an effort to claim the product is actually produced by the other company.

This would mean only a subset (willful or fraudulently misrepresenting source) of a subset (counterfeit) of a subset (trademark) of the full body of intellectual property law corresponds to medical products that raise public health concerns by their nature. And as discussed in subsequent paragraphs, drug regulatory and other consumer protection mechanisms already provide ample authority to deal with this subset. Further, willful trademark counterfeiting on a commercial scale is itself only a small subset of the medicines that raise quality concerns, including non-mark infringing fakes, substandards, adulterated medicines, and medicines that are not adequately safe or efficacious. Intellectual property law does not reach these quality concerns. Rather, it is drug regulatory authority that provides standards to deal adequately with each.

TRIPS creates an enforcement distinction between counterfeiting in general and cases of "willful trademark counterfeiting on a commercial scale," the latter being subject to criminal penalties (Article 61, emphasis added).

said to pose such a categorical risk. At the same time, there are many substandard medicines, and even some adulterated or fake drugs, that may not misappropriate a mark, and hence fall well beyond trademark law's reach. As a proxy for health, safety and fraudulent drug concerns, trademark law, applied as a whole, would be both over and under inclusive.

Further, trademark law is not a necessary, or even particularly logically beneficial, framework to identify fraudulent medical products. It is true most customs officials worldwide probably do not commonly have the resources to perform medicine quality tests. Instead, customs officials today, apart from actions mandated by court or administrative orders, are probably most routinely inspecting medicines shipments for evidence of fraudulent misrepresentation of source and fake packaging. But this is not an analysis unique to trademark, or for which trademark law is even required. And in cases of fraudulent misrepresentation where no valid trademark is copied, trademark law would not help.[10] Inspection for fake packaging is even more a traditional consumer protection, drug regulatory, anti-fraud or health and safety test than it is a trademark test – and trademark analysis does not add any special health or safety component to it.

The registration and sale of medicines is regulated by drug regulatory authorities. Selling an unregistered or adulterated medicine is typically a criminal offense, whether it infringes a trademark or not. Importantly, the trademark framework is not necessary to take fraudulently mislabeled or unsafe medical products into custody. A pharmaceutical product that fraudulently misrepresents its source or ingredients is not licensed, and can be removed from the channels of commerce in accordance with the Food and Drug Administration's statutory authority and other drug regulatory authorities' rules.

A product is not a dangerous fake because it may infringe a trademark. Rather, a product may infringe a trademark because it is a fake. We have policy tools to go after potentially dangerous fakes directly, and we should do so. It is not evident what standards, if any, trademark, or any intellectual property right, provide for taking action to protect public health that do not already exist in other areas of the law.

In a December 2009 story on counterfeits and intellectual property enforcement for

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[10] And, in a "likely confusion" trademark case, as opposed to trademark counterfeiting, analyses performed by customs officials would probably be considered cursory by the standards of U.S. legal tests. For example, the second circuit's oft-cited *Polaroid* decision establishes the following standard:

> Where the products are different, the prior owner's chance of success is a function of many variables: the strength of his make, the degree of similarity between the two marks, the proximity of the products, the likelihood that the prior owner will bridge the gap, actual confusion, and the reciprocal of defendant's good faith in adopting its own mark, the quality of defendant's product, and the sophistication of the buyers. Even this extensive catalogue does not exhaust the possibilities--the court may have to take still other variables into account.

Polaroid Corp. v. Polarad Elect. Corp., 287 F.2d 492 (2d Cir.), cert. denied, 368 U.S. 820 (1961).

Homeland Security Today, DHS Assistant Secretary for Immigration and Customs Enforcement John Morton said, "Consumers seeking a better price or wanting to buy drugs without a prescription often do not know that the drugs they order through the Internet are often manufactured in inferior facilities, with substandard or dangerous ingredients, and with a high likelihood that they will not perform as expected, or worse, will cause harm."[11] Note that public agencies are already empowered to take action against any of these problems without ever applying intellectual property rules. In fact, intellectual property rules do not even provide the authority to address any of these problems – unless an infringement of a commercial mark is also discovered. Instead, it is drug regulatory rules, along with law enforcement powers to act against public endangerment, which provide this authority regardless of mark infringement.[12]

This is not an objection to trademark enforcement appropriately conducted in the model of mark owners exercising market vigilance. Indeed, in the course of exercising private vigilance over its mark, a rights holder may identify a fraudulent imitator product that could be dangerous. It is important companies can easily report such information to responsive public health and law enforcement authorities for threat evaluation and swift action. Indeed, companies should be *required* to disclose such information of potentially dangerous fakes to authorities in a timely fashion. (In some cases, companies have been accused of being slow to report such knowledge, for fear of reducing public confidence in their brands – endangering public health in the process).[13] We propose such a statutory requirement (which should be subject to safeguards that deter any harassing reporting not based in legitimate public health concerns) in more detail in the following section.

But none of this implies intellectual property is the appropriate framework to guide *public* vigilance and safety efforts. Rather, the private vigilance of marks, subject to

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[11] "Counterfeit Goods Remain Huge Border Challenge," Phil Leggiere, December 7, 2009, *available at*: http://www.hstoday.us/content/view/11338/149/.

[12] Nor is intellectual property law required to identify the dangerous products in the first instance – because again, public officials can inspect packaging, follow leads and take action against fraudulently mislabeled drugs without ever needing trademark law.

[13] *See, e.g.*, "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; "Counterfeit medicines – What are the problems?" Pharma-Brief Special, BUKO Pharma-Kampagne, a member of Health Action International (2007).

For example, in 1995, GSK allegedly asked the Ghanaian government not to alert the public of the presence of fake halofantrine antimalarial syrup in the market, for the sake of the company's reputation. *BUKO, PLoS.* (GSK also was reluctant to share information about fake syrup with the authors of the PLoS article.) In 1998, the Brazilian government accused Schering do Brasil of failing to disclose knowledge of counterfeit contraceptives for thirty days (a court cancelled the government's fine on appeal). *PLoS.* In 2002 in Kansas City, BMS and Eli Lilly settled for $72 million with the families of deceased victims of counterfeit drugs, possibly to avoid the precedent that drug companies could be held liable for failing to disseminate information about counterfeits. *PLoS.* There are, of course, counterexamples. "In 2002, Johnson and Johnson issued 200,000 letters to health care professionals in the US warning them of fake Procrit…within one week of being notified of a severe counterfeit problem." *PLoS.*

safeguards and anti-abuse provisions that protect legitimate competition, can complement robust public mechanisms to protect consumers from unsafe products through appropriate frameworks, including but not limited to pharmacovigilance.

Trademark analysis and enforcement conducted by public agencies is not necessary, and probably not even beneficial, to protecting the drug supply, given that there are better available alternative mechanisms already in effect. More precise and inclusive policies specifically target fraudulent and deliberately mislabeled drugs – irrespective of trademark or any other intellectual property issues. This is indeed a serious public priority.

This is not to say that significant public investments in an array of trademark enforcement measures could not identify potentially dangerous fakes and take them into custody. They could. But these investments would ultimately be somewhat less efficient and less rationally related to the goals of protecting consumer health and safety than would similar investments targeting fraudulently mislabeled medicines and other quality, safety and efficacy problems directly.

Nor are public agency inertia or intellectual property rightsholder enthusiasm appropriate reasons to pursue anti-medical counterfeiting efforts through an intellectual property framework. In addition to the risks of missing non-mark infringing fakes and underinvesting in remedies for other critical (and probably more common) medicine quality problems, a trademark framework may also come with the following public health costs:

- First, trademark disputes can implicate licensed generics. For example, if customs authorities, acting properly on an administrative order alleging commercial misappropriation of a trademark, seize generic medicines that correctly cite their source and have been licensed by the proper drug regulatory authorities, this could delay or prevent a quality medicine from reaching patients. The legitimate interests of the mark holder in such a case could be adequately addressed by court proceedings and traditionally available remedies. The interests of patients need not suffer.

- Second, the present push to catch infringers, with incentives seemingly organized around increasing the volume of goods taken into custody and protecting the interests of rights holders, without corollary measures and incentives to protect the interests of competition and access, increases the risk of overzealous enforcement actions targeting goods that prove not to infringe any intellectual property right in the end analysis. In other words, agencies participating in IP enforcement efforts today have strong motivation to err very far on the side of overenforcement, potentially stopping generics that are not only registered, but ultimately non-infringing.

- Third, addressing health and safety through an intellectual property framework has already led to irrational and harmful applications of IP standards other than

trademark, particularly in international contexts. Prime examples are Kenya's anti-counterfeiting law, Tanzania's regulations and proposed laws in Uganda and other countries that define counterfeiting so irrationally as to criminalize trade in generics.

By treating intellectual property enforcement as a proxy for consumer health and safety interests, the U.S. government may contribute to these undesirable trends and policy outcomes. Enforcement investments may shore up models of economic monopoly, which may not be the most productive for society, under guise of protecting health and safety concerns. Finally, there is reason for concern that some intellectual property enforcement investments may come at the expense of more direct investments in health and safety regimes.

The best way to ensure public interests are rationally protected is to apply policy frameworks that correspond precisely and directly to their objectives. There are legitimate interests at stake in the reasoned enforcement of intellectual property rights. But intellectual property enforcement is ultimately a poor framework for protecting public health and safety. IPEC's Federal register notice requests comments, "identifying … duplication of efforts, waste … and other unjustified impediments to effective enforcement actions." Many public agencies and law enforcement authorities worldwide already directly target medicines that misrepresent their source. Trademark law duplicates this authority, and without care, investments in broad IP enforcement measures could come at an opportunity cost to investments specifically related to health and safety. Given the public's ability to invest in better frameworks, broad intellectual property enforcement efforts, taken as a whole, should not be justified on health and safety grounds.

These matters require much more attention and analysis than they have received, and should be carefully considered in the Joint Strategic Plan.

Proposed policies to protect public health & safety

IPEC's Federal register notice requests "specific strategies for reducing the threats to public health and safety caused by the use or consumption of infringing goods (for example, counterfeit drugs, medical devices, biologics and ingested consumer products)."[14]

Public Citizen proposes that public safety should be protected through public safety frameworks, including pharmacovigilance, rather than through regimes designed primarily to protect exclusive commercial rights. As regards medicines and medical devices, the United States already has such frameworks in FDA rules. Interagency and international efforts best protect public health by focusing squarely and specifically on

[14] FR. Doc 2010-3539, Number 17.

fraudulently mislabeled, adulterated and unlicensed medicines, as well as substandards and other quality failures, rather than intellectual property.

Policies should strengthen drug regulatory authorities and consumer protection agencies in the U.S. and abroad. Policies should increase post-marketing pharmacovigilance and testing. This could include support for training as well as equipment. The U.S. government should direct resources toward these priorities. Targeted international law enforcement cooperation efforts that identify criminal operations producing fake medicines also merit continued support. We commend recent successful operations by agencies such as U.S. Pharmacopoeia and others to identify adulterated malaria medicines and remove them from the channels of commerce.

IPEC's instructions in the Federal Register state, "Submissions directed to threats to public health or safety must include a detailed description of the threat, identify the source of the information substantiating the existence of that threat, and provide a copy of or a citation to each such source."[15] Public Citizen commends IPEC's insistence on specificity and verified accounts. Policies established to fight "counterfeit medicines" have often been informed by too little empirical data.[16] Agencies should develop reliable, impartial empirical data on the prevalence of a variety of quality problems in the market, including substandards and drugs that misrepresent their source. This data could inform rational decisions for allocating scarce public resources to maximum effect.

An additional policy for assisting in the detection of fraudulent mislabeled drugs would be mandatory disclosure requirements. The United States should require companies to disclose any information they have about potentially dangerous mislabeled medicines on

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[15] F.R. Doc. 2010-3539 *at* Part I.

[16] *See e.g.*, Kevin Outterson, "Import Safety Rules And Generic Drug Markets," in Import Safety: Regulatory Governance in the Global Economy (Cary Coglianese, Adam Finkel, & David Zaring, eds., 2009) (The University of Pennsylvania Press) (http://ssrn.com/author=340746):

> Statistics on counterfeit medicine are widely distributed but are neither reliable nor transparent (Outterson & Smith 2005:527). Estimates on the scope of the counterfeit drug problem vary greatly. Estimates on prevalence in various countries range from 1% to 50% of the drug supply, with reports of 40%, 30%, 17%, and 10% (Bird 2008:389). Recently, IMPACT estimated the prevalence of counterfeit medicines to be less than 1% of sales in developed countries – despite the fact that the potential profit of criminal counterfeiters is highest in these countries – and between 10% and 30% in developing countries, where the profit potential is lower. These estimates do not come from peer-reviewed journals, and many actually come from the pharmaceutical companies themselves (Park 2009:23-24).
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> In many of these studies, substandard, adulterated, parallel traded and generic drugs have been improperly conflated with deliberate violations of trademark law (counterfeits), often under the imprecise catch-all category of "fake." The few studies that did differentiate found the majority of the problematic drugs bore genuine trademarks but were substandard. For example, in India it has been estimated that 8.19 – 10.64% of drugs are substandard (but apparently bearing a proper trademark), while only 0.24 – 0.47% are actually counterfeit in the trademark sense (Park 2009:25; Outterson & Smith 2006). The primary health issue appears to be drug quality, not criminal counterfeiting.

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.[17] Some consider PSI's counterfeiting database the world's best, yet it "is not accessible to the WHO, health authorities or the public."[18]

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.[19] Companies would be required to 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 potentially dangerous criminal adulteration.[20] Countries could also commit to sharing such information. Again, disclosure and notification requirements should focus on quality issues and include appropriate anti-abuse provisions, so they are not used to taint licensed competition.

IPEC's Federal Register notice requests "specific strategies to significantly reduce the demand for infringing goods or products both in the U.S. and in other countries."[21] There is broad consensus that high prices of medicines and other 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." [22] Therefore one

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

[18] "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.

[19] PLoS, *supra* at 307.

[20] H.R. 2345, 109th Congress. Section 2(3): A manufacturer of a drug that receives or otherwise becomes aware of information that reasonably suggests that a violation described in paragraph (3) or (4) of section 303(a) may have occurred with respect to the drug shall report such information to the Secretary not later than 48 hours after first receiving or otherwise becoming aware of the information.

[21] FR Doc. 2010-3539, Number 19.

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

important global strategy to reduce demand is promoting access to quality products through robust, price-lowering competition.

Recommended principles for enforcement of patents, trademarks and copyright

IPEC requests "detailed recommendations from the public regarding objectives and content of the Joint Strategic Plan and other specific recommendations for improving the Government's intellectual property enforcement efforts." We believe the following principles can help IPEC avert unintended anti-consumer and anti-competitive effects in the enforcement of copyright, patents and trademarks.

Process

- We recommend IPEC host public meetings toward designing a tailored and appropriate enforcement policy, as a necessary component of the development of the Joint Strategic Plan.

- We recommend IPEC establish a consumer protection advisory committee, with civil society representation, to consult and receive analyses on the interests of competition, access, health and safety.

Framework

- The Joint Strategic Plan should reflect a sophisticated and analytical understanding of interagency and international efforts already underway to protect consumers from unsafe products, including but not limited to pharmacovigilance. The Joint Strategic Plan should not superimpose intellectual property enforcement mechanisms over health, safety and consumer protection tools already in use at agencies. The Joint Strategic Plan should include a detailed assessment of opportunity costs that could arise from expending public resources intended in part to protect public health and safety through an intellectual property enforcement framework, as opposed to investing in tailored mechanisms that protect health and safety directly.

- The United States should require companies to disclose information they have about potentially dangerous mislabeled medicines on the market.

- IPEC should always treat trademarks, patents and copyright as distinct and discrete commercial rights, each with its appropriate standards for infringement, enforcement measures and remedies. Sound policy rests on applying the appropriate standards and measures to each, rather than conflating all in law or policy as general "intellectual property rights."

- We recommend that the Joint Strategic Plan, in addition to considering the legitimate interests of copyright, trademark and patent holders, also consider the

legitimate interests of licensed businesses attempting to compete in the global market.

- In response to IPEC's request for "ways to improve the adequacy, effectiveness and/or coordination of the enforcement training and technical assistance provided by the U.S. Government,"[23] we recommend IPEC adopt the principles included in Appendix B, "Public Citizen Recommended Guidelines for U.S. Government Provision of Technical Assistance in Matters Concerning Intellectual Property Rights." Additionally, Public Citizen cautions against the proposition included as FR Doc. 2010-3539, Number 12(c), "to enhance industry participation in relevant training programs," which would self-evidently bias the content of the trainings toward industry – and presumably rights-holding industry – interests.

- The JSP should count among its objectives and measures of success the principles of:
    - Accuracy – limiting the frequency and scope of enforcement actions that ultimately prove to have targeted non-infringing products
    - Non-interference with legitimate commerce.

Safeguards

Public Citizen urges, at a minimum, the following principles for any enforcement policies that could affect the international medicines trade. We suggest IPEC explicitly endorse these principles:

- Enforcement measures must not compromise generic medicine supply chains.

- All enforcement policies must include robust anti-abuse provisions, including strong liability provisions adequate to deter wrongful action by private parties or wrongful action by public authorities induced by private parties.

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

- 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 at borders, whether in-transit or at their point of destination.

- Alleged trademark infringement based on a "likelihood of confusion" is not a valid ground for detaining medicines at borders, whether in-transit or at their point of destination. Rather, border measures should be applied to medicines only on case-specific and good faith belief of public endangerment or evidence of willful, commercial scale criminal trademark counterfeiting.

[23] FR Doc. 2010-3539, Number 12.

- Patent infringement and non-counterfeiting "likelihood of confusion" trademark infringement are not criminal offenses. IPEC should reject efforts by international enforcement partners to criminalize either. Third parties should not be held liable for patent infringement or "likelihood of confusion" civil trademark infringement.

- Pharmaceutical patent holders should not be able to enforce patents that they have not disclosed publicly and identified as protecting inventions in a named medicine at the time of marketing application. For more information, see Appendix C.

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

Sincerely,

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Appendix A – Essential Action, "Comments of Essential Action on the Proposal for an Anti-Counterfeiting Trade Agreement," attached.

Appendix B – Public Citizen, "Recommended Guidelines for U.S. Government Provision of Technical Assistance in Matters Concerning Intellectual Property Rights," attached.

Appendix C – Essential Action, "Ensuring Effective Biogenerics Legislation: Timely Patent Dispute Resolution and Patent Disclosure," attached.