

Notice of Intent to Testify

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Hearing Statement of Essential Inventions, Inc. on the 2012 Special 301 Review.

About Essential Inventions

Essential Inventions, Inc. is a US-based corporation created to distribute generic medicines. In order for this small company to operate, it must overcome patent and other barriers to enter markets.

Essential Inventions has previously been involved in several compulsory licensing cases. One case involved a request to manufacture and export generic versions of imatinib mesylate, a drug used to treat certain rare forms of cancer, from Canada to Chile. A second case involved a request for compulsory license in order to import AIDS medicines from India to Cameroon. A third case involved a request to NIH to exercise its march-in rights on the patents on Xalatan (generic name latanoprost), a government funded invention that Pfizer sold for higher prices in the United States than were charged in any other high income country. The fourth case involved march-in rights for patents on ritonavir, a government funded invention sold by Abbott. Abbott charged US consumers prices that were 5 to 10 times than Abbott charged consumers in Europe or Canada. Essential Inventions also petitioned OMB to use government rights in several AIDS drugs, in order to supply inexpensive generic drugs to US HIV/AIDS patients that received federally-funded reimbursements. The Bush administration opposed our efforts in each of the cases described above. In the imatinib mesylate case, the US intimidated the governments of Chile and Canada, ultimately harming the final outcome.

Although the Bush Administration opposed these cases, some public benefits have nonetheless been realized as a result of actions by Essential Inventions. The case of ritonavir went to a hearing—the only NIH march-in case to do so—and Abbott ultimately made very large concessions in the pricing of ritonavir to federal program, saving the US taxpayers millions of dollars. Thus, while Essential Inventions has not yet delivered drugs to customers, it has created a large public benefit in the US, in the form of lower prices for ritonavir.

Soon, Essential Inventions will file another compulsory licensing request. Among other requests, Essential Inventions will ask the NIH to adopt a general rule that it will grant march-in requests on patents when the prices for products in the United States are higher than the companies charge consumers in other high income countries.

Essential Inventions is also in discussions with suppliers for possible distribution of a generic version of Herceptin, an expensive drug now used to treat breast cancer. In order to do so,

however, Essential Inventions needs a workable pathway for the manufacturer and distribution of this important drug for HER2+ breast cancer patients.

The Special 301 process can negatively impact our operations by encouraging the creation of patent and non-patent barriers that exceed international obligations, thus reducing the likelihood that Essential Inventions will be able to achieve its goals. Herceptin is a life-saving drug for many women suffering from breast cancer and it is critical for this Committee to recognize the real and tangible impacts its Special 301 review process will have for patients. The Special 301 process, because of its potential negative impacts, is a health issue, a human rights issue, and in particular for Herceptin, a women's health and women's rights issue.

As a corporation involved in compulsory licensing requests with a mission to distribute inventions that support public health, Essential Inventions opposes actions in the USTR Special 301 process that create barriers to the distribution of generic medicines.

TRIPS Standards and Other International Commitments

The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) provides for global norms on intellectual property protection. This global standard, in conjunction with other important international instruments or documents such as the Doha Declaration on TRIPS and Public Health or the World Health Organization (WHO) Global Strategy and Plan of Action, set forth global commitment and standards. It is inappropriate for the US to use a unilateral process to pressure countries to provide for increased levels of intellectual property protection that go beyond the minimum TRIPS standards. Efforts to pressure countries to implement heightened intellectual property standards not only undermines important protections for the general public, including those that improve access to knowledge or access to medicines, but also creates a form of cultural imperialism. Countries are pressured to adopt US norms to avoid placement on the Special 301 watch list, without regard to the development concerns or cultural context, in what appears to be a form of cultural imperialism by the US.

Essential Inventions is in the business of creating and distributing generic versions of life-saving medicines and cannot conduct its mission when the USTR Special 301 reports encourage countries to implement higher levels of intellectual property rights than are mandated by international law. Prior reports evidence a commitment by USTR to encourage countries to give up their TRIPS flexibilities and instead follow a US model, even when such provisions would clearly hinder access to medicines.

In order to have a clear pathway to distribute essential medicines, such as Herceptin, TRIPS flexibilities and safeguards must be preserved. Prior Special 301 reports indicate that USTR either ignored or seeks to eliminate the use of important TRIPS flexibilities. It is also important to recognize that TRIPS obligations can be implemented in a variety of ways and the US model is often inappropriate.

Patent Extensions

Essential Inventions opposes the promotion of laws that extend patent terms beyond the twenty-years mandated by the WTO.

Patentability Criteria

Essential Inventions also opposes USTR pressure on countries to lower patentability criteria. Article 27 of TRIPS lays out the framework for patentable subject matter; however a key flexibility retained by countries is the determination of what inventions meet the standards that inventions are “new, involve an inventive step and are capable of industrial application.” In last year’s Special 301 report, USTR placed India on its “priority watch list” and cited concerns that India prohibits patents for new forms of known inventions where there is no showing of increased efficacy. The Philippines was similarly placed on the “watch list” with the same objection noted. By pressuring countries to lower patentability criteria results in more patents, contributing to a system of “evergreening,” and delays entry of generic drugs into the market, even where the original patent on the invention has long expired.

Domestically, it should be noted that when Essential Inventions submitted its request to the Department of Health and Human Services to exercise government march-in rights on ritonavir, Abbott Laboratories sought to block the request by claiming, in part, that in addition to the NIH funded patents on the drug itself, Abbott had obtained patents on the use of gel tabs to deliver ritonavir to patents, and also on its combination with any protease inhibitor used to treat HIV/AIDS. Abbott claimed these patents would prevent Essential Inventions from producing and distributing generic versions of the medicine. Although the government funded, and therefore had march-in rights under the Bayh-Dole Act to, the active pharmaceutical ingredient in ritonavir, Abbott’s patents over its formulation and combination provided additional barriers.

Abbott’s claims were dubious as they applied in the domestic context, and not necessarily relevant in the case in other countries that did not grant patents on gel tabs or new combinations of older drugs. For many developing countries, it is important to preserve their rights to determine the appropriate patentability criteria within the flexible definition of Article 27 of TRIPS and prevent systems of evergreening. Countries should be free, for example, to reject patents for minor modifications of formulations, or the creation of heat-stable formulations, as failing one of the elements for patentability under TRIPS.

Patent Linkage

Essential Inventions objects to policies of exporting the practice of linking drug registration to patent status. Not only is it extremely difficult for regulators to evaluate such patents, but the US system has demonstrated that patent linkage has been a colossal failure as companies routinely file spurious patents with the FDA which are later invalidated by courts. Patent linkage creates particular problems in countries that cannot afford to challenge low quality patents.

Exclusive Rights Over Regulatory Test Data

We also emphasize that placing pressure on countries to adopt US models of protection or TRIPS implementation is not only often inappropriate, but is, at times, unethical. For example,

Article 39.3 of TRIPS requires member states to protect “undisclosed test or other data” that involves “considerable effort” from “unfair commercial use.” Such obligations do not apply “where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.” TRIPS does not require countries to grant exclusive rights to rely upon test data to register new products. Indeed, if the TRIPS did so require, the United States would have succeeded in bringing a WTO case against the many countries that refuse to recognize such exclusive rights.

The US has elected to implement Article 39.3 of TRIPS, relating to the protection of undisclosed regulatory test data, by providing for exclusive rights over test data. By providing the originator of the data with exclusive rights, generic companies cannot rely on such data proving the safety and efficacy of a drug where the exclusive rights remain in effect even when the patent has expired. Exclusive rights in test data thus result either in a delay in generic entry into the market--keeping the prices of important medicines high and out of the reach of many patients--or forces the generic company to replicate the test data in violation of certain medical ethics. A number of countries listed on the 2011 Special 301 watch list were encouraged to “provide adequate protection against unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approvals for pharmaceutical products.” Exclusive rights in test data creates additional barriers for corporations like Essential Inventions to overcome, delays entry of generic products into the market, and contributes to a wasteful or unethical system.

It is important to note that exclusive rights in test data is not the only way to implement Article 39.3 of TRIPS. It does not even represent the most efficient method, and it also presents a direct conflict with established medical ethics. Paragraph 20 of the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects notes:

Physicians may not participate in a research study involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians must immediately stop a study when the risks are found to outweigh the potential benefits or when there is conclusive proof of positive and beneficial results.

The WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property explicitly cites the Declaration of Helsinki and notes the importance of promoting ethical principles. Element 6.2 states a commitment to:

establishing and strengthening mechanisms to improve ethical review and regulate the quality, safety and efficacy of health products and medical devices . . .

[. . .]

(g) Promote ethical principles for clinical trials involving human beings as a requirement of registration of medicines and health-related technologies, with reference to the Declaration of Helsinki, and other appropriate texts, on ethical principles for medical

research involving human subjects, including good clinical practice guidelines.

As noted above, the Agreement on TRIPS does not require the granting of exclusive rights. Additionally, in cases where it is appropriate to protect TRIPS economic rights in test data, there are other mechanisms for doing so. For example, for middle- and high-income countries, proposals have been made to institute cost-sharing mechanisms that avoid unnecessary duplication of clinical trials. Such proposals represent a superior implementation of Article 39.3 than exclusive rights over test data because they serve to fairly compensate the originator of test data while minimizing barriers to entry for generic medicines and complying with medical ethics. That the US would demand for other countries to enact unethical standards is unacceptable and we strenuously object to any pressure on foreign governments to enact systems of exclusive rights over regulatory test data.

Compulsory Licenses

One extremely important flexibility under TRIPS is the right of states to grant compulsory licenses and we object to the practice of USTR placing countries on its Special 301 watch lists for issuing or threatening to issue a TRIPS-compliant compulsory license for medical inventions.

Although the US has claimed to support the sovereign right of countries to issue compulsory licenses, it has placed countries such as Ecuador in 2011 on its “watch list” and Thailand on its “priority watch list” over the course of several years for concerns over compulsory licensing. Despite the fact that the US has issued several compulsory licenses over the years, including numerous judicially imposed compulsory licenses after the Supreme Court in *eBay v. MercExchange* refused to require enforcement of injunctions in all cases of intellectual property infringement, it seeks to eliminate this important flexibility in other countries. Placing pressure on countries not to issue compulsory licenses severely impacts the public health of citizens of those countries and will impede the ability of Essential Inventions to distribute critical, life-saving drugs.

Conclusion

We must question what the Special 301 report is intended to achieve and what value it provides. As the examples above illustrate, the Special 301 process is clearly not a system that merely checks compliance with TRIPS obligations but, rather, encourages excessive TRIPS-plus measures. If its design is to create or increase patent and non-patent barriers, we have strong objections to such a system both because of its impact on public health and human rights, but also because it creates roadblocks for the business of Essential Inventions. Countries should not be forced to give up its internationally recognized TRIPS-flexibilities, particularly at the expense of dying patients.