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## Risks of the Trans-Pacific Free Trade Agreement for Access to Medicines

*Briefing Memo:*

### *Analysis of the Leaked U.S. Paper on Eliminating Patent Pre-Grant Opposition*

A leaked U.S. paper recently circulated to countries negotiating the Trans-Pacific Partnership Agreement (TPPA) outlines the U.S. argument for eliminating “pre-grant opposition,”<sup>1</sup> an important tool for preventing patent applicants from gaining patent monopolies based on weak or erroneous information, for improving the quality and efficiency of patent office examinations, and for safeguarding access to medicines.

The leaked paper is available at: <http://www.citizen.org/documents/Leaked-US-TPPA-paper-on-eliminating-pre-grant-opposition.pdf>.

Pre-grant opposition procedures that permit broad participation<sup>2</sup> allow any person, including researchers, NGOs, health organizations, and market competitors to oppose a patent application by submitting information and analysis to patent examiners, under an adversarial administrative process. Pre-grant opposition helps improve patent quality and the accuracy of patent claims. This process helps to prevent pharmaceutical monopolies based on unmerited patents that contribute little to innovation but greatly to price.

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<sup>1</sup> The U.S. has proposed eliminating existing, lawful pre-grant opposition procedures in Article 8.7 of its February 2011 proposed TPPA text: “Where a Party provides proceedings that permit a third party to oppose the grant of a patent, the Party shall not make such proceedings available before the grant of the patent.”

<sup>2</sup> The most effective pre-grant opposition procedures, like those in India, are open to ‘any person’ and not limited to only interested parties such as potential competitors or researchers in a field relating to the relevant patent application.

The U.S. proposal would eliminate pre-grant opposition from the laws of TPPA negotiating countries, including New Zealand, Australia, Peru, Chile and Vietnam. The U.S. attack on pre-grant opposition, like other U.S. positions on intellectual property in the TPPA, can also be read as an effort to isolate India's system of more rigorous patent standards.

Eliminating pre-grant opposition procedures benefits giant pharmaceutical companies at the expense of public health programs and access to medicines. For example, India is the developing world's leading supplier of affordable generic medicines. Pre-grant oppositions filed in India by health groups have warded off lengthy monopolies based on follow-on patents filed for HIV/AIDS medicines, including lamivudine/zidovudine, paediatric nevirapine, tenofovir, darunavir, and recently heat-stable lopinavir/ritonavir. The opposed patent application for lopinavir/ritonavir had sought years of monopoly protection for presenting an old medicine in a new form.<sup>3</sup>

Ironically, the leaked U.S. paper argues that pre-grant opposition causes undue burdens on patent applicants and patent offices, creates uncertainty, and "is susceptible to abuse" by third parties that would harass examiners and applicants. This flipped-world view ignores the following:

- Substandard patent applications are a persistent problem, especially in highly technical areas, including pharmaceuticals, and especially in new fields of technology, *e.g.* biotechnology. Unmerited patents impose high costs on governments and consumers, as well as significant transaction costs on legitimate competitors. Pre-grant opposition helps prevent patent applicants from gaming the system and improves patent quality by rigorously weeding out unworthy patent applications.
- Pre-grant opposition actually increases certainty for business decisions for both innovator and generic companies by settling contested patent claims much earlier (and less expensively) than post-grant litigation could.
- Frivolous and weak patent applications place undue administrative burdens on patent offices.
- Pre-grant opposition can improve regulatory efficiency and accuracy by bringing prior art (publications, prior use, and other forms of disclosures of existing knowledge that may pre-empt the requested patent) to the attention of patent examiners so that they might

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<sup>3</sup> For more information on this case, see the Initiative for Medicines, Access and Knowledge (I-MAK): <http://www.i-mak.org/lopinavirritonavir/>.

examine claims of novelty and inventiveness. Patent examiners in developing countries have limited time and resources and do not always have access to the best research tools. Patent applicants sometimes negligently or even intentionally fail to disclose relevant prior art.

- Pre-grant opposition is cost-effective. For example, according to data provided by IP Australia, third parties oppose only about 1.5% of accepted applications. At the end of opposition proceedings, the patent office most commonly restricts the scope of the claims of the opposed patent. Pre-grant opposition in Australia improves patent quality with minimal interference to well-drafted patent applications.<sup>4</sup>
- Countries concerned about misuses of pre-grant opposition can adopt time lines and even cost-shifting to prevent abuse. In this case, the countries should impose the same kinds of penalties on applicants that file frivolous or overbroad applications or that negligently or intentionally fail to disclose all relevant prior art.

In its leaked paper, the U.S. provides some information on what it considers to be alternatives to pre-grant opposition available under U.S. law: “third-party submissions” and “third-party protests.” But the U.S. options have major shortcomings, and if adopted in the TPPA the consequences could be particularly pronounced in smaller and developing countries:

- “Third-party submissions” may only include patents and publications (i.e. prior art documents that are widely available and which the office would discover on its own with an ideal prior art search). Some

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<sup>4</sup> A European Commission competition report on the pharmaceutical sector found that at the European Patent Office level, sixty percent of drug patents studied that were subject to *post*-grant oppositions were revoked. In another fifteen percent, oppositions led to reductions in the scope of patent claims. The report also found that of the drug patents studied and which were litigated in court, fifty-five percent were annulled. European Commission Competition DG, Pharmaceutical Sector Inquiry, Final Report, 8 July 2009, page 249-250.

These figures are only slightly higher under India's system, which includes both pre and post-grant opposition. According to a study by I-MAK, as of September 2010, of the 58 Indian pre or post-grant opposition decisions for pharmaceutical patents, 72% led to patent refusal or revocation. See <http://www.i-mak.org/storage/Columbia%20TRIPS%20at%2010.pdf> (slide 9).

This suggests that pre-grant opposition successfully weeds out unmerited patents and overly broad claims that could otherwise be eliminated later. By ensuring unmerited patents are not granted in the first place, pre-grant opposition increases market certainty, reduces litigation costs and protects public health.

jurisdictions wisely include other forms of prior art including prior use, oral disclosures, and disclosures inferable from multiple sources. Moreover, in the U.S. third parties are prohibited from submitting any analysis of the patents or publications, any arguments regarding the merits of the opposed patent, or any documents a publication- or patent-based prior art search would not reveal.

- “Third-party protests” may include analysis, for example limited arguments regarding why a given patent should not be granted. But third-party protests must be filed even before the patent application is published, a period that most competitors, health groups and others have no ready or systematic means of monitoring.
- Third parties cannot challenge patent claims for failure to demonstrate “industrial applicability” (in the U.S. “usefulness”) – only for failure to be novel or take an inventive step.
- No formal administrative process ensures that timely and relevant submissions or protests will receive a hearing.

The U.S. patent regime has come under criticism due to the high number of questionable patents issued and increasing litigation and transaction costs. Some American scholars are concerned that “the firm with the best lawyers or the greatest capacity to withstand the risk of litigation wins the innovation wars -- rather than the company with the brightest scientists or most original, valuable ideas.”<sup>5</sup> A coherent and efficient opposition procedure that better taps into patent validity information (much of which is in private hands) could help solve some of the problems plaguing the current U.S. patent system.<sup>6</sup>

Other TPPA countries offer formal pre-grant opposition with administrative hearings (*e.g.* New Zealand and Australia) and/or much more open time frames and broader grounds for opposition (*e.g.* Vietnam). Even U.S. allies as close as Israel use formal pre-grant opposition. Robust pre-grant opposition procedures embody standard lessons of legal process: adversarial proceedings before a neutral arbiter improve the accuracy of judgments, and through participation, better evidence, and transparency, improve public confidence in the rule of law.

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<sup>5</sup> Jaffe Adam B & Lerner Josh, *Innovation and its Discontents: How Our Broken Patent System is Endangering Innovation and Progress, and What to Do About It*, Princeton University Press, Princeton, 2004.

<sup>6</sup> See *e.g.*, Merges, Robert P., *As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 Berkeley Tech. L.J. 577 1999. For arguments for incorporating pre-grant opposition specifically, see Kesan, Jay B., *Carrots and Sticks to Create a Better Patent System*, 17 Berkeley Tech. L.J. 763, 2002.