US Trade-Enhancing Access to Medicines (Access Window) in its proposed TPP IP text is a sham

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October 23, 2011

Well before the new leak of the US's September 2011 Trans-Pacific Partnership Intellectual Property Rights Chapter (Selected Provisions), the US has been touting its alleged Access Window, Trade-Enhancing Access to Medicines or TEAM, which is now revealed as a hoax. Basically the US has created a window within which pharmaceutical companies must apply for patent term extensions, for data protection, and for patent/registration linkage. Although the term of years is not yet specified, basically a company will not get some of these TRIPS-plus IP protections unless the company promptly files for marketing approval in that country. However, the silver lining for Big Pharma is contained in Article 9-8.(a), which requires the TPP country to allow initiation of marketing registration in that country based on any information available to the applicant, including "evidence of prior approval of the product in another Party [country]." This easy-to-meet standard does little to ensu
re quick
er product approval, but it comes at the very high price of much stronger monopoly rights.

Article 9-8.(a) may seem innocuous at first glance, but it really is a barn door for Big Pharma. Big Pharma has long chaffed over the lack of harmonization of drug regulatory authorities' marketing approval requirements, standards, and processes. Big Pharma would like something very like what is provided by the WIPO Patent Cooperation Treaty, an easy-to-use, standarized mechanism that will allow companies to use one unitary application to initiate patent examination and granting under the auspices of WIPO or reliance registration in the instance of national drug regulatory authorities. Article 9-8. says:

"Where a party chooses to apply subparagraph 6(e) of Article 8 and paragraphs 4 and 6 of this Article [Article 9], the following provisions shall apply: (a) a Party shall permit an applicant to commence the process of obtaining marketing approval by providing the regulatory authority of the Party information supporting approval of the new pharmaceutical product in the Party that is available to the person at the time the request is made, such as evidence of the prior approval of the product in another Party [most commonly the US or EU]. It is understood, that, while a Party may impose reasonable additional requirements or deadlines as a condition of authorizing the person to market to market the pharmaceutical product in its territory, satisfaction of those additional requirements or deadlines or the granting of approval shall be recognized by the Party as necessarily occurring after the commencement of the marketing approval process within the meaning of subparagraph 6(e)
of Arti
cle 8 or paragraphs 4 and 6 of this Article."

This provision requires countries to modify their drug registration laws to allow pharmaceutical companies to choose the information they want to submit - in other words, they do no have to submit complete dossiers and may not even be required to use required forms to cross the start-line for drug registration. They can drag their heels for years thereafter, as they often do now, in completing and prosecuting their registration application, but based on having satisfied the misnamed Access Window time-frame they will be entitled to multi-year patent term extensions, to successive data exclusivity periods that will run from the time final marketing approval (not from the time of the simplified initiation of the registration request), and patent-registration linkage.

The US has stated that it developed the Access Window to expedite access in TPP partners of the newest medicines. Although the "register early or lose extensions, data exclusivity, and linkage" provisions (subparagraph 6(e) of Article 8 or paragraphs 4 and 6 of Article 9) provide some incentives for earlier product introduction, the requirements are so minimals - file what you have and you've in the door - that the Access Window provisions will be meaningless in practice.

However, the problem is not simply making a big deal out of very minor process, the Access Window provisions are also likely to result in pressure from the US and Big Pharma for what is essentially a harmonized global registration system. We can expect that US will argue with trade partners that they should vicariously grant registration in their countries based on prior marketing approval by drug regulators in the US, Europe, or Japan. If countries are hoodwinked into adopting wholesale vicarious or reliance registration, they will have reduced ability to assess medicines in light of the particular patient risks and benefits in their country. Although reliance registration may have certain advantages for countries with weak regulatory authorities and although lack of procedural harmonization adversely impacts both Big Pharma and generics, countries are being asked to given up far to much TRIPS-plus territory for a quick-registration Access Window that doesn't require fas
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tion and prosecution of registration applications and that results in greater and longer monopoly protections that will inevitably lead to higher prices and reduced generic competition.

Big Pharma should be forced to introduce new life saving medicines more quickly in developing country markets. Drug regulatory systems should be made more transparent, efficient, and even harmonized, but only so long as country-specific, high standards for assuring quality, safety, and efficacy are maintained. The desirability of earlier product introduction should have nothing to do with a trade off involving greater IP protections that extend and strengthen drug company monopolies.

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