



## TPP vs. Access to Medicines in Developing Countries

### *TPP Rolls Back “May 10<sup>th</sup> Agreement” Reforms*

On May 10, 2007, Democratic leaders in the U.S. House of Representatives brokered a deal with the George W. Bush Administration designed in part to reduce the negative consequences of U.S. trade agreements for global access to medicines. The May 10 Agreement<sup>1</sup> placed limits on the new monopoly powers that would be granted to pharmaceutical companies in trade agreements, including those with Peru and Panama. This would facilitate the continued generic competition on which many people depend for access to affordable medicine.

The Trans-Pacific Partnership (TPP) does not conform to May 10 standards, and it will harm access to medicines in developing countries. TPP provisions<sup>2</sup> requiring patent term extensions and marketing exclusivity for new uses and forms of old drugs clearly exceed the bounds of May 10 and will contribute to preventable suffering and death.

The most controversial provision concerns biotech drugs, or biologics – medical products derived from living organisms. While TPP countries refused to agree to an automatic monopoly term longer than five years, nevertheless USTR insisted on text that will allow the U.S. government to pressure and pull countries along to a longer period, toward eight or even more years of protection. The eight-year position is dangerous, will likely cost lives, and contravenes the May 10 Agreement.

### **Analysis: TPP Final Text vs. May 10**

U.S. trade policy under May 10 made “hard” patent linkage<sup>3</sup> and patent term extensions optional for pharmaceuticals and provided important limitations on data or marketing exclusivity rules for developing countries. There were no transition periods by which developing countries were expected to adopt more pro-monopolistic rules.

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<sup>1</sup> See e.g. “A New Trade Policy for America,” summary by U.S. House Ways and Means Committee, May 11, 2007, available at [http://www.bilaterals.org/IMG/pdf/07\\_05\\_10\\_New\\_Trade\\_Policy\\_Outline.pdf](http://www.bilaterals.org/IMG/pdf/07_05_10_New_Trade_Policy_Outline.pdf), and the U.S.-Peru Trade Promotion Agreement Intellectual Property Chapter, available at <https://ustr.gov/sites/default/files/uploads/Countries%20Regions/africa/agreements/pdfs/FTAs/peru/16%20IPR%20Legal.June%2007.pdf>.

<sup>2</sup> See TPP Intellectual Property Chapter, available at <https://ustr.gov/sites/default/files/TPP-Final-Text-Intellectual-Property.pdf>.

<sup>3</sup> Though the U.S.-Peru FTA does not require “hard” patent linkage *per se* (regulatory action blocking generic marketing approval), it does require certain administrative rules to be in place.

**Exclusivity:** Marketing and data exclusivity rules delay generic drug registration for a specified period of time by limiting the ability of generics manufacturers and regulatory authorities to make use of an originator company's data.

- **May 10<sup>th</sup> standard:** Exclusivity normally runs for a five-year concurrent period, meaning that the clock runs on exclusivity from the date of first marketing in the United States or agreement territory. This expedites generic entry.
- **TPP rule:** Exclusivity runs for a minimum five years.<sup>4</sup> Countries must choose between offering an extra three years exclusivity for new uses, forms and methods of administering products, or five years exclusivity for new combination products.<sup>5</sup> Only Peru may run the exclusivity clock by the concurrent period measurement.<sup>6</sup> Other countries must provide at least five years exclusivity from date of marketing approval in their country, which may be considerably later than the first marketing approval, including cases that are purely a result of the pharmaceutical company moving slow to register a product in a developing country. Biologics exclusivity includes USTR insistence that countries adopt “other measures” toward providing a market outcome comparable to (presumably) eight years.<sup>7</sup> A TPP Commission shall review the biologics exclusivity period,<sup>8</sup> under likely industry pressure to lengthen it.
  - Malaysia will have an “access window,” allowing them to foreclose marketing exclusivity if a company waits more than eighteen months to begin product registration.<sup>9</sup>

**Patent Term Extensions:** Patent term adjustments (typically called extensions) significantly delay market entry of generic medicines and restrict access to affordable medicines. While they are allocated ostensibly for “delays” in regulatory review or patent prosecution, variance in review periods is a normal part of each system, and patent terms are not shortened when review proceeds more quickly than usual.

- **May 10<sup>th</sup> standard:** No requirement. Countries may choose whether or not to make available patent term extensions for pharmaceuticals.
- **TPP rule:** Patent extensions are required for regulatory review periods or patent prosecution periods deemed “unreasonable” (regulatory review) or beyond a period of years (prosecution periods) – five years from application or three years from examination request.<sup>10</sup>

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<sup>4</sup> TPP Article 18.50.1.

<sup>5</sup> *Id* at Art. 18.50.2.

<sup>6</sup> *Id* at Annex 18-D Peru Part 2.

<sup>7</sup> *See id* at Art. 18.52.1.

<sup>8</sup> *See id* at Art. 18.52.3.

<sup>9</sup> *See id* at Annex 18-C Malaysia.

**Patent Linkage:** TPP’s “soft” patent linkage option<sup>11</sup> may be considered similar to May 10 standards.

**Transition Periods, Exemptions:** Unlike the May 10 Agreement standard, the TPP would require developing countries to transition to the same rules that apply to wealthier countries. The periods are short and have been provided for only a few rules.<sup>12</sup> Some countries have negotiated exemptions from one or two TPP rules. But again, the rules are beyond the limits of May 10, and will apply to the rest of the TPP parties, including developing countries that may join this aspired “living agreement” in the future.

**Additional Rules:** While the May 10 Agreement did not make express reference to patent evergreening or other intellectual property rules that can compromise access to medicines, many health advocates take the content of the U.S.-Peru Trade Promotion Agreement as the standard. That agreement did not, for example, require the grant of patents for new uses of old medicines. TPP does.<sup>13</sup>

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<sup>10</sup> See *id* at Art. 18.46.

<sup>11</sup> See *id* at Art. 18.51.

<sup>12</sup> See *id* at Art. 18.83.

<sup>13</sup> See *id* at Art. 18.37.2.