



## What does the TPP do as regards prices of drugs and other medical technologies?

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- The TPP will lock in many of the worst features of US policy regarding intellectual property on drugs.
- The TPP will mandate extensions of patents terms beyond the 20 years required by the WTO<sup>1</sup>.
- The TPP will mandate the granting of more patents on drugs, than is required by the WTO, including cases where the inventions do not result in improved efficacy of a known product.<sup>2</sup>
- The TPP will require countries to have state enforcement of private patent rights, in cases involving patents of dubious relevance or validity.
- The TPP will create much tougher standards for damages on patent infringement, and eliminate space for exceptions or independent statutory norms for damages.<sup>3</sup>
- Biologic drugs:
  - USTR has proposed that the TPP will create 12 year monopoly on the evidence that biologic drug is safe and effective<sup>4</sup>, creating delays in registration of new biosimilar drugs, and creating conflicts with the Helsinki Declaration on ethical norms for testing drugs on humans.<sup>5</sup>
  - USTR has proposed language on damages that would eliminate current caps on damages for patents on biologic drugs, when drug companies fail to make timely disclosure of assertions that patents are relevant to a biologic drug. This increases the risk to manufacturers of biosimilar drugs, because they have more uncertainty they can sell the new biosimilar products in the US market.<sup>6</sup>
- The current TPP text replaces the current WTO standard for compulsory licensing of drugs, with a new more restrictive standard.<sup>7</sup>

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<sup>1</sup> TPP IP Chapter, May 16, 2014 leaked version, Article QQ.E.12

<sup>2</sup> Article QQ.E.1: {Patents / Patentable Subject Matter}

<sup>3</sup> Article QQ.H.4: {Civil Procedures and Remedies / Civil and Administrative Procedures and Remedies}

<sup>4</sup> Article QQ.E.20

<sup>5</sup> <http://www.wma.net/en/30publications/10policies/b3/> For example, paragraph 18.

<sup>6</sup> 35 USC 271(e)(6)(B)

<sup>7</sup> See discussion here: <http://keionline.org/node/2231>

- The TPP will regulate the decisions to reimburse new drugs, and give drug companies new rights to challenge decisions on reimbursements, when they are not favorable to the drug company.
- Drug companies can bring suits against governments, through an Investor State Dispute Settlement (ISDS) mechanism in the TPP, which will be used to intimidate and fine countries that undermine drug company profits.
- All of the above will prevent efforts for future health care reforms, by making it illegal (under the TPP) or difficult to fix the bad policy.
- The US population is aging:<sup>8</sup>
  - By 2015, the percent of the population 65 or older will be 14.7 percent
  - By 2020, the 65 and over population will be 16.6 percent
  - By 2030, the 65 and over population will be 20.1 percent
- More old people means more cancer, and other expensive illnesses. How are we going to pay for this, unless we can check runaway prices for drugs?
- Cancer is expected to be a bigger problem for the US than for developing countries, because their population is younger.
  - In Brazil,
    - By 2015, the percent of the population 65 or older will be 8 percent
    - By 2030, the 65 and over population will be 13.6 percent
  - In China,
    - By 2015, the percent of the population 65 or older will be 9.5 percent
    - By 2030, the 65 and over population will be 16.2 percent
  - In India,
    - By 2015, the percent of the population 65 or older will be 5.5 percent
    - By 2030, the 65 and over population will be 8.2 percent

More expensive drug prices make cancer treatment unsustainable in the United States, and result in making our workforce (the people who pay for everything) less competitive globally.

For more information:

Andrew Goldman, office 1.202.332.2670, cell +1.917.348.5579  
[tpp-info@keionline.org](mailto:tpp-info@keionline.org)  
<http://keionline.org/>  
[http://lists.keionline.org/pipermail/ip-health\\_lists.keionline.org](http://lists.keionline.org/pipermail/ip-health_lists.keionline.org)

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<sup>8</sup> United Nations, Department of Economic and Social Affairs: World Population Prospects, 2012 Revision. [http://esa.un.org/wpp/unpp/panel\\_indicators.htm](http://esa.un.org/wpp/unpp/panel_indicators.htm)