Intellectual Property in the Trans-Pacific Partnership

Dangers for Access to Affordable Medicines in New Zealand
Intellectual Property in the TPP

New Zealand and the United States are currently negotiating a new free trade agreement, the Trans-Pacific Partnership (TPP), with seven other countries in the Asia-Pacific region (Australia, Brunei, Chile, Malaysia, Vietnam, Peru, and Singapore). Canada and Mexico have also recently joined. According to leaked texts, the United States is pushing for aggressive measures that would further endanger access to affordable medicines against cancer, heart disease, and HIV/AIDS, among others.

The United States has proposed TRIPS+ and FTA+ terms that would transform New Zealand's laws on patents and clinical trial test data and attack government purchasing and medicine formularies. These provisions would limit generic competition and raise pharmaceutical prices, thereby restricting access to affordable medicines. The same provisions would hinder local pharmaceutical production and innovation in New Zealand.

The U.S. proposal would:

- Greatly expand patent scope
- Impose patent protection for surgical techniques and other methods of treating patients
- Further delay access to cheaper generic medicines
- Eliminate safeguards found in New Zealand law
- Risk faciliting patent abuse
- Expand pharmaceutical monopolies through data exclusivity

See back for more on how the U.S. proposal will hurt access to medicines in New Zealand.

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Specifically, the U.S. proposal would:

Greatly expand the scope of patent protection

New uses and minor variations of older, known medicines would be patentable even if they do not enhance therapeutic value. NZ case law has established limited exceptions for second/subsequent uses of known products that comply with drafting requirements of the IPONZ. The U.S. proposal eliminates these patenting restrictions. Pharmaceutical companies would be able to freely file patent applications on new uses, new methods of preparation and methods of treatment.

Impose patent protection for surgical techniques and other methods of treating patients

For moral and ethical reasons, World Trade Organization (WTO) rules do not require patent protection for therapeutic, surgical, or diagnostic methods of treatment. The TPP would impose patent protection for each. This could create more cost burdens for the NZ health system as hospitals and medical professionals could be required to pay royalties if they use patented methods for treating, diagnosing, or operating on patients.

Further delay access to affordable generic medicines

Pharmaceutical companies would be able to request patent term extensions if examination at the patent office or regulatory authority exceeds a certain period of time. This would allow pharmaceutical companies to extend patents beyond the WTO standard of 20 years and lengthen their monopolies.

Eliminate safeguards against patent abuse

Health agencies, among others, would no longer be able to oppose patents before they are granted. The absence of this "pre-grant opposition" would allow for more undeserved, low-quality patents in NZ that contribute little to innovation but greatly to price.

Risk facilitating patent abuse

Medsafe would be required to condition market approval on patent status (patent linkage). Under patent linkage, even spurious patents may function as barriers to the registration of generic medicines. NZ would have to introduce a notification system for patent holders, an automatic delay of generics marketing approval and measures to block allegedly infringing products for the duration of the patent.

Extend commercial control over regulatory information and medical test data (expand "data exclusivity")

The U.S. proposal seeks to expand data exclusivity, another means for blocking generic competition. Medsafe would be unable to use test data and other information necessary for registering generic medicines for at least five years in cases of new products and for at least three more years in cases of new uses for old medicines--even when that information is already in the public domain. Generics applicants would have to wait until the exclusivity period expires or otherwise duplicate tests on humans or vertebrate animals to demonstrate safety and efficacy. The proposal also includes a placeholder provision on biotech medicines, for which the US may propose an even longer exclusivity period.

For more information, visit www.citizen.org/tppa

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