Intellectual Property in the Trans-Pacific Partnership

Dangers for Access to Affordable Medicines in Canada
Intellectual Property in the TPP

Canada and the United States are currently negotiating a new free trade agreement, the Trans-Pacific Partnership (TPP), with eight other countries in the Asia-Pacific region (Australia, Brunei, Chile, Malaysia, Mexico, New Zealand, Peru, Singapore and Vietnam). 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 require additional changes to Canada's laws on patents, clinical trial test data, and enforcement and attack government purchasing and medicine formularies. These provisions would further limit generic competition and raise pharmaceutical prices, thereby restricting access to affordable medicines. The same provisions would affect the export interests of Canadian generics companies and hinder local pharmaceutical manufacturing and innovation.

The U.S. proposal would:

- **Broaden patent protection for medical methods of treating patients**
- **Further delay access to cheaper generic medicines**
- **Further expand pharmaceutical monopolies through broader data exclusivity terms**
- **Favor right holders in courts**

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

Public Citizen's Global Access to Medicines Program

Website:
www.citizen.org/access

Email:
medsaccess@citizen.org

Twitter:
@PCMedsAccess

PUBLICCITIZEN

November 2012

Specifically, the U.S. proposal would:

Broaden patent protection for medical methods of treating patients

For moral and ethical reasons, World Trade Organization (WTO) rules do not require patent protection for therapeutic and surgical methods of treatment. The TPP would impose patent protection for each. This could increase cost burdens for the Canadian health system as hospitals and medical professionals could be required to pay royalties for using patented medical methods.

Further delay access to affordable generic medicines

Currently, Canada does not provide patent term extensions. With the TPP, pharmaceutical companies could request patent term extensions if examination at the patent office or regulatory authority exceeds a certain period of time. Patent term adjustments would be available for both patents covering new pharmaceutical products and patents covering methods of making or using the product. This would allow pharmaceutical companies to extend patents beyond the WTO standard of 20 years and lengthen their monopolies.

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

The U.S. proposal seeks to expand data exclusivity. Canada currently provides extensive protection to the clinical test data of an "innovative drug". The TPP goes one step further and expands protection to any information submitted in an application for all pharmaceutical products (innovative and non-innovative), even if the information is in the public domain and the product is not marketed in Canada. Minor changes to an existing product (ie. new uses or indications) would also benefit from at least three years of additional data exclusivity. This would not only affect local manfuacturing and the export interests of Canadian generics companies but would also increase the costs of pharmaceuticals for healthcare payers--provinces, territories, private insurers, and patients.

Unlike the United States, Canada does not provide longer data exclusivity protection for biologics. The TPP proposal includes a placeholder provision on biotech medicines, for which the US may propose an even longer exclusivity period.

Favor rights holders in courts

The U.S. proposal introduces the use of suggested retail price when determining damages in a patent infringement case. According to Canadian law, only the harm caused by infringement is compensable as damages. A suggested retail price is a hypothetical price; generally greater than the damage suffered by the right holder. Further, suggested retail prices submitted by a right holder may turn out to be inflated or otherwise inaccurate and higher than actual retail prices. This would lead to an unrealistic determination of damages, which would empower right holders in court settlements and discourage generics manufacturers from litigating cases where there is uncertainty.

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

Public Citizen's Global Access to Medicines Program

Website:
www.citizen.org/access

Email:
medsaccess@citizen.org

Twitter:
@PCMedsAccess

PUBLICCITIZEN