



**GENERIC DRUGS
SAME QUALITY
BETTER PRICE**



CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION

ANTI-COUNTERFEITING TRADE AGREEMENT (ACTA)

THE ISSUE

The generic pharmaceutical industry is concerned that the proposed Anti-Counterfeiting Trade Agreement (ACTA) is taking an over-broad approach by generalizing measures to combat counterfeiting and piracy as applicable to all forms of intellectual property rights. This could lead to the criminalization of legitimate patent disputes between two companies, and have serious consequences for Canadians.

BACKGROUND

Since June 2008, Canada has been engaged in formal negotiations with the United States, European Union, Mexico, Japan and several other countries in the development of ACTA. According to the Foreign Affairs and International Trade Canada website, ***"The proposed Anti-Counterfeiting Trade Agreement (ACTA) aims to establish new global standards for the enforcement of intellectual property rights (IPR) to more effectively combat the increasingly prolific trade in counterfeit and pirated goods."***

The proposed content for ACTA does not indicate that the discussions will address appropriate limitations on the scope and reach of intellectual property enforcement mechanisms. Patent disputes during the normal legitimate business development of a product

could become – in the context of ACTA – a crime related to counterfeiting instead of remaining a private civil matter between two companies.

Patent disputes are an everyday commercial risk for both brand-name and generic pharmaceutical companies due to the technical complexities of drug development and the domestic regulatory system. Article 61 of the World Trade Organization's agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) makes an important distinction between trademarks, counterfeiting and copyright piracy – activities which generally involve criminal intent – and patents and other forms of intellectual property rights disputes between legitimate companies. Any move to abolish this internationally accepted distinction would set a dangerous precedent.

Counterfeit medicines are a public health concern, and both patented and non-patented medicines can be targeted by counterfeiters. A focus on patents in combating counterfeit medicines would therefore be both inappropriate. The criminalization of domestic patent disputes would have dire consequences for consumers, employers, governments, the economy and the generic pharmaceutical industry – without being effective in targeting criminals engaged in counterfeit medicines.

It is also important to note that the domestic occurrence of counterfeit medicines is extremely low. As Canada's Criminal Intelligence Service has observed, our highly-regulated pharmaceutical system is largely affordable to most Canadians, which ***"significantly lessens any potential market for illegitimate supplies of pharmaceuticals in Canada."*** As such, it is imperative that any additional measures to combat these illegal products involve strengthening existing regulatory controls, and must appropriately target the criminals engaged in counterfeit activities – without creating unintended consequences.

Ironically, the criminalization of patent disputes could have the effect of creating a domestic market that is attractive to counterfeiters. The significant increases in drug costs that would occur through the resulting prolonged periods of monopoly drug prices could lead Canadians to seek lower-cost alternatives through less-than-reputable sources, which in turn could put them into contact with counterfeit medicines.

CGPA POSITION

CGPA and Canada's generic pharmaceutical industry support appropriate and targeted measures to combat illegal counterfeit drugs worldwide. Expanding the enforcement provisions for patents would be a completely ineffective measure in combating counterfeit medicines in Canada, and would undermine well-established policies and business practices that support competition in Canada's pharmaceutical industry. As such, patents should be explicitly excluded from the scope of ACTA.