

## THE PATENT ACT & LINKAGE REGULATIONS

# Essential tools for the advancement of medical science in Canada

The Linkage Regulations are a critical component of Canada's patent law regime that have been the target of an aggressive lobbying campaign by generic drug manufacturers. These regulations must be preserved, because they are the only effective tool patent holders have to defend their patents against illegal infringement.

For the research-based pharmaceutical industry, patent protection is our life-blood. Strong patent laws are critical to the continued attraction of research investments to Canada and the building of a knowledge-based economy.

Patent law represents a balance. Inventors agree to make the details of their discoveries available to the public, helping to stimulate further research by others. In return, innovators are given rights to prevent the use of their inventions by others for commercial gain over a period of 20 years. (After a patent is awarded, a new drug goes through 10-12 years of clinical trials and government approvals, so the medicine is actually on the market for less than half of that patent term.)

For many years, very little pharmaceutical research was conducted in Canada. That changed when the Patent Act was amended to bring it in line with minimum international standards. Since 1987, as a result of these changes, annual research and development spending by Canada's Research-Based Pharmaceutical Companies grew from \$106 million to more than \$1.18 billion, between 1987 and 2002.

Improved patents have created new research opportunities in Canada, while fulfilling our international obligations under such treaties as NAFTA and TRIPS. One challenge facing our government is how to ensure that our patent law is enforced properly so that the exceptions built into the Patent Act do not violate those treaties.

For example, the "early working exception" provides a major benefit to generic companies by allowing them to develop and seek regulatory approval for their generic versions of a patented product even while relevant patents are still in force. It does not, however, permit those generic drugs to be marketed until after relevant patents expire – something that would be very difficult to enforce. Market entry before patents have expired would be an illegal infringement under the Patent Act, NAFTA and TRIPS.

The Linkage Regulations are the only mechanism to stop such infringement. They establish a process by which Health Canada is obliged to address the status of any relevant

patents before final approval to sell a generic is granted. Without the Linkage Regulations, there would be no means under Canadian law to prevent infringement. In the US and other countries, court orders known as interlocutory injunctions can be used to remove an illegal product from the market. But in Canada such court orders are rare, leaving the Linkage Regulations as the sole means to defend these patents.

It's clear that generic manufacturers would have a lot to gain from the removal of the Linkage Regulations. Likewise, they also want to prevent patent owners from listing more than one patent in relation to the same medicine.

Such a change minimizes the importance of continuous innovation. If additional research and development leads to a more effective form of a medicine or a new use for that drug, then the innovation should be patented – otherwise there would be no incentive for improvements. The government has clear criteria for what can and cannot be patented, so these patents are not awarded lightly. These patents do not prevent generic companies from copying earlier versions of the medicine, once an original patent has expired. Generic companies cannot copy the most recent versions of the medicine, until patents on those improvements have expired.

Rather than responding to generic manufacturers' demands, government should address the serious questions as to whether or not our current patent law regime is sufficient to prevent infringement and encourage Canadian research.

Significant shortcomings in the patent enforcement system include inadequacies in judicial procedures, red tape in the system for placing patents on the Patent Register, and a lack of protection for confidential information submitted by patentees. Countries that are more serious about competing for research investments offer additional protections, such as patent term extensions that make up for lost time while a drug moves through government approvals.

Enough time has been spent discussing the generic manufacturers demands. It is now time to move forward and ensure that patent law is used to make Canada a research leader.

### **AstraZeneca's Position**

**The Linkage Regulations are the only effective means of patent enforcement available under Canadian law. They need to be protected and strengthened to encourage innovation and attract research investments. As well, Canada needs to implement data protection to make the intellectual property system fairer to patent holders.**