Canada's billion-dollar drug industry will be at risk if patent laws are eroded

Patently Wrong

STEVEN PELECH

Despite recent industry charges that the drug approval process in the United States is "slowing", Canadians today much wait significantly longer than patients in both the United States and the European Union for the approval of new life-saving or life-enhancing pharmaceuticals. Last year, Canadians endured waits of more than two years – six months longer than in 1999 – versus a U.S. average of 12 months. Ironically, and as a consequence, citizens in other countries have been able to benefit from medicines developed in Canada before Canadians.

Moreover, these longer approval processes are eroding the 20-year term now granted for pharmaceutical patent protection. Drug discovery and development is very expensive and highly risky. The average drug costs hundreds of millions of dollars to develop and test. Yet less than one in five promising drugs that enter advanced human trials make it into the market place. These successful drugs typically have less than eight years left of patent coverage by the time they become commercially available. It is during this period that the pharmaceutical companies must recoup their expenses for the development of the successful drug and those that failed.

Without adequate intellectual property protection, individuals and industrial partners will neither invest in nor undertake the risks associated with the expensive research and development required to bring innovative new treatments and medicines to market. The need for strong intellectual property protection policies is more apparent now than ever.

Critics claim that current IPP policies are blocking access and stifling innovation. But do the facts, in reality, support their arguments? Looking back over the past 15 years, it would appear not. Moreover, if we look ahead to what is possible should Canada's IPP laws be rightfully preserved and defended, their arguments become even more ineffectual.

Consider that since 1987, when the Canadian government first enacted its patent protection laws, spending by research-based pharmaceutical companies has increased more than 700%, with $1-billion invested in Canadian medical research in 2001 alone. Today, as a result of this investment, the Canadian health research community employs approximately 30,000 clinical investigators and technical personnel in 16 medical schools, 30 university departments, 75 research institutes and numerous companies.

But in addition to pumping billions of dollars into the Canadian economy and making Canada a globally recognized centre of research excellence, the results of this research are also having a direct impact on the health of Canadians and people world-wide. It has been estimated that medical research is adding one year of life expectancy every four years.

Canada has had a long leadership role in developing powerful new medications starting with Banting and Best's discovery of insulin for treatment of diabetes. Canadian research and innovation has spurred several of today's breakthrough medicines. Among many others, these drugs include 3TC, which has, arguably, changed the course of treatment for HIV/AIDS; Premarin the most widely prescribed hormone replacement drug in the world; and Visudyne, the only effective treatment for macular degeneration, which is the most common form of blindness in elders. With Canada representing just 1.8% of the total pharmaceutical world market, we can be justifiably proud of the accomplishments of our academic and industrial researchers in providing new hope in the struggle against disease.

OUR BIOPHARMACEUTICAL FIRMS ARE CURRENTLY DEVELOPING 370 PRODUCTS

It is often erroneously held that the increasing use of drugs by the aging population is overtaxing the public health care system. Rather, new and more effective treatments are actually translating into significant savings for Canada's over-burdened and under-funded hospitals by ensuring Canadians spend more time recovering at home with their families. Canada's biopharmaceutical industry also has benefited from IPP, as today it accounts for approximately $2-billion in revenues and which is growing four times faster than in any other G7 economy.

In the last five years alone, more than 200 biopharmaceutical companies have been created, 60 of which are genomics companies. During the same period, venture capital investments has risen from a lowly $200-million to $1.2-billion. Today, more than 370 products are under development, and the research is among the most competitive in the world.

By themselves, these facts alone make a compelling case for ensuring that Canada's IPP laws are valued and protected. While over the last decade, Canada has steadily increased pharmaceutical patent protection towards international standards, we still have a way to go. Further improvements in IPP are actually needed to strengthen the competitiveness of our innovative Canadian pharmaceutical research-based industry.

Further improvements in IPP are actually needed to strengthen the competitiveness of our innovative Canadian pharmaceutical research-based industry. There remains significant gaps in data protection and exclusivity, enforcement of Intellectual Property rights and patent-term restoration for patents filed before October 1, 1989.

Now, as we look ahead to the new frontiers of medicine – genomics and proteomics, in particular – the argument for strong IPP becomes even more convincing. Clearly, if the potential of the human genome project to develop new medicines and treatments is to be fully exploited, appropriate policies and safeguards must be in place. However, these policies must include a commitment to strong IPP.

New breakthroughs as a result of genomics research are already reaping rewards. Recently, an international team of scientists led by Canadian Genetic Diseases Network researchers identified a gene that causes a childhood form of familial amyotrophic lateral sclerosis. There is now hope where there was none before. Breakthroughs such as these will transform how patients are treated. We need only look at the result of non-specific therapies used to treat cancer. Thousands are treated each year and yet about 45% will still die as a result of ineffectual treatments.

Of an estimated 50,000 proteins encoded by the human genome, a mere 500 have been investigated as drug targets. The potential for developing more powerful medicines is staggering. Already, researchers have identified 5,000 more proteins that look promising for developing treatments for various illnesses.

And yet none of this will happen without strong IPP to protect the years of research and hundreds of millions of dollars invested by these companies to deliver the cures of tomorrow. Canada must continue to protect and support the patent rights of medical research-based and life sciences industry as a means to build an innovative, dynamic health research sector.

For the simple reason that researchers can now see the light at the end of the tunnel for so many diseases, the Canadian government must both continue to invest in Canada's R&D sector and help create the policies that will ensure Canadian companies lead the breakthrough treatments needed to enhance and sustain life in our aging population.

Dr. Steven Pelech is president and CEO of Kinexus Bioinformatics Corporation and professor, department of medicine, and the University of British Columbia.