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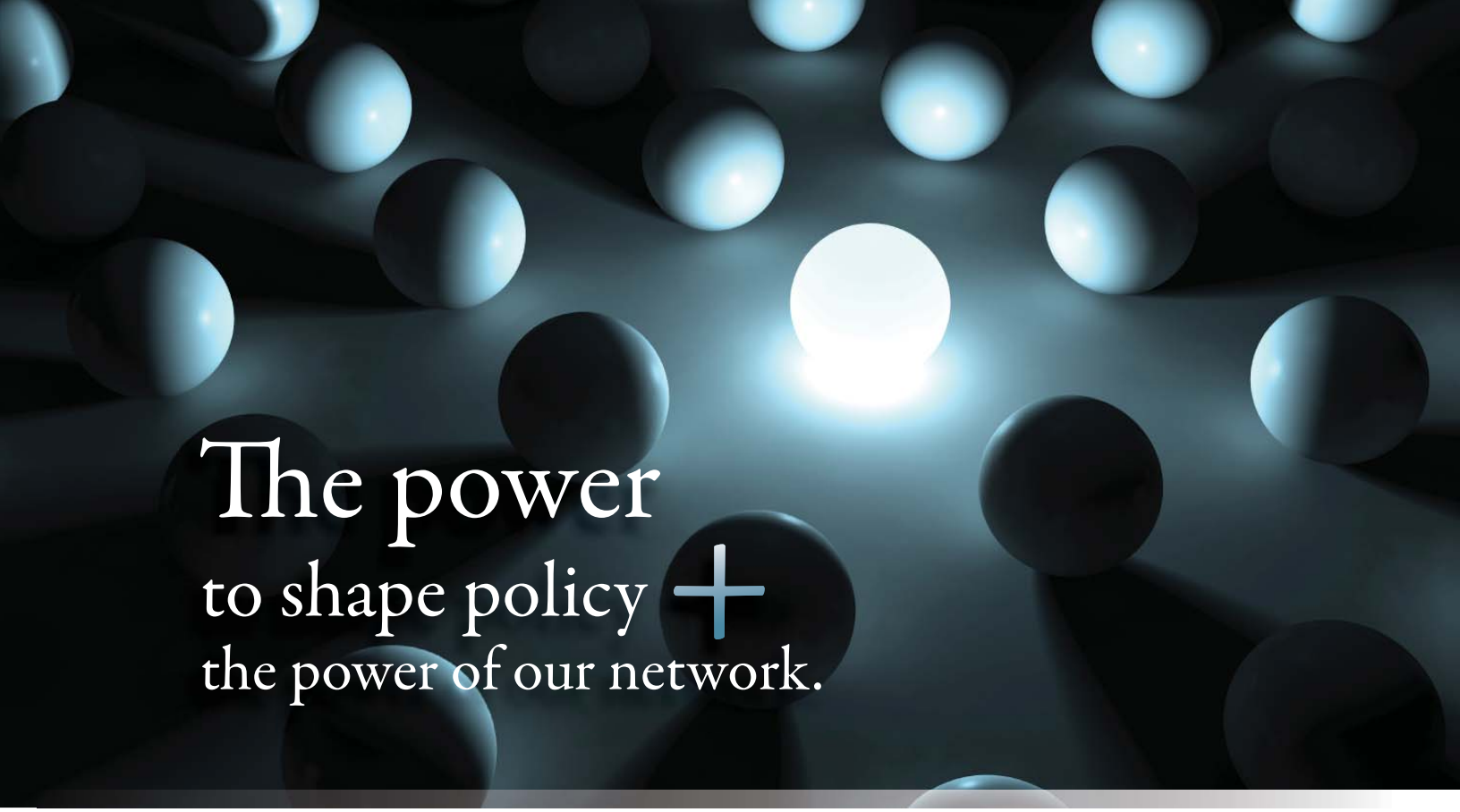
Fostering Innovation in the Bio/pharmaceutical Industry

The Need for Greater Intellectual Property Protection in Canada

Autumn 2010



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1 Introduction

Bio/pharmaceutical innovations are part of everyone's life today. Canadians no longer die of tuberculosis, polio or measles, and many of the viruses and infections that used to be a threat to public health are now a part of our country's history. Bio/pharmaceutical innovation makes everyone's life better. Whether it is to relieve a simple headache, treat an infection or prevent child diseases, medications and vaccines allow us to stay healthier longer, and help reduce the pain and suffering of those who are ill. However, today's bio/pharmaceutical products are neither miracle nor magic; they are the product of decades of research and experiments. One of the greatest Canadian discoveries, insulin, required years of research to turn a deadly disease like diabetes into a manageable disease. Another example is the discovery of penicillin in 1928 by Alexander Fleming. Intensive research to find ways to produce massive amounts of this revolutionary medication led to the successful treatment of the bacterial infections that were affecting the Allied soldiers fighting World War II. Bio/pharmaceutical research has given us treatments for diabetes, high blood pressure, cholesterol, asthma, migraines, pain, angina, skin problems and depression, to name a few. Without the dedication of the research-based bio/pharmaceutical companies investing billions in trying to find new medicines, our lives would be tremendously different, our life expectancy would be much shorter and bloodletting and enemas might still be the favoured techniques to treating almost everything. Canada is also facing a serious demographic problem, the ever growing number of aging people calling for a strong push on medical and bio/pharmaceutical research.

Bio/pharmaceutical research helps Canadians live better and receive better treatment when sick, but it also makes an important contribution to the economic growth of the country. Research-based bio/pharmaceutical companies invest billions of dollars every year in research and development (R&D) and they employ thousands of people in highly skilled and well paying jobs[1].

Investment and jobs created by the research-based bio/pharmaceutical companies in Canada

Canada's Research-Based Pharmaceutical Companies (Rx&D) is an association of research-based bio/pharmaceutical companies representing over 15,000 people working for more than 50 member companies that are responsible for generating 60,000 jobs across Canada and for funding 27% of all health science research and development in Canada. Source: www.canadapharma.org

Montreal ranks eighth in North America for bio/pharmaceutical jobs, with a pool of 32,000 stable, experienced and skilled workers in the bio/pharmaceutical industry and over 13,000 researchers in the public biomedical research centers. Source: www.investquebec.com

Ontario's bio/pharmaceutical industry employs over 15,000 people and generates revenues of $8.3 billion annually. It includes global giants such as AstraZeneca, Bayer, Eli Lilly, GlaxoSmithKline, Pfizer and Sanofi-aventis. Source: www.investinontario.com

1 Pham, Nam D., *The Impact of Innovation and the Role of Intellectual Property Rights on U.S. Productivity, Competitiveness , Jobs, Wages, and Exports,* ndp consulting, April 2010.

Knowledge-based industries, such as the bio/pharmaceutical industry, are recognized as engines of the new economy and will help Canada achieve its stated goal of a world leadership position in health innovation. The government is striving to enhance our competitiveness and the economic base in which the discovery, development and commercialization of new innovations can thrive. At the same time, policy makers are seeking to moderate and control healthcare expenditures.

A robust bio/pharmaceutical industry will result in improved "health and wealth" in the form of better patient outcomes, job creation and a strong economy. Innovation can contribute to all of the principles and objectives that our healthcare system must strive for. Bio/pharmaceutical R&D into innovative medicines contributes value to the health of Canadians by helping them live longer and more productive lives. Furthermore, patient care is best served by making new innovations rapidly available, as new medicines save valuable dollars by helping to reduce the number of expensive hospitalizations and surgeries. Industry investments into R&D for innovative new medicines have the additional benefits of enhancing economic growth within the knowledge-based life sciences sector, creating new high-value, highly skilled jobs and creating a competitive advantage for Canada in adapting and implementing world-class technologies as they become available.

The evolving global context is very challenging. Other nations are competing aggressively in the global marketplace with Canada for the same innovative bio/pharmaceutical jobs and investments. However, the potential for growth is huge. With two per cent of total global sales, Canada currently accounts for only one per cent of global bio/pharmaceutical investments. It is time for the federal and provincial governments to establish a globally competitive climate for increased R&D and investment in this key part of the knowledge-based economy.

Knowledge-based economy

"The term 'knowledge-based economy' results from a fuller recognition of the role of knowledge and technology in economic growth. Knowledge, as embodied in human beings (as "human capital") and in technology, has always been central to economic development. […] The OECD economies are more strongly dependent on the production, distribution and use of knowledge than ever before. Output and employment are expanding fastest in high-technology industries, such as computers, electronics and aerospace. […] Although the manufacturing sector is losing jobs across the OECD, employment is growing in high-technology, science-based sectors ranging from computers to pharmaceuticals."

Source: OECD, The knowledge-based economy, Paris, 1996, pp.1&10.

2 Intellectual property rights and the bio/pharmaceutical sector

The Canadian Intellectual Property Council (CIPC) is a Canadian business coalition, under the banner of the Canadian Chamber of Commerce, that has come together to provide a strong voice advocating for an improved intellectual property rights (IPR) system in Canada. As Canada continues to rely more on the knowledge-based sector, we need to make sure we can compete globally with other nations on a level playing field for businesses that rely heavily on intellectual property for their success. Bio/pharmaceutical issues are a priority for the CIPC as they are a key component in the Canadian IPR system and involve industries that are of primary importance in terms of innovation and world competitiveness.

The bio/pharmaceutical industry is a heterogeneous group with some companies strongly relying on intellectual property rights and others not. In order to understand why IPR is important to some companies and not to others, it is necessary to first distinguish the two main groups in the bio/pharmaceutical sector—the research-based bio/pharmaceutical companies and the generic companies— and their respective roles in the innovation, production and distribution of medicines.

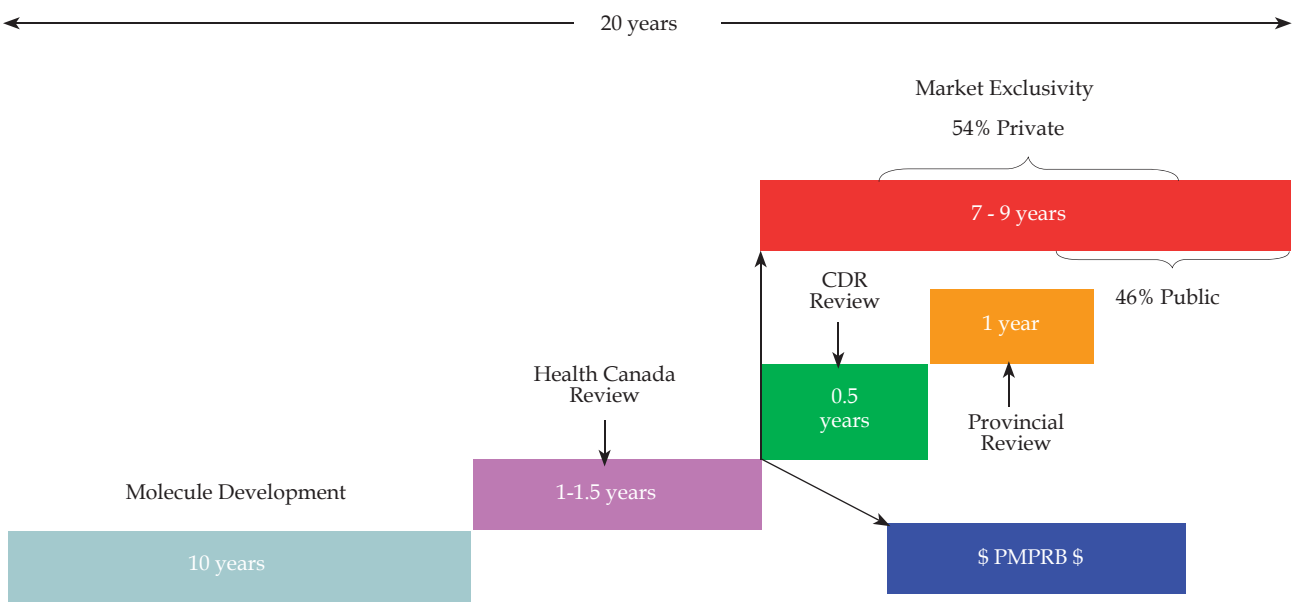
The innovative research-based bio/pharmaceutical companies are involved in the production and distribution of drugs, but their fundamental role is the development of new medicines. We refer to them as innovative because they create new products and bring to market revolutionary medicines such as Ritalin and Lipitor as well as older products like Aspirin. The research-based companies differ from the generic companies in many ways. While the former create, the latter replicate. The main purpose of the generic companies is to find ways to replicate, produce and distribute a copy of the innovative product at a low cost. The reproduction of an innovative medicine is possible almost as soon as the product is on the market, but market approval and distribution is legally only allowed once the patents on the innovative medicine have expired, which can take between seven and nine years after the innovative drug enters the market in Canada. Once the generic version of a drug enters the market, the sales of the innovative drug decline dramatically, mostly due to the lower price of the generic drug (sometimes up to 75 per cent lower) and the fact that the provincial formulary rules and some private plans encourage generic substitution at the pharmacy level. Therefore, the seven to nine years of market exclusivity are critical for the research-based companies. Even this period of exclusivity is not guaranteed since generic drug companies engage in concerted and systematic litigation strategies that are intended to prematurely invalidate innovator patent protection.

The generic companies are able to offer a product for a fraction of the price of the innovative drug because they do not need to recoup R&D investments. Hence, they are able to generate a healthy profit margin while offering a very competitive market price for a product deemed the bio-equivalent by Health Canada. Interestingly, the price of generic drugs in Canada is much higher than anywhere else in the world. For example, in 2006, Canadian consumers were paying 115 per cent more for their generic drug than their American neighbours[2]. Unlike the innovative drugs, generics drugs are not subject to any price regulation at the federal level. Recently in some provinces such as Ontario, Quebec and British Columbia, there have been initiatives to reduce generic prices by the provincial public reimbursement programs, presumably due to the growing realization that Canadian generics are not internationally cost-competitive.

2 Skinner, Bret J. and Marc Rovere, *Generic drugs in Canada overpriced and underused,* Fraser Institute, February 2009.

Another important difference between the two industries is the high risk and costs associated with the work of the research-based companies. According to the Association of British Pharmaceutical Industry, as few as one out of 5,000 molecules screened makes it onto the market as a bio/pharmaceutical drug[3]. Of the drugs that reach the market only three out of 10 will generate revenue that equals or exceeds the R&D costs[4]. In 2003, the total cost of developing a new drug was $897 million[5], around 60 per cent of which was the cost for clinical trials[6]. The development of a new drug, including the early stage development and the clinical trials takes about 10 years during which the drug generates no revenue; the need to recoup the massive investment once the drug finally gets to the market is critical in order to fund further and on-going R&D. The image below shows the timeline of the drug development process over the 20 years of the patent life.

Timeline of the drug development process for research-based companies



Source: Rx&D website https://www.canadapharma.org/en/research/industryfacts/processchart.aspx consulted July 15, 2010.

In the case of the generic bio/pharmaceutical companies, the story is very different. The commercialization risk associated with the production of an already marketed drug is non-existent and the costs associated with the production of the drug are relatively insignificant compared to the amount invested by the innovative companies. The following table shows the differences.

3 Association of Bristish Bio/pharmaceutical Industry, *The development of medicines,* London, ABPI, 2002.

4 Torstensson, David and Dr. Meir Pugash, *Courting confusion? Where is Canada's Intellectual Property Policy Heading?*, Stockholm Network, August 2008, p.10.

5 Ibid.

6 Ibid

Drug development process comparison table

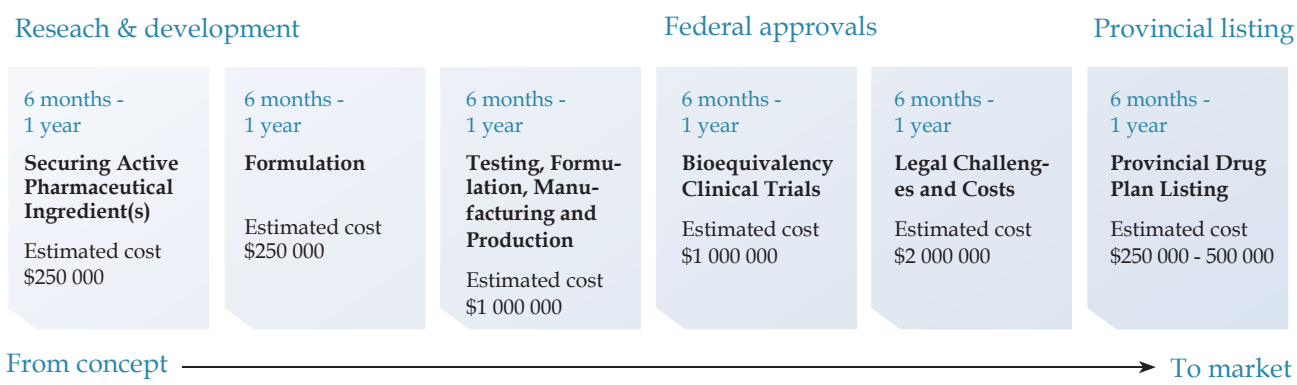
Drug development phases	Innovative companies	Generic companies
Research & Development	2-6.5 years (early stage development)	6 months-1 year (secure active ingredient and formulation)
Tests & Trials	7 years for 60% of total costs	3-6 months for 1 million
Time from laboratory to market	11-13 years	2.25 -6.5 years
Estimated Total Costs	897 million	4 million
Time to recoup investments	7-9 years	No limit of time

Source: Merck Website, http://www.merck.com/mmhe/sec02/ch010/ch010b.html consulted July 15, 2010.
Canadian Generic Pharmaceutical Association, Generic prescription drug development process, February 2010.

According to the Canadian Generic Drugs Association[7], the development of a generic drug costs around $4 million and takes between three to six years. First, securing the active ingredient can take between six to 12 months and can cost approximately $250,000. Once the active ingredient is secure, the work on finding the right formula (mix of active and non active ingredients) can begin, usually taking another six to 12 months and costing $250,000. Thirdly, the testing and manufacturing of the drug can cost up to $1 million and take up to a year. Next, the bio-equivalence clinical trials can take three to six months and cost about $1 million. Any legal challenges that arise can cost about half the total budget ($2 million) and take up to two years to settle. Such battles are the result of the generic companies attempting to market a generic version of the product prior to the expiration of the relevant patents. Finally, listing the drugs on provincial drug plans can take three months to a year and cost between $250,000 and $500,000. The following image illustrates the generic drug development process. The time line is three to six years. However, the work on securing the active ingredient and the formulation can start before the expiration of the patent. As soon as the patent expires, a generic manufacturer can immediately enter the market, as Canada has an early working exception that allows the work-up to be completed and the regulatory approval to be sought in advance of patent expiry.

7 Canadian Generic Bio/pharmaceutical Association, *Generic prescription drug development process,* February 2010.

Timeline of a the drug development process for generic companies



Source: Canadian Generic Pharmaceutical Association website http://www.canadiangenerics.ca/en/resources/docs/GenericDrugDevelopment.pdf consulted July 15, 2010

The research-based companies spend more than 200 times the amount spent on the development of a drug than do the generic companies. Therefore, the need for a strong and predictable protection of their intellectual property is an absolute necessity. Without such protection of their discovery and fair market exclusivity, why would research-based companies stay in Canada?

Canada's effort over the past two decades to improve the protection of IPR for research-based bio/pharmaceutical companies and the implementation of economic agreements, such as the North American Free Trade Agreement (NAFTA) and the World Trade Organization Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), have strengthened the image of Canada as a destination for bio/pharmaceutical companies. However, players compete internationally for R&D investment; other countries recognize the importance and the value of having world-class research-based bio/pharmaceutical companies in their territory. If Canada wants to keep attracting investment and high paying jobs, some work still needs to be done to achieve the same kind of IPR protection that other jurisdictions, such as the United States and the European Union, offer.

3 Canada in the global market

In today's globalized world, Canada needs to be competitive in the global marketplace in order to attract part of the limited amount of available research dollars. The competition is greater; the new markets are gaining importance, and other countries have moved forward in implementing sectoral strategies to attract innovation. A recent report on innovation, conducted by the Conference Board of Canada[8], ranks Canada very low, giving it a D grade for innovation. Switzerland, Ireland and the U.S. take the three first positions. Countries that are leaders in innovation have in common public policies and government programs that promote national innovation and encourage investment. While Canada has taken some steps to promote innovation, like the Scientific Research and Experimental and Development (SR&ED) tax incentive program and the recent establishment of a federal secretariat to review innovation in Canada, more needs to be done.

Canada has improved over the last few decades. Since 1987, as a result of amending the *Patent Act,* Canada's research-based bio/pharmaceutical companies R&D spending grew from $106 million to $1.18 billion[9], but more can be done. While the life of a patent is the same (20 years from the filing date) in almost all countries, as required by TRIPS, the actual time during which a drug is on the market with exclusivity differs. In Canada, a drug usually has market exclusivity for seven to nine years. In the U.S. and in the European Union the patent can be restored for an extra five years after the basic 20 years. Other regulatory issues for research-based bio/pharmaceutical companies in Canada are both the duration and scope of data protection and the lack of an effective right of appeal under the Patented Medicines (Notice of Compliance) Regulations PM (NOC). The following table compares the Canadian and non-Canadian bio/pharmaceutical IP regimes.

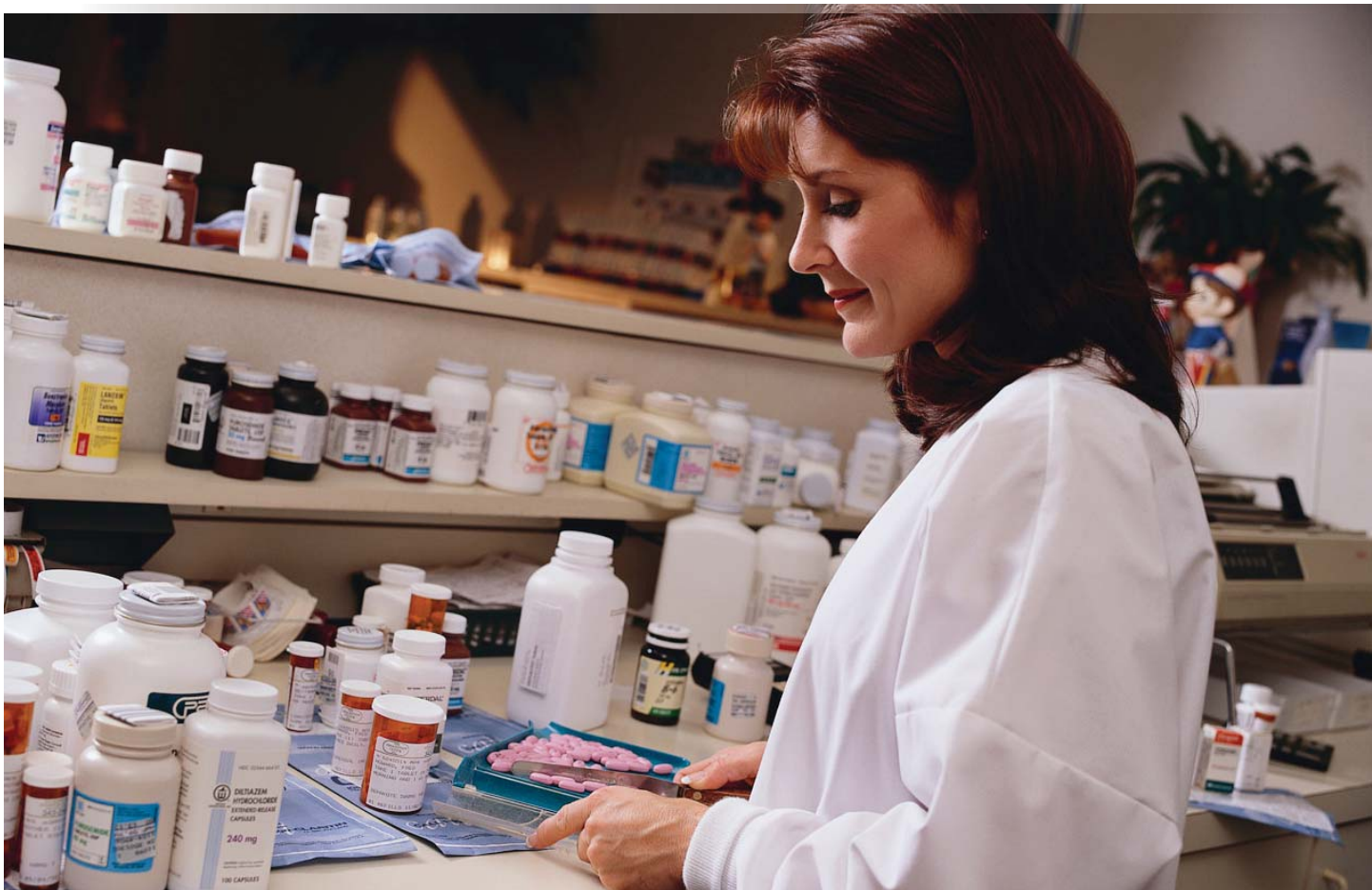
8 CNW, *Sanofi-aventi Canada Transforms to Support Sustainable Business Model,* May 5, 2010.

9 AstraZeneca, *The patent act & Linkage regulations*, www.astrazeneca.com

Comparison of Canadian and Non-Canadian Bio/pharmaceutical IP Regimes

	European Union (27 Member States)	Canada	United States		Other Countries
Right of Appeal	No "linkage" regimes like in Canada or in US. However, provisional measures (e.g. interlocutory relief) also available in EU to prevent patent infringement.	PM (NOC) Regulations that link market approval to patent validity. No provisional measures available. Inequities in "linkage regime" (e.g. no effective right of appeal for innovators) favor generic manufactures over innovators.	Linkage regime similar to Canada's (the "Hatch-Waxman" system) Absence of problematic inequities: e.g. innovators have an effective right of appeal. Provisional measures available.		Canada and US are only major countries with "linkage" regimes.
Data Exclusivity	**10** years exclusivity + **1** Year extension for new indications	**8** years exclusivity **No** extension for new indications	**5** years exclusivity + **FDA** approval time (1+ years) + **3** year extension for new indications	**12** years exclusivity for biologics	Japan: **8** years equivalent + **4** years for new indications Korea: **5** year exclusivity + **3** year extension for new indications Switzerland: **10** years
Patent Term Restoration	Maximum **5** years additional market exclusivity through Supplementary Protection Certificates (SPC). Maximum combined patent/ SPC post-approval market exclusivity of **15** years.	**None**	Maximum **5** years additional market exclusivity. Maximum combined post-approval market exclusivity **14** years.		Japan: Like EU, combined **5** year / **15** year max. Korea: Max **5** year additional market exclusivity. Switzerland: Max **10** years additional market exclusivity.

Source: Rx&D



4 Canada's Intellectual Property Shortcomings

Many of the IP issues facing the business community in Canada can be fixed at the national level through action from the federal government. The issues facing the research-based bio/pharmaceutical companies are no exception: the patent term restoration, the data protection regime and the PM (NOC) Regulations can all be amended by the federal government. As noted, bio/pharmaceutical issues are a priority for the CIPC as they are a key component in the Canadian IPR system and involve industries that are of primary importance in terms of innovation and world competitiveness. The CIPC is advocating for these changes in order to protect and create highly skilled jobs in the industry and to foster investments that would benefit all Canadians.

4.1 Patent Term Restoration

In Canada, like in most other developed countries, the *Patent Act* provides innovators with a basic 20-year exclusivity protection for an invention, from the moment they file the patent application. However, this does not mean market exclusivity for 20 years. When the innovative bio/pharmaceutical company files a patent, it is just the start of a very long and expensive process that will give the company seven to nine years of market exclusivity. During the 20-year term of patent protection, the company will have to go through additional R&D, Phase I through III clinical trials, regulatory New Drug Submission reviews (including the stringent procedures required by Health Canada) and subsequent reimbursement/listing procedures with the federal and provincial/territorial governments. The time lost by these government-required procedures is at least two and a half years. This delay significantly reduces the time the drug can be exclusive on the market.

Many other countries have adopted a mechanism referred to as Patent Term Restoration (PTR) or "patent term extension" to compensate for the time lost in the regulatory and governmental approvals procedures. This helps innovative companies recoup more of their investment by reinstating the benefits of the IP protection which would otherwise be lost. Most developed countries (such as the U.S., the European Union members, Russia, Japan, Australia, Korea and Israel) grant innovative patent holders a period of up to five years of Patent Term Restoration to compensate for the time they lost in the regulatory and administrative processes and to recoup their investments, often worth billions of dollars. In Canada, there is no PTR and the life of the patent once the drug is on the market is significantly shorter than in any other G7 country. Given this serious shortcoming, it is harder for innovative research-based bio/pharmaceutical companies to preserve existing investments and footprints in Canada and to bring new investments here.

The Canadian government recently reaffirmed its desire to make Canada a world-class research leader, investing over $200 billion to attract internationally renowned scientists as Canadian universities' Research Chairs[10]. Research and innovation go hand-in-hand, fostering innovation investment in the public sector is important, and a favourable environment for business is essential to encourage partnership between the private and the public sector. Innovative research-based companies are the largest single funder of health research in the private sector, funding more than $1 billion in R&D in 2006[11]. The same year, partnering with the Canadian Institutes

10 The Globe and Mail May 18, 2010.

11 Standing Committee on Industry, Science and Technology, *Evidence contents*, May 8, 2008.

of Health Research (CIHR), the innovative research-based companies invested $320 million in biotechnology research[12]. To become a world-class research leader and to attract innovation, Canada needs to address the legislative and regulatory issues impairing the full capacity of its innovative bio/pharmaceutical industry.

Recommendation

Canada needs to implement a five-year Patent Term Restoration system to be on the same competitive level with other G7 countries. Local market conditions matter and the complete absence of PTR in Canada is a clear and negative market differentiator.

4.2 Data Protection

Before any innovative drug is allowed to enter the market, many trials have to be performed in order to make sure the drug is safe and effective. The clinical trials can last up to seven years and involve at least three phases; the table below describes those stages.

Clinical studies overview

Phase I	20-80 healthy volunteers	To establish basic safety and blood levels achieved with different doses of the drug	1.5 years
Phase II	Up to 100 people who have or who might develop the disorder being studied	To establish the drug's effectiveness and dosage range, and to identify side effects	2 years
Phase III	300-30,000 people who have the disorder being studied	To confirm the most effective dosage regimen; to obtain more information about the drug's effectiveness and side effects not seen during phases I and II; and to compare the drug with existing drugs, a placebo, or both	3.5 years

Source: Merck website http://www.merck.com/mmhe/sec02/ch010/ch010b.html consulted July 15, 2010

12 Ibid.

Data arising from clinical trials of a new drug are the product of years of effort and millions of dollars; it is the price to pay to demonstrate the safety of a drug and is essential to gaining government approval. In recent years, the clinical trials phase has become increasingly expensive for the companies and can take up to 60 per cent of the total cost of bio/pharmaceutical R&D[13]. Data Protection Regulations (DPR) protect the data from being used by the generic companies to gain product approval for a period of eight years (eight and half years for drugs on which pediatric trials have been conducted).

The generic companies need the clinical trial data for their own drug approval, in order to demonstrate their product is "bioequivalent" to the innovative drug. Because they replicate an already existing medicine, the generic companies are not required to conduct expensive clinical trials that the innovative company was required to conduct. Bioequivalence tests comprise of a relatively short and inexpensive process, during which the generic drug is tested in comparison with the innovative one. During the first six of the eight-year period of data protection, no drug manufacturer can file a regulatory submission that would use and rely on the innovator's data to seek its own approval. At year six, a generic product submission can be filed, but no approval can be issued until at least eight years have passed from the date the innovative product obtained its approval. Unfortunately other countries provide greater protection. To remain competitive in the international market place, Canada needs to improve its DPR and allow protection in cases of new clinical indication. For example, the European Union provides an extra two years of protection over Canada's regime, and the United States recently approved four more years of protection than Canada for biological medicines.

Bioequivalence tests

"A generic drug manufacturer may file an abbreviated new drug submission for an NOC. By establishing that its product is equivalent to a drug that has already been approved, the manufacturer can demonstrate its safety and effectiveness by comparison, without having to do extensive clinical studies, thus saving time and money. The Minister of Health will issue a NOC only if the manufacturer also complies with the requirements of the regulations."

Dominique Valiquet, The Patented Medicine (Notice of compliance) Regulation, Library of Parliament, May 2006, p.4.

"Manufacturers must conduct studies to determine whether their version is bioequivalent to the original drug – that is, that the generic version releases its active ingredient (the drug) into the bloodstream at virtually the same speed and in virtually the same amounts as the original drug. Because the active ingredient in the generic drug has already been shown in testing of the trade-name drug to be safe and effective, bioequivalence studies only have to show that the generic version produces virtually the same levels of drug in the blood over time and thus require only a relatively small number (24 to 36) of healthy volunteers."

Merck website http://www.merck.com/mmhe/sec02/ch017/ch017b.html consulted July 15, 2010

13 Torstensson, David and Dr. Meir Pugash, *Courting confusion? Where is Canada's Intellectual Property Policy Heading?*, Stockholm Network, August 2008,

For every new clinical use of a medication, the research-based company needs to perform new tests to prove its safety. Without an effective data protection of this new data, the generic companies can immediately run bioequivalence test for the new use of the drug, enter the market and seriously damage the market share of the innovative company.

Before the implementation of NAFTA and TRIPS, bio/pharmaceutical test data were protected as a trade secret both in the United States and in the European Union; they were not in Canada. With the ratification of international trade agreements, more uniform rules apply to countries around the world. According to article 39.3 of TRIPS, the basis on which countries need to build their data protection system is as follows:

> Members, when requiring as a condition of approving the marketing of bio/pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public or unless steps are taken to ensure the data are protected against unfair commercial use.

TRIPS, however, does not specify the minimum period of data exclusivity, neither does it detail what is a considerable effort and if the bioequivalence test are acceptable or not. In fact, the bioequivalence tests are not a disclosure of data but a reliance on the data. For example, Health Canada, without disclosing the data to a generic company, relies on it to compare the innovative drug and the generic one. In the absence of detailed rules to follow, looking at the models adopted by the U.S. and the European Union, one can conclude that Canada needs to be stronger on data exclusivity. The U.S. gives a basic five years of data protection but up to an extra three years for new clinical indications and 12 years for biological products, while the European Union gives 10 years of data protection. When combined with PM (NOC) system deficiencies, and considering the complete absence of any form of patent term restoration, an uncompetitive data protection regime is clearly another cumulative and significant issue for innovators. The eight years given in Canada is no longer competitive.

Recommendation

The Canadian government needs to implement additional data protection equivalent in both scope and duration to that provided by our key trading partners and competitors. This would raise our level of protection, making it consistent with that of other industrialized nations with whom we compete for investments and highly skilled and well paying jobs.

4.3 Patented Medicines (Notice of Compliance) Regulations

The Patented Medicine (Notice of Compliance) Regulations are also referred as PM (NOC) Regulations or more colloquially as the patent linkage system. It is a process by which Health Canada cannot grant a Notice of Compliance (NOC), which is the final approval before a drug accesses the market, to a generic drug until the original patent has expired (hence providing a linkage between the patent regime and the safety regime). Market entry while a patent is still valid would be an illegal infringement to the *Patent Act*, TRIPS and NAFTA. The linkage system provides innovators with a protection of their patents, which is essential for their survival.

While the system serves a good purpose, some aspects of it are clearly unfair to the innovative companies. When an innovative bio/pharmaceutical company discovers a new drug, after years of research, it registers its patents on the Patent Register. The generic manufacturers are allowed to copy an innovative drug before the patent for this drug expires, but they are not allowed to market it unless they successfully address the patents listed on the Patent Register. When they try to do so by requesting a NOC from the Health Minister (which is the final approval before marketing the product), the linkage system will not allow them to get the approval because, after verifications, the minister will see that a valid patent is registered for that drug. From there the generic company has at least two options: wait for the patent to expire to receive the NOC or send a Notice of Allegation to the patent holder to contest the validity of the patent or assert that it is not infringed.

When the patent holder receives the Notice of Allegation, he has 45 days to react by asking the federal court to issue an order prohibiting the Health Minister from issuing a NOC until after the expiration of the patent. Once this order is issued, the minister cannot grant a NOC to the generic for a period of up to 24 months, except if the patent expires before that or if the court rules in favor of the generics. If the tribunal rules in favour of the generic and provided they have already obtained Health Canada safety approval, they will get their NOC and they are allowed to enter the market before the innovator patent has expired.

The innovative companies are denied an effective right to appeal the court decision. However, if the court rules in favour of the innovative company, the generic company does have the right to appeal the decision. This is one of the most concerning issues for the innovative companies established in Canada. Sanofi-aventis Canada, the country's largest investor in innovative bio/pharmaceutical R&D with over $211.5 million investments in 2008, discussed the PM (NOC) regulations in a press release dated May 2010: "Canadian Innovative pharmaceutical companies have no effective right of appeal when facing intellectual property challenges. This lack of government policy leadership is leading to genericization of branded medicines even while they are still under patent protection. This threatens the company's ability to maintain its R&D investments, capital expenditures and job creation opportunities."[8] Not only are research-based companies denied the right of appeal, but the rule is different whether applied to a generic company or to a research-based company, creating an inequitable and discriminatory system.

The consequences for the innovative companies can be disastrous; the market share they lose is significant and lowers their revenue considerably. When an innovative company plans its budget for a drug, it takes into account that it will have the market exclusivity for a certain period during which it should be able to pay back its investments. If this period is cut short or is unpredictable, it challenges the ability of innovative companies to carry out intensive R&D by impairing their revenues and ability to plan.

This shortcoming in the linkage system creates a lack of stability and predictability for the innovative companies because they never know if or when their patent will be dismissed in court, reducing the period of market exclusivity and making it impossible to properly manage their business.

Recommendation

The Canadian government needs to restore the stability and predictability in the business environment by granting the research-based companies an effective right to appeal the initial adverse PM (NOC) system court decisions.

5 Conclusion

Despite a relatively good performance of the life sciences sector as a whole in Canada in recent years, some key issues remain problematic for research-based bio/pharmaceutical companies. Unless they are addressed systematically, there is a significant risk to the entire sector, since bio/pharmaceutical companies bankroll starts-ups are essential to bringing new innovative products through increasingly difficult and lengthy approval processes. In order for them to achieve their full potential, bio/pharmaceutical companies require a stable, predictable and internationally competitive IPR system. As we have highlighted in this report, innovation-based businesses are key to the economic growth in Canada, and they also provide Canadians with highly skilled and well paid jobs. We have seen that changes to legislation and regulations can have tremendous impact on the level of R&D investment. After Canada amended the *Patent Act* in 1987 changes were staggering. The value of research-based bio/pharmaceutical companies' investment in R&D grew from $106 million to $1.8 billion in 2002. To strike a balance between providing Canadians with lower-cost drugs and encouraging innovation and R&D, Canada needs a system that is fair for all players. To achieve that goal, we strongly encourage the government to follow our recommendations.

Summary of Recommendations:

- Canada needs to implement a five-year Patent Term Restoration system to be on the same competitive level with other G7 countries. Local market conditions matter and the complete absence of PTR in Canada is a clear and negative market differentiator.
- The Canadian government needs to implement additional data protection equivalent in both scope and duration to that provided by our key trading partners and competitors. This would raise our level of protection, making it consistent with that of other industrialized nations with whom we compete for investments and highly skilled and well paying jobs.
- The Canadian government needs to restore the stability and predictability in the business environment by granting the research-based companies an effective right to appeal the initial adverse PM (NOC) system court decisions.

14 CNW, *Sanofi-aventi Canada Transforms to Support Sustainable Business Model*, May 5, 2010.

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