



The Stockholm Network Experts' Series on Pharmaceutical Intellectual Property Rights



Courting Confusion? Where is Canada's Intellectual Property Policy Heading?



Foreword

Why would the Stockholm Network – a pan-European think tank – decide to look at the issue of pharmaceutical intellectual property rights (IPRs) in Canada?

In order to answer this question, let us stand back and ignore Canada for one moment. Instead we should look more broadly at the Stockholm Network's overall body of work on intellectual property and on healthcare. Since it was established in 2004, the Intellectual Property and Competition Programme of the Stockholm Network has dealt extensively with the various discussions associated with the field of pharmaceutical IPRs. Through our books, articles, reports, DVDs, workshops and seminars we have been able to develop our own in-house expertise (as well as by being assisted by external experts) in order to deal with the different discussions and debates within this field and make recommendations about how to improve policymaking. Today's debates about pharmaceutical IPRs are more interesting than ever and the related disputes over both the theory and practice of IP policymaking are as emotional as they are rational. Do pharmaceutical IPRs represent a barrier to access to medicines or are they essential to it? Do patents prevent or enhance pharmaceutical research and development? Are compulsory licenses a legitimate tool for price negotiations or are they a predatory mechanism aimed at circumventing the rights of innovators? These are but a few of the questions that are being debated today.

So, why Canada? Not only is the debate in Canada over the pharmaceutical IP landscape fascinating at a national level, but perhaps more importantly the lessons that it can teach us have global implications. In a period in which international forums, such as the World Health Organisation, are discussing and debating the issues of IPRs, innovation, access to medicines, the use of compulsory licences and other forms of state or global intervention, Canada has some instructive stories to tell us.

In this paper we attempt to track and analyse the path that Canada took with regard to its own pharmaceutical IP environment. We discuss the changes that led Canada – which until the 1990s was an "outlier" among developed countries in terms of the level of protection provided to pharmaceutical IPRs – to go ahead and strengthen its pharmaceutical IP environment, making it much more aligned with the environments of other developed countries such as the US, the EU Member States and Japan. Still, we argue that this shift has not yet been completed. As suggested by the title of this paper Canada is still undergoing some significant internal debates about the future of its pharmaceutical IP landscape, not least in the context of its judicial system. Indeed, in what may seem to be a contrast to the policy and legislative developments during the last two decades, Canada's judiciary still seems to apply a more critical approach towards IPRs; an approach that can be termed as being part of "received wisdom" in Canada before the 1990s.

The lessons that one can draw from the Canadian experience are therefore of great value in assessing which types of IP policymaking environment lead to more innovation, better access to new medicines

and ultimately, how policymakers can create a healthy outcome for both national economic growth and individual patient health.

Dr Meir Pugatch, August 2008

Executive Summary

This paper discusses and analyses the pharmaceutical intellectual property (IP) environment in Canada. In particular it examines the evolutionary process underlining the policymaking of intellectual property rights (IPRs) in the field of pharmaceuticals, with a focus on Canadian policy since the 1970s. The paper also seeks to compare these policy developments with some key legal rulings handed down by the Canadian judiciary. It identifies a potential contradiction between the legal and regulatory framework introduced in Canada since 1992 – a framework which is more supportive of the domestic innovative pharmaceutical sectors – and some of these key court rulings. The latter tend to provide a legal interpretation of pharmaceutical IPRs that seems to be based on a rationale reminiscent of the pro-generic IPR policy of the 1970s and 1980s, rather than the one established in the early 1990s.

This potential contradiction should be addressed since it affects the *de facto* nature and direction of the contemporary pharmaceutical environment in Canada. A greater emphasis should be placed on the fact that over the last two decades, Canada has experienced (and is experiencing) a noticeable and ongoing shift of policy towards more robust systems of IP protection, aimed at supporting the innovative segment of the domestic pharmaceutical and biotechnology sectors. This change of policy, however, should not only be limited to the policymaking level but should also "spill over" to the judiciary. This is not to argue that policies aimed at supporting the production and dissemination of generic drugs should not take place in Canada. Such policies are relevant and important to any country's health care system. Yet these policies are only part of the equation and not a wholesale solution. Indeed, experience suggests that it is possible to combine both a pro-innovation policy with a pro-generic one without sacrificing either. For example, the United States, while having its own problems with the high cost of drugs, actually has the highest rate of market penetration of generics in the world yet, at the same time, has a very robust system of IP protection. Popular misconceptions about the cost-cutting benefits of favouring a large generic sector should be engaged and where appropriate refuted.

Structurally, the paper does the following:

- i) provides a brief overview of the pharmaceutical industry, and the process of drug discovery and development, as well as of the IPRs that are relevant to this field;
- ii) analyses the Canadian health care model in the context of the fundamental shift from a generics-based mentality towards one that is more pro-innovator;
- iii) analyses several key rulings, which seem to suggest that the Canadian courts are not consistent in their interpretation of this broad shift in IPR policy; and
- iv) finally, the paper provides policy recommendation that seek to address the seeming gap between the legislative and the judicial.

Courting Confusion? Where is Canada's Intellectual Property Policy Heading?

By David Torstensson and Dr Meir Pugatch

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Canadian IP Dilemmas

Surprisingly few people take the time to conceptually disaggregate Canada from its larger southern neighbour, but as, any Canadian will tell you, the culture and outlook of Canadian politics and policy-making is very different from that of the United States. Like the United States, Canada has a federal structure to its government with substantial budgetary and political responsibilities in the hands of Provincial governments, yet its social and health policies bear more resemblance to European welfare states.

Canada has historically had a tendency for a type of state protection and provision of health care which is in many ways the opposite of what one might label “the US” or free-market model. Canada, for example, does not allow any private provision of primary medical care. Instead, all primary health care is funded by the Federal and Provincial governments. Up until the late 1980s and early 1990s, its pharmaceutical policy was based on encouraging the domestic production of generic medicines – that is, pharmaceutical medicines that are imitations of existing, usually patented drugs – through the Government’s liberal issuing of compulsory licenses. These licenses – which essentially allow producers of generic drugs to override existing pharmaceutical patent protection – have resulted in Canada having one of the developed world’s biggest generic drug manufacturing industries. It has also resulted in the Canadian government having a strained relationship with the research-based pharmaceutical industry (which accounts for most of the research and development that generic medicines are based on). Perhaps more importantly, Canada, as a result, has a relatively low level of pharmaceutical R&D. From 1973 to 1987, Canadian Pharma R&D as a percentage of OECD Pharma R&D hovered between 0.9% and 0.6%. Only from 1989-90 onwards – when new IPR-friendly legislation was introduced – has there been any real growth and change in these numbers.¹

Indeed, over the course of the last two decades Canada’s pharmaceutical policies have undergone significant changes. Through the combination of domestic forces and the international obligations established by the NAFTA (1993) and TRIPS (1995) agreements, Canada has embraced a stronger pharmaceutical IPR regime. This regime now seeks to actively encourage more R&D within Canada and the growth of a research-based pharmaceutical industry alongside an already well-established generic counterpart. This move has left Canada with a number of difficult policy dilemmas.

First, how does Canada reconcile the long public policy history of favouring generics with this newly-adopted idea of embracing a stronger and pro research-based pharmaceutical system of IPRs? At a superficial level, this would not seem like a paradoxical situation at all, regulations and legislation have changed; thus attitudes and actions should change accordingly. But, changing public policy is not just about changing Federal primary and secondary legislation. Laws and regulations cannot in themselves

¹ Pazderka, Bohumir, ‘Patent Protection and Pharmaceutical R&D Spending in Canada’, *Canadian Public Policy*, No 1, 1999, p. 37.

change behaviour, particularly not when that behaviour is as frequently challenged in the courts of law as pharmaceutical IPRs.

The Canadian judiciary is an independent institution that, as in other common law countries, wields a good deal of power through the legal system's reliance on case law and case precedents. Canadian courts are active and of the utmost importance to the *de facto* climate of pharmaceutical IPRs, as opposed to the *de jure* one. The result is that in Canada, just as in the United States, disputes over the interpretation of existing legislation and regulation of the IPRs of the pharmaceutical sector is as likely to be settled in the courts by judges as in Parliament or in Government Ministries. This has led to another potentially difficult dilemma – the seeming conflict between the direction of federally passed legislation versus the thinking of the courts. Over the past 10 years this has produced a large number of important precedent-setting court rulings that seem to be more in line with pre-1987 pro-generic legislation than subsequent pro-research policies.

As a result, Canadian policymakers are faced with a situation where they not only need to reconcile their pro-generic tradition with the aim of supporting the development of a research-based pharmaceutical industry, but they also have to deal with a judiciary that appears to base many of its rulings on the pharmaceutical IPR system of the 1970s and early 1980s.

Understanding the nature of these dilemmas and how they came into being is absolutely essential if one wishes to make sense of where Canada's pharmaceutical IPR regime sits today and to draw some conclusions about where it is heading.

Before doing so, however, it is worth briefly outlining some of the specific characteristics of the pharmaceutical industry, the process of discovering and approving drugs, as well as explaining why IPRs are so intrinsic to the pharmaceutical industry's business model.

The Nature of the Pharmaceutical Industry, the Process of Drug Discovery and Development, and IPRs

Why is an analysis of the overall structure and characteristics of the pharmaceutical industry linked to the field of IPRs? The reason for this is relatively straightforward: arguably more than in any other sector or field of technology, IPRs have a profound effect on the scope, structure and behaviour of pharmaceutical companies and of the sector as whole. IPRs affect the pharmaceutical sector across the board. For example, research-based pharmaceutical companies rely heavily on the protection of IPRs for the sake of carrying out the highly risky, lengthy and costly process associated with the research and development of new medicines; IPRs also affect the ability of these companies to recoup

their investments and generate profits in the market. At the same time, IPRs also have a profound impact on generic-based pharmaceutical companies, whose business model is based on the copying of drugs that have already been developed and introduced onto the market by research-based companies. As such, generic-based companies tend to treat IPRs as a barrier to market entry since they adversely affect their ability to launch generic drugs to the market.

For the sake of simplicity, the pharmaceutical industry can be divided into the two types of dominant players that have been referred to above: research-based companies, which focus on the research and development of new pharmaceutical products, and generic-based companies, that focus mainly on the production of existing compounds for which IP protection has either expired or can be legally challenged.

Traditionally, research-based companies have been big, blue-chip, multinational companies with the financial resources as well as the infrastructure to carry out the lengthy, costly, and risky process of developing a new medicine. Generic-based companies, on the other hand, have traditionally been more focused on domestic markets and (in terms of scope of operations, capital base, product diversification, etc.) were considered to be much smaller than research-based companies.

But the pharmaceutical market is currently undergoing some significant changes that make the above distinction less clear-cut.² For example, some multinational drug companies, such as Novartis, now have their own generic divisions (Sandoz) while many generic manufacturers are beginning to look more like their multinational competition in size and market share. For example, the Israeli giant Teva has direct operations in more than 50 countries with 17 generic R&D centres around the world and a 20% market share of the US generics business. Apotex, a Canadian-based generic, controls 34% of the Canadian generic market and was the market leader in 2006.³

Nevertheless, in the context of this paper and as a means of understanding the history behind the current situation of pharmaceutical IPRs in Canada, the traditional distinction between research-based and generic-based companies will be used.

The amount of time, money and investment an innovator spends on the R&D process is both substantial and highly risky, as very few of the drugs that are researched ever become marketable medicines. Industry figures suggest that as few as 1 out of 5,000 molecules screened actually make it onto the market as pharmaceutical drugs.⁴ Moreover, out of the drugs that make it onto the market,

² Von Braun, J. and Pugatch, M. P. "The Changing Face of the Pharmaceutical Industry and Intellectual Property Rights", *Journal of World Intellectual Property*, vol. 8:5 (September 2005), pp. 599-623.

³ *Business wire*, February 26, 2008, 'Generics in 2007 Accounted for more than 46% prescriptions and 19% sales out of the total Canadian pharmaceutical market', http://www.businesswire.com/portal/site/google/?ndmViewId=news_view&newsId=20080226005721&newsLang=en

⁴ Association of the British Pharmaceutical Industry, *The Development of Medicines*, London, ABPI, 2002.

it is estimated that only 3 out of 10 prescription drugs generate revenue that equals or exceeds the average cost of research and development.⁵

The cost of developing and getting new drugs approved has always been high, but over the past 25 years it has exploded. In 1979 the total cost of developing and getting a drug approved for public sale was \$138m. In 2003 this figure was a staggering \$802m.⁶ Tufts Center for the Study of Drug Development recently estimated that the 'fully capitalized cost to develop a new drug, including studies conducted after receiving regulatory approval, averages \$897 million'.⁷ This cost consists mainly of two research and data-gathering elements: so-called pre-clinical trials and clinical trials. The purpose of these trial periods is to establish whether or not the drug proposed for approval is safe for human consumption. The cost of clinical trials has grown the most. Grabowski estimates that the accumulation and compilation of the data included in a pharmaceutical registration file (which is carried out by clinical trials) is around \$US467m, more than 60% of the total cost of pharmaceutical R&D.⁸

The testing and approval process for a new drug is also very long. Each new medicine has to undergo a complex and lengthy process of selection, testing and development in order to make it safe for human use and effective in terms of treatment. This constitutes the clinical trials. A typical pharmaceutical R&D project consists of one pre-clinical stage and four clinical stages (clinical stages are also referred to as phases).⁹ At the pre-clinical stage scientists attempt to isolate new chemical or biological entities using advanced screening and synthesizing techniques. This stage also involves initial safety tests on animals and various assessment studies, such as toxicology. Clinical phases involve safety trials on volunteers (phase I), small patient groups, (phase II), large patient groups (phase III), and regulatory and post-marketing studies (phase IV). Overall, current pharmaceutical R&D projects take about 10 to 14 years to complete.¹⁰

A generic company, on the other hand, – which is essentially producing a copy of an existing drug – does not need to recoup R&D costs associated with the development of the original drug. In fact, the process required of a generic to bring its drug to market is substantially less time-consuming and costly than a research-based pharmaceutical. Most regulatory approval bodies – such as America's Food and Drug Administration (FDA) – use an Abbreviated New Drug Application process that generally does not require a generic applicant to file any preclinical or clinical data.¹¹ Instead, generic

⁵ Grabowski, H and Vernon, J., 'Returns to R&D on New Drug Introductions in the 1980s', *Journal of Health Economics*, Vol. 13, 1999.

⁶ Dimasi, Hansen, and Grabowski, October 2002.

⁷ Tufts Center for the Study of Drug Development. *New Release -Total Cost to Develop a New Prescription Drug, Including Cost of Post-Approval Research, is \$897 Million* (13 May 2003), <http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=29>

⁸ Grabowski, H. *Patents and New Product Development in the Pharmaceutical and Biotechnology Industries* (Duke University: July 2002), p. 5 and Figure 1; Data is adjusted to 2003 R&D expenditures

⁹ For an overview of different pharmaceutical R&D phases see: Gambardella (1995: Chapter 2); Ballance, Pogany and Forstner (1992: Chapter 4); Economist, *A Survey of the Pharmaceutical Industry*, (1998: 4); ABPI (1996: 8-10); IFPMA (1998: Chapter 3); PhRMA (1999: Chapter 3).

¹⁰ Pugatch, M.P. *The International Political Economy of Intellectual Property Rights* (Edward Elgar: Cheltenham, UK, June 2004), chapter 4.

¹¹ <http://www.fda.gov/cder/regulatory/applications/anda.htm>

applicants need only to prove that the proposed generic drug is bioequivalent to the original drug, that is, have statistically similar chemical and biological effects as the compared innovator drug.¹² Therefore they can set a price that is lower than that of the original drug.

It is because of the above that IPRs are so crucially important to research-based pharmaceutical companies. For them, IPRs have two major functions. First, they are used as "insurance" during the different stages of research and development. The development of innovative pharmaceutical products is a time-consuming, expensive and risky business. That, combined with fierce competition surrounding the introduction of new drugs, drive research-based pharmaceuticals to seek the protection of IPRs, as a means of protecting their massive R&D investment. Indeed, it is estimated that between 60 to 65% of pharmaceutical products would not have been introduced or developed in the absence of patent protection.¹³ Secondly, IPRs function as the main business platform upon which research-based companies are able to recoup investments and generate the commercial returns from the introduction of a new successful drug to the market. Consequently, the term and scope of the IPRs that are granted to a given product essentially determine the ability of the originating company to commercially exploit this product. For example, once its innovative product has exhausted its patent protection the originating company would be forced to compete with much cheaper generic substitutes. As a result, the company may experience a serious drop in sales (especially if this drug is considered a "blockbuster", i.e. a drug that generates sales of more than \$1 billion). Evidence suggests that a combination of expected patent expiries and a lack of new promising pipeline products can adversely affect companies' equity prices. Patent protection and patent expiries also play a role in intra-industry merger considerations.¹⁴

The success of generic-based companies relies on their ability to enter a market as early as possible by challenging the scope and exclusivity of the IPRs granted to original products. Since generic-based companies are not required to recoup the costs associated with the development of an innovative drug (as well as the costs associated with the attempts to develop drugs that fail to reach the market), they are able to set a price that is sometimes significantly lower than the price of the original drug. Because of this ability to provide much cheaper drugs to the market, the behaviour of research-based companies is sometimes described as "monopolistic" and contrasted with the practices of the generic company which are perceived as being "benign". Yet regardless of their geographical origin (be they from the developed or developing world) or their orientation (research-based or generic), pharmaceutical companies are all motivated by profit. Indeed, dominant generic companies, such as Indian-based Ranbaxy, Israeli-based Teva, and Canadian Apotex, use the most sophisticated legal tools available to them in order to challenge the IPRs of original drugs in lucrative markets, including in Canada.¹⁵

¹² Ibid. A more thorough discussion of the term bioequivalence will be provided below in the case study section.

¹³ Mansfield, E. 'Patents and Innovation: An Empirical Study', *Management Science* (February, 1986), pp. 173-181

¹⁴ Pugatch, M.P. *The International Political...*, (Edward Elgar: Cheltenham, UK, June 2004), chapter 4.

¹⁵ Von Braun, J. and Pugatch, M. P. 'The Changing Face of the Pharmaceutical Industry and Intellectual Property Rights', *Journal of World Intellectual Property*, vol. 8:5 (September 2005), pp. 599-623.

Once one realises the nature of this relationship between research-based and generic-based companies and the manner in which they are affected by the IP system, one can more easily understand the wide scope that exists for conflict and dispute between these two segments of the pharmaceutical industry. Primarily this dispute boils down to judicial interpretations of the duration, scope and strength of the protection mechanisms that cover the IPRs relevant to any given drug.

Having briefly described the structure of the pharmaceutical industry and its relationship with the field of IPRs we can resume our discussion about the manner in which the battle over the pharmaceutical IP landscape is taking place in Canada.

The Canadian Health Care Model and IPRs

In the preface to the 2002 final report of the Commission on the Future of Health Care in Canada, Roy Romanow – chairman and author of the report as well as former premier of the Canadian province of Saskatchewan – outlined what he saw as Canada’s social and health care policy credo:

It has been suggested to me by some that if there is a growing tension between the principles of our health care system and what is happening on the ground, the answer is obvious. Dilute or ditch the principles. Scrap any notion of national standards and values. Forget about equal access. Let people buy their way openly to the front of the line. Make health care a business. Stop treating it as a public service, available equally to all. But the consensus view of Canadians on this is clear. No! Not now, not ever. Canadians view medicare as a moral enterprise, not a business venture.

This report was a major source of discussion and caused a good deal of controversy in the policy community with then leader of the Opposition, and now Prime Minister, Stephen Harper describing it as moving in ‘entirely the wrong direction’.¹⁶ Both the report and the above quote illustrates the sentiment that health and medical care within a Canadian context is predominantly viewed as being separate from the commercial world. In this regard, Canada’s relationship with the private sector in its wider health care system is a good place to start when seeking to explain its relationship with pharmaceutical IPRs.

The Canadian health care system is based on the publicly funded model of a single-payer system for primary care which is divided into a Federal and a Provincial level. Most of the funding is provided in the form of block grants from the Canadian Federal Government, but the actual health care provision is run and implemented by each individual Province. As a result, a relatively large degree of independence and control is left in the hands of the Provinces; the only proviso being that the

¹⁶ For Harper’s comments see CBC News, November 28, 2002, ‘Harper Says Romanow report ‘entirely wrong.’ http://origin.www.cbc.ca/canada/story/2002/11/28/romanow_reax021128.html For the debate within the policy community see for example Crowley, Brian, et al, *Definitely NOT The Romanow Report: Achieving Equity, Sustainability, Accountability and Consumer Empowerment in Canadian Health Care*, published by the Atlantic Institute for Market Studies (AIMS), December 2002, <http://www.aims.ca/library/notromanow.pdf>

Provincial health care delivered complies with Federal law, in particular the Canada Health Act.¹⁷ Compared with, say, the UK's National Health Service in which the British Government employs and runs virtually all medical facilities, over 90% of health care services in Canada are delivered through a private doctor or medical provider.¹⁸

Yet, Canada is one of the few developed countries that has an outright ban on the provision of private care in place of publicly provided health care. Indeed, this is an important point, as this attitude towards health and medical care is also reflected in what was up until the mid 1980s, the Canadian Government's relatively lax attitude towards protecting pharmaceutical IPRs and its strong support of the generic industry.

Early Canadian IP legislation and the differences between Research-based and Generic Pharmaceuticals

Until 1993 the Minister of Health was not directly concerned with patent issues. Indeed, Parliament's policy since 1923 had been to favour health cost savings over the protection of intellectual property by making available to generic manufacturers a scheme of compulsory licensing of an "invention intended or capable of being used for medicine or for the preparation or production of medicine".¹⁹

- Supreme Court Canada, 2005

In 1869 Canada saw its first Federal Patent Act come into force. While patents had been in existence and officially recognised for close to 80 years prior to this, this was the first time legislation was introduced on a Federal level. Fifty four years later, in 1923, Canada passed several important amendments to the Patent Act. While being primarily about changing the Act to allow Canada to join the *Paris Convention for the protection of Industrial Property* – the world's first international treaty on intellectual property and the organisational precursor to WIPO²⁰ – the Patent Act was also amended to allow for the compulsory licensing of patent rights for the manufacture of foods and medicines.

This amendment is of real importance to the legal philosophy of the next 60 years of regulatory and judicial policy vis-à-vis pharmaceutical innovators. It was the first step in establishing a regime of Government preference for the generic industry by establishing the principle of compulsory licensing. As will be seen in section 2 of this paper, 'Legislating from the Bench?', which looks at the recent court room history of pharmaceutical IPRs, this has had a profound impact on the Canadian judiciary.

¹⁷ http://en.wikipedia.org/wiki/Medicare_%28Canada%29#_note-2

¹⁸ Ibid.

¹⁹ Paragraph 8, *Biolyse Pharma Corporation, Appellant, v. Bristol-Meyers Squibb Company, Bristol-Meyers Squibb Canada Inc., and Attorney General of Canada (Respondents) – and – Canadian Generic Pharmaceutical Association, Pfizer Canada Inc., Interveners*, 19/05/2005, Docket: 29823, Citation *Bristol Meyers Squibb Co. v. Canada (Attorney General)*, [2005] 1 S.C.R. 533, 2005 SCC 26

²⁰ http://www.wipo.int/treaties/en/ip/berne/summary_berne.html

Indeed, 80 years later the Canadian Government admitted as much. They described the effect of these amendments as having enshrined compulsory licensing 'virtually as a right'.²¹

The Patent Act amendments of 1969

Support of a domestic Canadian generic industry was bolstered in 1969 when the 1923 compulsory rules were amended to allow compulsory licenses for the import of patented medicines from outside Canada.²² The amendment also allowed for the Active Pharmaceutical Ingredient (API) – also called pharmakon – of the compulsory licensed and domestically manufactured drug to be imported from abroad.²³ Prior to this amendment all active ingredients in a generic drug had to be Canadian manufactured. The 1969 legislation marked a watershed in the history of Canadian pharmaceutical IPRs. Even more so than the 1923 amendments, the new Patent Act of 1969 created an IP environment that was explicitly pro-generic.

The 1969 change to the Patent Act was recommended by the Harley Committee (a Special Committee on Drug Costs and Prices) in a 1967 report to the Canadian House of Commons. The Committee's recommendations were based on the perception that Canadian consumers and patients were paying more for drugs than their foreign counterparts (the US in particular). The recommendation to change the compulsory licensing legislation was made in order to encourage greater domestic pharmaceutical production and lower costs. In an analysis of the impact of this legislation on the cost of drugs carried out 15 years after the amendments, Fowler and Gordon argued that

the rationale behind this move [the 1969 amendments] appears to be that the pharmaceutical industry was perceived to be dominated by non-resident firms and that Canadian consumers were thought to be paying higher prices than consumers in other countries and, therefore, were paying excessive monopoly rents on inventions conceived elsewhere.²⁴

As patients and doctors were not convinced of the quality and efficacy of the drugs the immediate effect of the amendment was not the widespread use of generic drugs.²⁵ Long term, it would seem that the 1969 amendments did contribute to the nominal lowering of the cost of drugs: combined with subsequent provincial product selection legislation, the cost of drugs in Canada went down from

²¹ Duy, Vic, 'Brief History of the Canadian Biotechnology Advisory Committee Project Steering Committee on Intellectual Property and the Patenting of Higher Life Forms', Canadian Biotechnology Advisory Committee, Government of Canada, 2001, <http://www.cbac-ccc.ca/epic/site/cbac-ccc.nsf/en/ah00405e.html#historical>

²² Garland, Steven B. and Want, Jeremy E., 'The Enforcement of Intellectual Property Rights in Canada', PDF file, p. 16-8. <http://strategis.ic.gc.ca/epic/site/ipdd-dppi.nsf/en/ip01397e.html>

²³ WTO, Canada – Patent Protection of Pharmaceutical Products, *Complaint by the European Communities and their member states*, p. 13. An API is the compound which causes the reaction or therapeutic activity of a drug; one could say that this is the actual drug itself and the rest of a compound is simply the delivery agent or method.

²⁴ Fowler, David J and Gordon, Myron J, 'The Effect of Public Policy Initiatives on Drug Prices in Canada', *Canadian Public Policy*, 1984, p. 65.

²⁵ Shapiro, Daniel M. and Switzer, Lorne N., 'The Stock Market Response to Changing Drug Patent Legislation: The Case of Compulsory Licensing in Canada', *Managerial and Decision Economics*, Vol. 14, No 3, 1993. Canada, in 1971, established the Federal Drug Quality Assessment Program (QUAD), the purpose of which was to provide an objective assessment of the quality of a product and certify that it met appropriate government standards.

roughly 86% of the 1968 US price to 45% of the US price in 1980.²⁶ Having said that, there does exist strong evidence that the savings made on the lower cost of the manufacturing of drugs were not passed on to the consumer, but simply pocketed by pharmacists.²⁷ Accordingly, some studies also suggest that the market penetration of generic drugs increased substantially because of compulsory licensing. One case study claims that 10 drugs supplied under the Ontario Drug Benefit Plan showed a market share, in terms of units sold, of 55% in 1977 and 64.4% in 1980 for generics.²⁸

But the legislation also led to a serious loss of long-term investment in research-based pharmaceutical R&D. According to the Fowler study:

The majority of manufacturers' would agree with the view that government policy should support innovation rather than imitation...There is no doubt that compulsory licensing tends to do the latter rather than the former. **The gains achieved through reduced prices [by the 1969 amendments] may be partially or wholly offset by a loss of R&D activities in the country.** [Emphasis added]²⁹

Such a negative view of the effects of innovation created by the generous compulsory licensing regime would seem to be confirmed by the drastic change in policy the Canadian Government implemented in the mid 1980s and early 1990s.

NAFTA, TRIPS and Bill C-91

During the 1980s the trade association representing research-based pharmaceutical companies (at the time called the Pharmaceutical Manufacturers Association of Canada (PMAC) and now Canada's Research-Based Pharmaceutical Companies) criticised the Canadian Government's policies on IPRs. It claimed that the policy of compulsory licensing was having a negative impact on the pharmaceutical industry's willingness to invest and conduct R&D in Canada.³⁰ In 1985, in reaction to this criticism from members of the PMAC, the Canadian Government established a Commission of Enquiry, the Eastman Commission, to look into the matter.³¹ The purpose of this Commission was to investigate what the impact of the 1969 amendments had been on the drugs manufacturing industry and their levels of research investment. The Commission concluded – contrary to the case put forth by PMAC – that the Patent Act had not had much of a discernable impact on rates of R&D expenditure and the drugs manufacturing industry. Contrary to this finding the Commission recommended several measures to encourage more domestic R&D investment from the pharmaceutical industry – in effect appeasing the complaints vocalised by PMAC – at the same time as, ultimately, retaining compulsory licensing as official policy. These recommendations included an increase in patent protection and market exclusivity to 4 years and an increase in royalty rates from 4 to 14% of sales on the

²⁶ Fowler et al.. p. 71. Whether or not the study takes into account any steep rise in the cost of drugs in the United States, thus exaggerating and potentially skewing the cost comparison is not specified in the study. If this were the case it would obviously question the basis for the conclusions reached.

²⁷ Ibid.

²⁸ Ellis, Ned, Comment, *Canadian Public Policy*, 1982, p. 362. The data is taken from Gorecki's 1981 *Regulating the Price...*

²⁹ Ibid.

³⁰ Shapiro, Daniel M. and Switzer, Lorne N., 'The Stock Market Response...', *Managerial and Decision Economics*, Vol. 14, No 3, 1993.

³¹ Ibid.

compulsory licenses issued (royalties were paid to the patent holders whose patents had been overridden by the issuing of a compulsory license).³²

Together with the difficulties compulsory licensing presented to the successful completion of a Free Trade Agreement with the United States (which would also later become a problem for Canada's prospective membership of NAFTA) and a pledge from PMAC to raise R&D expenditure from the 1984 level of 4.9% to 8% by 1991 and 10% by 1996, these recommendations resulted in a new Patent Act amendment; bill C-22.

This 1987 bill amended the Patent Act by providing for protection from compulsory licensing for a period of 10 years in the case of licence to import and 7 years in the case of manufacturing. Drugs invented and developed in Canada were protected for a period of 20 years. The legislation also established the Patented Medicine Prices Review Board which was put in place to monitor the prices of patented medicines in particular.³³

In fact, the PMPRB exists to this day and is, under current Canadian legislation, not only charged with monitoring the price of patented medicines, but when and if it determines such prices are "excessive", has the right to order a patentee to lower its price or pay a fine to the Canadian Government. This legislation is outlined in section 83 of the Patent Act, Excessive Prices:

Where the Board finds that a patentee of an invention pertaining to a medicine is selling the medicine in any market in Canada at a price that, in the Board's opinion, is excessive, the Board may, by order, direct the patentee to cause the maximum price at which the patentee sells the medicine in that market to be reduced to such level as the Board considers not to be excessive and as is specified in the order.³⁴

The debates raised by bill C-22 and the Eastman Commission in many ways marked the beginning of a sea change in policy-makers' and legislators' thinking about the pharmaceutical industry and compulsory licensing.

In combination with the requirement that Canada comply with international standards in order to become a signatory to NAFTA and the World Trade Organisation (which was at this time still being negotiated through the Uruguay Round) Canadian policy-thinking on pharmaceutical IPRs had by the early 1990s made a complete retreat from its long-standing history of supporting compulsory licensing. Indeed, even the official Government history of this amendment suggests that Canada had understood that the NAFTA agreement and the pending Uruguay Round of free-trade talks would be incompatible with its then patent legislation: 'the Canadian compulsory licensing regime for pharmaceutical products in existence at this time [pre NAFTA] was incompatible with Article 31 [of

³² Ibid.

³³ <http://www.pmprb-cepmb.gc.ca/english/home.asp?x=1>

³⁴ Patent Act, section 83, subsection 1, Department of Justice, http://laws.justice.gc.ca/en/ShowFullDoc/cs/P-4//20080110/en?command=search&caller=SI&search_type=all&shorttitle=Patent%20Act&day=10&month=1&year=2008&search_domain=cs&showall=L&statutyear=all&lengthannual=50&length=50

TRIPs].³⁵ This is significant, as it reveals how the international importance and benefits of free trade led Canada to re-evaluate its system of IPRs.

The culmination of this change came in 1992 when the Canadian Parliament passed another major amendment to the Patent Act, bill C-91. This amendment completed the process begun in 1987 by repealing the compulsory licensing provisions established in 1923 and fundamentally re-shaped the IP climate in Canada.

Many external commentators saw the legislation as a true watershed. The significance of the 1992 amendment was even recognised in the EU's 1997 complaint before the WTO over Canada's Bolar and stockpiling exceptions (see below for a full discussion of this case): 'Bill C-91 was drafted in order to protect innovator pharmaceutical companies' distribution and sales rights to patented drugs **and represents a reversal of government policy adopted by Parliament in 1923**'. [Emphasis added]³⁶

While C-91 does indeed mark a turning point in Canadian patent history, important elements of the legislation were questioned by the EU under the TRIPs agreement. Specifically, bill C-91 allowed for the overriding of patent protection under two working exceptions: the so-called "early working" exception (more commonly known as the "Bolar exception") and the "stockpiling" exception. The following passage is a description of these two exceptions by the Canadian Government

The first exception, known as the "early working" exception, allows a person to use a patented invention while the relevant patents are in force only for obtaining regulatory approval to sell an equivalent product after the patents have expired (section 55.2(1)). Under this provision, a generic drug manufacturer could develop a generic version of a medicine and take whatever steps were necessary to meet the regulatory requirements pertaining to its sale before the expiry of the relevant patents. The second exception ("stockpiling" exception) allows a person to use a patented invention for a period of time before the patent expires in order to manufacture and store a product intended for sale after the expiry of the patent (section 55.2(2)).³⁷

Significantly, both of these exceptions were brought before the WTO by the EU³⁸ in 1997 and a dispute settlement process was initiated by that body the same year. These two exceptions are important and understanding their history – particularly Bolar – is vital to understanding why Canada was faced with the somewhat precarious situation of the EU WTO complaint.

As described above, the Bolar exception was, and is, a mechanism whereby generic companies are allowed under legislation to begin the testing and regulatory approval process for a generic drug using the patented drug without acquiring the consent of the patent's right holder. This exception was first

³⁵ Ibid.

³⁶ WTO, Canada – Patent Protection of Pharmaceutical Products, *Complaint by the European Communities and their member states*, p. 7.

³⁷ Government of Canada, 'Patent Protection for Pharmaceutical Products in Canada – Chronology of Significant Events' <http://dsp-psd.pwgsc.gc.ca/Collection-R/LoPBdP/BP/prb9946-e.htm>

³⁸ At this time the European Union was still the European Community (EC).

established in the United States under the Drug Price Competition and Patent Term Restoration Act of 1984 (the so-called Hatch-Waxman Act) in order to eliminate the time lag that existed between the expiration of a patent and the launch of a generic substitute.³⁹ According to Senator Orrin Hatch – who was one of the co-sponsors of the legislation – the Bolar exception was a crucial part of the Act. In a 2002 statement before the United States Senate Committee on Health, Education, Labor and Pensions, Hatch outlined his reading of what Bolar meant:

There is one exception to this general rule against patent infringement. This provision, the so-called Bolar amendment of Hatch-Waxman, is codified at 35 USC 271(e). Here is what it says: 'It shall not be an act of infringement to make or use a patented invention solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs...' What this means is that generic drug firms — and only generic drug firms among all other generic product industries — get statutory protection from activities that would otherwise constitute blatant acts of patent infringement.⁴⁰

As a form of compensation to the research-based industry, Hatch-Waxman allowed for an extension of the patent term of up to five years for medical devices, food additives, and colour additives.⁴¹ For medical devices – that is the pharmaceutical industry – the reasoning behind this provision was to compensate and restore a patent holder with time lost during the drug development and approval process when the drug produced could neither be sold nor marketed. But, the legislation mandated that even with this extension the maximum patent protection a pharmaceutical drug could receive would be 14 years; which would still be 6 years less than the 20 years mandated in patent law:

if the period remaining in the term of a patent after the date of the approval of the approved product under the provision of law under which such regulatory review occurred when added to the regulatory review period...exceeds fourteen years, the period of extension shall be reduced so that the total of both such periods does not exceed fourteen years.⁴²

In 1997 the EU argued before the WTO that Canada was violating the international patent length of 20 years agreed in TRIPS both through its use of Bolar and allowing the stockpiling of the concerned drug. The EU argued that by allowing the manufacturing and stockpiling of pharmaceutical products during the six months immediately prior to the expiration of the 20-year patent term, Canada was in violation of articles 28.1 and 33 of the TRIPS agreement. That is, Canadian legislation did not provide 20 years of patent protection, but just 19 years and six months: 'In practical terms this meant that anybody in Canada was allowed to perform the acts of making, constructing and using the invention

³⁹ In 1988 the Generic Animal Drug and Patent Term Restoration Act added animal drug and veterinary biological products to the list of those products eligible for patent extension.

⁴⁰ Statement of Senator Orrin Hatch before the Senate Committee on Health, Education, Labor, and Pensions. "Revising the 1984 Waxman-Hatch Act", May 8th, 2002.

http://hatch.senate.gov/newsite/index.cfm?FuseAction=PressReleases.Detail&PressRelease_id=182648&Month=5&Year=2002

⁴¹ IP Handbook of Best Practices, chapter No 10.9, 'The Interface of Patents with the Regulatory Drug Approval Process and How Resulting Interplay can Affect Market Entry', Dennis S Fernandez, Managing Partner, Fernandez and Associates, James Hui, formerly Associate Fernandez & Associates LLP, USA, 2007, p. 969.

<http://www.iphandbook.org/handbook/chPDFs/ch10/ipHandbook-Ch%2010%2009%20Fernandez-Huie-Hsu%20Patent%20and%20FDA%20Interface%20rev.pdf>

⁴² The Patent Act, Chapter 35, U.S.C. 156, Extension of patent term, subsection c, paragraph 3, http://www.uspto.gov/web/offices/pac/mpep/consolidated_laws.pdf

during the last six months of the patent term without the authorization of the patent holder.⁴³ Accordingly, it was argued that no particular authorisation had to be sought and there was no limit on the extent or volume of the infringement. By the same logic Canada was also in violation of article 27.1 of the TRIPS agreement as it discriminated against pharmaceutical patents and did not apply the same set of rules to other forms of patents. Furthermore, the marketing approval process in Canada – apart from testing the safety, quality and efficacy of a product – could also involve full batch testing which meant that a significant quantity of drugs would have to be produced by the generic applicant.

The Government of Canada argued that the relevant sections of the Patent Act – 55.2(1) and 55.2(2) – actually did comply with TRIPS because it considered them to be a limited exception to the exclusive rights conferred by a patent in TRIPS' article 30. Thus the early working and stockpiling exceptions neither discriminated against any particular field of technology (read pharmaceutical innovators) or actually reduced the minimum term of patent protection.⁴⁴

In March 2000, the WTO ruled that Canada was in fact violating TRIPS with its stockpiling exception, but that the early working, Bolar, exception was consistent with the agreement. One month later the Canadian Government announced that it would implement the WTO's finding.

Data Exclusivity

More recently, Canada has also seen major changes in regulations regarding data exclusivity; before describing these changes it is worth briefly describing what is meant by data exclusivity actually.⁴⁵

Data exclusivity is one of the most contentious issues in current discussions on pharmaceutical IP policy-making. Stated briefly, data exclusivity is aimed at protecting and safeguarding pharmaceutical registration files—the data submitted by pharmaceutical companies to regulatory authorities, such as the United States Food and Drug Administration (FDA) and the European Agency for Evaluation of Medicinal Products (EMA), for the purpose of obtaining marketing approval for new drugs.⁴⁶ Proponents of data exclusivity consider it an integral and inseparable part of the array of existing IP protection for pharmaceutical products, while its opponents argue that data exclusivity is, in effect, a monopolistic extension of the patent system.

⁴³ WTO, Canada – Patent Protection of Pharmaceutical Products, *Complaint by the European Communities and their member states*, p. 8.

⁴⁴ Government of Canada, 'Patent Protection for Pharmaceutical Products in Canada – Chronology of Significant Events' <http://dsp-psd.pwgsc.gc.ca/Collection-R/LoPBdP/BP/prb9946-e.htm>

⁴⁵ Pugatch, M. P. "Intellectual Property and Pharmaceutical Data Exclusivity in the Context of Innovation and Market Access", in: Vivas-Eugui, D. Tansey, G. and Roffe, P. (eds.) *Negotiating Health* (Earthscan & International Centre for Trade and Sustainable Development: Geneva, February 2006), pp. 97-132.

⁴⁶ For a review of data exclusivity see: Pugatch, M. P. "Intellectual property and pharmaceutical data exclusivity in the context of innovation and market access", in: Vivas-Eugui, D. Tansey, G. and Roffe, P. (eds.) *Negotiating Health* (Earthscan & International Centre for Trade and Sustainable Development: Geneva, February 2006)

17. M.P. Pugatch, *Data Exclusivity in the Context of EU Enlargement*, *IPR Bulletin*, No. 12, December 2003–January 2004, pp. 10–15.

Compared with patents, the market power of data exclusivity is, in theory, less restrictive, mainly because it does not legally prevent other companies from generating their own registration data. However, in practice, the vast financial resources and extended time required for gathering and generating pharmaceutical registration data for a new drug create a market barrier that is too high for generics-based pharmaceutical companies to overcome.

The data included in the registration file of a pharmaceutical product is disclosed to the health regulatory authorities; without this data, a drug cannot be approved for market use. In this context the very idea of data exclusivity is linked to the responsibility and willingness of governments to protect this data.

There are two conceptual and practical layers to this responsibility. The first – non-disclosure – is quite straightforward. Non-disclosure aims to ensure that rival companies (usually generics) do not gain access to the registration file of the original product.

The second layer – non-reliance – aims to prevent the authorities themselves from relying on the registration file of an original drug in order to compare it to the chemical and toxic levels of a potential generic substitute (so-called bio-equivalence tests). The issue of non-reliance is further complicated by the differences between direct and indirect reliance or active and passive reliance.

Internationally, the distinction between patents and data exclusivity as an expression of trade secrets (or undisclosed information) is based, *inter alia*, on the provisions of NAFTA Article 1711 and the TRIPS agreement. TRIPS Article 39.3 states that:

Members, when requiring, as a condition of approving the marketing of 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 that the data are protected against unfair commercial use.

However, TRIPS Article 39.3 leaves three major issues unresolved. First, it does not specify the minimum period of data exclusivity required of WTO Members. As discussed below, the term of data exclusivity in Europe and in the United States is 10 and 5 years, respectively. Second, Article 39.3 is not clear-cut, when referring to the use of such information by the authorities, particularly in cases of reliance, as to when a Member country may choose to rely on the proprietary information of the original product in order to compare it to the chemical and toxic levels of a potential generic substitute (via the so-called bio-equivalence tests). Finally, it is not clear what types of activities are within the scope of “considerable efforts”.

The two existing and contradictory prototypes for data exclusivity at the national level are those of the United States and the EU. Data exclusivity in the United States is provided for by Section 355 of the Federal Food, Drug, and Cosmetic Act of 1997.⁴⁷ The United States model provides a five-year period of data exclusivity to new drugs and three years of data exclusivity to new indications of existing drugs. In December 2003, the European Parliament harmonised and upgraded Directive 2001/83/EC in order to provide a data exclusivity period of ten years (or more accurately adopted the “8-plus-2-plus-1” formula: 8 years data exclusivity, 2 years of marketing exclusivity and an additional year of protection for new indications of existing products).⁴⁸

In Canada, up until very recently regulators had in place a relatively limited model, providing little in the way of concrete protection for clinical data submitted in the market approval process. The then Food and Drugs Act, which defined periods and types of data exclusivity, stated that if in the event the Minister of Health, who is responsible for the market approval of drugs, in the course of approving a generic drug made use of existing clinical data submitted by an innovator – by examining or relying upon it to approve of the generic – the Minister could not issue a Notice of Compliance (NOC) to the generic for a period of 5 years after a NOC had been issued for the original drug. This meant that innovators in effect were granted a period of 5 years of market exclusivity from the date of having a drug approved for sale and obtaining a NOC. While in an international context this did not seem overly generous or excessive – after all both the United States and the EU have longer periods of data exclusivity – in Canada this regulation was virtually rendered ineffective by a 1998 Federal Court ruling in the *Bayer Inc v Canada (Attorney General)* case. Here the judge ruled that the 5 year period of market exclusivity did not apply in most cases when a generic producer is applying for a NOC since the usual approval process of a generic drug did not include actual examination and, hence, a “direct reliance” on the innovator’s data. Instead, most cases were deemed to involve an “indirect reliance”, that is the regulator only relied on a previous submitted application as part of the new drug’s approval process, in which case market exclusivity was deemed not to apply at all.

While *Bayer* is truly a landmark case in the history of Canadian IP and will be examined in more detail as one of the case studies in the following section, suffice it to say that the legal interpretation of the existing regulation as presented in the ruling provided a very stark contrast with the commonly held reading of the Food and Drugs Act.

In 2004-05 important changes to these regulations were proposed in order to both increase the period of exclusivity available to innovators from 5 years to a maximum of 8½ years and clarify the

⁴⁷ United States Federal Food, Drug, and Cosmetic Act of 1997, Chapter 5, “Drugs and Devices”, Section 355, 25 United StatesC. 305(c)(D)(ii) and (iii), United States Food and Drug Administration, Washington, D.C.; available at: www.fda.gov/opacom/laws/fdcact/fdcact5a.htm.

⁴⁸ Legislative Resolution on the Common Position Adopted by the Council with a View to Adopting a European Parliament and Council Regulation Laying Down Community Procedures for the Authorization and Supervision of Medicinal Products for Human and Veterinary Use and Establishing a European Medicines Agency, 10949/2/2003–C5-0463/2003–2001/0252(COD), Strasbourg, 17 December 2003, P5_TA-PROV(2003)0577; Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Medicinal Products for Human Use, Official Journal of the European Communities, 28 November 2001, L 311/67.

regulations' position to avoid a judicial interpretation like *Bayer*. Indeed, according to a 2005 *Managing Intellectual Property* article, the effect of these proposed regulations would be that the 'basis for the Court's rejection of data exclusivity in *Bayer* effectively disappears'.⁴⁹

In June 2006 the Food and Drug Regulations were officially amended and Canada introduced these stronger data exclusivity measures, increasing the period of protection from 5 years to a standardised 8 years with the possibility of a six month extension if a drug was for paediatric use. During this time period there is a six-year no-filing period during which generic producers cannot file a NOC application. In addition, the phrasing of the new regulations effectively neutralises the *Bayer* ruling making reliance alone – not examination and reliance, as was the case in the old regulations – enough grounds for data protection.⁵⁰ It remains to be seen if the courts will uphold these new, tough data protection measures. As will be illustrated by the below legal case studies, this is far from certain.

The benefits of stronger IP – Canadian Pharmaceutical R&D since the early 1990s

The change in policy thinking that was started in 1987 with the amendments to the Patent Act and cemented by the WTO disputes has continued over the past 20 years. Canadian policy-makers have begun to embrace a much more supportive line on IP and protecting the rights of pharmaceutical innovators. In many cases this has also been about reaping the rewards of previous reforms.

For example, in conjunction with the reform initiatives of the late 1980s and early 1990s, the PMAC announced that they would support such policies by increasing R&D investment. According to a 1999 study this is exactly what they did. This study suggests that there is a strong correlation between changes in the legislation on patent protection and limitation of compulsory licensing and rates of Canadian R&D investment: In 1987 pharmaceutical R&D as a percentage of all industries was 2.5%, 3 years later in 1990 it had nearly doubled to 4.9%.⁵¹ Compared to R&D spending levels in the rest of the OECD this judgement seems to be borne out as Canada's rate of investment has since then been considerably higher.⁵² In fact, the study concluded that 'the passage of Bill C-22 had a positive effect on the growth of R&D spending in Canada after 1987'.⁵³

More recent figures also bear up this assessment. According to the research-based pharmaceutical industry's own figures, since 1987 annual investment by the former PMAC members has increased by 605%, reaching 1.17 billion CAD in 2004 and 1.21 billion in 2006.⁵⁴

⁴⁹ Heller, David and Zahl, Adrian (Ridout & Maybee LLP), 'Proposed Regulations to adjust generic balance', *Managing Intellectual Property*, Supplement Life Focus 2005

<http://www.managingip.com/Article.aspx?ArticleID=1321531>

⁵⁰ Regulations Amending the Food and Drug Regulations (Data Protection), Government of Canada
<http://canadagazette.gc.ca/part1/2006/20060617/html/regle4-e.html>

⁵¹ Pazderka, Bohumir, 'Patent Protection and Pharmaceutical R&D Spending in Canada', *Canadian Public Policy*, No 1, 1999, p. 34.

⁵² *Ibid.* p. 36

⁵³ *Ibid.*

⁵⁴ http://www.canadapharma.org/Pubs/Fact_Sheets/ElectionFactCard_Dec2005_EnFINAL.pdf and
http://www.canadapharma.org/Pubs/Fact_Sheets/2007e/I-Canada%20EN%20September%202007.pdf

Despite these impressive numbers, there are some important issues in Canada's IP system that remain unresolved and could potentially be holding back R&D investment. For example, the research-based pharmaceutical industry has long voiced its concern that an innovator does not have the same right of appeal as a generic manufacturer when a patent is being challenged in a court of first instance. Under current rules, a generic product may be approved for production when an innovator fails to win a case, the result being that an appeal is by default ruled out. The pharmaceutical industry has argued that the extra cost and time incurred by innovators who, in effect, have to initiate new legal proceedings under such a scenario is a real weakness of Canada's IP regulations.⁵⁵ While no academic studies have quantified the potential impact of this situation on long term R&D investment, it does illustrate the importance of courts to modern-day systems of IP regulation; as will be seen, in Canada they are of particular importance.

Legislating from the Bench?

To be effective, primary and secondary legislation needs to be implemented and accepted by all related stakeholders including the judiciary, which plays a pivotal role in setting the tone of a common law country's IPR climate. As the following case studies illustrate it is not at all clear that Canadian courts have wholly accepted the legal and cultural shift which pharmaceutical IPRs have undergone over the past two decades; nor is it clear that they are united in their understanding of what this shift actually means.

This section provides examples of precedent-setting court cases which have – depending on your viewpoint – either seen judges legislating from the bench or upholding the original intent of Canadian pharmaceutical primary and secondary legislation. These cases are of real importance as they have shaped and continue to shape Canada's IP climate by indirectly – and sometimes directly – affecting the actual legislation and regulation. The purpose of this case study analysis is not to write a legal treatise seeking to define and defend what constitutes judicial activism and what does not. Instead, it will be argued that the following legal cases reveal what, at the very least, can be described as a pretty substantial conflict both within the judicial community over current pharmaceutical IPRs and between judicial rulings and subsequent, post-ruling, changes to Government legislation and regulation.

Case Studies

Bayer Inc v. The Attorney General of Canada and the Minister of Health, 1998

This case is the oldest of those examined and arguably the most important for the long-term changes to Canada's IPR climate. The ruling turned out to be truly precedent-setting, setting the tone for almost a decade of regulatory interpretation. It had a considerable impact on the debate over generics and IPRs and was, as described above, a contributing factor to the subsequent 2006 regulatory changes to the Food and Drug Regulation concerning data exclusivity for pharmaceutical products. In

⁵⁵ See, for example, Pharmaceutical Research and Manufacturers of America (PhRMA), *Special 301 Submission, 2008*, p. 202-3. This submission was presented to the Office of the United States Trade Representative in February 2008.

fact, the *Bayer* decision was explicitly referred to in the Regulatory Impact Analysis Statement as clarifying previous regulatory interpretation:

Under the current Regulations [pre-June, 2006], data protection arises when the Minister of Health examines and relies on an innovator's undisclosed data in order to grant a notice of compliance to a generic manufacturer. However, to receive a notice of compliance in Canada, a generic manufacturer need only demonstrate bioequivalence by comparing its generic product to the innovator's product. Therefore, in actual practice, the Minister typically does not examine the data contained in the innovator's submission in order to grant a notice of compliance for a generic product. **As a result, data protection does not arise where bioequivalence forms the basis of a generic submission, as affirmed by the Federal Court of Appeal in *Bayer Inc v Canada*...While the comparison necessary to demonstrate bioequivalence rarely involves an examination of the innovator's data, it does involve reliance on the innovator's product...[and] the Government will now incorporate a no-filing period within the [new] eight-year term of data protection.**⁵⁶ [Emphasis added]

Apart from emphasising the significance of the *Bayer* ruling, the above extract also illustrates the extent to which the new regulation acted to circumscribe *Bayer* by incorporating a no-filing period in the data protection, thereby bypassing the whole argument over indirect or direct reliance.

Clearly *Bayer* is important, but what were the actual arguments heard in the case? Essentially this was a dispute over the decision by the Canadian Minister of Health to issue a Notice of Compliance to an Abbreviated New Drugs Submission (ANDS) by a generic manufacturer of a drug originally produced by Bayer Inc. Bayer argued that the NOC issued was in violation of its rights under the Food and Drug Regulations (Data Protection). As explained above, the thinking behind applying for an ANDS, as opposed to a New Drugs Submission (NDS), is that the new applicant only has to prove bioequivalence to an existing approved drug and no clinical trials need to be submitted. (This means that not only does the applicant not have to perform any expensive test trials, but the approval process itself is much shorter.)

Bioequivalence is a measurement of how one drug (usually a generic) compares in its rate of absorption and availability in the bloodstream with another (usually patented) drug. According to the FDA, establishing bioequivalence is about establishing: 'pharmaceutical equivalents whose rate and extent of absorption are not statistically different when administered to patients or subjects at the same molar doses under similar experimental conditions.'⁵⁷ The then Canadian Food and Drugs Regulations – in which Canada's data exclusivity regulations were included – stated that in cases where an ANDS was submitted the Minister of Health should not issue a NOC if he had relied on clinical trials and information submitted in the first, original drug application. The regulations read as follows:

⁵⁶ Regulations Amending the Food and Drug Regulations (Data Protection), Regulatory Impact Analysis Statement, published by the Department of Health in the *Canada Gazette*, Vol 140, No. 24, June 17, 2006, <http://canadagazette.gc.ca/part1/2006/20060617/html/regle4-e.html>

⁵⁷ Buehler, Gary J., 'The FDA Process for Approving Generic Drugs', October 29, 2002, Center for Drug Evaluation & Research, FDA p. 28, http://www.fda.gov/cder/OGD/02-10_BCBS_gjb/sld001.htm

Where a manufacturer files a new drug submission, an abbreviated new drug submission...for the purpose of establishing the safety and effectiveness of the new drug for which the submission or supplement is filed...and the Minister, in support of the manufacturer's submission or supplement, **relies** on data contained in the information or material filed by the innovator, the Minister shall not issue a notice of compliance in respect of that submission or supplement earlier than five years after the date of issuance to the innovator of the notice of compliance or approval to market that drug...' [Emphasis added]⁵⁸

The central issue raised in *Bayer* was regarding the interpretation over the existing data protection laws and what the term reliance actually meant. In fact, 3 out of the 4 questions formulated by the plaintiff, Bayer, had to do with how the reliance issue was to be defined and used.⁵⁹ Bayer's main contention was that it was part and parcel of the ANDS process to actually rely on information submitted in previous NDSs. In handing down its ruling, the Federal Court described Bayer's argument that the Minister of Health would invariably be relying on the information of previous submissions when making an ANDS decision:

...the plaintiff's argument goes, even though it may be said that the Minister "relies" on the fact that an NOC has already issued in respect of drug X as proof of the safety and effectiveness of the drug, the NOC will only have been issued to Bayer on the strength of the proof of drug X's safety and effectiveness contained in the information in Bayer's NDS. Hence, in a substantive sense, the Minister will nearly always rely on information filed by the innovator of a drug when considering an ANDS filed by a second manufacturer of a functionally equivalent drug.⁶⁰

But the Minister of Health is described as arguing the opposite, claiming that:

...the Minister did not "rely" on the information in the innovator's NDS when considering the issuance of an NOC to a second manufacturer on the basis of an ANDS naming the innovator's drug as the "Canadian reference product". Rather, the Minister "**relies**" on the information contained in the **ANDS** in deciding whether to grant an NOC, and does not refer to the material previously filed by the innovator. [Emphasis added]⁶¹

Crucially, the Court found that Bayer's argument was wanting and that the Minister of Health, given the context and overriding purpose of the Food and Drugs Regulation, was right:

At first blush, the Minister's argument may seem very formalistic, in the sense that, in granting approval to a generic drug manufacturer because its product is the functional equivalent of a drug for which the Minister has already issued an NOC on the basis of the information supplied by the innovator, the Minister is indirectly, at least, "relying" on that information to establish the safety and effectiveness of the generic drug manufacturer's

⁵⁸ Canada Food and Drug Act – Food and Drug Regulations, Division 8-New Drugs

⁵⁹ *Bayer Inc v. The Attorney General of Canada and the Minister of Health*, docket T-1154-97, Office of the Commissioner for Federal Judicial Affairs (Reports), <http://recueil.cmf.gc.ca/en/1998/1999fc23457.html/1999fc23457.html.html>

⁶⁰ Ibid.

⁶¹ Ibid.

product. The NOC, on which the Minister says that he relies, was itself issued on the basis of the confidential test data compiled by the innovator-manufacturer. **However it is also important that this provision of the Regulations be read in the context of the overall scheme, which is to facilitate the approval process for new drugs when sought by manufacturers other than the innovators, and thus to reduce the cost of drugs to provincial governments and members of the public...If Bayer's contention were, then it would effectively undermine the efficacy of the ANDS provisions by imposing a delay of five years on the issue of an NOC to a generic manufacturer. The scheme of the Regulations does not suggest that the issue of an NOC is normally so delayed: if this had been the intended result, the wording of C.08.004.1 is a very oblique way to express it.**⁶² [Emphasis added]

Crucially, the Federal Court relied on *its* understanding of the overall context and intent of the regulations to pass judgement on the arguments presented. And it was the Court that ruled what was direct and what was an indirect reliance. In light of the subsequent regulatory changes to data exclusivity under the Food and Drugs regulations – which effectively eliminated this distinction by applying a no-filing period – it would seem that the verdict certainly added a new interpretative element to the regulations, unintended or not.

Biolyse Pharma Corporation, Appellant, v. Bristol-Myers Squibb Company, Bristol-Myers Squibb Canada Inc., 2005

This case centred on the tongue-twisting substance paclitaxel. Paclitaxel was, during the 1970s, discovered by the United States' National Cancer Institute to be an anti-carcinogenic.⁶³ The substance was derived from the bark of the Pacific yew tree, samples of which had begun to be collected by the United States Department of Agriculture as early as 1962.⁶⁴ Today paclitaxel is used in the treatment of breast, lung, and ovarian cancer. It is sold across the world by Bristol-Myers Squibb (BMS) as Taxol and is one of the best-selling cancer drugs ever manufactured.⁶⁵

The argument in this case was about whether or not Biolyse – an independent, Canadian manufacturer of cancer treatments using the compound paclitaxel which is, and was, a naturally occurring compound – was infringing BMS' registered patents for Taxol, a pharmaceutical drug using the paclitaxel compound. The two main Canadian patents BMS held were patents 2086874 and 2132936 and were described by the Court as covering 'new and useful formulations and methods of administration'.⁶⁶

Prior to the case's Supreme Court hearing, Canada's Federal Court of Appeal had ruled that Biolyse was indeed infringing BMS' patents relating to Taxol. But the Supreme Court took the opposite view,

⁶² Ibid.

⁶³ 'Success Story: Taxol', National Cancer Institute, http://dtp.nci.nih.gov/timeline/flash/success_stories/S2_Taxol.htm

⁶⁴ Ibid.

⁶⁵ Ibid.

⁶⁶ *Biolyse Pharma Corporation, Appellant, v. Bristol-Meyers Squibb Company, Bristol-Meyers Squibb Canada Inc., and Attorney General of Canada (Respondents) – and – Canadian Generic Pharmaceutical Association, Pfizer Canada Inc., Interveners*, 19/05/2005, Docket: 29823, Citation *Bristol Meyers Squibb Co. v. Canada (Attorney General)*, [2005] 1 S.C.R. 533, 2005 SCC 26, par 26

finding that because paclitaxel was not in itself a patentable product there could be no patent infringement: ‘BMS has no patent on *paclitaxel* and the mere fact that *paclitaxel* is found in the Biolyse product does not mean that Biolyse took advantage of BMS inventions for the purpose of “early working” a generic copy or “stockpiling” in anticipation of the expiry of the BMS patents.’⁶⁷

This argument hinged on the Supreme Court’s reading of the NOC Regulations. It argued that the previous Federal Court of Appeals ruling was in fact in violation of the intentions of the original Notice of Compliance regulations which, it was further claimed, had been written specifically for the Bolar and stockpiling exceptions, not for general use.⁶⁸ The court argued that despite the seeming clarity of the regulations’ use of the word ‘submission’, a literal interpretation of the word – which would seem to aptly cover Biolyse’s actions – would not be enough. Instead, it was deemed necessary to look beyond the actual legal text to establish what the regulations meant. The Court was instructed to

suspend judgement on the precise scope of the word “submission”...and turn to other elements of the Driedger approach [a legal scholar]. As Professor J.M. Kernochan puts it: “The precise words which are in issue in relation to the facts must be weighted in the light of successive circles of context”⁶⁹

Thus, the Court was arguing – as had been the case in the Bayer case – that they had a responsibility to look beyond the specific legal or regulatory text in question and interpret the context in which the law and regulation had been produced. In a long and detailed account of the scope of the regulatory powers inherent in the Patent Act, the Court concluded that the arguments proposed by BMS would provide the regulations with far more influence than lawmakers had originally intended:

The broad interpretation urged by BMS would lead to an absurd result. The “medicine” in the drug to which the patent list relates itself need not itself be patented, or indeed owe anything to the ingenuity of the “first” person. It could be a “medicine” whose usefulness was discovered by somebody else (as in the case of *paclitaxel*) or something in the public domain as common as penicillin. So long as such “medicine” shows up as a component, however minor, in the chemical composition of the drug to which the patent list relates, the “second person” (including an innovator who is seeking to manufacture a new and useful drug) is barred from proceeding to market by the automatic statutory freeze, and this “bar” will continue for so long as the patent list holder can evergreen its product by resort to patentable improvements to other components or additions, be they ever so minor. **This would stifle competition and innovation in the pharmaceutical industry and produce a result at odds with what the regulator was trying to achieve.** ⁷⁰ [Emphasis added]

Crucially, the above presented argument was not based on a textual reading of the regulations themselves – as previously explained the Court chose to widen the case and interpretation of the word “submission” to include a “circle of context” – but on the Court’s interpretation of the wider

⁶⁷ Ibid.

⁶⁸ Ibid. Par. 39 and 51-55.

⁶⁹ Ibid. Par 44

⁷⁰ Ibid. Par 66

intent and concerns of the legislation. Indeed, the final sentence of the above quote is indicative of the wider context and concerns the Court felt it had to address in its ruling.

Revealingly, this was not a consensual ruling. Instead, in the dissenting view Justice Bastarache expressed his disappointment in the majority ruling by arguing that it was going too far: 'This is a case of regulatory interpretation, and nothing more. The Court must always be careful not to overstep its boundaries. Public policy must be left to the legislature and government, especially when dealing with competing interests where the government has consulted stakeholders and asked Parliament to legislate.'⁷¹ Bastarache further argued that examining the wider meaning of the regulations – the majority ruling's main contention – was not necessary as it was quite clear from the existing regulations and legislation what was meant:

The courts must be careful not to confuse policy considerations leading to the adoption of an act or regulations, which are examined in order to discover legislative intent, and the appropriateness of policy choices which are a matter that must be left to legislators. Contextual interpretation does not justify departures from ordinary rules of statutory interpretation; **in particular, reading in words cannot be justified in the absence of a demonstrable ambiguity.**⁷² [Emphasis added]

In conclusion, Bastarache argued forcefully that the majority ruling was, in effect, not only interpreting the legislation, but re-defining it:

...this legislative scheme [the patent system] is just that: legislated. Parliament and the Governor in Council created the patent right and regulated every aspect of it. They decided on the appropriate balance between the various interests after serious consultations with stakeholders. It is not for this Court to question the choice they made, in the absence of any constitutional challenge. This Court's role stops at the interpreting stage with the above used tools i.e., context, intention and object. Going further would constitute a grave transgression on the part of this Court...⁷³

This point was further emphasised 3 paragraphs further down the opinion:

Statutory interpretation is a legal art which needs to be applied very carefully by the courts without losing sight of the underlining principle of such a task. The *NOC Regulations* purport to maintain a balance between the protection of patentees' rights and the timely market entry of generic competitors. **This Court should not undertake to fill in the alleged gaps or resolve the alleged deficiencies of the legislative and regulatory scheme.** [Emphasis added]⁷⁴

Determining which side of the court was right and which side was wrong is a daunting task. Suffice it to say that the intensity of this disagreement illustrates the wider point of this paper: that the history of Canadian pharmaceutical IPRs has created a series of paradoxes complicated by the reorientation

⁷¹ Ibid. Par 77

⁷² Ibid. Par 103

⁷³ Ibid. Par 190

⁷⁴ Ibid. Par 192

of policy away from a pro-generic model to one conferring more rights onto innovators. As this case suggests, this paradox is evidently on vivid display even within the judiciary.

AstraZeneca Canada Inc v Canada (Minister of Health), 2006

In 1989 AstraZeneca received market and regulatory approval to begin selling the drug omeprazole, marketed as *Losec 20*, a drug used in the treatment of acidic stomach conditions. *Losec 20* was sold up until 1996 when AstraZeneca pulled the drug off the market. In 1993 Apotex filed an ANDS for a generic version of *Losec 20*. AstraZeneca's original patent for *Losec 20* expired in 1999, but in 2002 the company was granted two new patents associated with *Losec 20*. These two patents, the 037 and 470 patents, were applied for in 1996 and 1998, respectively.⁷⁵ In 2004, the Minister of Health awarded Apotex a NOC for the production of its generic version. Granting this NOC, the Minister of Health ruled that the generic drug Apotex was hoping to produce did not have to be compared with any other drug other than the original 1989 version of *Losec 20*, therefore it was not necessary for Apotex to issue a notice of allegation to AstraZeneca; a notice which would have triggered a 24-month statutory freeze or until a legal settlement was reached over the validity of the patents challenged. Thus AstraZeneca's later patents were deemed not to be relevant in the context of this ANDS. AstraZeneca challenged this decision in the Courts where, initially, the motions judges upheld the Minister's rulings. But the Federal Court of Appeal ruled otherwise, in effect invalidating Apotex's NOC.

In contrast to the other cases analysed in this section, the argument here was not over alleged patent infringement, but over regulatory process and specifically Apotex's alleged failure to issue a notice of allegation. The Minister of Health's decision to sidestep AstraZeneca's latter patents was very unusual in that not all patents listed on the *Patent Register* were compared to Apotex's ANDS. In effect, this meant that the regulator, that is the Minister of Health, decided which patent was to be used in an ANDS application and which ones were not, regardless of being listed on the *Register* or not. Therefore, in terms of setting a long-term legal precedent the final Supreme Court ruling in this case was of very real significance.

In 2006 the Supreme Court heard the case and ruled that the Minister had acted correctly by issuing an NOC. It was found that Apotex's application should not have triggered a notice of allegation and a subsequent 24-month statutory freeze. The Supreme Court ruled that:

...the Minister was entitled to issue the NOC to Apotex on the basis of Apotex's abbreviated new drug submission without subjecting it to the 24-month statutory freeze in respect of the after-issued patents. The *NOC Regulations* are concerned only with patents relevant to the innovator product actually copied and not with subsequently issued and listed patents from which a generic manufacturer could not receive a benefit. AstraZeneca's interpretation of the *NOC Regulations*, which is rejected, would permit "evergreening" a product indefinitely by the addition of new patents of marginal significance, which would trigger an indefinite series of

⁷⁵ *AstraZeneca Canada Inc v Canada (Minister of Health), 2006, November 3, 2006, Supreme Court of Canada, Docket 30985, par 9, 10, and 11.*

24-month statutory freezes, even though such subsequently listed patents are not the subject of “early working” by the generic manufacturer, and from which (as in the circumstances here) the generic manufacturer derives no advantage.⁷⁶

AstraZeneca, on the other hand, argued that a ‘patent list is submitted in respect of a drug and not in respect of any particular submission.’⁷⁷ Thus, it was a moot point whether or not evergreening had or would take place. Interestingly, the Supreme Court ruling cited an internal memorandum between a departmental official and the Deputy Minister of Health (a document which was originally cited in the first trial) in which the official claimed that

To date, the administrative policy has been to address all patents listed for a drug. However, this is the first time a patent has been listed for a supplemental new drug submission introducing a change to a drug which was clearly never marketed, and to which the generic could not have made a comparison. The Patent Unit is recommending that Apotex should not be required to address the ‘470 patent.’⁷⁸

While this extract quite clearly states that Apotex should not have to address a later patent (patent ‘470, which was added to the Patent Register in 2002) it does also confirm the principle AstraZeneca was arguing, that previous administrative policy had been to address all patents listed for a particular drug, not just one. However, due to the deemed novelty of AstraZeneca’s situation (in effect having a set of patents for a drug which had been taken off the market) the Minister, and lower court, felt it warranted a break with administrative precedent.

In the IP trade press, the Supreme Court’s decision was viewed as having real significance since generic manufacturers would interpret the verdict to mean that they ‘no longer need to address every patent listed on the Patent Register in respect of the drug that they seek to copy.’⁷⁹ Of equal significance the Court’s ruling was partially incorporated into the amended Food and Drugs Regulations (Data Protection) in the summer of 2006 and in the parallel changes to the Patented Medicines Notice of Compliance regulations. The former regulations specifically outlined that data exclusivity (which was albeit not at issue in the *AstraZeneca v Minister of Health* case) was not to be extended to drugs that were no longer marketed in Canada.⁸⁰ With the latter the Court’s verdict, as well as some of the principles that AstraZeneca was arguing, were incorporated. First, these new regulations made clear that all patents on the Patent Register were to be part of any comparison. Second, new patent supplements to existing patents could only be added prior to a generic filing for a comparison. According to the ‘Regulator Impact Analysis’ provided by the Canadian Government:

⁷⁶ Ibid. Introductory outline of the case.

⁷⁷ Ibid. Par 23.

⁷⁸ Ibid. Par 8

⁷⁹ IPFrontline.com, Magazine of Intellectual Property & Technology, ‘Canada: Supreme Court Decision with Important Consequences’, November 17, 2006 <http://www.ipfrontline.com/depts/article.asp?id=13399&deptid=7>

⁸⁰ Regulations Amending the Food and Drug Regulations (Data Protection), Government of Canada <http://canadagazette.gc.ca/part1/2006/20060617/html/regle4-e.html>

a generic manufacturer that files a submission or supplement for a NOC in respect of a generic version of an innovative drug is only required to address the patents on the register in respect of the innovative drug as of that filing date. Patents added to the register thereafter will not give rise to any such requirement.⁸¹

This arrangement addresses both the tradition of regulators using all relevant patents listed on the Patent Register, as well as the perceived problem of innovators presenting supplemental patents subsequent to a generic's filing.

***Eli Lilly Canada Inc v Apotex Inc and the Minister of Health, 2007, and
Eli Lilly Canada Inc. v Novopharm Limited and the Minister of Health, 2007***

Due to their chronological propinquity and similarity in legal issues raised, these two cases will be treated together. In both cases the argument was about the validity of Eli Lilly's patent for the substance olanzapine, which in drug form was, and is, sold as Zyprexa, a product primarily used to treat schizophrenia. Both cases are important because – although concerning different technical aspects of patent validity – they illustrate the manner in which there seems to be a distinct split within the Canadian judiciary over the interpretation of current patent legislation's and the application of NOC regulations' to the generic drugs industry.

In the first case, *Lilly v Apotex*, the former were seeking an order prohibiting the Minister of Health from issuing a NOC to Apotex. The NOC would have allowed Apotex to produce and sell olanzapine, which Lilly had been granted a Canadian patent for in the early 1990s as Zyprexa. Crucially, and confusingly, the case centred around two separate patents for olanzapine and what would eventually become Lilly's Zyprexa: a '687 patent which was granted in 1980 and was an originating patent (that is, one that involved the discovery of a new chemical reaction or new compound or genus) and thus indirectly covered olanzapine. The second patent was the more recent '133 patent and can be termed a selection patent. This is a patent based on a selection from related compounds derived from the original compound (or genus) and which have been described in general terms and claimed in an originating patent, which in this case was the '687 patent.

Apotex challenged Lilly's '133 patent on three accounts:

- i) Lilly's patent for olanzapine was not original enough as 4 scientific articles/studies from the 1980s were said to provide enough information for the alleged invention to be made (a claim which would violate the anticipation clause of patents);
- ii) Lilly's olanzapine patent did not live up to the obviousness requirements of a patent, (in this case obviousness and anticipation were widely overlapping);
- iii) Lilly had, in effect, used double-patenting by not disclosing vital information to the Patent Commissioner regarding the above cited articles, as well as a previous dog study which had sufficiently outlined the beneficial therapeutic results of olanzapine.⁸²

⁸¹ 'Regulatory Impact Analysis Statement', <http://canadagazette.gc.ca/partII/2006/20061018/html/sor242-e.html>

In support of these claims Apotex asserted 'that the invention as described in the claims of the '113 Patent is fully disclosed in the '687 Patent and in the Schauzu [scientific] article.'⁸³ Apotex's argument on anticipation and obviousness were based on the idea that the conclusion that olanzapine could be used as a treatment for antipsychotic afflictions could be reached prior to the publication and patenting of the '113 compound. Thus, existing contemporary evidence in the form of scientific articles and the already published '687 patent, according to Apotex, meant that a person skilled in the art could easily take the steps towards understanding and using olanzapine as described in the '133 patent. Therefore, it would follow that the discovery of the compound was not inventive at all (a prerequisite for a patent), but obvious. The Court, however, disagreed:

The Court has examined very closely the evidence of Apotex's experts in light of Apotex's original arguments (memorandum) as well as the outline on obviousness used at the hearing. The Court cannot conclude either that an ordinary person skilled in the art would have been led directly and without difficulty to olanzapine.⁸⁴

This finding was significant as Apotex's argument on the double-patenting of patent '113 was based on its argument of obviousness and anticipation. The Court ruled that because the arguments on obviousness and anticipation were flawed the case for double patenting could not be upheld:

Apotex asserts that the '113 patent is invalid on the ground of double patenting. It submits that as against the '687 Patent both forms of double patenting apply. However, for the rest of the argument Apotex relies on obviousness double patenting and it relies on the same art and arguments that were raised in respect of obviousness...As I have concluded in my analysis of Apotex' argument that the prior art cited in the NOA and referred to in the various expert affidavits before me do not anticipate or make olanzapine and its advantages for the treatment of schizophrenia obvious, the Court concludes that there cannot be double patenting.⁸⁵

4 months after this ruling was handed down, in June 2007, Justice Hughes of the Federal Court ruled in a separate case concerning olanzapine and Lilly's patents that 'Lilly has not demonstrated that the allegation by Novopharm [another generic company] that the specification of the '113 patent is insufficient is not justified. This application is dismissed with costs to the Respondent Novopharm.'⁸⁶ In this case, *Lilly v Novopharm*, the Federal Court, only a few months after the ruling for *Lilly v Apotex* was handed down, ruled the complete opposite.

Involving several related issues, *Lilly v Novopharm*, boiled down to the validity of the actual 113 patent.⁸⁷ Through a long and complex discussion the Judge claimed that validity was 'the only issue

⁸² Eli Lilly Canada Inc v Apotex Inc and the Minister of Health, April 27, 2007, Docket T-156-05-T-787-05, Citation: 2007 FC 455, Par 52-58.

⁸³ Ibid. Par. 246.

⁸⁴ Ibid. Par. 314

⁸⁵ Ibid. Par. 360 and 363

⁸⁶ Eli Lilly Canada Inc. v Novopharm Limited and the Minister of Health, Docket T-1532-05, June 5 2007, Federal Court, Justice Hughes, <http://decisions.fct-cf.gc.ca/en/2007/2007fc596/2007fc596.html>

⁸⁷ Ibid. Par 2

before the court in this proceeding.⁸⁸ Of particular interest to this paper is the argument the Judge used to sideline the above analysed Apotex ruling, which stated that it did not find Lilly's 113 patent invalid.

First, the Judge ruled that although he was aware of the Apotex proceedings and although he was satisfied that both the evidence submitted by Novopharm as well as Lilly were the same as in Apotex, he could not incorporate this case into the proceedings because it was not part of the Court's record:

It would not be proper to compare the precise evidence given by the witnesses in the Apotex case with that given by the witnesses, both the identical witnesses and the others, in the present case since the evidence given in the Apotex case is not of record in the present case. I do point out however that this exercise has been done. **I am satisfied that the affidavits of the Lilly witnesses are essentially the same, and no material differences exists in respect of cross-examination. I am satisfied that the nature of the evidence given by the Apotex witnesses both by affidavit and in cross-examination is not materially different in any meaningful respect from that given by the Novopharm witnesses in the present proceeding. However, I will not refer to that comparison nor use it in arriving at my decision in the present case. The reason why I refrain from comparing the evidence in the two proceedings, other than using only what is apparent from the Reasons of Justice Gauthier, is that the evidence in the Apotex proceedings forms no part of the record in these proceedings.** [Emphasis added]⁸⁹

Somewhat confusingly, despite his claim of not relying on the Apotex evidence, the Judge argued that there were, in fact, two new issues raised by the Novopharm case that were not treated in the Apotex ruling: 'sufficiency and utility'.⁹⁰

When explaining the sufficiency issue the Judge stated that what Novopharm was referring to – and herein lay the novelty of its argument – was the failure of Lilly to comply with section 27 (3) b of the *Patent Act*, which is to provide enough information in the patent application so as to allow others to reproduce the patented product.⁹¹ This argumentative novelty, according to the Judge, meant that there were sufficient grounds for sidestepping the Apotex ruling: 'This argument is sufficiently different from the arguments considered by Justice Gauthier...in arriving at the Apotex decision...It is therefore open to Novopharm to raise this issue in these proceedings and argue it as a matter of first principle.'⁹²As it turns out sufficiency was central to the final verdict.

With regard to the other analytical categories used by the Court to determine patent invalidity – deliberate misleading on part of the patentee, anticipation, obviousness, double-patenting, and utility – the evidence presented by Novopharm was deemed not to be sufficient. In fact, the final verdict was,

⁸⁸ Ibid. Par 6

⁸⁹ Ibid. Par. 34-35

⁹⁰ Ibid. Par 41

⁹¹ Ibid. Par. 41-44

⁹² Ibid. Par 44.

apart from utility (which was not analysed in the Apotex proceedings), in complete agreement with the Apotex judgement.⁹³ But the big exception was sufficiency. Here the Judge ruled that what had been disclosed in the '113 patent by Lilly was not substantially different from the preceding '687 patent:

I find that the '113 patent fails to provide sufficient disclosure in its specification as to the invention, if any, in selecting olanzapine from a previously disclosed group of compounds. The prior art British patents [patent on which Canadian patent '687 was based] says that the whole class of compounds to be useful in treating central nervous system disorders. The invention in selecting olanzapine is the so called "surprising and unexpected" properties of olanzapine in "comparison with flumezapine and other related compounds". No such comparison is made anywhere in the '113 patent. No data was given. We are left only with rhetoric such as "high level of efficiency" and "mild and transient" and "lower" side effects.⁹⁴

Based on this reading the Judge concluded:

Given that Lilly has already enjoyed a patent monopoly for a group of compounds that included olanzapine all said to be useful in treating central nervous disorders, it simply has not paid the price, by way of a clear and explicit disclosure to what the invention is, if any, in the properties of olanzapine alone that merit a further monopoly in a separate further patent.⁹⁵

As can be expected, Lilly did not agree with the ruling. In a press release the company said: 'Lilly believes these decisions are deeply flawed and are inconsistent with both the evidence presented at trial and with the legal principles that the company believes apply'.⁹⁶

It is worth noting that recent court cases challenging Zyprexa's patent in the United States had been either dismissed or the patent had been upheld. See for example *Eli Lilly & Co. v. Zenith Goldline Pharmaceuticals Inc.* from 2005 in which the Judge ruled that the patent should be upheld; a decision that was affirmed by the United States Court of Appeals for the Federal Circuit (CAFC) on December 26, 2006. Similarly, the US Supreme Court in September 2007 upheld Lilly's Zyprexa patent and rejected Teva's and Dr Reddy's challenge.⁹⁷

While one should never make too broad and conclusive generalisations based on case comparisons – each case is in itself a reflection of a particular technical aspect or application of a law or line of legal reasoning and is thus unique – it is nonetheless puzzling to find an overwhelming majority of recent North American cases upholding the Zyprexa patent and only one in Canada rejecting it. At the very least this would seem to suggest that the Canadian judiciary is divided over how patent disputes should be handled.

⁹³ Ibid. Par 166-190

⁹⁴ Ibid. Par 162

⁹⁵ Ibid. Par 164

⁹⁶ 'Eli Lilly to appeal 'flawed' Canadian, German court rulings on Zyprexa', June 6, 2007, <http://www.forbes.com/afxnews/limited/feeds/afx/2007/06/07/afx3798592.html>

⁹⁷ 'Lilly Withstands U.S. High Court Challenges to Zyprexa Patent', Bloomberg News, http://www.bloomberg.com/apps/news?pid=newsarchive&sid=a_ToCtMujlWVs

Pfizer Canada Inc and Warner-Lambert Company, LLC v The Minister of Health and Ranbaxy Laboratories Limited, 2008

This very recent case adds another layer to the debate over sufficiency discussed in the above Zyprexa cases. Here the issue before the Appeals Court was whether or not the Indian generic Ranbaxy's challenge of Pfizer's '546 Canadian patent for its cholesterol lowering blockbuster drug Lipitor should be upheld. Central to the eventual ruling was the issue of sufficiency and the interpretation of subsection 27(3) of the Patent Act.

In Canada Pfizer had obtained two patents for Lipitor: the '546, which is a selection patent and was, in turn, based on the second patent, the '768, a broader/general patent covering a large class of cholesterol-lowering statins. The '546 patent contains 12 claims covered by the '768 patent; claims that all pertain to atorvastatin salts. Ranbaxy initially filed an ANDS for its drug, Ran-Atorvastatin, comparing it to the '546 and '768 patents. In January 2005 Ranbaxy sent a NOA to Pfizer alleging that in making, using and selling this drug it would not be infringing the '768 patent. However, in the same NOA it challenged the '546 patent alleging that it was invalid for obviousness, double-patenting, insufficiency and anticipation. Pfizer countered by filing a prohibition application in March 2005. In January 2007 a court found that Pfizer's prohibition application was not justified and dismissed it. Instead it found that the '546 patent was invalid because it did not meet the requirements of subsection 27(3) of the *Patent Act*. The basis for this ruling was that evidence submitted by Pfizer in support of the therapeutic work of Lipitor and patent '546 seemed to be misleading. The ruling stated:

In essence, the 546 Patent makes two assertions, one as to activity the other as to preferred salt. The first assertion is that there is an unexpected and surprising inhibition of cholesterol biosynthesis because of the ten-fold increase in activity between atorvastatin calcium and the racemic calcium salt. However, from the evidence presented, this statement is incorrect. The only reliable data available, the AICS data, suggests an increase in activity barely over the expected two-fold when the racemate is resolved into its individual enantiomers. This is not anywhere close to ten-fold. I fail to see how this amounts to 'correctly and fully describing the invention'. A patentee has an obligation to make truthful statements regarding the nature of the invention in the disclosure of the patent...Here we clearly have an assertion of a ten-fold increased activity on the face of the specification. This false suggestion of a ten-fold increase in activity cannot be backed up by the data provided. Accordingly, I find the 546 Patent to be invalid for failing to meet the requirements of s. 27(3) of the Patent Act.⁹⁸

But in the Appeals Court the Judge thought otherwise. He argued that the Applications Judge had 'mischaracterized the scope of the disclosure requirement under subsection 27(3) of the Act and, in so doing, allowed Ranbaxy to attack, through an alternative means, the patent's utility, novelty, and/or obviousness.'⁹⁹ According to the Appeals Judge the real issue that Ranbaxy was trying to address – under the banner of a sufficiency argument – was whether or not Pfizer had obtained the '546

⁹⁸ Pfizer Canada Inc and Warner-Lambert Company, LLC v The Minister of Health and Ranbaxy Laboratories Limited, Docket A-79-07, Federal Court of Appeal, March 20, 2008, paragraph 22, quoting from previous ruling.

⁹⁹ Ibid. paragraph 32.

selection patent *without* having provided the kind of data proving that the class of compounds selected for that patent were any better in lowering cholesterol than those covered in the '768 genus patent.¹⁰⁰ But sufficiency in this sense was not at issue in subsection 27(3) of the Patent Act. Sufficiency here, according to the Appeals Judge, was concerned with the sufficiency of the *disclosure* in the patent, not the data underlying it: 'Whether or not a patentee has obtained enough data to substantiate its invention is, in my view, an irrelevant consideration with respect to the application of subsection 27(3). An analysis thereunder is concerned with the sufficiency of the disclosure, not the sufficiency of the data underlying the invention.'¹⁰¹

Accordingly, only two matters were viewed to be at issue with regards to the sufficiency argument in the context of subsection 27(3) – what was the invention and does it work?¹⁰² In answering both of these questions, the Judge found that Ranbaxy's claims of invalidity were not sustained and therefore the Application Court's ruling should be overturned.

With regards to the other cases examined above, the Appeals Court's ruling illustrates the broader point of fundamental disagreements existing within the Canadian judiciary over the interpretation of important legal concepts, such as, sufficiency. Indeed, in *Eli Lilly Canada Inc. v Novopharm Limited and the Minister of Health*, June, 2007 the Judge ruled – referring explicitly to the same subsection, 27 (3) – that not enough data and evidence as to the therapeutic effects of Lilly's newer '113 patent existed to warrant patent protection. But here, in the Lipitor case, the ruling explicitly stated that what subsection 27 (3) was interested in was not any value judgement as to quantifying the beneficial effects of the substances patented in a newer patent, but of fulfilling the key questions of what the invention was and if it actually worked:

The patent must disclose the invention and how it is made. The 546 patent does this. It also discloses the advantages that underlie the selection. This, in my view, is the extent of the requirement under subsection 27(3) of the act, the purpose of which is to allow a person skilled in the art to make full use of the invention without having to display inventive ingenuity.¹⁰³

Such a fundamental disagreement in legal interpretation again underlines the point that the Canadian judiciary is divided over interpreting statute in patent litigation; yet another example of the challenges of moving from a pro-generic regime to a more pro-research based system of IPRs.

¹⁰⁰ Ibid. paragraph 51

¹⁰¹ Ibid. paragraph 56

¹⁰² Ibid. paragraph 59

¹⁰³ Ibid.

Concluding Discussion and Policy Recommendations

This paper has sought to explain contemporary Canadian pharmaceutical IPRs and place them in the context of Canadian IP history, its health care system, and its legal tradition. It has explored and examined how Canada has, over the years, radically re-configured its pharmaceutical IPR framework from a pro-generic model based on the issuing of compulsory licensing during the 1970s and 1980s, to a model based on patent protection and encouraging the research-based pharmaceutical industry that took shape in the late 1980s and early 1990s. This transition has created a seemingly distinct Canadian tension between the will of policymakers in cementing this transformation and the outcome in several key court cases over the past decade.

Where does one draw the line between the responsibilities of the courts and those of the legislative and executive branches? Just over two years ago Supreme Court nominee Judge John G. Roberts, during the course of his United States Senate hearings, gave his opinion. Judge Roberts likened the role of a judge to that of a baseball umpire:

Judges are like umpires, umpires don't make the rules. They apply them. The role of an umpire and a judge is critical. They make sure everybody plays by the rules. But it is a limited role. Nobody ever went to a [base-]ball game to see the umpire...I will remember it is my job to call balls and strikes and not to pitch or bat.¹⁰⁴

It is not within the scope of this paper to pass judgement on whether or not the rulings in any of the above discussed cases have been the result of judicial activism. However, there does seem to exist a real discrepancy between the intentions of policy-makers and large parts of the judiciary with regard to the nature and direction of Canada's pharmaceutical IP environment. It also seems clear that within the judiciary there is a real and intense debate over the legal interpretation of existing IPRs for pharmaceuticals.

Examples of this can be seen in the 1998 *Bayer* ruling which effectively side-stepped the existing data protection regulations and contributed to new more IP friendly ones being put in place (the case even being mentioned in the official guide to the new regulations); in the seemingly contradictory rulings on Lilly's Zyprexa drug from the spring and summer of 2007 (the cases' chronological proximity only underlining the starkness of the courts' differing interpretations of the patent's validity); the 2006 regulatory changes to both the PMNOC and the Food and Drugs Regulations which incorporated the central arguments from both plaintiffs in *AstraZeneca v Minister of Health*; and, finally, the *Biolyse* case in which Justice Bastarache's dissenting opinion illustrates the intensity and difference in view over the role of the judiciary in shaping IP policy. More recently, this conflict between government intent and

¹⁰⁴ Supreme Court Nominee John Robert's, September 2005, from *The Wall Street Journal*, 'The Umpire Strikes Back', September 14, 2005, <http://opinionjournal.com/nextjustice/?id=110007254>

court rulings is reflected in the June 2008 amendments to the Patented Medicines (Notice of Compliance) Regulations. These amendments – which allow patents that may have been rejected by the Minister of Health after March 2007 and filed before June 2006 to be resubmitted and possibly listed on the Health Canada patent register – were explicitly put into force to tackle a number of, in the Government’s view, unfortunate court rulings. In fact, the Regulatory Impact Analysis Statement in the Government’s official newspaper, *Canada Gazette*, states quite clearly that the current amendments are a reaction to a 2006 Supreme Court ruling and subsequent Federal Court of Appeal citing the Supreme Court’s ruling:

While it can be said that this new [Supreme Court] interpretation brings the old patent listing requirements closer into line with how the 2006 amended requirements are intended to operate, the impact of such a marked departure from **precedent would be inconsistent with the intention and purpose of the Government’s decision to grandfather the [patent] register**...The Government is also concerned about the possibility that the Court of Appeal’s recent decision to revisit its own precedent may mark the beginning of a trend. If the Supreme Court of Canada’s reasoning opens the door to a broader unsettling of the jurisprudence on the listing requirements as they were prior to the 2006 amendments, this could give rise to a proliferation in litigation, contrary to one of the stated objectives of the 2006 amendments. [Emphasis added]¹⁰⁵

What to do about these dilemmas? First of all, it needs to be recognised that Canadian primary and secondary legislation has gone a very long way from where it was during the 1970s and 1980s. Canada has, furthermore, through international agreements confirmed its commitment to a pharmaceutical policy based on IPRs and not compulsory licensing. Most recently in September 2003, Canada joined together with the United States, most of the EU, and a host of other developed countries to opt out of their right to import pharmaceutical products manufactured through the issuing of compulsory licenses under paragraph 6 of the TRIPS agreement.¹⁰⁶ For a country that for so long used compulsory licensing as a public policy tool to contain the cost of pharmaceutical products, this is indeed a considerable step.

The evidence examined in this paper suggests that stronger levels of IP protection have indeed led to more robust growth in the Canadian domestic pharmaceutical R&D sector. Yet, the relationship between new pro-innovative IP policies and the courts’ interpretation of the purposes of these policies is not clear. If a trend is emerging, it is that regulators are taking on board court decisions and clarifying regulations accordingly. This can be seen in the Bayer and AstraZeneca cases which both prompted changes to existing secondary legislation. But it is unsatisfactory for both research-based and generic-based pharmaceutical companies to be in a situation where policy is inconsistent and reversed or drastically changed by court rulings. The following two policy recommendations seek to address this confusion.

¹⁰⁵ Regulations Amending the Patented Medicines (Notice of Compliance) Regulations, Government of Canada, *Canada Gazette* June 25, 2008, <http://gazette.ducanada.gc.ca/partII/2008/20080625/html/sor211-e.html#6>

¹⁰⁶ http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm#fnt3

Recommendations

Policymakers need to place a greater emphasis on the fact that over the last two decades Canada has experienced (and is experiencing) a noticeable and ongoing shift of policy towards more robust IP systems aimed at supporting the innovative segment of the pharmaceutical and biotechnology sectors. This change of policy, however, should not only be limited to the policymaking level but should also "spill over" to the judiciary, it needs to be clearly conveyed to the courts and the public at large with regard to the intent and purpose of existing primary and secondary legislation. Of course such action should not become prescriptive, but, rather, serve as an instructive guide. It is clear from the cases analysed that courts frequently examine the context of a given piece of legislation or regulation when making a judgement; see, the *Bayer* and *Biolyse* cases in particular. If such action were taken it may help to make it clearer to the judiciary what the intentions of policymakers and legislators were.

Popular misconceptions about the cost-cutting benefits favouring a large generic sector should be engaged and where appropriate refuted. This is not to argue that policies aimed at supporting the production and dissemination of generic drugs should not take place in Canada. Of course such policies are relevant and important to any country's health care system. Yet one should note that these policies are only part of the equation and not a wholesale solution. Indeed, experience suggests that it is possible to combine both a pro-innovation policy with a pro-generic one without sacrificing either.

This second recommendation, regrettably, is much more difficult to achieve. The debates between those who are for and those against pharmaceutical IPRs are often acrimonious and highly emotional. Pharmaceutical drugs have the potential to be life-altering and life-saving. Consequently, it is small wonder that the laws and regulations determining their availability and cost mean so much to so many. However, at times it would seem emotions run too high. In the *Building on Values* report, Roy Romanow made a prescient point on the importance of IP and the lack of evidence that existing Canadian pharmaceutical legislation had increased the cost of drugs when he said:

While some may suggest that Canadian drug patent legislation is a key obstacle to controlling drug prices, in fact, Canadian legislation is in line with international standards. Furthermore, there is no empirical evidence to suggest that Canada's protection laws are responsible for increasing drug prices.¹⁰⁷

On this, as opposed to the other major arguments of his report, Romanow was right. Indeed, the fact that there is no evidence to suggest that Canada's IP regime led to an increase in the prices of drugs should be re-emphasised in public policy discussions and in the legal debate over patents and pharmaceutical IPRs.

¹⁰⁷ Romanow, Roy J., 'Building on Values: The Future of Health Care in Canada', Final Report November, 2002, Commission on the Future of Health Care in Canada, http://www.hc-sc.gc.ca/english/pdf/romanow/pdfs/HCC_Final_Report.pdf

Canada has turned a corner. While its IPR regime still faces serious challenges, the policy reforms over the past two decades have reversed a trend of declining R&D investment in the pharmaceutical industry. Perhaps more importantly, it has seriously questioned the idea that a cost-containment policy based on the issuing of compulsory licenses was good for the long term viability of a modern health care system. If anything, modern health care systems need both a vibrant and innovative pharmaceutical industry alongside a prosperous and a robust generic one. To this extent IPRs are not part of the problem but rather part of the solution.