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Generic Drug Pricing and Procurement: A Policy for Alberta

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Summary

Canadians pay very high prices for generic drugs compared to international norms. The reason is not inefficient or uncompetitive generic drug companies, but provincial government pricing and insurance policies that are distorting the market. This paper by Professor Aidan Hollis, an expert in the economics of pharmaceutical markets, evaluates provincial government policies regarding generic drugs and proposes a new approach which could save governments and private insurers tens of millions of dollars a year.

Executive Summary

Generic drugs are becoming an increasingly important component of health care expenses in Canada. Thus, it is very important that the right policies are established to capture the benefits of reduced prices. Unfortunately, current policies across Canadian provinces fail to ensure low prices or early entry of generic products. This paper lays out key aspects of generic drug competition in Canada; presents principles for generic pricing and procurement; analyzes existing policies in Canadian provinces; and finally, presents a new approach for Alberta, with the potential to save millions of dollars a year.

The paper describes the structure of generic drug markets and the two obstacles to competition in the market for generic drugs. First, pharmacies are in a position to capture the benefits of competition among manufacturers, and for a variety of reasons, including insurance, consumers are reluctant to invest the effort to look for lower prices. Second, Canada's laws make litigation almost a prerequisite for generic competition to occur; if the firm with the first generic drug on the market does not benefit from investing in litigation, no other firm have an incentive to challenge patents, possibly significantly delaying the entry of other generics. It is important for policies to deal with both of these problems simultaneously.

Having described these characteristics of the market, the paper lays out seven principles which are relevant to generic drug-pricing and procurement policies:

- there should be adequate incentives for innovation;
- competition should be encouraged;
- the benefits of competition should accrue to payers;
- security and stability of supply should be encouraged;
- prices should be the same for all buyers in a province;
- a province should not enact a policy that harms all provinces if replicated elsewhere; and
- pharmacies should be fairly compensated by all payers.

With these principles in mind, as well as an understanding of the obstacles to competition, an evaluation of the drug-pricing and procurement of Ontario, Quebec, Saskatchewan, and British Columbia finds problems with the approaches adopted in all of these provinces.

The paper then proposes a new approach for Alberta designed to obtain low prices for payers and fair treatment for pharmacies and manufacturers. The proposal contains the following elements:

- *A descending maximum price, with inflation indexing.* The province should maintain a price schedule that provides for a maximum price for a generic drug that decreases with each additional entry into the market by a generic manufacturer – from 55% for one entrant down to 25% and below. The maximum price should apply across the province, in both the public and private sectors, and should be calculated as a fraction of the average price of the patented reference drug during the two years prior to entry. The lower price should apply to all manufacturers, and the maximum price should be adjusted each year by the rate of inflation.

- *A cap on rebates or other considerations granted to pharmacies by manufacturers, whether directly or indirectly.* A limit of, at most, 10% of the price of the drug being sold should be set on rebates. The limit should apply in both the public and private sectors. In the event of a rebate above that amount, both parties should be penalized. Dispensing fees and mark-ups should be adjusted to ensure that pharmacies are fairly compensated.

- *An open formulary.* Listing as a benefit on the provincial formulary should be automatic upon meeting certain threshold requirements. There should be no need for generic drug firms to meet any additional requirements beyond having a Notice of Compliance from Health Canada and committing to being able and willing to supply the product at the listed price.

- *A "royalty" paid to the first generic entrant that successfully challenges a patent.* As a reward to generic firms that enable competition through challenging invalid or non-infringed patents, the province should direct a temporary royalty to the first independent generic that successfully challenges patents and obtains a Notice of Compliance to sell the drug. Only an independent generic, not a licensee or firm under the control of the patentee, should be able to obtain the royalty, and more than one firm should be able to share the royalty in some circumstances.

Generic Drug Pricing and Procurement: A Policy for Alberta

Aidan Hollis

INTRODUCTION

What is the right strategy for the procurement and pricing of generic drugs? Canadian provinces have recently been experimenting with a variety of mechanisms to reduce the cost of drugs. There is a common assumption that once a drug is available generically, competition effectively will drive the price down, but because of special characteristics in pharmaceutical markets – especially insurance – this is not true. Retail drug prices consist of the net wholesale price, mark-ups by pharmacies, and dispensing fees. While generic competition drives down the net wholesale price, pharmacy mark-ups might increase to compensate, resulting in little, if any, savings for buyers. Ontario, in response, established maximum prices for generic drugs, which created an informal national standard in pricing on which Alberta relied. This model has disintegrated, as Ontario has successfully separated pricing for its public plan from that of the rest of the country. Generic drug prices in Alberta are now approximately 20% higher than Ontario *public sector* prices for identical multi-source products, though they are still lower than *private sector* prices in Ontario. This paper presents a review and analysis of generic drug procurement strategies across the country, and proposes a new mechanism for Alberta.

In 2007, generic drugs represented 51% of total prescriptions filled in Alberta, and cost approximately $400 million.[1] About half of this cost was borne by the provincial government. Thanks to the expected arrival of generic versions of several blockbuster drugs, it appears that generic drugs will be one of the fastest-growing elements of health expenditures in Canada over the next few years. Thus, given both the importance of generic drug expenditures and the extensive revision of drug procurement policies in other provinces, the time seems ripe for a review of Alberta's policies. Of course, while this paper has a particular focus on Alberta, the principles apply equally well to other provinces, too.

Alberta has developed unique solutions in a number of areas to respond to its own particular needs and aspirations. Alberta was, in 1962, the first jurisdiction in Canada to allow a pharmacist to substitute a generic for the equivalent brand written in the prescription.[2] Alberta can continue to lead in its design of an effective set of regulations to enable savings to consumers to arise from competition among drug manufacturers.

Despite the importance of generic drugs, the problem of procurement policy in Canada has attracted little academic attention. A 2003 study of Ontario's "70/90" rule, which operated from 1993 to 2006,

• As will be evident from the analysis and discussion in this paper, determining the appropriate policy with respect to the pricing of generic drugs in Canada demands that close attention be paid to government legislation and that consideration be given to measures of cost and drug characteristics. An effective contribution to any understanding of policies with respect to generic drug pricing therefore demands access to information that is sometimes of a confidential nature. Many individuals – employees of pharmaceutical manufacturers, pharmacies, insurers, employers, and associations – contributed to the formation of this paper through discussions, but have requested anonymity. I thank them for the generosity they showed in providing the information required for the preparation of this research. I also thank Wendy Armstrong, Herb Emery, Ron Kneebone, and Paul Grootendorst for their helpful comments and suggestions. Brogan Inc kindly contributed data-enabling comparison of private payer prices across provinces. In the interest of full disclosure, I have been a consultant to many generic drug companies in Canada, including Apotex, Novopharm, Cobalt, Genpharm, Nupharm, the Canadian Generic Pharmaceutical Association, and the US Generic Pharmaceutical Association; to governments in Canada, both provincial and federal; and to consumer groups, all on matters relating to generic drug policy and competition.

1 IMS Health Canada, "Generic Dispensing Trends by Province, 2007"; accessed online (20/06/08) at http://www.imshealthcanada.com/vgn/images/portal/cit_40000873/8/0/79016663Trends13_En_07CORR.pdf; and Canadian Institute for Health Information, ***Drug Expenditure in Canada 1985-2007*** (Ottawa: CIHI, 2008).

2 Harold J. Segal, "The Canadian Health Care System: The Pharmacy Experience," ***Journal of Research in Pharmaceutical Economics*** 5(3, 1994): 51-68.

found that the rule seemed ineffective at reducing generic drug prices, since drug prices clustered at the maximum level permitted.[3] The Fraser Institute has published a series of papers comparing Canadian generic drug list prices against those in the United States, arguing that the higher Canadian prices are a justification for removing all price regulations on any drugs in Canada.[4] A 2007 study examines a broad set of policies used in New Zealand for possible application in Canada, and suggests that tendering could be used to obtain low prices for generic drugs.[5] And a 1992 study by Paul Gorecki reviews pricing mechanisms used at that time in Canada as well as a proposed mechanism.[6] The key issue he addresses is the effectiveness of different mechanisms in ensuring that public insurers obtain the lowest available prices, so that the benefits of generic competition are passed on to the payer. The chief concern in 1992 was the "spread," or difference, between the effective price at which pharmacies purchased generic drugs and the price at which they were reimbursed. As Gorecki notes, "It appears that history is repeating itself. The two previous attempts to eliminate the spread in 1979 and 1984, while initially successful, saw its eventual reappearance" (p. 68). History has been repeating itself since 1992 as well, and the "spread" has continued to be a troubling policy issue, as we will see.

An excellent 2007 study by the Competition Bureau of the generic drug sector provides a comprehensive analysis of how that market operates. A 2008 follow-up report offers policy recommendations, including suggestions for private payers to seek lower prices by negotiating for discounts with networks of preferred pharmacies. It suggests that public plans should coordinate across provinces and that there should be limits on the ability of pharmacies to capture profits through the "spread."[7]

This paper briefly reviews the nature of competition in generic drug markets, highlighting the points at which problems have arisen in Canada. It then introduces seven principles on which to base a generic drug procurement strategy. In light of these principles, the paper examines the cost-control strategies employed by the provincial drug plans of Ontario, Quebec, British Columbia, and Saskatchewan, and shows that the strategies used in those provinces are problematic and might not be suited for use in Alberta. The paper proposes instead a market-oriented system that is structured to use private incentives to enable public and private cost savings.

One complication of drug markets is that there are three types of "payers" in each province: the provincial government, employers that provide insurance,[8] and patients. Ultimately, however, it should be

3 A. Anis, D. Guh, and J. Woolcott, "Lowering Generic Drug Prices: Less Regulation Equals More Competition," ***Medical Care*** 41(1, 2003): 135-141.

4 In Brett J. Skinner and Mark Rovere, ***Canada's Drug Price Paradox 2008*** (Vancouver: Fraser Institute, 2008), the most recent Fraser Institute publication on this topic, the policy section begins with the statement, "If public drug-benefit programs only partially reimbursed consumers directly at a flat percentage of the price of the prescribed drug, all drug sales would be subject to market forces that would put downward pressure on prices" (p. 26). As it happens, that is exactly how most provincial drug programs operate. The paper continues, "The only customer is government and, because retailers all get the same reimbursement price, there is no incentive to undercut the competition on final retail price" (ibid.). In fact, government is only half the market, and the private insurance plans actually pay higher prices than government does, despite not having fixed reimbursement rates. The paper's policy recommendations, all based on a comparison of generic drug prices in Canada and the United States, include repealing the ban on direct-to-consumer advertising and repealing price-control rules on patented drugs.

5 S. Morgan, G. Hanley, M. McMahon, and M. Barer, "Influencing Drug Prices through Formulary-Based Policies: Lessons from New Zealand," ***Healthcare Policy*** 3(1, 2007): 1-20.

6 Paul Gorecki, ***Controlling Drug Expenditures in Canada*** (Ottawa: Economic Council of Canada, 1992), especially chap. 5, which has a discussion of mechanisms used in different provinces.

7 See Canada, Competition Bureau, ***Canadian Generic Drug Sector Study*** (Ottawa: Competition Bureau Canada, 2007); accessed online (20/06/08) at http://www.competitionbureau.gc.ca/epic/site/cb-bc.nsf/en/02495e.html; and idem, ***Benefiting from Generic Drug Competition in Canada: The Way Forward*** (Ottawa: Competition Bureau Canada, 2008).

8 The federal government also provides drug insurance for certain groups such as First Nations peoples and veterans.

recognized that all these payers are the same people: employees tend also to be taxpayers, and they often make co-payments for the drugs that are insured by their employers or by the province. In effect, drug insurance for employees is just a cost of employing a person, much like a wage, so higher drug insurance costs are simply reflected in lower wages and/or fewer employees. While it is possible in principle to shift the burden of payments from the province to employers, such a move would really only shift the way that individuals pay for drug insurance. Thus, in this paper, I use the word "payer" to refer to the person or insurer that pays. Where I refer to prices paid by the public insurer — such as British Columbia's PharmaCare or the Alberta Health Care Insurance Plan — or by a private insurer, I generally mean the price charged, some of which might be paid directly by the patient as a co-payment. Thus, high prices for the public payer create high costs for taxpayers and high co-payments for patients.

Generic Drug Prices in Alberta

In 2007, the Government of Alberta spent approximately $887 million on prescription drugs through community pharmacies, while private expenditures (by both third-party insurers and out-of-pocket) totalled $980 million.[9] About one-quarter of this spending was for drugs that are not patented. Table 1 shows public expenditures on 20 commonly prescribed generic drugs in Alberta, and ratios between Ontario and Alberta drug benefit prices. The ratios were determined using the lowest prices available in each province, and averaged 82% across these drugs — in other words, Ontario pays only 82% as much on commonly used generic drugs as Alberta does. The last column of Table 1 shows that, if Alberta had paid Ontario's prices during the 12 months ending March 2008, the province would have saved $15 million.[10]

Table 1: Government Expenditures on 20 Commonly Prescribed Generic Medicines, Alberta, fiscal year 2007/08

Molecule	Alberta Drug Plan Cost	Average Ontario/Alberta Price Ratio	Savings Potential
	($)	*(%)*	*($)*
Ramipril	12,189,840	0.76	2,962,808
Simvastatin	9,680,340	0.79	1,997,531
Venlafaxine Hcl	6,579,620	0.77	1,498,255
Gabapentin	5,964,050	0.79	1,230,599
Metformin Hcl	5,818,426	0.79	1,201,007
Alendronate Sodium	5,574,000	0.79	1,150,092
Pravastatin Sodium	4,189,587	0.79	863,594
Diltiazem Hcl	4,503,743	0.82	792,923
Paroxetine Hcl	2,865,823	0.79	591,360
Atenolol	2,172,857	0.79	447,575
Sertraline Hcl	2,062,407	0.79	425,576
Fentanyl	1,423,573	0.71	406,735

9 Canadian Institute for Health Information, ***Drug Expenditure in Canada 1985-2007***, p. 98; spending on drugs through cancer boards and hospitals is supplementary to this amount.

10 These figures do not include dispensing fees and mark-ups, which are, however, fairly similar between the two provinces for the public plans. Appendix 1 contains comparative details of these other fees.

Metoprolol	2,690,262	0.86	380,153
Ciprofloxacin Hcl	1,515,296	0.79	314,629
Olanzapine	1,482,488	0.80	300,190
Fluoxetine Hcl	1,376,954	0.79	284,187
Risperidone	681,081	0.79	140,572
Amoxicillin	739,020	0.96	30,487
Fenofibrate	2,855,151	1.00	0
Omeprazole Magnesium	12,548,940	1.00	0
Total	**86,913,458**		**15,018,273**

Note: Include only drugs insured under the Alberta Health Care Insurance Plan during the period from April 2007 to March 2008. Drug plan costs exclude dispensing fees. The average price ratio is the ratio of the prices of all dosages of each product sold in both provinces, using the drug benefit prices.

Source: Sales information abstracted from Brogan Pharmastat Database.

While Ontario has reduced the public prices of its generic drugs, it has not shown any appearance of concern regarding the prices paid by private payers. Indeed, the difference between prices is such that private payers' costs in Alberta, excluding dispensing fees, are about 10% lower than those in Ontario. (See Appendix 2 for a summary of private payer costs in all provinces.) Since the private market is about the same size as the public market, the average cost of a generic prescription is now slightly higher in Alberta, though the burden is allocated differently. This paper argues, however, not only that Alberta could do as well as Ontario, but also that it could reduce its own drug expenditures and those of private payers even further through an implementable solution. At the same time, these reduced drug expenditures need not reduce competition in the generic drug sector.

GENERIC DRUG COMPETITION

The generic drug industry is complex and widely misunderstood. Generic drugs — here used to refer to prescription medicines that are sold as "bio-equivalent" to a reference drug — are approved by Health Canada under special provisions of the *Food and Drug Act* and the *Patent Act*. Despite widespread perceptions of inferiority, generic drugs are tested in Canada to have the same clinical effect as branded products sold under patents. Indeed, a substantial share of the generic drugs sold in Canada is actually manufactured by or for the innovator companies.

From the perspective of consumers and payers, generic drugs create competition, driving prices down. To compete, however, the generic manufacturer must obtain a "Notice of Compliance" (NOC) from Health Canada. An NOC is granted only when the generic company has met four requirements.

First, the firm must demonstrate to Health Canada that it has or can produce a product that is safe and effective. Thus, in general, the generic firm will have to develop a suitable drug. This might involve some chemical engineering work to ensure that the drug is properly formulated and developing the processes for production.

Second, the generic product must be demonstrated to be bio-equivalent to the patented product. This typically means undertaking tests to show that the generic product has the same bio-availability in the bloodstream as the patented product; it also avoids the unnecessary duplication of expensive clinical trials.[11]

Third, since the generic firm is not required to undertake additional clinical trials beyond those required to show bio-equivalence, it must rely on the data produced through the patented product's clinical trials to show safety and efficacy. Therefore, the patentee also benefits from a period of eight years during which no other firm may rely on its data.[12] The data-exclusivity period is often simultaneous with the patent period and in many cases does not delay generic competition; in other cases, the generic firm must wait for data exclusivity to end.[13]

Fourth, under Canadian law, patentees may link certain types of patents with drugs through listing those patents in the Health Canada Patent Register. To obtain an NOC, the generic firm must demonstrate that it has addressed all the outstanding patents linked to the drug in the Register. This requires that the generic firm give notice to the patentee that it wishes to sell the drug, specifying that it can do so because it believes that all relevant patents either are invalid or are not infringed. The patentee can then apply for a court order to prevent the generic drug from being approved, at which point there is, in effect, a patent lawsuit. In addition, because of special regulations that apply only to the pharmaceutical industry, the patentee is granted an automatic two-year injunction against approval of the drug by Health Canada.[14] If the patentee is successful in its application, the generic is barred from entering. If the patentee is unsuccessful, the generic firm may be granted an NOC and commence sales of the drug in Canada.[15]

Typically, brand-name companies legitimately obtain several patents on their products over a period of years, of which some will be listed in the Health Canada Patent Register.[16] In 2006, the average number of patents linked to each medicine in the Register was 2.26, although, for some medicines, particularly products with large sales volumes, the number of patents is much higher – one drug had 22 patents registered.[17] A variety of inventions may be patentable with respect to a particular molecule. Patentable

11 Such trials, which compare the effectiveness of the drug against a placebo, would be unethical in any case for products already demonstrated to be more effective than a placebo.

12 Section C.08.004.1 of the Food and Drug Regulations, as amended in October 2006, provides for a period of eight years of data protection during which no generic drug may enter. A supplementary period of six months is granted if the manufacturer performs clinical trials on pediatric populations.

13 Data exclusivity was extended to eight years in Canada in 2006.

14 In other industries, patentees must apply in court for an "interlocutory injunction" to sales by the alleged infringer to prevent patent infringement until a decision is reached on the merits of the lawsuit. Because of linkage between patents and the NOC, such an injunction is granted automatically. The injunction is vacated when a decision is reached in court within two years or if the parties settle. In Australia, there is no linkage, so that patentees must apply for interlocutory relief if they wish to prevent generic sales until a decision is reached in the trial. In that country, there have been six applications for an interlocutory injunction in pharmaceutical cases since 2003, of which three have been granted; see Wayne Condon, "Issues for Pharmaceutical Companies Doing Business in Australia," ***Intellectual Asset Management Magazine***, 2008, pp. 22-25.

15 Notably, even if an NOC is granted following a finding of invalidity in the application, the patentee may still sue the generic firm for patent infringement to stop the Minister of Health from granting an NOC. Evidently, if a court has already found a patent invalid in an NOC hearing, it is more likely, but not by any means certain, that a patent infringement action would be unsuccessful.

16 No criticism is intended of patentees who file multiple patent applications that are issued by the Patent Office. Patentees may not be certain exactly which claims will be found invalid and which valid, and there should be no presumption that they file applications for patents that they expect to be found invalid. However, the uncertainty might lead to their applying for more patents than would be granted if the judge's decision could be known in advance; this, in turn, means that many patents ultimately will be found invalid.

17 See Canada, Health Canada, Office of Patented Medicines and Liaison, ***Therapeutic Products Directorate Statistical Report 2006: Patented Medicines (Notice of Compliance) Regulations*** (Ottawa, 2007); accessed online (20/06/08) at http://www.hc-

inventions relating to a drug may include the following:

- its basic composition, including new or alternative compounds;
- the method of treatment, including new use of known compounds, different dosing, and therapies in combination with other drugs;
- synthetic production;
- its formulation and drug delivery;
- prodrugs-releasing active ingredient;
- substances resulting from metabolism in the body;
- different crystalline or hydrated structures;
- gene markers showing response to drug therapy; and
- devices such as patches for administering the drug.[18]

Even within the category of basic composition, there are typically "originating patents," where there is an originating invention involving the discovery of a new reaction or a new compound; and "selection patents," which are based on a selection from related compounds derived from the original compound and which have been described in general terms and claimed in the originating patent.[19]

Given the ability of patentees to apply over a period of years for a variety of patents, each of which can independently prevent generic entry, it is not typically the case that the "patent" expires.[20] Instead, a large proportion of the drugs that become available generically do so only after the remaining patents are shown to be either invalid or not infringed. Thus, one of the most important requirements for generic competition to be enabled in a timely manner is for one or more generic firms to challenge the relevant patents. In the absence of such challenges, patentees would have an incentive to continue to make new patentable discoveries on which they could apply for patents.

Canadian federal law contains a mechanism intended to deter baseless litigation by patentees under the Patented Medicines (Notice of Compliance) (PM(NOC)) Regulations. Section 8 of the Regulations allows a generic manufacturer to make a claim for damages against a patentee for any loss the generic drug suffers as a result of an application made by the patentee that is later withdrawn or dismissed in court. In principle, this provision could provide some reward to the manufacturer of a generic drug that was kept off the market because of an invalid or non-infringed patent. In practice, however, no Canadian court has ever granted an award for such damages under this provision; moreover, even if such an award were granted, it would not efficiently deter excessive patenting, as Appendix 3 shows.

Lipitor provides an extreme example of how brand-name companies can use the patent system to protect their products from generic competition. Pfizer owns 17 Canadian patents on atorvastatin (Lipitor) that are listed in the Health Canada Patent Register, and any firm wishing to sell generic atorvastatin in Canada is required to address all the listed patents, the earliest of which were filed in 1990 and will expire in 2010, while the latest were filed in 2002 and will not expire until 2022. Health Canada first granted an NOC for Lipitor in February 1997. While it is possible that some of the later-filed patents would be found invalid in court, no one will know unless a generic company invests in challenging their validity. In the absence of such a challenge, the monopoly will last until at least 2022, while further

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sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodpharma/ patmrep_mbrevrap_2006-eng.pdf.

18 This list drawn from European Generic Medicines Association, ***Pharmaceutical Patents*** (Brussels, 2008); accessed (20/06/08) at http://www.egagenerics.com/gen-phrmapatents.htm.

19 This description is drawn from ***Pfizer Canada Inc. v. (Minister of Health)***, 2006 FCA 214.

20 Not every class of patent is eligible for listing in the Health Canada Patent Registry, but all may be used as the basis for an infringement lawsuit.

patents might be issued that would extend the monopoly beyond that date. The questionable quality of these patents has been revealed, however, by Pfizer's decision to license the firm Ranbaxy to sell an authorized generic atorvastatin; generic atorvastatin is now expected to become available in Canada by around 2011.[21]

The process of patent litigation — whether under the PM(NOC) application or under a patent-infringement action — is both expensive and risky.[22] Generic firms, like patentees, cannot know in advance which patents will be found invalid or not infringed; thus, to be successful, generic firms will in some cases have to be unsuccessful. In a way, this uncertainty renders the process of generic patent litigation similar to the process of research and development that leads to a drug in the first place. Therefore, generic challengers must be "over-compensated" in cases in which they are successful in order to make such challenges profitable on an expected basis after adjusting the return for the probability of a successful challenge.

Generic firms consider a variety of factors when deciding whether to invest in developing a product and face patent litigation, including the likelihood of success in litigation; the size of the market; the costs of production; the costs of litigation; and the prospect of competition from other generic firms and the branded product.

Once one generic firm enters the market, other generic firms are also likely to enter since the patentee typically has relatively little incentive to prevent further generic entry. In many cases, multiple firms obtain their NOCs on the same day or in close succession. Patentees sometimes abandon litigation against other generics once one generic has been successful, since the loss of market share to the brand does not generally depend on the number of generic firms.[23]

One approach that has become common in the United States — and that is certainly possible in Canada — is settlement of litigation that delays the arrival of generic competition.[24] In the United States, these kinds of settlements are particularly noxious because of certain provisions in that country's law that might prevent other entrants. Even in Canada, only a few generic firms effectively challenge patents, so that if a generic firms were to settle its litigation by agreeing to delay entry in exchange for a payment from the patentee, this might lead to significant delays in the arrival of generic competition.

21 Ranbaxy Laboratories Limited, "Ranbaxy and Pfizer settle Lipitor litigation worldwide," press release (Gurgaon, Haryana, India: Ranbaxy, 18 June 2008); accessed online (20/06/08) at http://www.ranbaxy.com/news/newsdisp.aspx?cp=890&flag=LN. To be clear, this is not to suggest that the Pfizer patents that will expire after 2011 are invalid, but merely to observe that Pfizer appears to believe it possible or even probable that a court would find them invalid or insufficient to exclude generic competitors. A more complete discussion of strategic patenting is beyond the scope of this paper, but a useful analysis highlighting key issues, many of which pertain to Canada, is available in European Generic Medicines Association, ***Pharmaceutical Patents***.

22 Although I was unable to obtain detailed information on litigation costs generic firms face in Canada, reports indicate that similar challenges in the United States can cost US$20 million; see Sapna Dogra, "The Para IV Charm Continues" (Mumbai, India: Express Pharma, 1-15 August 2006); accessed online (20/06/08) at http://www.expresspharmaonline.com/20060815/market11.shtml. The Competition Bureau notes: "Legal costs for the first generic to challenge were said to be commonly in excess of $1 million and potentially much higher in complicated cases. However, the costs for subsequent generic manufacturers, for the same reference product, can be as low as a few thousand dollars when [Notices of Allegation] are no longer being challenged" (Canada, Competition Bureau, ***Canadian Generic Drug Sector Study***, p. 14).

23 The failure of the number of generic competitors to have any effect on the market share of the brand-name drug might be due to the fact that retail prices of generic drugs typically do not change much as the number of generic suppliers increases.

24 The US Federal Trade Commission has been actively following the growth of these settlements, which increasingly tend to include a later entry date for the generic in exchange for no authorized generic during the 180-day exclusivity period. For more details, see United States, Federal Trade Commission, ***The FTC in 2008: A Force for Consumers and Competition*** (Washington, DC: Federal Trade Commission, 2008); accessed online (20/06/08) at http://www.ftc.gov/os/2008/03/ChairmansReport2008.pdf.

It is important to understand that, if NOCs are issued to several firms on or around the same day, there is no benefit to being the generic firm that litigated: the most profitable firm will be the one that waited for litigation to finish and then entered without bearing those costs. Of course, if no firm has an incentive to invest in litigation but merely wishes to free-ride on the efforts of another firm, then patents that are found invalid or not infringed, if challenged, will, despite their weakness, effectively block competition. Any kind of policy analysis of generic competition should not act in ignorance of this key aspect of competition: that the timing of generic entry is not determined exogenously to the expiry of a patent but is responsive to the incentives for entry. This is important, since a mechanism that prevents the first generic entrant from obtaining a reward for successfully showing patent invalidity or non-infringement will lead generic firms to decide not to invest in risky litigation from which they cannot earn a profit. It is possible that, if the PM(NOC) regulations were substantially reformed to remove linkage, some of the problems of generic competition might be avoided. However, such an approach would also create new problems and uncertainties, and is outside the constitutional responsibilities of provincial governments. I therefore assume in this paper that all federal laws and regulations are unchangeable.

How Generic Competition Works

The Branded Product

Once the entry of a generic has occurred, competition does not tend to follow the normal route. For one thing, the maker of the brand-name drug typically does not reduce its price in response. The reason for this is well known: the brand-name manufacturer is attempting to capture profits from those relatively price-insensitive consumers who prefer to choose the better-known brand.[25] The brand-name manufacturer will also sometimes sue generic entrants for patent infringement, even after a decision under the PM(NOC) regulations, since such a decision does not determine infringement. A generic manufacturer that faces an infringement claim will have to manage its liability carefully, since it does not want to sell at a very low price and then find it must pay back the brand-name manufacturer's much higher losses.

Authorized Generics

The brand-name manufacturer also will often release its own "authorized" generic, typically the brand-name product but labelled and priced as a generic. Such authorized generics might be distributed through an agreement with an unrelated generic firm or through an in-house arrangement. Authorized generics allow the brand-name manufacturer to sell its branded product at a high price *and* to participate in the lower-priced generic market. An important feature of this strategy is that the authorized generic generally will be marketed before or simultaneously with the first independent generic, so that it splits the total generic sales volume. Thus, the benefit of being the first independent generic — that is, the benefit from challenging patents — might be reduced by half or more.[26]

Thus, the authorized generic strategy is very attractive for the patentee: it discourages investment into patent challenges and it enables the patentee to obtain a share of generic sales while also selling at the high branded price. For the consumer or payer, authorized generics create some potential benefits as well as harm. On the one hand, if an authorized generic enters before any other generic, it enables the consumer or payer to buy the same product at a lower price. However, it does so at the cost of harming generic firms' incentive to challenge patents, which, in turn, is likely to slow the entry of generics into other markets.

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25 In Canada, however, the regulations of the Patented Medicine Prices Review Board (PMPRB) limit price increases to the rate of inflation. Some provinces also restrict price increases.

26 A generic that enters alone benefits from high prices *and* high market share, while the authorized generic tends to split the market share and reduce the price and/or increase the rebate demanded by pharmacies.

The Institutional Setting and Competition for the Pharmacy

Once patent barriers have been cleared, manufacturers of generics compete in a complex institutional setting, with each province having its own rules and regulations. There are, however, a few key similarities. To obtain sales in the public sector, the generic product must be listed as a benefit in the provincial formulary. Typically, this means that the generic product must be priced no higher than other generics. The first generic entrant might be required to provide a minimum discount off the brand price to be listed as a benefit. The share of sales in the public sector varies by drug, but it averages about half the total expenditure. Private insurers tend to have more inclusive formularies, and in many cases they include almost all drugs that have obtained an NOC from Health Canada.

Pharmacies choose to carry specific products based on their profitability, so they will generally carry at least one generic product in each interchangeable group that is listed as a benefit. In most cases, generics are priced at the same level in the provincial formulary, so that any one of the products will suffice. Since carrying multiple interchangeable products adds costs, pharmacies typically will carry only the brand-name drug and one or two generics.

The decision as to which generic product a pharmacy will carry is determined in large part by "allowances" or "rebates" the manufacturer pays to the pharmacy — what Gorecki calls the "spread." Pharmacies typically negotiate with manufacturers the level of rebates or allowances they will be paid for a bundle of products, so it might not be possible to identify exactly the rebate for a specific product. Given a choice between different generics, pharmacies naturally will select the product or bundle of products that offers the largest profit. Chain pharmacies such as Shoppers Drug Mart can operate on a national scale, and might receive allowances based on national sales volumes. Given different retail prices and mark-ups in different provinces, the commercial relationship between such chain pharmacies and manufacturers can be complex.

Since almost all Canadians have some form of drug insurance, there is little personal benefit in their trying to find a lower price for a drug for which they pay, at most, a fractional co-payment.[27] Moreover, many seniors, in addition to being covered by their provincial health plan, also have supplementary insurance through their former employers that covers drugs not included in the provincial formulary. This supplementary insurance might also cover co-payments required under the provincial plan. In many cases, pharmacies know who has what insurance, enabling them to price discriminate among customers based on their insurance status — although some provinces, such as Saskatchewan and Alberta, limit such discrimination.

For sales of drugs to the public, provinces tend to restrict the size of the mark-up over the nominal wholesale price, as well as the dispensing fee.[28] Pharmacies therefore find it more profitable to buy drugs at a high list price and to receive rebates or allowances. If they purchase at a low list price — that is, at the same price net of the allowance — their net revenue is restricted to the allowed mark-up plus the dispensing fee. If they purchase at a high list price as well as receive an allowance, they can earn the allowance in addition.

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27 Out-of-pocket expenditures represented approximately 17% of total expenditures on prescription drugs in 2007 (Canadian Institute for Health Information, ***Drug Expenditure in Canada 1985-2007***, p. 60), but most of these private expenditures are on co-payments for drugs that are insured under private or public plans. Such plans cover approximately 98% of all Canadians, although the extent of coverage varies (Canada, Competition Bureau, ***Canadian Generic Drug Sector Study***, p. 3).

28 Private plans allow pharmacies to charge "customary and usual" dispensing fees and mark-ups; as a result, pharmacies differ considerably in the fees and mark-ups they charge for products outside the public plans.

The effect of the combination of these formulary rules and insurance is that generic firms historically have not competed on the list price in most Canadian provinces. Instead, they tend to seek a listing of their product at the maximum allowed price, and to compete to get their products into as many pharmacies as possible. (The list price may vary between public and private plans, and between provinces.) All the public plans, and many private plans, will pay only an amount equal to the "best available price" in a group of interchangeable drugs (or, if there is a co-payment, some fraction of that price). This means that generic firms tend to match each other's prices, and lowering the list price on a product does not increase volume but merely causes other firms to match the list price.

Thus, generic companies can increase their sales by reducing the effective wholesale prices of their products without changing the list prices, historically through rebates, discounts, and free goods.[29] In 2007, such rebates were estimated to average 40% and to range as high as 80% of the list price of drugs,[30] while my own discussions with generic manufacturers confirm that rebates and other incentives for pharmacies continue to average at least 50% of the list price.[31] In effect, generic manufacturers in Canada have been competing for market share by lowering the net price to the retailer without changing the list price payers face.[32]

For their part, pharmacies tend not to use discounting on drug prices to attract additional business since patients are relatively price insensitive;[33] they do, however, differ somewhat in the dispensing fees they charge, since these are less extensively covered by insurance and consumers are more price sensitive to them. Furthermore, most employers find it difficult to bargain with pharmacies over price since they lack the ability to threaten to limit payments to them. Pharmacies, in turn, will require consumers to make supplementary co-payments, which leads to employee dissatisfaction with their employers' benefit plans. Unionized employees, on the other hand, are more likely to rely on union contracts and union bargaining power to force non-restrictive drug insurance plans.[34]

The Core Problems in Generic Competition

The discussion above can be summarized in terms of two core problems of generic competition that provincial drug policy must take into account if it is to be effective. First, there is the failure of generic competition to be reflected in low prices for buyers and/or payers because of the presence of insurance for most drug purchases, so that patients lack sensitivity to prices. As a result, pharmacies cannot substantially increase market share by discounting generic drugs: it is more profitable for them to exercise market power through maintaining a high retail price.

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29 Since these all have much the same effect, I use the term "rebates" to refer to any kind of off-invoice discount offered to a pharmacy.

30 Canada, Competition Bureau, ***Canadian Generic Drug Sector Study***.

31 Other sources confirm the large size of these rebates and discounts; see, for example, Vernon Chiles, Green Shield Canada, Letter to the PMPRB, 9 May 2005; accessed online (20/06/08) at http://www.greenshield.ca/NR/rdonlyres/E8DCE938-3672-40E8-9934-4D08F6B98F14/0/AdvocacyMay2005PMPRB.pdf.

32 A similar phenomenon appears to have occurred in other countries. In the United Kingdom, for example, a recent study reveals that pharmacies obtain margins on generic drugs as high as 50%; see United Kingdom, Office of Fair Trading, ***The Pharmaceutical Price Regulation Scheme*** (London: Office of Fair Trading, 2007), p. 32.

33 In the United States, price discounting by some pharmacies is widespread —Wal-Mart offers many generic prescriptions for only $4 —which seems to suggest that, in principle, a different set of arrangements could lead to lower prices. However, various studies show that the average cost of filling a prescription in Canada easily exceeds $4. It is possible that Wal-Mart is using those prescriptions as a loss leader to attract more volume into its stores. It has also been suggested to me that Wal-Mart does not offer the same level of personal attention that would be expected in a Canadian pharmacy.

34 In Alberta, discounts offered to employers also have to be offered to both Alberta Blue Cross and the provincial government, thus limiting an employer's ability to obtain discounts.

Second, generic competition is often delayed because of patents that ultimately are found to be invalid or not infringed by generics. In almost every market that generics enter, patents initially shield the market from competition but are found wanting when competitors test them in court—and sometimes patents simply expire. While this might be a problem in the system, it is no fault of patentees who apply for, and are granted, patents that they legitimately use to block competition. Health Canada monitors patents to avoid inappropriate listings, but it cannot refuse to list patents that conform to its standards but that later might be found to be invalid or not infringed by a generic. Such a situation, however, demands an adequate mechanism to ensure that such invalid or non-infringed patents do not prevent competition and lower prices—and no such mechanism currently exists in Canada. Historically, the first generic entrant has tended to achieve and maintain a higher market share than might otherwise have been expected, which has created some incentive to challenge patents, although as I describe below, this market share advantage is now under threat by new policies.

PRINCIPLES

In view of the history and institutional setting of the use of generic drugs, provincial government policy should take in account a number of basic principles.

Principle 1: Ensure adequate incentives for innovation. Provinces should respect the patent rights and data exclusivity of innovative firms and adequately compensate them through the prices paid.

Principle 2: Encourage competition. This principle has two key parts. First, when there are no patent obstacles to competition, provinces should encourage an industry structure with many participants. Second, provinces should enable entry as early as is consistent with the patent rights and data exclusivity of the innovators.

Principle 3: The benefits of competition should accrue to payers. While manufacturers have competed aggressively against each other, this has not resulted in low prices for payers; instead, the competition has benefited pharmacies.

Principle 4: Ensure the security and stability of supply. One way to increase security of supply is to diversify the sources of products; domestic production might also be desirable.

Principle 5: Prices should be the same for all buyers in a province. Although not everyone might agree with this principle, its underlying rationale is that the provinces, as large buyers, are in a far superior position to exercise bargaining power than are uninsured consumers who walk into a pharmacy with a prescription. A weaker version of this principle is that provinces, as insurers, should not obtain low prices *at the expense* of other consumers. This implies that governments should not knowingly facilitate the charging of high prices to uninformed consumers in order to obtain low prices—after all, governments have a responsibility to all their citizens, not just to reduce the burden of provincial drug insurance programs on taxpayers.

Principle 6: Policies should not harm other provinces. If one province's policy harms all other provinces, it could lead to retaliation, which is inconsistent with the principles of Canada's federation. If the final outcome, after all provinces have retaliated in kind, is that all provinces are worse off than if no province had implemented the policy, then that policy is an undesirable one.[35]

35 There is a range of policies that could be beneficial for one province and harmful for another, however, and not all such policies should be condemned. For example, if one province reduced taxes for firms in a given industry, such a policy might harm other provinces if it induced firms to locate only in the province with the lower taxes, but no harm would necessarily be done if the other provinces provided an equal tax reduction. Clearly, however, a policy of discriminating against imports from other provinces would be harmful if all provinces retaliated in kind.

Principle 7: Pharmacies should be fairly compensated by all payers. This principle requires, first, that pharmacies should be adequately compensated for their contribution to the health of patients. Second, fair compensation requires that all payers — not just public or private ones — should make a proportional contribution to pharmacy revenues. Third, fair compensation requires that the contribution across different drugs be proportional among different molecules and between branded and generic drugs.

With this set of principles in mind, one can now examine and compare policies regarding payment for generic drugs in four provinces — Ontario, Quebec, Saskatchewan, and British Columbia.

ONTARIO'S RESPONSE: HARD PRICE LIMITS AND NO REBATES

Historically, Ontario had a system in which the generic price ceiling was set at 70% of the brand-name price when the first generic entered and 63% when there were multiple generics. Manufacturers paid large rebates to pharmacies, but prices paid by payers typically were not reduced below the price ceilings. Generally, all payers in the province paid the price listed in the formulary.

In response, the Government of Ontario elected to capture rebates by setting a lower reimbursement price for sales covered by the Ontario Drug Benefit (ODB) program. Under the *Transparent Drug System for Patients Act, 2006*, the province now requires that the ODB reimbursement price of a generic listed in the formulary be capped at only 50% of the reference brand-name price at the time the generic is listed.[36] (An exception to the 50% rule is sometimes made for drugs for which there is only one interchangeable generic product.) The effect of the Ontario legislation has been a reduction of 15% to 20% in the price of generic drugs to the province.

The *Act* also authorized the newly created Executive Officer of the ODB program to negotiate rebates with drug manufacturers.[37] Such negotiations allow the ODB to list drugs at high prices, while receiving confidential rebates. These rebates are likely chiefly paid on sole-source products, although there is nothing to prevent their being used for generically available products as well.

The *Act* made the payment of rebates to pharmacies unlawful, and adjusted mark-ups charged by pharmacies as well as the dispensing fee.[38] The *Act* did, however, allow manufacturers to pay pharmacies "allowances" for "professional services" to patients, such as patient education days, but, for sales insured under the ODB, these allowances cannot be greater than 20% of the price of the drug. Because the allowances must not be rebates, pharmacists are required to report the use of the professional allowance monies received for products dispensed under the ODB program, as well as the total amount of professional allowances.[39] Such reporting might, however, create a substantial burden on pharmacies. Pharmacies can also be separately compensated by the Ministry of Health and Long-Term Care for enhanced patient counselling and other professional services.

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36 See Ontario, Ministry of Health and Long-Term Care, Ontario Public Drug Programs, Office of the Executive Officer and Assistant Deputy Minister, "Re: Submission Requirements for Generic Drug Products" (Toronto, 25 September 2007). Available at http://www.health.gov.on.ca/english/providers/pub/drugs/dsguide/docs/submit_req_generic_drug_20071105.pdf.

37 ***Ontario Drug Benefit Act*** - O. Reg. 201/96, 12.1 (1) 7.

38 Pharmacies are permitted a mark-up of 8% on the ODB price, plus a dispensing fee of $7 per prescription.

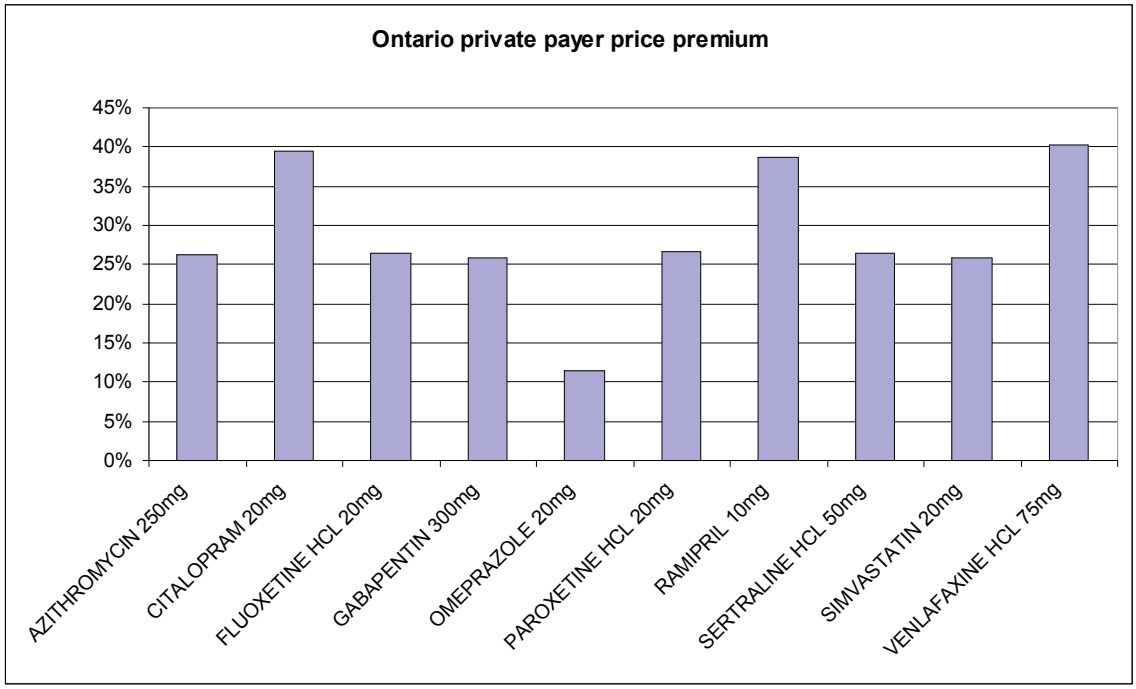
39 Ontario, Ministry of Health and Long-Term Care, Ontario Drug Benefit Program, "Notice from the Executive Officer: Reporting Framework for Professional Allowances" (Toronto, 6 March 2008); available at http://www.health.gov.on.ca/english/providers/program/drugs/opdp_eo/notices/ reporting_framework_20080306.html. The total amount to be reported includes drugs paid for privately as well as those of the ODB.

The *Act* also made a few smaller changes, including permitting the interchangeability of "same or similar" medicines, which, in turn, has facilitated the interchangeability of tablets and capsules; and it enabled "off-formulary interchangeability" so that generics could be substituted for brand-name drugs that were not listed as a benefit in the formulary.

The "Transparent Drug System" and Private Payers

One of the most important aspects of the *Transparent Drug System for Patients Act* is that its chief application is to drugs sold in the public sector, so that there is now a separation between private and public sector drug prices. Private sector drug prices have stayed at approximately the old level, while ODB prices have fallen considerably; as Appendix 2 shows, there has been no significant change in costs for private payers in Ontario since 2005. As of early 2008, for private plans, the price premium on generic drugs was approximately 30% over the public price (see Figure 1). Similar differentiation applies to other fees charged by pharmacies: while the dispensing fee for ODB drugs is $7 per prescription, pharmacies may charge "usual and customary" dispensing fees of their choosing to other payers; such fees currently range from $1.99 to $16.95 for payers not in the public sector.[40]

Figure 1: Private Payer Price Premium, Ontario, 2008



Notes: Figure shows the percentage by which private payer prices were above public payer prices for each product in the first quarter of 2008. Prices include mark-ups but not dispensing fees.
Sources: Private prices are from the Brogan Private Payer Database; public prices are abstracted from the ODB List.

40 Ontario, Ministry of Health and Long-Term Care, "Ontario Drug Benefit: Dispensing Fees" (Toronto); accessed 20/06/08) at http://www.health.gov.on.ca/english/public/pub/drugs/dispense.html.

While rebates are not payable even for drugs outside the ODB, there is no cap on allowances relating to professional services. The set of services for which pharmacies may be paid is precisely defined by regulation. However, this set of services is quite wide, and probably enables some scope for creative accounting.[41] Given that money is fungible, an allowance paid to support "pharmacy staffing costs for patient care activities, including counselling services" might be just as good to the pharmacist as an unrestricted rebate.

There are other reasons to suspect that it might be difficult to control payments to pharmacies. A national pharmacy chain can negotiate on the basis of stores in all provinces, and arrange that rebates be paid only in respect of sales in some provinces. Such a strategy, on the face of it, would comply with the Ontario regulations but in effect would be no different from a manufacturer paying the same total rebate, including in Ontario.

Industry participants have indicated to me that, if one were to treat professional allowances as rebates, the average level of rebates has not changed nationally since the implementation of the *Transparent Drug System for Patients Act*. Professional allowances are perceived as nothing more than rebates, and the fact that allowances are capped at 20% only for ODB sales is clearly meaningless, since this simply drives up the amount of allowances reported for non-ODB sales.

Ontario's drug system thus has become, in effect, two systems. There is a public system, in which generic drugs are priced at 50% of the brand-name price, professional service allowances are capped at 20% of the generic price, and mark-ups and dispensing fees are strictly controlled. And there is a parallel private system, in which the same pharmacies render exactly the same services for the same set of drugs, but charge much higher prices, mark-ups, and dispensing fees, and are paid large "professional allowances" by generic manufacturers. In effect, the costs of pharmacy are being borne disproportionately by private payers, who receive the same services for much higher prices.

One might imagine that cash-paying consumers and employers should be able to negotiate better deals with pharmacies. That this is not easy to do is shown by the fact that no such deals appear to be materializing. The failure to negotiate lower prices is due to the lack of market power exercised by employers and patients. Moreover, insured patients lack incentives to search for low prices. A patient with private insurance who obtains a prescription from the doctor is not much interested in the price of the drug if it is covered by insurance. Even if a co-payment is required, it might be a fixed amount or some fraction of the price, the out-of-pocket expense of which the patient hardly feels, particularly compared to the inconvenience of shopping around to other pharmacies for a product whose relative price is unknown.

This rather small elasticity of demand on the part of insured consumers means that employers, if they are to control expenditures on drugs by their employees and other insured parties, must either increase the size of co-payments, which tends to defeat the purpose of the insurance, or else negotiate with pharmacies to ensure better deals. Negotiating with pharmacies, however, requires the employer to have some bargaining power, and this essentially means directing insured patients to preferred pharmacies that offer better prices and refusing to pay the full price at other pharmacies.[42] Patients, however, dislike this kind of limitation, since it might involve travelling long distances to a preferred pharmacy, and employers who sponsor private drug plans would rather not face that kind of dissatisfaction, which

41 See ***Ontario Drug Benefit Act*** - O. Reg. 201/96, Section 8.

42 Appendix 5 describes the use of "Pharmacy Benefit Managers" in the United States, which enables the exercise of significant market power over pharmacies.

can lead to expensive complaints. The position of employers is particularly constrained when a union contract specifies the characteristics of the drug plan.

The Effect of Secret Rebates

One power of the ODB Executive Officer is to negotiate secret rebates with drug manufacturers. This allows the manufacturer to list one price in the formulary and to pay secret rebates based on ODB product volume to the province. This is an attractive feature of the system for both brand manufacturers and the government, since manufacturers can set high public prices for their products without losing sales to the ODB, although these high prices might have repercussions on prices paid by private payers, not only in Ontario, but also elsewhere in Canada and even in other countries. In some cases, the manufacturer might also be able to obtain supplementary sales. Two interesting examples are the products Fosavance and Coversyl.

Fosavance

Fosavance, made by Merck, is used to treat bone-density loss. It is a fixed-dose combination pill of 70 mg of alendronate and 2,800 IU of vitamin D_3, and is priced on the ODB list at $9.765 per tablet.[43] In turn, alendronate (under the brand name Fosamax) is available generically on the ODB list at $4.425 for a 70 mg tablet, while 3,000 IU of vitamin D_3 can be purchased for less than $0.25 – thus, the cost of the combination of products is approximately $4.675. Clearly, the ODB does not pay $9.765 for each unit of Fosavance, but more likely approximately $4.425 after accounting for the rebate, and perhaps even less. How does this affect other payers in Ontario? The fact that Fosavance is a benefit under the ODB (though not in other provincial drug insurance programs) makes it easier for physicians to prescribe it widely. This, in turn, increases the cost to private insurers, who are paying an extra $5 per pill. It might also harm generic manufacturers of alendronate, since their product is not interchangeable with Fosavance. (Notably, without generic sales of alendronate, the ODB would not be able to obtain a low price on Fosavance.)

Coversyl

Coversyl is an ACE (angiotensin-converting enzyme) inhibitor used to treat hypertension. Recently, the 8 mg dosage of the drug became generically available in Canada as Apo-perindopril. When the generic manufacturer, Apotex, approached the ODB for a listing at a price equal to 85% of the brand-name price, the Executive Officer refused to list it either as a benefit or as an interchangeable product, giving as the reason that an agreement had been reached between the ODB and Servier, the manufacturer of Coversyl. While details of the agreement are not public, it seems likely that Servier is paying a secret rebate to the province.[44]

The Executive Officer controls access to two important lists: the list of drugs that the ODB reimburses, and the list of drugs that can be dispensed interchangeably. A product that is interchangeable but not reimbursed cannot have any financial implications for the ODB. Thus, while the Executive Officer's decision not to list Apo-perindopril as a benefit would make sense if the net price of Coversyl (after confidential rebates to the province) were below the list price of the generic, the refusal to list the generic as an interchangeable product harmed all other payers in the province, none of whom benefited from secret rebates on Coversyl, without any apparent benefit to the province.

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43 For ODB drug prices, see Ontario, Ministry of Health and Long-Term Care, "Drugs Funded by Ontario Drug Benefit (ODB) Program"; available online at http://www.health.gov.on.ca/english/providers/ program/drugs/odbf_eformulary.html.

44 Details of this case are available in ***Apotex Inc. v. Executive Officer for the Ontario Public Drugs Programs and Attorney General of Ontario***, Ontario Superior Court, Court File 518/07, 8 June 2008. Servier sued Apotex for patent infringement and was awarded a decision in its favour in July 2008. Subject to appeal, Apotex will now have to pay damages for all sales of the generic, vindicating its decision not to list in Ontario at 50% of the price of the brand-name product. Following further litigation, the generic is now listed as interchangeable with the brand-name drug but not as a benefit.

To summarize, the province appears to have made an arrangement with one particular firm, which has had the effect of preventing competition that would benefit Ontario consumers while starving the firm that created the competition. In responding to Apotex's complaint about its treatment, the Executive Officer noted that she has "broad discretionary powers to list drugs in the Formulary where she is satisfied that it is in the public interest to do so."[45] Here, however, the definition of the public interest appears to be restricted to the short-term interests of the Ontario government, since private payers were clearly paying higher prices because of the Executive Officer's refusal to list Apo-perindopril as an interchangeable product and because, in the long term, even the Ontario government cannot benefit from deterring generic firms from challenging patents and thus enabling competition.

Before the implementation of the *Transparent Drug System for Patients Act*, the ODB, in effect, acted as a gatekeeper with respect to drug prices for all Ontario residents — indeed, at that time, drug prices were transparent. The effect of the *Act* has been to allow the Ontario government to reduce the costs of its own drug purchases, in part by sacrificing private payers to a much less attractive system in which they are facing less transparent prices than before.

Moreover, Ontario has constructed the price system very strangely, given its desire to achieve lower costs for the province. In many cases, the cost of manufacturing and distributing generic drugs is well below even the Ontario generic price. For example, a comparison of the ODB price per pill for several major products (omeprazole, amoxicillin, simvastatin) with prices available in the United States reveals that the US prices are considerably lower. The effect of the 50% price rule is thus to leave prices far above US prices for at least some products, as one would expect from such an arbitrary rule.[46] When one compares Ontario's prices and the lowest international prices, the former seem very far out of line — indeed, international export prices for some products are a small fraction of the generic price paid by the ODB (see Table 2).[47] One should be careful in interpreting this comparison, and it indicates nothing about the competitiveness of the generic suppliers in Canada, who are providing at the specified price and, on the basis of the high prices at which they are selling these products, are offering pharmacies quite substantial rebates or "professional allowances." Indeed, these are products for which many manufacturers hold an NOC, so there is no reason to suspect a lack of competition among the manufacturers. What the table does indicate is that provincial governments likely could obtain much lower prices for many products.

45 ***Apotex v. Executive Officer***, Ontario Superior Court, Court File 518/07, Factum of the Respondents, p. 2.
46 For a recent study comparing Canadian drug prices to US prices, see Skinner and Rovere, ***Canada's Drug Price Paradox 2008***. The price comparisons there are for average national prices in Canada with some amalgam of US prices. The data show clearly that Canadian generic drug prices tend to be relatively high, especially for some products.
47 One point of caution is that, in Canada, generic drugs are usually sold in the same colour, size, and shape as the original branded drug, rather than as a standard round white pill. It is somewhat more expensive to duplicate the unusual shapes of branded pills, so it might not be possible for generic manufacturers in Canada to match the lowest international prices.

Table 2: ODB vs. International Pricing, Selected Drugs				
Product	**ODB Brand Reference Price**	**ODB Generic Price**	**Number of NOCs Granted**	**Durbin Price**
Omeprazole 20 mg	$2.20	$1.10	5	$0.09
Ciprofloxacin HCl 250 mg	$2.47	$1.11	12	$0.04
Amoxicillin 250 mg	n/a	$0.17	10	$0.02

Note: The sample here is constrained by the relatively small set of products available through Durbin. However, there are competitive suppliers of other generic products with similarly low pricing. The Durbin prices are available only for a limited set of medicines, and prices quoted are not necessarily for drugs manufactured in facilities approved by Health Canada.
Source: Durbin PLC; accessed (20/06/08) at http://www.durbin.co.uk/exports.htm.

Ontario instituted, in late 2008, a tender system to address this failure of the existing mechanism to achieve low prices for the ODB system. The tender system is to be used for multi-source generic products for which the current generic price in Ontario appears to be far above the actual average costs of production. Because the complexity of the tender system introduces many additional considerations, I address the mechanism later in this paper, after examining more straightforward tender systems that have been implemented in Saskatchewan and British Columbia.

Viewed in the framework of the principles proposed above, the current Ontario system of pricing generic drugs fails to satisfy principle 2 (encouraging competition) in cases such as perindopril, where the Executive Officer inhibits competition. In such cases, the manufacturer of the generic that has invested in the patent challenge is not rewarded, and so there is no inducement to create competition through eliminating legal barriers to entry. The current Ontario system also fails to ensure that the benefits of competition are passed on to payers (principle 3) since, for private payers, prices have remained high, and even for the ODB, prices are not reduced to levels that reflect the underlying costs. It also fails to satisfy principle 5, since prices vary significantly for different payers, and it fails to satisfy principle 7, since both private payers and buyers of generic drugs make a disproportionate contribution to the costs of pharmacy. Indeed, the only principles the Ontario scheme seems to satisfy are numbers 1, 4, and 6.

QUEBEC'S RESPONSE: HARD PRICE LIMITS AND LOWEST-PRICE REQUIREMENTS

Quebec modified its generic drug regime with the 2006 *Loi sur l'assurance medicaments* (Bill 130). Like Ontario, Quebec has a bifurcated system with price controls on the products insured by the Régie de l'assurance maladie du Québec (RAMQ) and no limits on prices charged to private payers. Quebec also has a number of special regulations.

The 2006 changes limit generic drug reimbursement under the RAMQ to 60% of the innovator drug price if there is only one generic product and 54% of that price when there are two or more generic competitors. However, in many cases, this law is not binding, since Quebec imposes a "most-favoured-nation" clause that requires the manufacturer to commit not to charge the RAMQ a higher price than t does any other provincial drug insurance program.[48] Since the ODB requires prices at 50% of the

48 According to the ***Loi sur l'assurance-médicaments***, Règlement sur les conditions de reconnaissance d'un fabricant de médicaments et d'un grossiste en medicaments, Annexe I, Engagement de fabricants, "Le prix de vente garanti...ne doit pas être supérieur à tout prix de vente consenti par le fabricant pour le même médicament en vertu des autres programmes provinciaux d'assurance de médicaments" [The price must not be higher than any price granted for the same medicine by the manufacturer

reference drug price, the effective price listed for most generic drugs in Quebec is the same as in Ontario. Quebec also limits the margin that wholesalers can earn for sales made under the RAMQ, and forbids rebates of any sort. As in Ontario, there is a cap of 20% of the drug price for professional allowances; unlike in Ontario, this appears to apply to all generic drugs that are included in the basic plan, even for private insurers.[49]

Since the implementation of Bill 130, prices of drugs have been permitted to rise at the rate of inflation annually. (This corresponds to the principle established by section 85 of the *Patent Act*, which allows consideration of the rate of inflation in the determination of "excessive price" by the PMPRB.) For generic drugs, however, no inflation adjustment can be expected, since Quebec's most-favoured-nation price clause interacts with Ontario's regulations, which lack any similar inflation adjustment mechanism.

The price limits imposed by the RAMQ do not apply to other payers, and prices for private payers in Quebec are much higher than those obtained by the RAMQ. Margins and dispensing fees for private payers are also unregulated. However, rebates are prohibited, and professional allowances, as mentioned above, appear to be restricted to 20%, even for drugs sold to private payers. This combination of rules makes Quebec's generic drug market an outlier in Canadian drug pricing. Prices for private payers are extraordinarily high compared with prices elsewhere in Canada for the same drugs, principally due to very high mark-ups, which, as Appendix 2 shows, average over 50% for major generic drug products. Thus, pharmacies, rather than using rebates or professional allowances, appear to be successfully capturing profits by charging substantial mark-ups to private payers. (The Quebec market appears to be in the process of adjusting to the new rules, so it is likely that these high prices might not be sustained over the next few years.)

Quebec has one other special rule that somewhat affects generic sales: it permits RAMQ reimbursement of the brand-name medicine at the full price for 15 years following its inclusion in the provincial formulary, even if generic competitors have entered during that time. This naturally reduces the sales volumes of generics in many cases, so that the proportion of prescriptions filled with generic drugs in Quebec (42%) is substantially less than in the rest of Canada. (In Alberta, for example, the generic proportion is almost 10% higher.)

As in Ontario, generic drug pricing in Quebec fails to ensure that the benefits of competition accrue to consumers through price reductions. It also allows for very unequal prices between private and public payers. The most-favoured-nation clause that requires manufacturers not to grant any other provincial drug program a lower price fails to satisfy principle 6 (provincial policies should not be enacted that would harm all provinces if replicated).[50] This policy has particularly harmed Saskatchewan's ability to obtain low generic drug prices (as we will see in the next section). Arguably, it has also caused British Columbia to engage in subterfuge to avoid the effect of this comparison. There are two objections to this policy.[51] First, it tries to win lower drug prices for Quebec through a process that undermines the ability of other provinces to obtain lower drug prices for themselves. Second, if other provinces were to imitate Quebec, they, in turn, would reduce Quebec's ability to obtain lower prices. In the context of drug price

to other provincial drug insurance programs].

49 Regulation respecting benefits authorized for pharmacists, R.Q. c. A-29.01, r.1.01. The regulation requires the pharmacy to keep a record of the allowances received, but not of how the allowances were spent, unlike in Ontario. This regulation also specifically refers only to generic drug manufacturers, not to brand-name manufacturers. Thus, a brand-name manufacturer facing generic competition could offer larger professional allowances than its generic competitors.

50 For further commentary on this issue, see Canada, Competition Bureau, ***Benefiting from Generic Drug Competition in Canada: The Way Forward***.

51 The ***Patent Act*** (S. 85(1)(c)) also explicitly endorses a comparison with other countries in determining whether a drug price is excessive.

negotiation, the bargaining power of provincial drug insurance plans to obtain price reductions is based on the threat that, if no reduction is granted, the drug will not be listed. If all provinces were to imitate Quebec, the costs to the manufacturer of lowering the price in one province to obtain a listing would be amplified, since it would then have to lower the price in all provinces. In effect, Quebec's policy weakens the bargaining power of each province since the threat of not listing in one province cannot possibly induce the manufacturer to lower the price there, since it would have to match the price drop in all provinces.

SASKATCHEWAN'S RESPONSE: "STANDING OFFER CONTRACTS"

Saskatchewan, unlike Ontario and Quebec, has a one-tier system in which the price for the province is the same as the price for other payers.[52] The province's public insurance system is universal in the sense that all residents are eligible for coverage under the provincial plan once they have reached a deductible for the year.

Saskatchewan is unique in Canada in that, for many years, it has used a system of "standing offer contracts" (SOCs) for some generic drugs. Under the SOCs, the government seeks tenders for a single firm to supply the entire province for a fixed period of time at the price specified in the tender. In return, the manufacturer's product is used exclusively, except by individuals who have a medical need for an alternative product or if the manufacturer is unable to meet the demand. Only the drug of the firm that wins the contract can be used to fill a prescription in an interchangeable group with an SOC. If a prescription is written as "no substitution" for any brand other than the winning firm, provincial insurance will cover the actual acquisition cost up to the listed unit price of the winning firm. Any excess is the responsibility of the consumer.

An important part of the SOC mechanism is that manufacturers that participate in these tenders are not required to pay any rebates to the pharmacies and, therefore, are better able to offer low prices. The SOC mechanism thus provides meaningful savings to the Saskatchewan government and to consumers, estimated to be approximately $13 million in fiscal year 2006/07.[53] There are currently 46 molecules in the SOC mechanism in Saskatchewan. Appendix 4 lists and compares the prices of all products for which there was an exact match in the Ontario formulary; for most products, the Saskatchewan SOC price is slightly less than the ODB price – on average, the price in Saskatchewan is 92% of the Ontario price.[54] After accounting for different mark-ups and dispensing fees, however, the savings to the Saskatchewan government are rather small. In Ontario, the maximum dispensing fee is $7 per prescription and the mark-up is 8% on all products; in Saskatchewan, the dispensing fee is $8.63, while the mark-up averages over 10% for generic drugs.[55] Thus, in Ontario, for a drug with a wholesale price of $25, the total price paid to the pharmacy would be $34, including mark-up and dispensing fee. In Saskatchewan, if the drug's wholesale price were 92% of the Ontario price, it would be $23; adding the mark-up and dispensing fee, the total amount paid to the pharmacy would be $33.93, a cost savings of 7 cents. The higher mark-up and dispensing fee paid in Saskatchewan might in part compensate pharmacies for the fact that, under SOCs, they receive no rebates or professional allowances from generic manufacturers.

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52 Notably, the ***Prescription Drugs Act*** (s. 5(d)) specifically authorizes the Minister of Health to determine "the amount that may be charged to a resident for the purchase of a drug dispensed in the pharmacy if such drug is listed in the formulary," quite separately from the Minister's authority to determine the amount paid by the government for insured drugs.

53 See Saskatchewan, Ministry of Health, Drug Plan and Extended Benefits Branch, "About the Saskatchewan Formulary" (Regina); accessed online (26/05/08) at http://formulary.drugplan.health.gov. sk.ca/.

54 This percentage is only an average of the prices, and does not account for volume.

55 In Saskatchewan, the maximum mark-up allowance calculated on the prescription drug cost is 30% for drug costs up to $6.30, 15% for drug costs between $6.31 and $15.80, 10% for drug costs between $15.81 and $200.00, and a maximum of $20.00 for drug costs over $200.00. Prescriptions filled with generic drugs rarely exceed $200.

Private payers clearly benefit from the SOC mechanism. As Appendix 2 shows, for private payers, the average price of drugs for which Saskatchewan used an SOC was considerably below that in other provinces. In contrast, private payer prices in Saskatchewan tend to be high for other products.

One limitation on the effectiveness of the SOC mechanism is that the aggressiveness with which most generic manufacturers can compete for an SOC is hindered by the Quebec interprovincial price comparison. The costs of supplying an SOC in Saskatchewan are relatively low, so one should expect low prices. In the SOC mechanism, the manufacturer deals with two wholesalers and pays no professional allowances, and payment is guaranteed within 30 days. In contrast, in Quebec, sales are made either directly to pharmacies or through a wholesaler, without any guarantee of payment and often with a prompt discount of 2% for payment made within 30 days. When sales in Quebec are made through a wholesaler, the wholesaler typically requires a margin of between 5% and 7.5%.[56] In addition, the Quebec government allows professional allowances of up to 20% of the price of the product, which are not paid in Saskatchewan for SOC drugs. Thus, since the costs of doing business as the sole supplier are considerably less in Saskatchewan than as one of many competing manufacturers in Quebec, the comparison between Saskatchewan and Quebec prices is not only unfair, but is harmful to the ability of generic firms to drop their Saskatchewan prices as much as is justified by the cost differences.

Thus, firms that wish to bid aggressively on the Saskatchewan SOCs are effectively inhibited from participating in Quebec, where they cannot profitably sell at the same price. Generic manufacturers have tried to evade this problem by selling to the SOC through small generic firms, which, of course, increases costs without any accompanying social benefits.[57] As a result, only two generic firms actively participate in the Saskatchewan SOCs: Nu-Pharm and Dominion. Thus, competition in Saskatchewan is likely to be less aggressive than one would expect if there were more firms bidding on the SOCs. It also explains why the prices in the Saskatchewan SOC are not particularly favourable for the province, and the lack of participants renders the continuing viability of the SOC system somewhat questionable.

There are two further objections to the SOC system. First, since the SOC mechanism leads to only one particular drug being available in each interchangeable group, this can be problematic for consumers who respond better to a different drug in the interchangeable group. Such differences might be rare, and the SOC mechanism does allow for "no substitution" prescriptions, but even then, the patient might have difficulty obtaining a drug that is not sold anywhere in the province. For pharmacies, the SOC mechanism could be problematic if the sole supplier is unable to provide the drug in sufficient quantities to meet demand — one advantage of a system with many suppliers is that if one firm faces a manufacturing or distribution problem, others can fill the gap. (Again, however, this problem could be addressed simply by purchasing from other manufacturers in such cases.) This suggests that the SOC mechanism is slightly less attractive than other mechanisms with respect to ensuring stability and security of supply.

The second objection to the SOC mechanism is that it might lead to reduced competition, for two reasons. First, it might reduce the number of firms actively engaged in producing a given drug, which, in turn, could reduce their interest in participating in the SOC process in the future on a given drug. Second, it might weaken somewhat the benefit of generic litigation, since, by giving no preference to early entrants, the process lessens the advantage to the firm of being the first to enter the market.[58]

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56 For a summary of these differences, see ***Nu-Pharm inc. c. Québec (Ministre de la Santé et des Services sociaux)***, R.J.Q. 2478, 36 Admin. L.R. (3d) 256, REJB 2000-20194, J.E. 2000-1857.

57 See Chiles, Letter to the PMPRB, 9 May 2005.

58 See Aidan Hollis, "The Importance of Being First: Evidence from Canadian Generic Pharmaceuticals," ***Health Economics*** 11(8, 2002): 723-734.

With respect to the other principles outlined earlier, however, the SOC process appears to work well. Could Saskatchewan's approach work for Alberta? There are a few points to note. First, tendering appears to be less well suited for some products than for others. For example, it does not appear to be suitable when there are only a few players in the market, since they have weak incentives to undercut each other; the system is likely to be more effective when there are many competing manufacturers. Thus, tendering should be used only on a case-by-case basis, and the province still needs to have an alternative mechanism that would apply, at least initially, to every generic product. Tendering, in other words, might be useful in some situations, but it can only be supplementary to some other approach.

Second, tendering creates a situation in which, at the end of the tender period, all patients could be required switch to some alternative, resulting in confusion and inconvenience for some and, in exceptional cases, others might not derive any benefit from the new product.

Third, as discussed above, tendering might significantly harm the benefit from being the first generic and thus harm the incentive to challenge patents.

Fourth, because tendering leaves no room for unsuccessful bidders to supply the drug, in time those firms might become less competitive manufacturers of the product. In turn, this reduces competition, leaving the successful tenders themselves less able to achieve their goal of low prices.

Finally, tendering seems likely to achieve only limited price reductions when a single list price applies to all buyers, because of the Quebec price comparison.

BRITISH COLUMBIA'S RESPONSE: TENDERING WITH SECRET REBATES

British Columbia's drug-pricing system resembles Saskatchewan's in that prices tend to be the same for private and public payers. British Columbia also has introduced some innovations that affect generic drug pricing – namely, reference drug pricing and tendering with secret rebates.

British Columbia uses reference pricing for a number of groups of drugs, such as proton pump inhibitors and ACE inhibitors. In each class, the Ministry of Health has classified certain products to be subject to a maximum price, determined by the price of a reference drug within that class. The provincial drug insurance plan, PharmaCare, will pay only up to the maximum price, and patients are responsible for any excess. This policy applies to both generic and brand-name products, and clearly has the largest effect on the latter. Reference pricing does not imply substitution at the pharmacy, and, in effect, is a way of controlling costs.

British Columbia has also experimented with tendering.[59] Saskatchewan's difficulties with its tendering process because of Quebec's interprovincial price comparison test are well known. In response, British Columbia has instituted a sole-sourcing arrangement for a generically available drug in which a single firm is contracted to be the only supplier for the province of a drug listed as a benefit under PharmaCare. This single supplier may charge a high price, but must pay a rebate to PharmaCare for every sale made of a drug that PharmaCare fully or partly insures. The rebate amount is confidential under the agreement, which avoids the problem of the Quebec inter-provincial comparison creating a floor price.

59 This section draws heavily from Aidan Hollis, "The Use of Secret Rebates by Provincial Drug Insurance Agencies: What Impact on Patients?" IAPR Policy Brief 08001 (Calgary: University of Calgary, Institute for Advanced Policy Research); available at http://www.iapr.ca/files/iapr/iapr-pb-08001.pdf.

British Columbia's sole-sourcing mechanism is now in use for one product, olanzapine, that is generically available everywhere in Canada except British Columbia, where only the brand-name product Zyprexa, made by Eli Lilly, is widely available. British Columbia's approach results in substantially higher prices for consumers whose purchases are not 100% insured by PharmaCare.

Novopharm, a generic drug manufacturer, challenged Lilly's patents on the grounds of invalidity under the NOC regulations. Lilly abandoned one infringement claim and a second patent was declared invalid, and Health Canada granted Novopharm an NOC to sell Novo-olanzapine, a generic form of the drug (Pharmascience has also received an NOC for its generic, PMS-olanzapine). Other provinces have listed Novo-olanzapine in their formularies at substantial discounts to Zyprexa.

In December 2007, the BC government issued a "Request for Proposals," offering firms the right to be the sole supplier of olanzapine to be listed in the provincial formulary. The contract does not bar other manufacturers from selling olanzapine in British Columbia provided they have obtained an NOC from Health Canada. In practice, however, it means that no competing firm can make meaningful sales of olanzapine since consumers whose purchases of the drug are insured by PharmaCare certainly will prefer to buy the sole-sourced item rather than a form of the drug that PharmaCare does not cover. Similarly, consumers whose purchases are covered by private insurance will prefer the sole-sourced product if their insurer's formulary is aligned with that of PharmaCare,[60] while uninsured consumers will prefer to purchase the sole-source olanzapine since that brings them closer to their deductible limit.[61] In these circumstances, since demand for competitive, lower-priced olanzapine is so small, most pharmacies are unlikely to stock it.

In their proposal, firms had to include two prices: a list price at which the drug would be listed and sold to consumers, and a confidential "cost recovery amount" or rebate that the firm would pay to the province for each pill insured in whole or in part by PharmaCare. Thus, the criterion for a successful proposal was not the price paid by the consumer, but the net price paid by PharmaCare.[62] In these circumstances, the obvious strategy for the winning firm is to charge a very high list price and offer a large rebate to PharmaCare.

The Effect of Sole Sourcing on Prices and Consumer Welfare

PharmaCare defends its sole-sourcing strategy on the basis that "the province is acting in the public interest to achieve the lowest drug prices possible for the people of British Columbia." Yet, as the comparison in Table 3 of current wholesale prices of olanzapine in British Columbia and Alberta 3 shows, BC consumers whose purchases of olanzapine are not 100% covered by PharmaCare (or by private insurance) pay 63% more than they would in the absence of the sole-sourcing agreement. These data suggest that PharmaCare is receiving a secret rebate sufficiently large to lower the net price of insured olanzapine below the generic price available in the rest of Canada. Moreover, PharmaCare is able to obtain this low price only by allowing the manufacturer to charge more for olanzapine purchased by consumers who are not fully insured by PharmaCare.

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60 Some employers allow a more comprehensive formulary that includes products not in the PharmaCare formulary. While the employers would prefer the insured to purchase the drug listed as a benefit, in order to bring the insured person closer to the PharmaCare deductible limit, it is possible that pharmacies might prefer to dispense a competitive generic product with a substantial rebate.

61 A drug that is not a benefit does not count as an eligible expense, a point confirmed by the author in a telephone call to the PharmaCare help desk, 15 May 2008.

62 The "Request for Proposals" specifically states that the list price will be relevant in determining the winner only if the net prices offered by two firms are identical.

Table 3: Prices for Olanzapine, British Columbia and Alberta			
Dosage	**British Columbia**	**Alberta**	**Price Difference**
	($)		*(%)*
2.5 mg	1.92	1.18	63
5 mg	3.85	2.36	63
7.5 mg	5.77	3.54	63
10 mg	7.69	4.73	63
15 mg	11.54	7.09	63

Source: All figures are drawn from the British Columbia and Alberta formularies as of November 2008.

It is apparent why PharmaCare finds this an attractive solution: it is able to obtain a low price on all sales that are 100% insured. And on sales that are partially insured, PharmaCare's savings are even larger, because the co-payment made by the consumer is a fraction of the high list price. The effect on patients, private insurers, PharmaCare, and sellers is illustrated in Table 4, which assumes a secret rebate of $3.00 per 10 mg tablet. As the table shows, for patients whose drugs are covered by PharmaCare (at least in part), the total price paid to the seller may in fact be lower than with competitive sales; however, the seller is compensated by being able to charge higher prices for purchases that are not covered by PharmaCare. So, while PharmaCare's costs are reduced, British Columbia residents, whether they are covered or not, end up paying more for their drugs when they are sick.

Table 4: The Effect of Secret Rebates on Payers				
	Private Insurance or No Insurance		**Insured by PharmaCare with Co-payment**	
	Competitive Market	Sole Sourcing	Competitive Market	Sole Sourcing
Price for 10 mg tablet	$4.73	$7.69	$4.73	$7.69
PharmaCare contribution	$0.00	$0.00	$3.31	$5.38
Assumed secret rebate	$0.00	$0.00	$0.00	$3.00
Net cost to PharmaCare	$0.00	$0.00	$3.31	$2.38
Net cost to patient	$4.73	$7.69	$1.42	$2.31
Revenue of seller	$4.73	$7.69	$4.73	$4.69

Note: The table assumes a secret rebate of $3.00 to PharmaCare. Prices are as listed in the formulary and do not include mark-ups or dispensing fees. In the case of partial insurance by PharmaCare, sole sourcing with secret rebate means that patients pay a co-payment based on the nominal, not the real, price.

It is even possible for the rebate to PharmaCare to be larger than the amount that it pays, so that PharmaCare could make profits from "insuring" certain drugs. For example, suppose in the above example that the rebate to PharmaCare was $5.50 per 10 mg tablet. The seller could be willing to pay a large rebate if it received the right to charge a high price on all purchases, including those not covered by PharmaCare. In this case, PharmaCare's contribution to the cost of the drug would be only $5.38, so for every pill consumed, PharmaCare would make a *profit* of $0.12.

An Evaluation of Tendering with Secret Rebates

The sole-sourcing approach with secret rebates is problematic in a number of ways. First, it obviously fails to satisfy principle 5 – that of having the same prices for all payers in the province. In fact, it fails this principle in an extreme way because it obtains low prices for the province in part by enabling high prices for other payers.

Second, it fails to satisfy principle 3 – that the benefits of competition should accrue to payers, since at least some payers are denied these benefits.

Third, it fails to satisfy principle 2 – that of encouraging competition. Normally, the firm with lower costs will win the tender contract. Certainly, that would be a desirable outcome from the perspective of efficiency. The firm with a tender that includes secret rebates, however, distorts the outcome, so that what matters is not so much how low the firm's costs are but how high a list price the firm can charge. This is so since the firm can, in effect, subsidize its low net price by charging a high list price. Indeed, Lilly increased the list price of Zyprexa following the BC "Request for Proposals." Had Novopharm tried to charge such a high list price for its generic, it likely would have found it hard to make significant sales to privately insured or cash-paying customers, since private insurance likely would have continued to permit reimbursement for the brand-name product Zyprexa.[63] In other words, the mechanism of tendering with secret rebates favours the brand-name product because of the expectations of pricing for generics and brand-name products and the willingness of private insurers to reimburse brand-name products.[64]

The disabling effect of tenders with secret rebates on competition also extends to the incentives for generic firms to challenge patents. In the case of olanzapine, Novopharm lost any advantage in British Columbia from being the first generic manufacturer to obtain an NOC for the drug since other manufacturers of the generic, such as Pharmascience, have now also obtained, or are in the process of obtaining, NOCs. Thus, by the time the British Columbia government issues its next tender contract for olanzapine or opens up this market to ordinary competition, Novopharm will have no advantage over other generic manufacturers. Novopharm will have made a considerable investment in litigation and product development and BC PharmaCare will have obtained lower net prices because of it – but Novopharm will benefit not at all. This is not a recipe for encouraging generic firms to challenge patents they believe might be found invalid in court.

Tendering with secret rebates also fails to satisfy principle 7 – fair compensation of pharmacies by all payers – since the British Columbia government is essentially appropriating the rebates that normally would have been paid to pharmacies; the costs of pharmacy are therefore shifted onto the buyers of other drugs.

Hard Price Limits

Since the beginning of 2009, British Columbia has matched Ontario's pricing maximum by reimbursing

63 Pharmacies, on the other hand, might have preferred to dispense a generic product that carried a substantial rebate.
64 Another obstacle generic companies face in competing for these contracts is that pharmacies might demand their normal rebates based on sales of the product; these rebates are not normally paid by brand companies.

multisource generic drugs paid for under PharmaCare at a rate not exceeding 50% of the brand-name product price.[65] It is not yet clear exactly how this new approach will work – multisource generic drugs continue to be listed in the formulary at the old prices, implying that private insurers will now pay higher prices than the province.

ONTARIO'S NEW TENDERING PROPOSAL

Ontario, recognizing that the public drug plan was still paying prices well above the cost of manufacture for at least some generic drugs, has recently introduced a tender system. It resembles that of British Columbia in that Ontario receives secret rebates or volume discounts on all sales insured by the province; however, the formulary list price remains at 50% of the brand-name price. To enhance security and stability of supply, the original plan was for the tender to be awarded to two firms that would then have to compete for public sector sales, presumably by paying allowances to pharmacies on their private sector sales. The system includes many innovative features that have yet to be tested, and it is too soon to evaluate how successful it will be in achieving significantly lower net prices for the province.

The tender initially was proposed for four products, but for reasons the province has not disclosed, only one drug, enalapril maleate, has been included in the system and the sole winner of the tender was the brand manufacturer, Merck.

Nevertheless, the tender system seems likely to create various problems. First, it essentially is designed to reduce the price paid by the public drug plan, while leaving the private sector – employers and the uninsured – paying the same high prices. This would simply reduce the amount of the rebates pharmacies collect on their private sector sales, as firms that win the tender would have to pay secret rebates to the province.[66] Since the pharmacy service delivered in the public and private sectors is the same and the net price at which the pharmacy buys the product to supply the public and private sectors is the same, the tender system would have the effect of reducing the total amount of rebates pharmacies collect. In addition, private payers, rather than the province, would bear an increasing share of the costs of pharmacy. If the Government of Ontario deserves to benefit from low prices, why should residents of the province not obtain the same benefit?

A second problem with the proposed tender system is that it is likely to lead to a redistribution of revenues from existing incumbent manufacturers – which have made a substantial investment in early market entry and the development of relationships with pharmacies – to generic firms with no manufacturing facilities in Canada or to brand-name multinationals like Merck. This could lead to the loss of manufacturing jobs in Canada, with no obvious efficiency rationale. The net revenues of manufacturers fall only if there are substantial economies of scale beyond those already realized – which seems unlikely, given the global nature of the business – but, under the proposed system, revenues would be allocated differently among manufacturers, with those that have had a large share of ODB sales in the past likely to lose share to others.

A third problem is that the proposed mechanism would make it more profitable for pharmacists to dispense medicines that do not win the tender to patients who have both ODB insurance and

65 See British Columbia, Ministry of Health Services, ***News Release***, 12 December 2008; accessed online (11/01/09) at http://www2.news.gov.bc.ca:80/news_releases_2005-2009/2008HSERV0117-001892.htm.

66 At present, when a generic firm pays a large allowance to the pharmacy, it obtains both private and public sales. The public sales have a rebate of 20% on a price equal to 50% of the brand-name price – that is, the generic receives a net price of 40% of the brand-name price on all sales under the public system. Given a cost of supply below that level – say, 25% of the brand-name price – the generic must pay a very large allowance on private sales in order to obtain those profitable public sector sales. When the margin on public sector sales falls, the willingness to pay large private sector allowances also diminishes.

supplementary private insurance. This could result in the shifting onto private payers of a substantial fraction of prescriptions for which the ODB would normally pay.

Finally, because Ontario's proposed tender system, like those in Saskatchewan and British Columbia, would eliminate any benefit of early entry by firms that have invested in patent challenges, it is likely to reduce such investment and lengthen the arrival of competition from other generics, ultimately resulting in higher prices for all payers.

Ontario's proposed tender system, in other words, would continue to violate the same principles as does the existing system. It would certainly fail to satisfy principle 7 – fair compensation of pharmacies by all payers – since private payers would end up paying an even greater share of the costs of pharmacy. It would also fail to satisfy principle 2 to an even greater extent by very substantially reducing the incentive to challenge patents and to enable generic competition.

AN APPROPRIATE RESPONSE BY ALBERTA

In this paper, I have argued that Alberta should reconsider its methods of drug pricing and/or procurement to obtain lower prices, and I have reviewed the mechanisms four provinces have advanced to reduce the costs of their generic drug purchases and identified the strengths and weaknesses of each. Should Alberta adopt one of these mechanisms directly or with some appropriate modifications?

Any solution should deal with the two key problems of a lack of incentive for firms to challenge patents that are invalid or not infringed by competition, and the failure of competition from generic manufacturers to result in low prices for payers.[67] It would also be desirable to construct a solution that could be exported to other provinces: if more provinces had similar approaches, it would enable a more coherent national strategy with respect to generic drugs.

Saskatchewan's relatively successful use of the SOC process suggests that tendering (without secret rebates) is worthy of serious consideration. As I noted earlier, however, while tendering can be used successfully in cases where there are enough generic competitors, it is not likely to be desirable immediately upon the entry of a generic; in such a case, it would probably fail to generate low prices, and might well fail to provide *any* reward to a generic competitor that eliminated barriers to competition. Therefore, tendering should be used in association with another mechanism, which I describe below, in cases where it is inappropriate (such as in the initial period of generic competition, and for specific products for which tendering would be undesirable). Later, I discuss how tendering might operate in tandem with the mechanism I propose.

The core features of my proposal are: a descending maximum price; inflation indexing; a cap on rebates or other consideration granted to pharmacies by manufacturers directly or indirectly; an open formulary; and a "royalty" paid to the first generic entrant that has shown patent invalidity or developed a non-infringing alternative.

A Descending Maximum Price

In Ontario, the old regulations allowed for a maximum generic price equal to 70% of the brand-name price when only one generic was available. With two or more generics, the price fell to 63% of the brand-name price. Quebec now employs the same kind of rule. Ontario now caps the generic price at 50%

67 One might, of course, question whether Alberta should bother trying to create incentives for entry by generic manufacturers. Given its relatively small size, Alberta's impact on such incentives also must be relatively small, which makes free riding attractive. There might be scope for a larger impact if the western provinces could band together to form a common policy.

when there are two or more generic manufacturers, but when there is only one, the price in some cases might be higher. This approach clearly leaves gains available, since the cost of many generic drugs is well below 50% that of the brand-name drug. There is thus no reason not to require further price reductions if more firms are willing to enter at increasingly lower prices. Therefore, I propose a price schedule that becomes lower as more generic manufacturers enter (see Table 5).

Table 5: Proposed Maximum Price Schedule

Generic Manufacturers	Maximum Price
(number)	*(%)*
1	75
2	55
3	45
4	40
5	35
6	30
7	25

The maximum price any payer in the province, public or private, would pay would be calculated as a fraction of the average price of the patented reference drug during the two years prior to entry. If more than six manufacturers entered, the price could continue to drop, perhaps by increments of 2% per additional manufacturer. The lower price would apply to all manufacturers.[68]

This approach has three chief benefits. First, the price would continue to fall as long as costs were lower than the price. In normal competitive markets, there is no need for such a mechanism because consumers hunt for lower prices. With insurers bearing most of the costs, however, consumers are insulated from real prices and lack an incentive to search for lower prices, which is particularly problematic when many consumers do not bear any of the cost and many are not in good health at the time of purchase.[69] Requiring the price to decline as more firms enter the market would have the effect of revealing the true costs of generic manufacturing, since additional firms would enter only if the price was above their expected costs of serving the market.[70]

The second chief benefit is that lower-cost producers would have an advantage in this kind of marketplace, since, as additional firms enter, the price would be driven down, forcing higher-cost producers out of the market, leading to greater productive efficiency.

The third chief benefit is that early entrants would have a significant market advantage, since later entrants likely would obtain relatively small market shares unless they could induce some early entrants

68 These proposed prices have not been carefully calibrated; the important point is to outline the appropriate mechanism rather than specific prices. In fact, however, one advantage of this mechanism is that prices would not need to be perfectly calibrated: the price would be driven down automatically only if new entrants believed that the price would be higher than their costs. Thus, this system is a cost-revelation mechanism.

69 This point is troubling because of the position of trust the pharmacist holds with respect to the patient, who may not be in a position to bargain over price.

70 Note that the relevant costs may be either marginal or average. If there is a worldwide market for a particular product, a generic manufacturer might need only to obtain a price greater than the marginal cost of production to make it worthwhile to enter. If the market is Canada, a firm might require a price that is at least equal to its average costs to enter.

to drop out of the market. This is attractive since early entrants would be the ones to eliminate barriers to competition.

Some important details of the proposal should be noted. A firm that competed in this system would have to be willing to supply as much as the market demanded in order to have its product accepted in the provincial formulary at the new price (as Ontario now requires). The reason this is important is that each time a new firm entered the market, it would drive the price down and might lead other firms to exit. Failure to meet demand at that price would require the province to step in and buy from higher-priced sellers. The entrant would be responsible for making up the supplementary cost to the province for at least one year following entry.

For example, suppose that there were two generics in a given market, with the generic reimbursement price equal to 55%, and a third generic then decided to enter and committed to fill demand at 45%. In such a scenario, it is highly probable that the first two firms would stay in the market at the new lower price while new entrant obtained some share of the market. If the first two firms refused to reduce their prices, however, the new entrant would obtain the entire market at its lower price. If the new entrant subsequently was unable to meet demand, the province would solicit bids for additional supply, with any cost above 45% to be reimbursed by the entrant.

A declining price schedule would require some adjustments with respect to stock that was acquired before the reimbursable price fell. I suggest the following two rules for dealing with this issue. First, all future sales would have to be at the new price, starting on the new firm's date of entry. Second, all previous purchases by pharmacies could be reimbursed at the actual invoiced higher price, provided that the product was submitted for reimbursement within 30 days; any product sold to patients more than 30 days following the entry date would be reimbursed at the new price. The motivation for the second rule is that the pharmacy's rebate would be larger if it were based on the older price, in which case both the pharmacy and the manufacturer would have an incentive to overstock at high prices.

The effect of these rules on the costs to the province would be substantial. For many of the most important generic drugs with multiple entrants, prices would be about half the levels achieved under the current system, assuming the same number of entrants (see Appendix 6). It should be noted, however, that the mechanism is flexible in that it would encourage entry only if the price remained above the cost of supply.

Inflation Indexing

Although, under the proposed scheme, prices would be forced down by competition, prices should also reflect costs. This implies that maximum prices should be adjusted every year by the rate of inflation, a rule that is applied by both Quebec and the PMPRB.[71] This kind of indexing would be fair to the manufacturers, and would discourage outcomes in which manufacturers are forced out, not by competition but by artificially low prices.

It is possible that, even with indexing, costs for certain drug products might rise above the maximum price, leading to a lack of adequate supplies. In such a case, it would be appropriate for the provincial government to use an SOC mechanism to reveal the true costs of serving the market.[72]

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71 See Canada, Patented Medicine Prices Review Board, ***Compendium of Guidelines, Policies and Procedures, Schedule 4 – CPI Adjustment Methodology*** (Ottawa); accessed (20/06/08) at http://www.pmprb-cepmb.gc.ca/english/view.asp?x=1034&mid=808#guid.

72 The mechanism proposed here would be effective in determining whether the true costs of serving a market were below the

A Limit on Rebates to Pharmacies

Historically, in Alberta as in most other provinces, pharmacies have earned substantial profits from rebates by manufacturers of generic drugs.[73] Industry sources suggest that the average level of rebates is approximately 50% nationally – thus, for a drug for which the pharmacy is reimbursed $1.00 plus mark-up and dispensing fee, the average wholesale acquisition cost is only $0.50. These substantial rebates explain why retail prices for generic drugs in Canada are high. A descending price scale would squeeze those rebates, but if pharmacies continued to demand high rebates, generic manufacturers would obtain less profit and be less willing to enter the market. And without additional entrants, prices would not decrease.[74]

Thus, rebates to pharmacies should be limited to approximately 10% of the price of the drug being sold,[75] with pharmacies perhaps compensated in a more transparent fashion through regulated mark-ups and dispensing fees. Quebec and Ontario already prohibit rebates and limit professional allowances to 20% of the price. The distinction between rebates and professional allowances seems to imply that a regulatory body would verify that the pharmacy was using the allowances for an eligible purpose, which would be extremely difficult to ascertain since money is fungible. It might be easier simply to allow limited rebates without any such restriction.

In Ontario, unlimited allowances may be paid on sales to the private sector, and the restriction on allowances applies only to sales to the public sector. This approach appears not to have been successful, since competition for pharmacies' business now focuses on the amount of allowances paid on drugs sold outside the public sector. The result is that pharmacies are still able to extract approximately the same total discount from manufacturers.

In Quebec, the limit on professional allowances, combined with prices that are still relatively high, means that the spread between costs and prices is also large. This approach either leaves substantial profits with manufacturers or, more likely, draws in additional manufacturers that seek a share of the market. The pricing mechanism means, however, that despite the presence of many manufacturers, prices are not falling and, arguably, the purpose of competition is defeated. Despite Quebec's limits on rebates, the profits that would be attributable to manufacturers are apt to be used up by competition for a share of the market.[76] At present, large generic rebates are an essential part of the pharmacy business model, and without them pharmacies might not be able to provide the same level of service. This means, of course, that, if rebates were reduced, the permitted mark-up and dispensing fees would have to be increased, ased on evidence on costs and a suitable profit margin.[77]

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current price – entry would reveal this. However, my proposal contains no mechanism for prices to be adjusted upward except through inflation adjustment. If costs rose above prices, all firms might drop out of the market, in which case a tender would be a reasonable way to determine the lowest available price.

73 Typically, manufacturers of brand-name drugs do not offer rebates as they are not competing for space in the pharmacy, although rebates on brand-name products could become more common as firms participate in tenders such as the proposed Ontario system.

74 One possible consideration is to allow a new entrant to give a rebate of, say, 12% for a limited time such as a month, to encourage take-up of the entrant's product.

75 Indeed, for many years, Quebec has not permitted rebates at all, although, as we have seen, Quebec pharmacies obtained supplementary revenues through large mark-ups charged to private payers. There are also allegations that rebates were paid despite the regulations. See, for example, ***Québec (Régie de l'Assurance-maladie) c. Pharmascience inc.***, 2004 CanLII 4667 (QC C.S.); see also files of the Cour Supérieure du Québec, 500-17-015571-030, 500-17-015460-036, and 500-17-015406-039.

76 In these circumstances, manufacturers engage in costly activities designed to boost market share by providing some "reward" for the pharmacy.

77 Of interest in this respect is a recent study that examines the costs of retail pharmacies in British Columbia; see A.T. Kearney, ***Activity Based Costing Study Final Report: Study Findings and Analysis*** (Vancouver, January 2007); accessed online (20/06/08) at http://www.health.gov.bc.ca/pharme/ ABC_Report_2007.pdf.

Since manufacturers and pharmacy chains operate on a national level, Alberta should lobby other provinces that permit rebates to limit them to avoid their use to influence purchasing decisions on a national level. Within Alberta, both the giving and receiving of excessive rebates should be penalized, with the penalty for the recipient being not only the loss of the amount received, but also an additional amount equal to some multiple of the excess. The manufacturer granting the excessive rebate should face a similar penalty.[78] An excessive rebate resembles a conspiracy between two firms: the manufacturer, which wants to get its product into the pharmacy at the expense of other manufacturers, and the pharmacy, which arranges this in exchange for a payment (rebate) from the manufacturer.[79] At the federal level, the Competition Bureau has been very successful in achieving convictions under the *Competition Act* after granting immunity to conspirators who offer information on the conspiracy to the Bureau, since such evidence helps to obtain a conviction of the party that did not confess and makes conspiracies more likely to be detected.[80] It would be sensible to use a similar system in the case of excessive rebates, allowing firms that admit to receiving or granting them to be awarded immunity. As an additional mechanism to reduce their use, whistleblowers could be awarded a share of any rebate detected. Ultimately, of course, the goal is not to detect excessive rebates but to prevent them from occurring, by making detection more likely.

It is important to note that a limitation on rebates is, in fact, a way of satisfying principle 7 – that pharmacies should be fairly compensated by all payers – since it is not fair if large rebates are paid on only some drugs but not others, which discriminates against patients using the high-rebate drugs. Of course, limiting rebates would mean that pharmacies would have to be paid more generous mark-ups and/or dispensing fees or otherwise compensated based on the provision of supplementary professional pharmacy services.

An Open Formulary

Since prices fall when new firms enter any given market, it would be in the interests of the province not to restrict the entry of generic drugs beyond requiring entrants to have an NOC from Health Canada and to supply as much of the drugs as needed at the specified price (assuming that they are truly interchangeable).[81]

A Royalty for the First Generic

Principle 2 requires the province to encourage competition, but competition itself is enabled by the elimination of legal barriers to entry by generic firms. The core problem with obtaining generic entry is that patentees legitimately list many patents in Health Canada's Patent Register, some of which might be found invalid or not infringed. Therefore, only if a generic firm challenges those patents will generic

78 In Ontario, the ***Drug Interchangeability and Dispensing Fee Act*** (R.S.O. 1990, SS. 12.1(4) and (11)) imposes a fine equal to the rebate on both the manufacturer and the pharmacist. Since the pharmacist can only lose the rebate, there is no harm in asking for one. The pharmacist also might face a loss of reputation, of course, but it seems strange to limit the fine to the amount unlawfully obtained.

79 I am not suggesting that the payment of a rebate constitutes a conspiracy in the sense of the ***Competition Act***; rather, I wish to draw attention to the potential value of an immunity provision.

80 See Canada, Competition Bureau, "Immunity Program under the ***Competition Act***," Competition Bureau Information Bulletin (Ottawa, October 2007); accessed online (20/06/08) at http://www.competitionbureau.gc.ca/epic/site/cb-bc.nsf/en/02483e.html.

81 The bioavailability of many drugs is relatively uncomplicated, but certain drugs – "Report C" formulations, in Health Canada's terminology – are more complex, and a review of their interchangeability might be justified. See Canada, Health Canada, Health Protection Branch, Expert Advisory Committee on Bioavailability, "Report C: Report on Bioavailability of Oral Dosage Formulations, Not in Modified Release Form, of Drugs Used for Systemic Effects, Having Complicated or Variable Pharmacokinetics" (Ottawa, December 1992); accessed (20/06/08) at http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodpharma/biorepc_biorapc-eng.pdf.

competition be enabled. At present, however, in many cases the generic firm that invests in litigation to overcome those patents obtains no advantage from doing so over other generic firms that invest nothing. Generic firms thus have every reason to wait for another firm to invest in a patent challenge.

One solution to this problem is to assume that, since Canadian patents are similar to those in other countries, Canadians should wait for global generic companies that are challenging patents in the United States to launch similar patent challenges in Canada. This approach, however, fails to address two key points. First, even if Canadian patents are similar to those elsewhere, they are not be identical. For example, no generic olanzapine or perindopril is available in the United States, but those products have been sold in Canada for over a year. Thus, failure to address Canadian patents based on Canadian laws likely would result in the unnecessary extension of patent monopolies. Second, even if patents, laws, and regulations are similar, the fact that they are not identical means that the expensive process of litigation needs to be duplicated in Canada. In the absence of any benefit from being the first to invest in litigation (rather than being a free rider), no firm can be expected to undertake such an investment.

Since it is payers — chiefly among them, provinces — that benefit the most from the removal of invalid patents and other artificial barriers to competition, payers should be the ones that engage in challenging patents. In practice, however, this is unlikely to occur. Provincial governments could apply under section 60 of the *Patent Act* for a patent to be overturned, but they would incur significant risks in doing so and, in any case, do not have the personnel to mount such challenges. In addition, in many cases, it is not patent invalidity but non-infringement that allows generic firms to proceed to market. To show non-infringement, a province would have to possess a non-infringing generic product.

In the past, Ontario rewarded the first generic to market by giving it a higher reimbursement than when there were two or more generics. Such an approach, however, is probably not very effective. In most important markets, several generic firms enter rapidly, leaving little or no reward for the generic firm that bears the costs of litigation — indeed, effectively penalizing the litigating firm since the other free-riding firms make greater profits. The United States offers an incentive to a generic firm that challenges an invalid or non-infringed patent by awarding it 180 days of partial "exclusivity" before other generic firms can enter.[82] The reward, however, comes at the expense of payers who might have benefited from the immediate elimination of obstacles to competition.

A more promising route would be for the province to reward directly the generic firm that enables competition by challenging invalid or non-infringed patents, since the firm can be seen as acting for the benefit of all payers. In a sense, this mechanism would be similar to the way patentees are rewarded for useful innovations by the high prices they are paid. It is important to note, however, that such a mechanism should pay only for success — that is, it should reward a generic firm that creates competition only when such competition has been stifled by an unsuccessful application in NOC proceedings by the patentee.

One way to address this issue is for competing generic drug manufacturers to pay a temporary royalty to the first independent generic that successfully challenges a patent and obtains an NOC to sell the drug. The royalty could cease either one year following the granting of the NOC or at the end of the latest patent included on the Health Canada Patent Register, whichever comes sooner. In effect, the royalty would raise prices to payers during the first year of generic competition, but it would never lead to higher

82 See Erika Lietzan and David E. Korn, "Issues in the Interpretation of 180-Day Exclusivity," ***Food and Drug Law Journal*** 62(1, 2007): 49-75.

prices for payers than they now face, and the size of the royalty would be small compared with the gain to payers from lower prices.[83] Even with a royalty, the highest price paid would be 50% of the brand-name price. This would be lower than the generic prices now paid and, more to the point, much lower than the brand-name price consumers would pay if not for the investment incurred by the generic firm in challenging the patent. The royalty would be similar in spirit to the patent right granted to the brand-name manufacturer, in that it would be a reward for discovering something of value to the consumer or payer — in this case, the elimination of an artificial barrier to competition. Table 6 shows how this temporary royalty would affect prices.

Table 6: Royalty Scheme

Generic Manufacturers	Maximum Price	Royalty Paid to First Entrant
(number)	*(%)*	*(%)*
1	75	0
2	55	0
3	50	5
4	47	7
5	45	10
6	40	10
7	35	10

Note: The royalty is a percentage of the brand-name price; thus, the net price earned by each generic manufacturer remains unchanged.

The process for determining royalty eligibility is described in Appendix 7, but, in essence, only an independent generic, not a licensee or firm under the control of the patentee, would be able to obtain a royalty, although more than one firm might be able to share the royalty in some circumstances. This mechanism effectively would create a meaningful incentive for generic firms to challenge patents they believed were invalid or to develop non-infringing products, but would not create further barriers to competition, as the US system of 180-day exclusivity does.

What would such a system be worth? Appendix 8 shows some rough calculations using several products, but compared with the savings payers would obtain from increased competition, the royalty should be designed to be small. For example, for a significant product such as simvastatin and with a system implemented on a national basis, the royalty to the first generic would be on the order of $16 million, while the savings to consumers would be approximately $90 million. In no case should the royalty to the first generic be more than 10% of the brand-name price times the volume of generic sales over the course of a year. Since this mechanism would reduce the price paid for a generic drug below the current amount, the royalty would be not much larger than the reduction in revenues to the first generic manufacturer. Of course, if all provinces did not adopt this system, both payments and savings would be proportionately smaller.

83 The administration of the royalty would be relatively simple. The province would indicate the price to pharmacies and, if a royalty were owing, the pharmacies would collect it on all sales of the generic interchangeable products and remit it to the Minister of Health to be paid to the qualifying generic firm.

A reward of a few million dollars would not be out of line with the costs of a challenge to patent invalidity or the development of a non-infringing alternative. It might not pay the full costs on a risk-adjusted basis, but at least it would make a contribution. Moreover, it would be commensurate with the benefits obtained by consumers: the larger the market size and the greater the price reduction, the greater the royalty to the successful challenging generic.[84]

Note that, in a market with only one or two generic firms, no royalty would be paid, since the first generic firm would receive the reward of a relatively high price and a large share of the generic market. In contrast, in a market that many firms entered quickly, competitors likely would strip away from the first generic a large part of the benefit of having created competition, and consumers would benefit enormously from the low prices of a competitive market. In effect, the royalty would compensate the challenging generic for having enabled the low prices.

Appendix 9 lists examples of products where the efforts of a generic firm to open up competition were rewarded with the arrival of ten or more generic competitors within the space of a few months – some within days. If the pricing schedule outlined above had been in place, the benefits to consumers would have been enormous, while the benefits to the challenging generic would have been relatively small. Provincial governments might object to such payments since they might appear to favour generic firms and discourage innovation, but generic firms would obtain benefits only from challenging invalid or non-infringed patents; challenging patents that were valid and infringed would lead neither to generic entry nor to the payment of any royalty. In fact, provinces commonly pay high prices for products protected by patents that ultimately are found to be invalid or not infringed; in such cases, they are rewarding the patentee for an innovation of no value. The proposal presented here simply would provide a modest correction to that situation, so that the firm that discovered the path to competition could be modestly rewarded.

Tendering

How, if at all, should tendering fit into the mechanism described above? In fact, the mechanism is designed explicitly to generate low prices, in a way that none of the existing non-tendering mechanisms other provinces use – such as Ontario's 50% price – can do, so that tendering would not likely to be necessary in most cases. However, tendering could be used as a back-up solution in two different situations.

First, tendering might be used if the declining-price system failed to elicit sufficient entry. Although each new entrant would force down the price, it would have no guarantee of substantial sales since it would not be able to distinguish its product in terms of its fundamental characteristics – after all, it would be marketing a *generic* drug – and could not offer a larger rebate to pharmacies. If the incentive to enter were too weak, even if prices were above costs, the declining-price mechanism would not work well. In such a circumstance, a province might note that international prices for a particular molecule were much lower, and decide to move to a tendering system. Yet, it is unlikely that a declining-price mechanism would fail to attract entry. If a firm has already entered the market in other provinces, the cost of entering a new one would be extremely low, and any incremental sales would be a benefit. Moreover, since pharmacies prefer to deal with companies that can offer a wide range of products, a potential new entrant would find it advantageous to be willing to supply even a relatively small amount of the product.

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84 This mechanism would also address the harmful effect of authorized generics – generic drugs licensed (and typically produced) by the patentee that compete as generics at generic pricing levels – on the incentive to enter, without losing their beneficial effects on price competition. I have argued elsewhere that these products reduce incentives to challenge patents; see Aidan Hollis, "The Anti-Competitive Effects of Brand-Controlled 'Pseudo-Generics' in the Canadian Pharmaceutical Market," ***Canadian Public Policy*** 29(1, 2003): 21-31.

The second situation in which tendering might be used would be if firms were unwilling to supply at the specified prices. Such a problem might arise, for example, if the cost of an active pharmaceutical ingredient were to increase substantially for reasons outside the control of individual generic producers. Then the question would naturally arise: at what price would generic firms be willing to supply? In such circumstances, tendering might be a useful tool with which to elicit an answer.

Given the experience of Saskatchewan, however, one should not expect this approach to result in large savings relative to Ontario formulary prices. Tendering should also be avoided in the initial year of generic entry, since it might result in the earliest generic firms' obtaining little benefit from their early entry. While a royalty scheme would help to minimize this problem, it might not be large enough, in the absence of an expectation of earning substantial sales revenues, to induce generic firms to engage in costly patent challenges. Tendering also would increase the risks generic firms face, since they cannot know whether they would obtain any share of the market even after they had invested in gearing up for production.

Summary

The approach described above could offer significant benefits over the Ontario and Quebec plans and compared with the status quo in Alberta, since it would use a market mechanism to force down the prices of generic drugs. The market mechanism would be, in effect, a kind of auction in which firms face price points they need to meet to continue to participate. It would also create enormous savings for all payers — patients, as well as private and public insurers.

It is worth examining this proposal from the perspective of the seven principles laid out earlier.

1. The proposal would continue to respect patent rights fully.
2. It would encourage competition by offering incentives to challenge invalid patents, and its open formulary would permit as many firms as possible to enter.
3. The benefits of additional competition would accrue to payers through low prices.
4. It would enable security and stability of supply by encouraging multiple suppliers.
5. Prices would be designed to be the same for both public and private payers.
6. It would not require the province to rely on the bargaining of other provinces for price reductions.
7. All payers would make a proportionate contribution to the costs of pharmacy, and dispensing fees and mark-ups would be set to ensure a fair income for pharmacies.

INTERPROVINCIAL PRICE COMPARISONS

A significant problem inherent in trying to reduce prices below levels in Ontario is the explicit and implicit comparison of prices across provinces. In particular, the regulations of three provinces — Quebec, Manitoba, and Newfoundland and Labrador — restrict companies from offering their drugs at lower prices in other provinces.

Under Quebec's *Prescription Drug Act* (section 60), only a medication from a manufacturer accredited by the Minister may be considered for entry in the provincial formulary. In order to receive accreditation, manufacturers must commit to provide drugs at a "guaranteed selling price" that "must not be higher than any selling price granted by the manufacturer for the same drug under other provincial drug insurance programs."[85] Any manufacturer that participates in another provincial program that Quebec

85 Section 1 of the ***Act*** defines the "guaranteed selling price" as the price that a buyer must pay for a drug, minus any rebate provided without consideration to a buyer, plus any amount received for marketing, service, guarantee, commission, transport, or delivery.

deems to violate this undertaking risks having the Minister of Health temporarily withdraw accreditation, thereby excluding from the provincial formulary all the medications produced by the manufacturer for a period of three months. This period is extended to six months if the manufacturer has been disaccredited in the five preceding years, and accreditation may be withdrawn permanently for a third violation. If accreditation is withdrawn, the manufacturer must pay the RAMQ any difference between the guaranteed selling price as defined in the manufacturer's commitment and the actual price of a medication sold by the manufacturer; moreover, the RAMQ has an independent right to sue for reimbursement of excess payments to manufacturers. Given such legislation and the size of the Quebec market, any other province that wished to obtain lower prices than those normally offered in Quebec would, in effect, be obliging manufacturers of generics also to lower their prices in Quebec.

Manitoba and Newfoundland and Labrador, like Quebec, have regulations requiring that manufacturers not grant lower prices elsewhere. Because these markets are not particularly large, however, such regulations do not have the same force in determining prices as those in Quebec. In addition, these provinces do not seem to be particularly effective in enforcing their regulations. A quick review of some commonly prescribed generic medicines shows that prices in both provinces are well above reimbursement prices listed in the Ontario formulary (see Table 7).

Table 7: Prices of Commonly Prescribed Generics, Ontario, Quebec, Manitoba, and Newfoundland and Labrador

Generic	Ontario Price	Quebec Price	Manitoba Price	Manitoba Price Difference	Newfoundland & Labrador Price	Newfoundland & Labrador Price Difference
	($)			*(%)*	*($)*	*(%)*
Paroxetine 20 mg	0.79	0.79	1.10	+39	1.09	+38
Ramipril 10 mg	0.47	0.47	0.66	+40	0.72	+53
Simvastatin 20 mg	1.10	1.10	1.52	+38	1.51	+37

Notes: Price differences indicate the price premium paid in Manitoba and Newfoundland and Labrador compared with prices in Ontario and Quebec.
Source: Prices are drawn from provincial formularies as of 16 June 2008, and rounded to the nearest cent per pill.

Clearly, if Alberta wished to avoid regulations that force generic manufacturers to offer very low prices, it would have to address Quebec's price-matching regulations. Several approaches are possible. First, Alberta should try to coordinate with other provinces on its pricing mechanism. This would make it more attractive for some manufacturers, at least, to compete in Alberta and in the other cooperating provinces, since the larger the number of provinces that have the same policies, the more attractive it would become for new manufacturers to enter, without consideration of pricing in Quebec.
Second, Alberta should lobby Quebec to eliminate its comparative pricing mechanism.

Third, Alberta could, at least on the face of the language in Quebec's legislation, evade the price comparison by using an open formulary and "requiring" firms to meet the prices specified, which Quebec might not interpret as the manufacturer's "granting" a price.[86] This might put considerable risk on the manufacturer, however, since the meaning of "granting" a price has not been clarified in the courts.

Fourth, since Quebec's regulations compare prices granted only to other provinces' drug insurance programs, not private insurance prices, it might be possible for Alberta to specify the private price for each drug and then set a price for the public insurance program that would be equal to the brand-name price. Alberta could then require manufacturers to grant the province what might be called a confidential "health system levy" (effectively, a rebate) on sales. If the levy were set appropriately, the province could end up paying a net price equal to the private price. Co-payments by patients insured by AHCIP would be based on the private price. Ontario, for example, appears to have obtained a lower price on Coversyl than the listed price, once one considers the rebates negotiated by the province. British Columbia, similarly, appears to obtain a lower price on Zyprexa, once one considers the rebate to the province. This has not caused Quebec to take any disciplinary action against Servier, the maker of Coversyl, or Lilly, the maker of Zyprexa. Quebec thus does not seem to require that manufacturers match the lowest price granted to a provincial insurance program, but only the lowest *published* price.

TRANSITION ISSUES

Moving to a system such as the one I propose would involve a number of transition problems, the most difficult of which would be to determine the reimbursement price for existing generic drugs. It would not be reasonable to use the same pricing rule as in Table 5, for example, since some of the firms currently in the market might not have entered had they expected the low price required under that pricing rule. Therefore, an *ad hoc* rule seems inevitable. One possibility would be to reduce the maximum prices of existing generic drugs to 45% of the reference prices for all drugs with three or more generic manufacturers currently participating in the market. Generic firms and pharmacies could provide information to the government regarding any drugs that should be treated as an exception to this rule. The rule of a descending price as new firms sought to enter would apply in the future to these older drugs, so that, when any new firm entered, the price would drop by 5%. No competition royalty would be paid on these products. Products with only one or two generic manufacturers currently in the market would have their prices set at 75% or 55% of the reference prices. Maximum prices would fall according to schedule for those products as new firms entered.

CONCLUSION

As provinces grapple with the budgetary requirements imposed by their health care systems, finding an efficient, equitable way of procuring and paying for generic drugs is a small piece of a very large puzzle — but each problem needs to be addressed on its own merits. In this paper, I have described a coherent set of principles for the design of provincial drug insurance and price control systems. In the light of those principles, I have reviewed the policies of different provinces with respect to generic drug pricing, and suggested a novel mechanism for controlling drug prices that could lead to considerable savings for payers, both public and private.

The proposed declining-price system would take advantage of the knowledge firms have about their own costs of production in order to generate low prices for payers. In other markets, one can rely on ordinary competition among firms to obtain low prices — but this does not work well in generic drug markets

86 The Saskatchewan SOC requires firms to offer a price; the Alberta declining-price mechanism instead would require firms to accept a price.

because of insurance and the health status of the consumers who are buying. As a result, some alternative mechanism is required. Tendering is attractive response, but it would fail to address the need to reward the first generic entrant that created the competition. Tendering also could not be used when there is an insufficient number of competitive generics and, once implemented, might undermine the ability of firms that have been unsuccessful in winning a tender to be competitive in future tendering opportunities. A declining-price system would address these failings while ensuring that prices paid by consumers reflect the true costs of supply. Implementing such a system offers the potential of saving taxpayers and employers millions of dollars annually by taking advantage of competition in generic drugs.

Appendix 1: Dispensing Fees

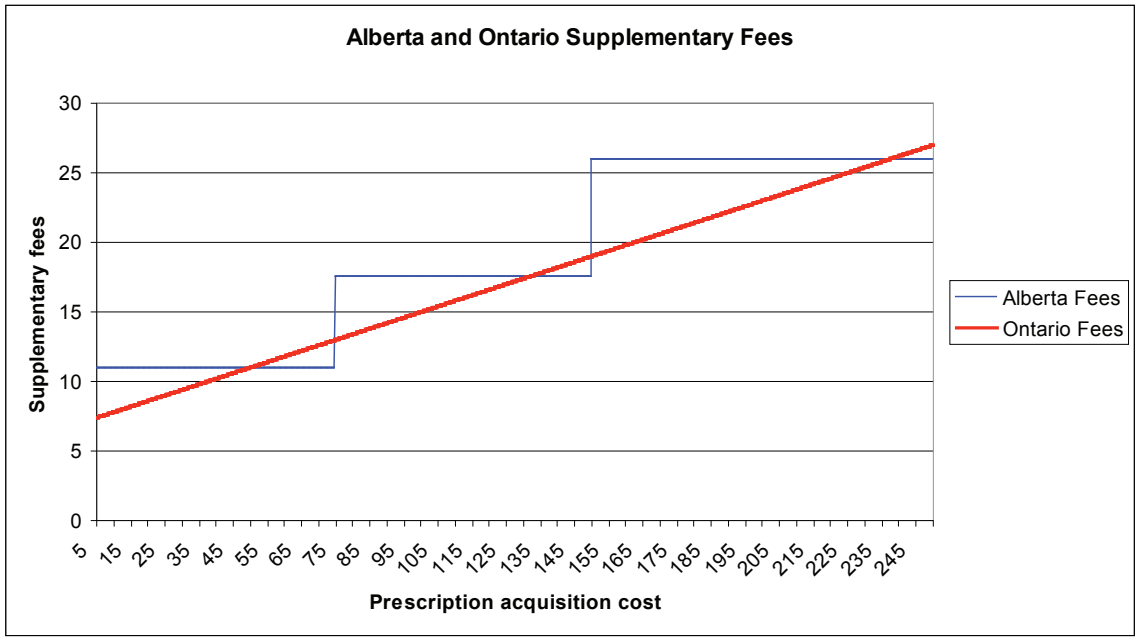
In Ontario, the amount the ODB pays under the guidelines set by the regulations (*Ontario Drug Benefit Act* - O. Reg. 201/96, 13) is the drug benefit price, plus an 8% mark-up, plus a dispensing fee of $7.00. In Alberta, the ACHIP pays the sum of the acquisition cost, the dispensing fee, and an inventory allowance, as shown in Table A-1. For prescriptions averaging $50, $100, and $200, Ontario pays total extra fees of $11.00, $15.00, and $23.00, respectively, while Alberta pays $10.93, $17.53, and $25.97, respectively. Figure A-1, which compares the relative supplementary fees, shows that typical Alberta fees are slightly higher than those in Ontario.

Table A-1: Dispensing Fees and Additional Inventory Allowances, Alberta

	Dispensing Fee	Additional Inventory Allowance
	($)	
Acquisition cost, to $74.99	10.22	0.71
Acquisition cost, $75–149.99	15.53	2.00
Acquisition cost, $150 and more	20.94	5.03

Source: Alberta, Health and Wellness, Prescription Drug Program, "Pharmacy Fee Reimbursement" (Edmonton); available at http://www.health.alberta.ca/AHCIP/drugs-fee-reimbursement.html.

Figure A-1: Supplementary Fees, Alberta and Ontario

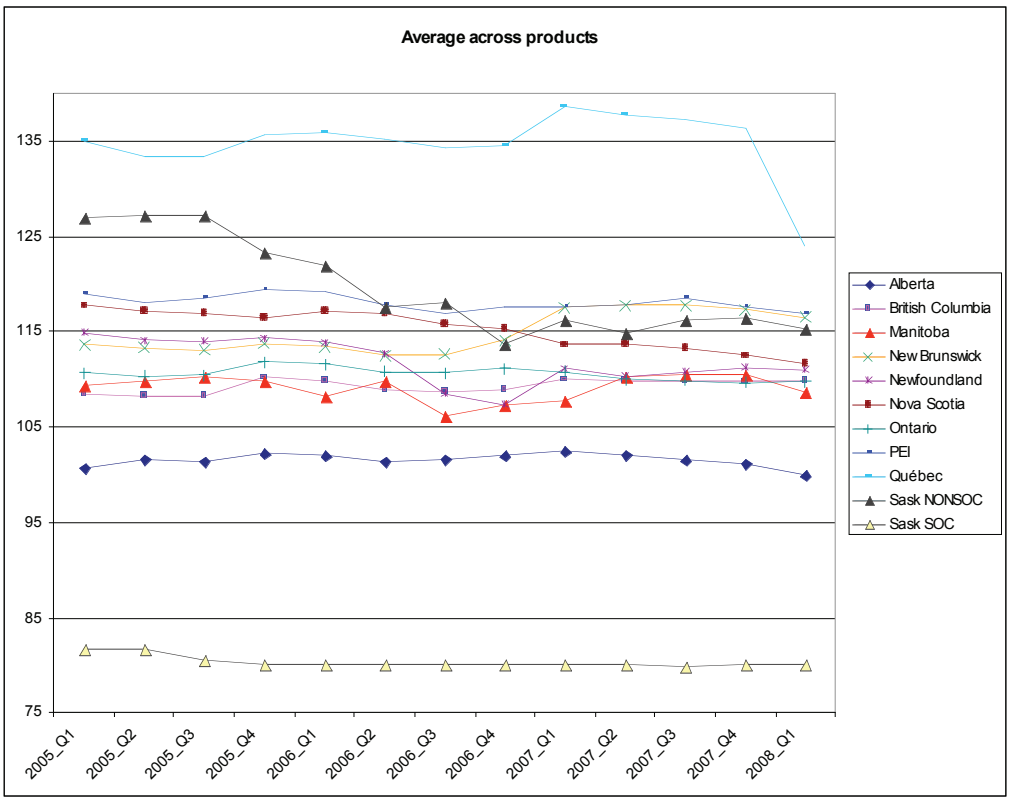


Appendix 2: Private Payer Prices

Private payer costs differ substantially across provinces, as shown in Figure A-2, which summarizes prices for ten highly prescribed products. In the figure, prices first were normalized, with the Alberta first quarter 2008 price normalized to 100 for each product, then averaged across products for each province. Generally, the averages shown in the Figure A-2 closely resemble those for each product and are not swayed by outliers. Data on unit prices, including dispensing fees, were available only for the first quarter of 2008, but the relationship between the average unit price ratio in Alberta, including mark-up and dispensing fees, was approximately the same as shown in Figure A-2, as follows: Saskatchewan (SOC), 0.8613; Alberta, 1; Newfoundland and Labrador, 1.0336; British Columbia, 1.0649; Ontario, 1.0729; Nova Scotia, 1.0749; Manitoba, 1.0978; New Brunswick, 1.1152; Prince Edward Island, 1.1196; Saskatchewan (non-SOC), 1.1698; Quebec, 1.2705.

Available data also allowed average mark-ups over the list price to be separated out only for the first quarter of 2008, as follows: Alberta, 5%; Nova Scotia, 11%; Saskatchewan, 12% (SOC, 5%; non-SOC, 23%); Manitoba, 13%; British Columbia, 14%; Newfoundland and Labrador, 15%; Ontario, 15%; New Brunswick, 22%; Prince Edward Island, 22%; Quebec, 57%.[87] Quebec's high mark-up is a function of the low list price in that province and the high retail price; dispensing fees are relatively low.

Figure A-2: Private Payer Prices Averaged across Selected Products, 2008



Notes: Private payer costs were averaged across the following products: Azithromycin, 250 mg; Citalopram, 20 mg; Fluoxetine Hcl, 20 mg; Gabapentin, 300 mg; Omeprazole Magnesium, 20 mg; Paroxetine Hcl, 20 mg; Ramipril, 10 mg; Sertraline Hcl, 50 mg; Simvastatin, 20 mg; Venlafaxine Hcl, 75 mg. Prices in include acquisition costs plus mark-ups, but not dispensing fees, which vary somewhat across provinces.

87 Data are drawn, with permission, from the private payer database maintained by Brogan Inc.

Appendix 3: Damages under the NOC Regulations

The reason the damages provisions of the PM(NOC) Regulations cannot provide a suitable incentive for patent challenges is explained in section 8 of the Regulations:

> (1) If an application made under subsection 6(1) is withdrawn or discontinued by the first person or is dismissed by the court hearing the application or if an order preventing the Minister from issuing a notice of compliance, made pursuant to that subsection, is reversed on appeal, the first person is liable to the second person for any loss suffered during the period
>
> (a) beginning on the date, as certified by the Minister, on which a notice of compliance would have been issued in the absence of these Regulations, unless the court concludes that
>
> (i) the certified date was, by the operation of An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa), chapter 23 of the Statutes of Canada, 2004, earlier than it would otherwise have been and therefore a date later than the certified date is more appropriate, or
>
> (ii) a date other than the certified date is more appropriate; and
>
> (b) ending on the date of the withdrawal, the discontinuance, the dismissal or the reversal.
>
> (2) A second person may, by action against a first person, apply to the court for an order requiring the first person to compensate the second person for the loss referred to in subsection (1).

The damages that may be paid to the generic firm are only the losses it incurs from being kept out of the market. One can immediately see why this does not provide a suitable incentive for challenging patents. First, because the monopolist's profits are larger for every unit sold than the generic firm's profits per unit, it will always pay the patentee to delay generic competition, even it is certain that it will have to pay the generic's lost profits.

Second, the generic firm that successfully challenges the patentee's monopoly creates cost savings for buyers that extend from the date of generic competition until the expiry of the invalid or non-infringed patent. This period might bear little or no relationship to the period during which the generic suffers losses because of the application of the patentee under the PM(NOC) Regulations. To illustrate, consider Figure A-3. In this situation, the benefit created by firm X is generic competition during the entire 2002-09 period, while the damages paid to firm X consist of an accounting of its lost profits for 2001 and 2002. The reverse could also be true. Thus, the damages paid might bear little relationship to the social value of challenging a patent.

Figure A-3: Example of a Timeline of Generic Entry

Third, the damages paid to firm X are only its lost profits, which since the firm would have been competing vigorously with five other generics, might be very small. Thus, as a mechanism both for deterring frivolous applications by patentees under the PM(NOC) Regulations and for rewarding generic firms for challenging invalid or non-infringed patents, section 8 is likely to have little effect.

In this kind of situation, an efficient solution would be for the patentee to pay not only lost damages to the generic, but also a fine equal to the damages to other parties (including consumers and other firms).[88] Such a solution would efficiently deter frivolous or unsupported patent litigation.

88 See John R. Boyce and Aidan Hollis, "Preliminary Injunctions and Damage Rules in Patent Law," ***Journal of Economics and Management Strategy*** 16(2, 2007): 385-405.

Appendix 4: Prices under the Saskatchewan SOC System

Table A-2: A Comparison of Generic Drug Prices in Saskatchewan and Ontario				
Drug Name	**Dosage/Form**	**Saskatchewan Price**	**Ontario Price**	**Ratio**
		($ per molecule)		
Acebutolol Hcl	100 mg tablet	0.1418	0.1294	1.10
	200 mg tablet	0.2122	0.1936	1.10
	400 mg tablet	0.4214	0.3847	1.10
Amantadine	100 mg capsule	0.3885	0.5179	0.75
Amiloride Hcl/ Hydrochlorothiazide	5 mg/50 mg tablet	0.1667	0.1917	0.87
Amoxicillin (Amoxycillin)	25 mg/ml oral suspension	0.0174	0.0353	0.49
	50 mg/ml oral suspension	0.0261	0.0540	0.48
	250 mg capsule	0.0898	0.1750	0.51
	500 mg capsule	0.1748	0.3417	0.51
Atenolol	50 mg tablet	0.3059	0.2790	1.10
	100 mg tablet	0.5025	0.4586	1.10
Baclofen	10 mg tablet	0.2078	0.2311	0.90
	20 mg tablet	0.4238	0.4498	0.94
Carvedilol	3.125 mg tablet	0.7033	0.6350	1.11
	6.25 mg tablet	0.7033	0.6350	1.11
	12.5 mg tablet	0.7033	0.6350	1.11
	25 mg tablet	0.7033	0.6350	1.11
Cephalexin Monohydrate	250 mg tablet	0.1272	0.2250	0.57
	500 mg tablet	0.2544	0.4500	0.57
Cimetidine	300 mg tablet	0.0722	0.0860	0.84
	600 mg tablet	0.1444	0.1720	0.84
	400 mg tablet	0.1134	0.1350	0.84
Citalopram Hydrobromide	20 mg tablet	0.6195	0.6250	0.99
	40 mg tablet	0.6195	0.6250	0.99
Clonazepam	0.5 mg tablet	0.0905	0.0925	0.98
	2 mg tablet	0.1426	0.1595	0.89
Diclofenac Sodium	50 mg enteric tablet	0.3339	0.3125	1.07
	75 mg sustained release tablet	0.4839	0.5706	0.85

Diltiazem Hcl	30 mg tablet	0.1760	0.1866	0.94
	60 mg tablet	0.3085	0.3273	0.94
Divalproex Sodium	125 mg enteric coated tablet	0.1139	0.1093	1.04
	250 mg enteric coated tablet	0.2047	0.1964	1.04
	500 mg enteric coated tablet	0.4095	0.3931	1.04
Domperidone Maleate	10 mg tablet	0.1155	0.1496	0.77
Famotidine	20 mg tablet	0.4625	0.4679	0.99
	40 mg tablet	0.8324	0.8423	0.99
	100 mg sustained release tablet	0.6677	0.6665	1.00
Fluoxetine	20 mg capsule	0.6929	0.8025	0.86
Furosemide	20 mg tablet	0.0336	0.0373	0.90
	40 mg tablet	0.0503	0.0558	0.90
Gabapentin	100 mg capsule	0.2069	0.2000	1.03
	300 mg capsule	0.4904	0.4865	1.01
	400 mg capsule	0.5996	0.5798	1.03
Glyburide	5 mg tablet	0.0536	0.0683	0.78
	2.5 mg tablet	0.0309	0.0393	0.79
Hydrochlorothiazide	25 mg tablet	0.0357	0.0313	1.14
	50 mg tablet	0.0517	0.0434	1.19
Indapamide Hemihydrate	1.25 mg tablet	0.1752	0.1490	1.18
	2.5 mg tablet	0.2500	0.2364	1.06
Lovastatin	20 mg tablet	0.8104	0.8657	0.94
Metformin	500 mg tablet	0.0604	0.0965	0.63
Metoprolol Tartrate	50 mg tablet	0.0859	0.0968	0.89
	100 mg tablet	0.1577	0.1747	0.90
Moclobemide	150 mg tablet	0.2916	0.2900	1.01
Naproxen	250 mg tablet	0.0929	0.1068	0.87
	375 mg tablet	0.1268	0.1458	0.87
	500 mg tablet	0.1834	0.2110	0.87
Oxybutynin Chloride	5 mg tablet	0.1728	0.1973	0.88
Paroxetine Hcl	20 mg tablet	0.7530	0.7950	0.95
	30 mg tablet	0.7976	0.8450	0.94
Pindolol	5 mg tablet	0.1840	0.2023	0.91
	10 mg tablet	0.3278	0.3490	0.94
Pravastatin	10 mg tablet	0.7476	0.7567	0.99
	20 mg tablet	0.8820	0.8925	0.99
	40 mg tablet	1.0624	1.0750	0.99

Ranitidine	150 mg tablet	0.3003	0.4042	0.74
	300 mg tablet	0.5787	0.7787	0.74
Sertraline Hydrochloride	25 mg capsule	0.3745	0.4000	0.94
	50 mg capsule	0.7490	0.8000	0.94
	100 mg capsule	0.8193	0.8750	0.94
Simvastatin	5 mg tablet	0.4214	0.4500	0.94
	10 mg tablet	0.8333	0.8900	0.94
	20 mg tablet	1.0299	1.1000	0.94
	40 mg tablet	1.0299	1.1000	0.94
	80 mg tablet	1.0299	1.1000	0.94
Sotalol Hcl	160 mg tablet	0.5091	0.6492	0.78
Sucralfate	1 g tablet	0.2557	0.2335	1.10
Sulfamethoxazole/Trimethoprim	400 mg/80 mg tablet	0.0420	0.0482	0.87
	800 mg/160 mg tablet	0.1062	0.1221	0.87
Terazosin Hcl	1 mg tablet	0.2957	0.2770	1.07
	2 mg tablet	0.3759	0.3521	1.07
	5 mg tablet	0.5105	0.4782	1.07
Ticlopidine Hcl	250 mg tablet	0.5985	0.5464	1.10
Trazodone	50 mg tablet	0.1708	0.2214	0.77
	100 mg tablet	0.3052	0.3956	0.77
Triamterene/Hydrochlorothiazide	50 mg/25 mg tablet	0.0416	0.0608	0.68
Verapamil Hcl	80 mg tablet	0.2378	0.2735	0.87
	240 mg sustained release tablet	0.6841	0.6940	0.99
Average				**0.92**

Note: Prices do not include mark-ups or dispensing fees.
Source: Prices are drawn from the current ODB and Saskatchewan formularies.

Appendix 5: Alternative Procurement Mechanisms

In this appendix, I briefly discuss some alternative procurement mechanisms.

Pharmacy Benefit Managers

In the United States, employers tend to use pharmacy benefit managers (PBMs) to help obtain lower prices from pharmacies. Three PBMs dominate the US market for pharmaceuticals.[89] A large PBM possesses substantial market power over pharmacies, and can squeeze large price concessions from them by threatening to prefer one chain over another for its clients. This leads to much lower recorded retail pharmacy prices in the United States than in Canada, where PBMs play a much smaller role. This does not, however, mean that PBMs are necessarily an attractive solution. The ability of PBMs to choose one pharmacy over another forces insured employees to shift their purchases between pharmacies, at some inconvenience. A more serious problem is that the ability of PBMs to exercise market power over pharmacies is directly correlated with their ability to exercise market power over employers. If a PBM represents a significant enough share of business, it can extract low prices from pharmacies but need not pass all the savings on to the employer. A firm with a large market share of pharmaceutical purchases, however, must also have a large market share of employers, which leads to market concentration. The result is that, although pharmacies receive low prices, it does not mean that employers' payments to PBMs are also low. In essence, PBMs simply capture the market power that would otherwise have been exercised by pharmacies. In Canada, the relatively small size of the private market suggests that it is unlikely to support more than a couple of large PBMs.

Market-Assessed Prices

Gorecki[90] proposes a benchmarking mechanism in which pharmacies would negotiate the best price from manufacturers and be reimbursed at a fixed price that would be reset from time to time based on the 90th percentile of prices actually transacted for a medicine. This mechanism would increase the incentive for pharmacies to negotiate for low prices; pharmacies that obtained low prices would earn higher profits, while manufacturers that were willing to sell at lower prices would increase their market share. Pharmacies in locations that are more expensive to serve could be paid a subsidy.

This is an attractive mechanism in many respects, but some problems might arise in its implementation (which has not yet happened anywhere). First, the mechanism lacks a way of setting prices in the period just after generic competition begins—what price would be set initially if there was only one generic? Second, the mechanism also lacks a way for price decreases to occur quickly as the number of competitors increases rapidly and real transaction prices drop, which is likely to lead to large windfalls for pharmacists. Third, since some pharmacy chains represent more than 10% of the market, they could maintain the fixed price at a very high level.

89 See "PBMs Raise the Curtain," ***Managed Care Magazine***, September 2006; accessed online (20/06/08) at http://www.managedcaremag.com/archives/0609/0609.pbms.html.
90 Gorecki, ***Controlling Drug Expenditures in Canada.***

Appendix 6: Proposed Pricing for Top Ten Generic Drugs

Table A-3: Proposed Pricing for Top Ten Generic Drugs							
Product and Dose	**Number of Generics**	**Current Generic Price**	**Current Brand-Name Price**	**Current Generic Price as % of Brand-Name Price**	**Proposed Generic Price as % of Brand-Name Price**	**Net Current Generic Price as % of Brand-Name Price (-50%)**	**Net Proposed Generic Price as % of Brand-Name Price (-10%)**
		($)		*(%)*			
Azithromycin 250mg	8	3.11	5.29	59	25	30	23
Citalopram 20mg	8	0.88	1.40	62	25	31	23
Fluoxetine 20mg	8	1.01	1.94	52	25	26	23
Gabapentin 300mg	6	0.61	1.09	56	30	28	27
Omeprazole 20mg	3	1.10	2.20	50	45	25	41
Paroxetine 20mg	4	1.00	1.90	53	40	27	36
Ramipril 10mg	6	0.63	1.07	59	30	30	27
Sertraline 50mg	7	1.01	1.72	58	25	29	23
Simvastatin 20mg	5	1.39	2.43	57	35	29	32
Venlafaxine 75mg	3	1.09	1.90	57	45	29	41

Notes: Products are one dosage each of the ten largest Canadian generic products. The net prices reflect the average level of rebates to pharmacies under the current system (50%) and the maximum level of rebates under the proposed system (10%). These prices are conditional on having the same number of entrants in each market.

Source: The number of generics and actual prices are drawn from the Alberta drug benefit list, as of June 2008.

Appendix 7: Proposed Regulations for Determining the "First Generic"

The proposed rule for determining unambiguously which firm or firms should be eligible to receive a "competition royalty" is as follows.

1. The "competition royalty" in respect of a drug should be paid to a company that has filed a submission for a notice of compliance in respect of that drug that makes a statement under s.5(1)(b) of the Patent Medicines (Notice of Compliance) Regulations for which all three of the following requirements are met:

    (a) a notice of compliance is issued;

    (b) the submission is the first in respect of the drug to meet one of the following two conditions:

        (i) the submission is not subject to an application made pursuant to subsection 6(1) of the Patent Medicines (Notice of Compliance) Regulations within the time period listed in subsection 6(1); or

        (ii) if the submission is subject to an application made pursuant to subsection 6(1) of the Patent Medicines (Notice of Compliance) Regulations, the conditions of subsection 7(2)(b) of the Patent Medicines (Notice of Compliance) Regulations are met; and

    (c) the brand has not received anything of value from the company, either directly or indirectly, in any way relating to the submission.

2. Where more than one company has fulfilled all the conditions of section 1 on the same day, those companies shall share the generic royalty in equal proportions.

Appendix 8: Cost Savings and the "Competition Royalty"

Table A-4 presents the cost savings that would accrue from a "competition royalty." In all cases, actual sales volumes and brand-name prices in the year before generic entry were used. Payer savings were calculated by multiplying the actual volume of generic sales by the relevant savings rate, where the savings rate is calculated as the difference between the brand-name price and the relevant generic price. The royalty is 10% of the brand-name price times the volume of generic sales. The change in the first generic's revenues was calculated by holding the first generic's volume constant, but assuming the net proposed price instead of 70% of the brand-name price. In both cases, rebates paid to pharmacies were deducted. In the base case, the rebates are assumed to be 50%; in the proposed case, the rebates are assumed to be 10%. The net effect on the first generic was calculated as the sum of the royalty and the change in its revenues in the first year. If the system were applied only to Alberta, the dollar values would be approximately 10% as large.

Table A-4: Cost Savings and the "Competition Royalty"										
Product	**Year**	**Generics, year 1**	**Savings at 70% of Generic Price**	**Proposed Price Ratio, year 1**	**Payer Savings, Proposed Price**	**Proposed Royalty to First Generic**	**Change in First Generic's Revenues**	**Net Effect on First Generic, Year 1**	**Proposed Price Ratio, Year 2**	**Payer Savings, year 2**
		(number)	*($ millions)*	*(%)*	*($ millions)*				*(%)*	*($ millions)*
Simvastatin	2003	5	50.1	45	91.9	16.7	-2.1	14.6	35	108.7
Citalopram	2004	8	30.8	35	66.8	10.3	-6.9	3.4	25	77.1
Paroxetine	2004	4	39.1	47	69.2	13.0	0.5	13.5	40	78.3
Azithromycin	2006	8	11.4	35	24.8	3.8	-1.6	2.2	25	28.6

Source: Numbers are based on IMS Drugstore sales data for Canada.

Appendix 9: Multiple Generic Entry

Table A-5 presents examples of products with multiple generics entering over a very short time. In each case, the challenging generic that would have been eligible for the royalty is listed first.

Table A-5: Examples of Multiple Generic Entry		
Product	**Manufacturer**	**Date of Notice of Compliance**
Paroxetine (Note: Four manufacturers entered within twenty days.)	Genpharm Inc.	2003-10-08
	Ratiopharm Inc.	2003-10-09
	Apotex Incorporated	2003-10-23
	Pharmascience Inc.	2003-10-28
	Novopharm Limited	2003-12-09
	Laboratoire Riva Inc.	2004-01-09
	Dominion Pharmacal	2004-01-09
	Pro Doc Limitée	2004-02-05
	Nu-Pharm Inc.	2004-02-12
	Pharmel Inc.	2004-03-09
	Prempharm Inc.	2004-06-21
	Rhoxalpharma Inc.	2004-09-15

Azithromycin (Note: Four manufacturers entered within four days.)	Apotex Incorporated	2005-11-01
	Cobalt Pharmaceuticals Inc.	2005-11-01
	Rhoxalpharma Inc.	2005-11-02
	Novopharm Limited	2005-11-04
	Pharmascience Inc.	2006-01-03
	Ratiopharm Inc.	2006-01-30
	Genmed, A Division of Pfizer Canada Inc.	2006-01-30
	Sandoz Canada Incorporated	2006-03-07
	Laboratoire Riva Inc.	2006-03-15
	Pharmascience Inc.	2006-04-18
	Genpharm Inc.	2006-05-01
	Genmed, A Division of Pfizer Canada Inc.	2006-06-13
	Pharmel Inc.	2006-08-10
Simvastatin (Note: Five manufacturers entered within a month.)	Apotex Incorporated	2002-12-20
	Nu-Pharm Inc.	2003-01-15
	Genpharm Inc.	2003-01-15
	Genpharm Inc.	2003-01-15
	Ratiopharm Inc.	2003-01-15
	Pro Doc Limitée	2003-02-17
	Laboratoire Riva Inc.	2003-03-04
	Prempharm Inc.	2003-04-30
	Rhoxalpharma Inc.	2003-07-09
	Cobalt Pharmaceuticals Inc.	2003-09-25
Citalopram (Note: Four manufacturers entered within a month.)	Genpharm Inc.	2003-12-19
	Apotex Incorporated	2004-01-12
	Pharmascience Inc.	2004-01-14
	Cobalt Pharmaceuticals Inc.	2004-01-19
	Pharmel Inc.	2004-01-23
	Dominion Pharmacal	2004-01-23
	Rhoxalpharma Inc.	2004-01-26
	Nu-Pharm Inc.	2004-03-03
	Laboratoire Riva Inc.	2004-03-23
	Novopharm Limited	2004-04-01
	Ratiopharm Inc.	2004-04-26
	Prempharm Inc.	2004-05-25
	Pro Doc Limitée	2004-08-13

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