Generic drug pricing in Canada: components of the value-chain

Aidan Hollis

Department of Economics, University of Calgary

ahollis@ucalgary.ca

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Executive Summary

The problem of obtaining fair pricing for generic drugs has led to a series of regulatory measures in Canadian provinces. This paper offers a new way of thinking about the problems that need to be addressed, by considering three core components of the value chain of getting generic drugs to Canadians: litigation, production, and pharmacy services. The paper proposes that each component of this value chain should be paid for separately, using a royalty to reward successful litigation that benefits payers; a competitive market framework to pay for production; and a transparent, independent regulatory process to set dispensing fees for pharmacies. This approach would enable the total expenditures to match costs, would enable provinces to set appropriate quality and convenience standards for pharmacy, and would provide a measure of predictability for investors.

The paper emphasizes that it is important to establish a separate mechanism for rewarding litigation that eliminates invalid patents. The savings to Canadians from such litigation exceeds one billion dollars annually. Without addressing the need to reward this valuable activity, it is dangerous for payers to drive down generic prices, since generic firms will lack incentives to invest in costly litigation. The paper also encourages governments to establish independent regulatory authorities to set fair fees for pharmacies by employing processes similar to those used in other price regulation agencies.

1. Introduction

What is the right pricing policy for generic drugs in Canada? Ontario has, over the last few years, had a sequence of policies setting the maximum price of generic drugs as a fraction of the price of the bioequivalent patented drug. First, the maximum price was set at 75%; then 70% (or 63% if multiple generics); then 50%; and now it is moving towards 25%. At every level, the price has always been wrong. Prices in competitive industries should be related to cost. Normally, this will arise simply through the competitive process, but in the case of pharmaceuticals, the distortions created by a lack of consumer sensitivity to price combined with local market power exercised by pharmacies result in retail prices that are weakly constrained by competition. This has led to a demand for price regulation, and the outcome is the set of prices listed above.

In this paper, I explore what it means to set prices for generic drugs in a way that relates to cost. There are individual costs for three core functions in this industry: litigation, production, and pharmacy services. All of these costs must be supported by the retail price paid by the payer, who may be the final consumer, or a private or public insurer. I will focus particularly on litigation costs, which are generally underappreciated.

Ontario's approach of fixing the generic price as a percentage of the patented product appears to be based on the idea that the government is able to guess the total costs of all three functions of the industry jointly, and that the resulting allocation of revenues within the system will be reasonable. It is apparent, however, that such a guess is likely to be very wrong. After all, the government had a very different idea of the total costs only a few years ago, and in any case there is no reason to expect that costs will be constant across products or over time.

We can think of the approach being used by the Ontario government as a form of price regulation, which is typically only used in natural monopoly settings such as electricity distribution or natural gas pipelines. The experience of using price regulation in those industries is salutary; however, wherever possible, regulators have avoided the use of price regulation in favor of competition. This can be seen recently in many jurisdictions with respect to telecom and electricity generation. Wherever price regulation – based on ensuring that prices reasonably reflect average cost – has been used, regulators apply due process; price regulation is designed to reflect the real costs of the regulated service by means of using audited data and an open process that creates opportunities for firms and

other interveners to provide evidence and to be tested on it.[1] What is apparent is that the pricing regulations on pharmaceuticals imposed by governments such as Ontario's do not apply this kind of process, or even offer a clear meaningful standard as to what is to be achieved by the pricing regulations.

Within the regulated industry model, a recent trend has been to divide integrated utilities into vertically separated components.[2] For example, previously integrated electricity utilities have been divided into unregulated, competitive generating firms; regulated transmission monopolies; regulated distribution monopolies; and unregulated, competitive retailers. The benefit of this vertical disintegration has been that those components of the industry that remain regulated are less complex and easier to regulate, while those components that are now competitive have better incentives to control costs, leading to lower prices for consumers.[3]

In pharmaceutical markets in Canada, we already have some of this vertical disintegration, but the pricing model does not account for the different components of the market. Instead, it is implicitly assumed that the final regulated price should simply subsume all the components. This will result in prices far from optimal.

In a competitive market, an optimal price reflects the long-term marginal costs of supply. These long-term marginal costs include both the variable costs of production and the costs of creating capacity to supply. In competitive markets, firms choose to enter a market based on private information and incentives, which will result in an optimal provision of goods and prices. The goal of price regulation, if competitive markets fail, is to replicate the result generated by a competitive market, and regulators attempt to provide a fair and reasonable return to the firms in the industry. This is achieved by setting regulated prices equal to the average cost of the firm, which allows for a reasonable rate of return on capital invested.

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[1] See, for example, Church J. and R. Ware, 2000, *Industrial Organization: A Strategic Approach*, Boston: Irwin, especially section 26.2.

[2] See, e.g. Newbery, D. 2002, *Privatization, restructuring, and regulation of network utilities*, Cambridge: MIT Press.

[3] The Ontario government, in its recent proposed changes to the regulations, requires vertical disintegration between pharmacies and manufacturers. Given this separation, it also makes sense to use independent pricing mechanisms for each sector.

In this paper, I explore these themes by attempting to dig down a little into the different functions. I begin by considering the central role of litigation in the process of creating generic drug competition and then introduce a mechanism to pay for litigation. I then consider production costs and propose a mechanism to pay for them. Finally, I consider the position of pharmacy and suggest how it should be compensated.

Background

The paper does not provide a comprehensive summary of the structure of the Canadian market for generic drugs. For more background information, see especially Competition Bureau (2007), Grootendorst et al (2008), and Hollis (2009).[4]

Despite the importance of generic drugs, the problem of procurement policy in Canada has attracted little academic attention. A study of Ontario's "70/90" rule, which operated from 1993 to 2006, found that the rule seemed ineffective at reducing generic drug prices, since drug prices tended to cluster at the maximum level permitted by regulation (Anis, Guh and Woolcott, 2003). The Fraser Institute has published a series of papers comparing Canadian generic drug list prices against those in the United States (e.g. Skinner and Rovere, 2008). Morgan *et al* (2007) examine a broad set of policies used in New Zealand for possible application in Canada, and suggest that tendering could be used to obtain low prices for generic drugs. (In a tender, firms are asked to submit an offer to supply the entire market; typically the firm with the lowest price wins.) And a 1992 study by Paul Gorecki reviews pricing mechanisms used at that time in Canada. The key issue he addresses is the effectiveness of different mechanisms in ensuring that public insurers obtain the lowest available prices to ensure that the benefits of generic competition are passed on to the payer. The chief concern in 1992 was the presence of rebates paid by generic manufacturers to pharmacies. Gorecki notes that this was a problem also in 1979 and 1984. History has been repeating itself since 1992 as well, and rebates continue to be a troubling policy issue, despite the newer nomenclature of "professional allowances."

A very useful 2007 study by the Competition Bureau of the generic drug sector provides a comprehensive analysis of how this market operates. A 2008 follow-up report offers policy recommendations, including

[4] Canada, Competition Bureau, *Canadian Generic Drug Sector Study* (Ottawa: Competition Bureau Canada, 2007); Grootendorst P. et al, "An economic analysis of the impact of reductions in generic drug rebates on community pharmacy in Canada" Leslie Dan Faculty of Pharmacy, University of Toronto, November 21, 2008; and Hollis A. "Generic drug pricing and procurement" School of Public Policy, University of Calgary, Discussion paper 2(1), February 2009.

suggestions for private payers to seek lower prices by negotiating for discounts with networks of preferred pharmacies. The report suggests that public plans should coordinate across provinces and that there should be limits on the ability of pharmacies to capture profits through rebates.

Grootendorst *et al* (2008) explore the importance of rebates to the pharmacy business, as well as the reasons for the existence of rebates.

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 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 some combination of lower wages and fewer employees. While it is possible in principle to shift the burden of payments from the province to employers, this 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 ultimately pays for drugs. 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 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.

2. The key role of litigation and its costs

One of the striking, and underappreciated, aspects of generic drug markets in Canada is the extent to which the system has made litigation central to the timing of generic entry for most important drugs. The core of the problem is that the Patent Medicines (Notice of Compliance) (PM(NOC)) regulations make it necessary for generic firms to address all patents for a branded product remaining on the Health Canada Patent Register before they can enter the market.[5] To address a patent, the generic firm must submit a "Notice of Allegation" explaining why it believes either that it will not infringe any of the patents on the register or that the remaining patents

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

[5] This is sometimes described as "linkage" regulations since regulatory approval is linked to patent status.

are invalid. A Notice of Allegation may cost the generic firm in the range of $200,000 to develop.[6] In turn, the patentee may object to this, resulting in litigation in court over the conflicting validity or infringement claims. Until a decision is made, or for at least 24 months, the generic is not permitted to enter the market.[7] In effect, pharmaceutical patentees benefit from an automatic interlocutory injunction to prevent competition; in every other field, a patentee would need to sue for infringement and then apply to the court for an interlocutory injunction.

The PM(NOC) process gives incentives for patentees to attempt to extend their exclusivity by registering all relevant patents, including those that are likely to be found invalid or not infringed if challenged. The time that it takes litigation to proceed can extend the exclusivity period by months or years, which, for most important drugs, makes it worthwhile for the patentee to engage in the additional expense of litigation. At the same time, the additional expense and risk of litigation helps to deter generic firms from challenging patents that are likely to be found invalid or not infringed in court.

To help understand this problem, it is useful to work through a case study of an individual product, amlodipine. The case is not typical in terms of the legal arguments used, but it is typical in terms of the results: lengthy and expensive litigation was necessary to allow generic entry following a demonstration of invalidity of the remaining patent blocking entry.

A Case Study

Amlodipine (sold by Pfizer as Norvasc) is used to treat high blood pressure and the chest pain of angina. It is one of the top-selling drugs in Canada, as well as globally, with sales in Canada of over $300m per year. The history of how this product was genericized is instructive, since it demonstrates clearly the critical role of the generic manufacturers in enabling generic competition.

Amlodipine was developed by scientists at Pfizer in the 1980s. The key patent on the drug was filed in Canada in 1986. Following additional work on the product to identify a particular molecular form, a further patent

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[6] E.g. Pfizer v. Novopharm, 2010 FC 509, at 6. The substantial cost of developing a Notice of Allegation relates to the requirement to make a comprehensive argument demonstrating why the remaining patents are invalid or not infringed.

[7] Even when 24 months have passed, unless the generic has obtained a favourable decision on patent validity, it may be hesitant to enter, since if it enters "at risk" of patent infringement, the potential liability to the patentee is much larger than the possible earnings to the generic.

1,321,393 was filed in 1990. This latter patent was a "selection" patent, claiming that the besylate salt of amlodipine had "a unique combination of good solubility, good stability, nonhygroscopicity and good processability which makes it outstandingly suitable …" The product was successful in clinical trials and was ultimately developed into a medically valuable, "blockbuster" drug which obtained a Notice of Compliance for sale in Canada in 1992.

In 2004, several generic companies issued Notices of Allegation (NOAs) under the PM(NOC) regulations, alleging non-infringement and patent invalidity, and that the Pfizer patents were ineligible for listing on Health Canada's Patent Register. Pfizer responded by seeking an Order of Prohibition against all the companies. The generic companies had varying success at trial, but following appeals, all the claims of the generic companies were ultimately dismissed.

One company, ratiopharm, followed up the claims with new litigation based on Section 53 of the Patent Act, arguing that key claims of the Pfizer selection patent were "purposefully made for the purpose of misleading," and that the patent should therefore be invalidated or "impeached".

Justice Hughes took the rare "opportunity to look behind what is said in [the] patent and compare that with what actually happened and what was actually known to the inventors and others." [113] This opportunity was "rare" since the litigation was separate from the PM(NOC) regulations, which restrict the extent of investigation into the development of the patent. Justice Hughes concluded that the patent was obtained on the basis of misstatements that enabled Pfizer to give the impression that its claimed innovation was not obvious:

> [199] The evidence has shown that the misstatements that are the subject of proper pleading were made, that they were misstatements and that they served to enhance the alleged uniqueness and outstanding characteristics of the besylate salt, which characteristics were not true. …
>
> [201] This effort in distancing oneself from the patent draft and placing blame on a trainee not very competent in chemical matters, who now cannot be found, has left this Court with the clear impression that Pfizer knew that there were problems with the patent as drafted. That being the case, Pfizer has taken no steps to do anything about it save to mount a vigorous defence to this action.[8]

[8] Ratiopharm Inc. v. Pfizer Limited (July 8, 2009) 2009 FC 711.

The patent was subsequently impeached, and eight generic competitors immediately entered the market. Pfizer has appealed the decision.

This history of litigation over amlodipine is simply another case of brand-generic litigation that is so common and often very confusing. However, there are some very important lessons to be learned from this case regarding drug markets in Canada.

Litigation is costly

The first point to make is that brand-generic litigation can be very costly. In a recent court decision, Justice Hughes summarizes the history of the patent dispute between Pfizer and ratiopharm:

> a. February 17, 2006: the Federal Court (von Finckenstein J.) in an NOC application between Pfizer, the Minister of Health and ratiopharm, T-1350-04, dismissed Pfizer's application for an Order of Prohibition, finding that ratiopharm's allegations as to invalidity of the '393 Patent were not shown by Pfizer to be not justified (2006 FC 220);
> b. June 9, 2006: the Federal Court of Appeal, A-75-06, allowed an appeal from the decision of von Finckenstein J. and issued an Order of Prohibition (2006 FCA 214);
> c. August 8, 2006: the Federal Court of Appeal dismissed ratiopharm's motion for reconsideration of its Judgment of June 9, 2006;
> d. February 1, 2007: the Supreme Court of Canada dismissed ratiopharm's application for leave to appeal from the Federal Court of Appeal's Judgment of June 9, 2006;
> e. July 8, 2009: the Federal Court (Hughes J.) in an action for infringement of the '393 Patent brought by ratiopharm against Pfizer declared the '393 Patent to be invalid (2009 FC 711);
> f. July 9, 2009: Pfizer files a Notice of Appeal to the Federal Court of Appeal from the Federal Court Judgment of July 8, 2006. That appeal A-281-09 is currently waiting to be set down for hearing subject to the disposition of several motions;
> g. Also on July 9, 2009: ratiopharm received its Notice of Compliance, the Federal Court of Appeal Prohibition Order was considered to be no longer operative since the prohibition only lasted till the expiry of the '393 Patent and the Patent had been declared invalid on July 8, 2009;
> h. August 14, 2009: ratiopharm filed a Notice of Motion in the present proceedings seeking to set aside the Order of the Federal Court of Appeal dated June 9, 2006 and to dismiss this application;
> i. October 9, 2009: Pfizer filed a Notice of Motion to quash or adjourn ratiopharm's motion pending the determination of the appeal in A-284-09.

(Pfizer v. Minister of Health, 2009 FC1165, at 3)

What is very apparent is that the regulations are extraordinarily complex, (or according to Justice Hughes, "Byzantine") and this naturally leads to extraordinary legal expense. In the amlodipine case, as in many others, there were two rounds of major litigation in addition to a series of appeals.

ratiopharm made a substantial investment in litigation – approximately $5m[9]. The court cases started in 2004, and have proceeded over a course of six years, with literally hundreds of hours of testimony and argumentation in court. While ratiopharm may have received partial compensation from Pfizer for some of its expenses, these costs assessed in court would have been only a fraction of ratiopharm's total legal bill – approximately 10%. At all times, ratiopharm faced a real risk that it could lose the case. Indeed, there is still an appeal in the works. ratiopharm's expenditure was thus undertaken with considerable risk. Assuming, for example, that there is a 10% chance of ratiopharm losing on appeal, the company would need to be compensated with over $10m in profits to make its investment profitable on an expected basis.[10]

There are strong incentives to extend patent exclusivity

The incentives for patentees to use the system to extend their period of exclusivity are very strong. Norvasc sales in Canada in 2009 were about $340m, and the costs of production of this product are only a tiny fraction of this figure. The '393 patent that was impeached by Justice Hughes would have expired in 2010, which would have effectively extended Pfizer's exclusivity period from 2006. Had it not been impeached, patent exclusivity of the product would have earned Pfizer roughly $1.2bn. It is important to understand that these earnings in Canada are based on an innovation that, according to the court, was obvious and lacked utility, and a patent that was obtained through intentional misstatements. While there were some patenting costs, and undoubtedly substantial legal fees paid by Pfizer in conducting what Justice Hughes characterized as "a vigorous defence", the total costs to Pfizer of the patent and associated litigation would likely have been over $10m, but far, far less than Pfizer's gains from the patent.

In these circumstances, it should be clear that it will be natural, and even inevitable, for patentees to attempt to extend their exclusivity period for important drugs by filing as many patent applications as possible and then

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[9] Telephone interview with Dr Kane Denike of ratiopharm, April 23 2010.

[10] If ratiopharm loses on appeal, Pfizer will seek damages for all sales made by ratiopharm. Assuming that ratiopharm sells approximately $40m of amlodipine at generic prices in a year, ratiopharm will face a damages claim for at least $80m of lost Norvasc sales, or perhaps $70m in lost profits to Pfizer, on a rough estimate. Thus, ratiopharm needs to earn profits during this year equal to its incurred litigation expenditures and probability-weighted infringement liability of $70m. Call π the probability that ratiopharm loses on appeal. Then it needs to earn profits of at least $\$5m + (\pi \times \$70m)$. For example, if ratiopharm faces a 10% chance of losing on appeal, it will need to earn at least $12m in profits during the year.

defending them vigorously. This means that exclusivity periods will last longer than is necessary if no one is motivated to attack patents that are likely to be found invalid or not infringed in court. In the case of amlodipine, the end of the exclusivity period was delayed from 2006 to 2009 through the use of the '393 patent.

Indeed, it is common for a drug to be protected by multiple patents expiring at different times. On one hand, this may reflect the multiple patentable technologies may be employed in the development and manufacturing of a new drug. On the other hand, it is clear that, for most high-revenue drug products, generic entry does not arrive upon the *expiry* of the last patent, but upon a court finding that the remaining patents on the product are either invalid or not infringed. For drugs with smaller sales, it is more common to observe patent expiry as the precursor to generic entry – but it is difficult to know whether this is because there is less incentive to engage in defensive patenting, or less incentive for generic firms to challenge weak patents when the potential gains are small.

In other circumstances, patentees maximize patents' strategic capabilities. For example, Janssen Ortho developed galantamine as a treatment for Alzheimers. Several generic drug companies filed Notices of Allegation and Janssen commenced litigation to prohibit entry based on patent 2,310,950. At the same time, Janssen developed an extended release formulation of the product and transferred most patients to this formulation. Following this, the PM(NOC) cases were discontinued, and no decision was made on the merits. There are now several generic companies authorized to sell galantamine without any objection from Janssen but also without much of a market, since most of the market was transferred to the extended release product. However, when Mylan filed a Notice of Allegation for galantamine extended release, Janssen applied for a prohibition order on exactly the same patent as before.

The gains of litigation flow mainly to payers, not generics

When generic competition is enabled, there are typically substantial gains for payers. In the case of amlodipine, savings for payers will be approximately $160m in the first year. However, payers do not contribute towards the costs of patent litigation. If generic markets are competitive, generics will be unable to earn substantial profits from litigation, but payers will obtain substantial savings. However, the payers are relying on the generics, who are poorly motivated, to invest in litigation to show that patents are invalid or not infringed. In other words, there is a misalignment of the benefits and costs of litigation. The benefits of litigation flow to payers, and the costs – and the decision authority to litigate or not – remain with generic firms. On the brand side, the patentee bears the costs of investing in patents and litigating them, but also receives the benefits of

these initiatives through the exclusivity rights conferred by the patent if successfully maintained.

It is obvious that when costs and benefits of decisions are poorly allocated across parties, optimal decisions will not be made. In general, competitive markets are characterized by a similar problem in the allocation of benefits and costs from the entry of a competitor, but for reasons unique to the pharmaceutical industry, this misalignment of benefits and costs is likely to be particularly severe in the case of generic drugs.

We can organize this idea by considering two dimensions: first, the intensity of competition between firms (or the extent to which the firms' products are good substitutes) and second, the extent to which there is a reduction in the entry costs of subsequent firms from the entry of the first competitor.

When firms sell good substitutes, the similarity of the products tends to increase the competitiveness of the market and to drive prices down towards marginal cost. (In a Bertrand model of differentiated products, the less the differentiation, the lower the prices.) It is evident that generic drugs are completely undifferentiated in their characteristics, which means that they must compete only on price, leading typically to low mark-ups over the cost of production. Consider a situation with one firm that offers a product at a high price. If a second firm enters with an undifferentiated product, in the extreme the two firms will compete with prices equal to marginal cost. (This is an example of the homogeneous goods Bertrand model, which leads to pricing at marginal cost.) In this case, all the benefits of entry accrue to consumers, and none to the entrant.

Perfect substitutability, however, need not imply perfect competition: competition also depends on the number of competitors. With only one firm in the market, prices will be set at the monopoly level. If entry is costless, then we can expect more firms to enter the market, which results in a market approaching perfect competition. However, if entry is costly, entrants will decide not to enter if they anticipate prices falling to near marginal cost. In generic drug markets, the first generic entrant, by demonstrating patent invalidity, typically paves the way for all subsequent generics.[11]

[11] Novopharm (Teva) recently applied to reduce the extent to which other firms could freeride on its Notice of Allegation, by having the Notice made confidential. Novopharm stated its argument: "If Novopharm's generic competitors are allowed to free-ride on Novopharm's investment and are able to again market access at the same time or shortly after Novopharm, then Novopharm would forever lose the opportunity to benefit from being the first or one of the first generics in the generic pregabalin market in terms of

Thus, generic drug markets are extreme in two dimensions: the products are perfect substitutes, and the benefit of investment of one firm in the fixed cost of litigation spills over completely to other firms.

In the case of amlodipine, some eight generic firms entered the market immediately following Justice Hughes' decision to impeach the patent, but only ratiopharm bore the cost of litigation. Thus, ratiopharm ended up in a highly competitive environment after investing millions of dollars in litigation. ratiopharm had costs $5m out of pocket, and higher after adjusting for the cost of capital.[12] Thus ratiopharm needs to make roughly $10m more than it would have had it relied on another firm to eliminate the '393 patent or waited for the patent to expire.

It is unlikely that ratiopharm's profits will compensate for these costs. The '393 patent was impeached approximately one year before it would have expired. ratiopharm will earn revenues of approximately $40m on amlodipine during this year, according to data from IMS Health Canada. To determine profits, we must deduct costs of production, marketing, and the payment of rebates and professional allowances. Twelve generic firms currently compete in the market for this product, so it unlikely that ratiopharm can earn a margin of more than 10% of the price of the product. Thus, its profits are likely to be less than $4m during the year, which is insufficient to even cover the costs of litigation.

The speedy entry of many generics into the market for amlodipine is not unusual for a molecule with substantial sales volume. Indeed, the patentee will typically have licensed an "authorized generic" that will enter the market at the same time as the first independent generic. In addition, the patentee will often have settled litigation with other generics by offering them an inducement of ceasing any objection to their entry into the market

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market share, after having incurred substantial cost to do so. Novopharm's competitors would profit from having access to the Novopharm NOA by gaining earlier and less expensive market entry, to Novopharm's direct detriment." Pfizer v. Novopharm, 2010 FC 409, at 12. The prothonotary declined to allow confidentiality.

[12] Systematic information on litigation costs faced by generic firms is unavailable. However, 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).

as soon as another generic has entered the market. In effect, this is like a "poison pill" for any generic that litigates. There may be several generic firms poised to enter simultaneously based on the success of the firm in litigation.

There is yet an additional obstacle to generic entry: patent infringement actions. The PM(NOC) decisions are not determinative of whether a patent is being infringed. For example, a generic firm may be successful in addressing a patent under the PM(NOC) regulations, resulting in a finding that the patent is invalid and that the generic can enter and compete. As soon as the generic actually enters the market, however, it faces a patent suit, in which the patentee has another chance to assert the validity of the patent. In effect, this is a double jeopardy situation. The risk of losing in a patent infringement action is particularly significant for generic firms, since they face the possibility of paying damages to the patentee equal to the patentee's lost monopoly profits, and are earning much thinner margins on their own sales. Thus, the generic might face damages equal to ten or twenty times the margin earned on each unit sold.

Not only are payers generally unwilling to contribute to the costs of generic litigation, but in some cases they create an environment that penalizes the generic litigant. For example, Saskatchewan elected to use a tender process ("Standing Offer Contract") to determine the sole supplier of amlodipine to all pharmacies in the province following generic entry. The winner of this contract was GenMed, a subsidiary of Pfizer, which apparently offered to supply amlodipine at the lowest price. The result, of course, is that although ratiopharm invested a substantial amount to *enable* generic competition, and although Pfizer invested a substantial amount to *prevent* generic competition (and on the basis of a patent obtained through intentional misstatements), ratiopharm will earn no revenues in Saskatchewan. Pfizer has enjoyed several years of charging monopoly prices because of that patent. Not surprisingly, the Saskatchewan tendering process allows no scope for rewarding pro-competitive behaviour, or penalizing anti-competitive behaviour, but the system has created perverse incentives to invest in patents that will extend exclusivity, even if it is likely or indeed certain that the patents will ultimately be found invalid.

This leaves the question of why ratiopharm invested in litigation, and whether it would do so again under similar circumstances. One theory is that generic firms earn such substantial margins, despite the presence of competition, that ratiopharm was able to cover its costs through the

increase in profits.[13] A second possibility is that ratiopharm anticipated success in claiming for damages under Section 8 of the PM(NOC) regulations. This point is discussed below. A third possibility is that ratiopharm incorrectly expected much quicker success in litigation. A fourth, though more unlikely, possibility is that the generic firms cooperatively challenge weak patents, and effectively take turns to bear the expense of litigation. What is clear is that these explanations are a slender thread on which to base policy encouraging bad patents to be challenged by generic companies.

The reliance on generic litigation

If amlodipine were an unusual case, it would be of limited interest. However, as that case shows, the gains from using the patent system to extend exclusivity are extremely large. If a patent can be used to extend exclusivity on a drug that sells the same volume as amlodipine, the extra revenues for the patentee can be about $1m per day. Thus, we find that most important drugs have multiple patents with different expiry dates.[14] The later-expiring patents are typically relatively weak, and a trial may demonstrate that they fail to disclose an innovation that is actually non-obvious. This is demonstrated by the following Table.

[13] One concern here is that the amlodipine litigation was initiated before Ontario's 2006 reforms reducing generic pricing, and that we can expect reduced generic willingness to invest in litigation in the future.

[14] The Therapeutic Products Directorate Statistical Report 2008 shows that there were approximately 1.8 patents per medicine on the patent register. For about half the products, there is only one patent listed. However, for 126 products, there were 3 or more patents listed. 26 products had 6 or more patents listed. One product had 22 patents listed. Available at http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodpharma/applic-demande/docs/patmedbrev/patmrep_mbrevrap_2008-eng.pdf

Table 1

The impact of litigation on payer costs

Drug	ODB Predicted Patent-Off Date (FY)	Patent Register Expiry (FY)	ODB spend ($m p.a.)	ODB savings ($m)	National savings ($m)
Prevacid	2010	2014	63.1	126	326
Caduet	2011	2023	14.6	88	205
Lipitor	2011	2023	354.0	2,124	7,497
Norvasc	2011	2015	166.3	333	700
Hyzaar	2012	2014	6.2	6	45
Singulair	2012	2015	1.2	2	121
Crestor	2013	2021	107.4	430	2,087
Plavix	2013	2020	56.3	197	949
Prograf	2013	2014	9.2	4.6	27
Aricept	2014	2018	67.3	135	245
Celebrex	2014	2018	29.3	59	285
Wellbutrin	2014	2015	2.4	1	16
Total				**3,504**	**12,503**

The table shows most of the high-revenue small-molecule drugs expected to face generic competition over the next few years. The second column is drawn from a presentation made by the Ontario Ministry of Health and Long-Term Care in the summer of 2009, and shows the date according to which the Ministry expected generic competition to arrive.[15] The third

[15] Delivering world class value for money in provincial drug system: A Case for Change, Ron Sapsford, Deputy Minister, Ministry of Health and Long-Term Care, July 2009. Available at

column shows the date at which the last remaining patent listed on the Health Canada Patent Register was due to expire. In the absence of generic litigation, this indicates the earliest date possible for generic competition. The fourth column shows the total annual expenditures made by the Ontario Public Drug Program (OPDP) for each product. The fifth column shows a rough estimate of the savings to the OPDP due to generic entry before expiry of the last patent listed in the Patent Register.[16] The last column shows the savings from this at a national level based on IMS Health Canada data.

The savings enabled by generic litigation are quite large. For example, the Ontario Ministry of Health recently announced that its reforms to generic drug pricing would save approximately $500m annually.[17] As Table 1 shows, the amount saved by just the OPDP is roughly $300m per year from anticipated generic litigation only on those drugs listed above over the next 13 years. If we were to consider savings to private payers, this practice could double the savings to Ontario. *At a national level, the total savings attributable to generic litigation on the products listed in this table only exceed $12bn.*

This list excludes drugs that had already been genericized because of litigation, and which would otherwise be priced much higher currently, such as olanzapine (Zyprexa). It also omits other products that generics are currently litigating, such as galantamine ER, escitalopram, irbesartan, oxycodone, dorzolamide, and anastrozole. The list also does not account for savings that would have been achieved if patents ultimately found invalid had never been filed at all.

There are two considerations that might help to minimize problems relating to these dysfunctional incentives to patent and litigate in Canada. First, a system of damages could reduce the benefits from gaming the patent system. Second, Canadian patents are part of an international system of patents, and international patent litigation could eliminate the necessity for litigation in Canada. However, as I discuss below, neither of

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http://www.health.gov.on.ca/english/providers/program/drugs/resources/drug_system_renewal_forum.pdf

[16] Savings are calculated assuming that (a) the generic price is half the brand price; and (b) the period of savings is simply equal to the difference between the date at which the last registered patent expires on the patent register and the date on which the Ontario government anticipates generic entry.

[17] Lee Greenberg, "Drug reform to save $500M" Windsor Star, April 9, 2010.

these considerations fully addresses the problems created by the linkage regulations.

Does the prospect of damages help to incentivize generic litigation?

The PM(NOC) regulations allow for damages to be paid to a generic firm that has been kept out of a market unduly because of the application of the regulations on the basis of a patent that is ultimately shown invalid or not infringed. While the regulations have been in force for many years, no payments have yet been made, and the first damages cases are only now being resolved. While in principle damages may appear to provide a solution, the amount of damages to be paid will not properly incentivize generic firms to invest in challenging patents, nor will it deter patentees from filing, registering, and litigating even patents that are certain to be found invalid. There are several reasons that damages are insufficient action towards these problems.

First, the regulations appear to offer the generic firm only its own lost profits for the period of injunction. If the generic market is highly competitive, the lost profits will be small for two reasons: (a) a competitive market with many manufacturers will allow very little scope for profits by generic firms, and (b) the effects of the injunction on the generic firm's position in the market following the injunction is not included in the damages calculation. Thus, the damages can contribute little to the expected profits of a generic firm that engages in litigation.

Second, the damages do little to deter patentees from attempting to extend exclusivity periods through registering even patents that they expect to be found invalid in court. This is again simply because the profits of a generic challenger by construction will be much smaller than the extra profits earned by extending the monopoly. Again, the more competitive is the generic market, the smaller are the profits of a single generic competitor, and the less substantial are any damages paid under Section 8 of the regulations.

In a typical bilateral setting, where A pays damages to B for harming B's property, it is appropriate to set the damages level equal to the damage actually suffered by B. The setting of generic drugs is different, however, because when B is harmed by being kept out of the market owing to A's invalid patent, *B is not the only party harmed*. Payers, who are chiefly the ones who suffer owing to monopoly prices, and other generics, who might have entered had the patent been eliminated, are also harmed, and the regulations offer no way for these parties to be compensated.[18] If the

[18] The opposite situation occurs when a generic enters a market and is then successfully sued for patent infringement. The generic is liable for the entire damages suffered by the

generic industry is very competitive, almost all the costs created by the invalid patent are borne by payers. In effect, benefits and costs are systematically misallocated. This creates incentives for patentees to game the system, induces large litigation costs, and transfers wealth from payers to patentees.

Will litigation in other countries solve our problem?

One interesting aspect of pharmaceutical patenting is that the "invention" occurs once somewhere in the world, and then there are patents issued in different jurisdictions on this invention. Thus, generic firms challenge similar patents in different countries at the same time. Given this situation, one might hope that generic firms in Canada could rely on discoveries of invalidity of the same patent elsewhere. The problem with this approach is that typically the patents to be addressed are national, so that even if similar patents have been addressed in other countries, Canadian patents must still be addressed in Canadian courts.

In the case of amlodipine, generic competition arrived in the US in 2007. At this point, Mylan was awarded 180-day exclusivity as it was the first to assert invalidity in American litigation.[19] Pfizer's monopoly continued in Canada until litigation by ratiopharm was successful in overturning the '393 patent. The US or other foreign decisions on this patent were not relevant for Canadians, and indeed the grounds for the US decision were quite different from those in Canada.[20] In other cases, such as olanzapine, important drugs have been genericized in Canada in advance of other jurisdictions.

Atorvastatin (Lipitor) offers an interesting example. Pfizer owns 17 Canadian patents on atorvastatin 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 a Notice of Compliance for Lipitor in February 1997.) Generic companies had been aggressively litigating the relevant products, and Apotex won a decision invalidating Pfizer's selection patent in 2007. Because of the existence of other patents that must also be addressed under the PM(NOC) regulations, Apotex has not entered, but it and other generic firms

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patentee, but is likely to have earned only a fraction of these damages: most of the benefit will have been captured by payers, who have benefited from low prices.

[19] Mylan press release, June 5 2007, available at http://investor.mylan.com/releasedetail.cfm?ReleaseID=406533.

[20] Pfizer v. Apotex, Fed. Cir. 2007, 06-1261.

are expected to enter in mid-2010, when the invalid selection patent expires.[21] Ranbaxy was litigating in the US and finally settled with Pfizer to enter there in 2011. While the US settlement incorporated a settlement with respect to other jurisdictions, the date of generic entry in Canada appears to have been determined by the decision in Canada. Had there not been generic litigation in Canada, there would have been no reason to grant Ranbaxy early market access in Canada.

Thus, while there is often some connection between patent litigation in different countries, and this may enable some use of the same experts to provide testimony in different countries, the varying patent laws and national courts mean that litigation needs to be conducted in Canada in order to address Canadian legal requirements. Reliance on litigation in other countries is, for the foreseeable future, not an option.

3. How should we pay for litigation?

The correct policy response to the problem of paying for generic litigation must be a mechanism to reward generic firms that successfully open the door to competition and are unable to benefit from it because of strong competition once the door is open. In essence, the patent provides a similar reward to innovative companies; firms that invest in order to create a valuable innovation are given the chance to benefit from the innovation which would not be possible if there existed strong competition in the market. A generic firm that invests in litigating and successfully eliminating an invalid patent, thus enabling generic competition, should be rewarded. If these firms are not adequately rewarded, the incentives to engage in socially valuable litigation are seriously weakened.

What form could this reward take? In the US, there is a 180-day exclusivity period granted to the generic challenger. The rules are complex and may be thought of as temporarily stifling competition. This limit to competition also has the undesirable effect of rewarding the patentee, since the patentee also benefits from the period of limited competition, during which it will often launch its own authorized generic. This system rewards the generic firm that has successfully demonstrated invalidity, but also rewards the patentee that has unsuccessfully tried to maintain an unjustified monopoly on the basis of an invalid patent by allowing the patentee to share in a further period of limited competition. Of course, rewarding both sides for litigation will tend to encourage litigation.

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[21] Of course, the PM(NOC) decisions do not limit Pfizer's right to sue for patent infringement, and it seems probable that there will be patent infringement actions relating to atorvastatin.

A proposal that avoids this undesirable outcome is a generic royalty system, as I proposed in Hollis (2009). This system would require generic firms that were enabled to enter because of one firm's investment in litigation to pay the litigant a fraction of their revenues on the product for some period (perhaps one year). The patentee would also have to pay this royalty if it wished to continue selling a bioequivalent product. The royalty could be based on the extent of competition;: the more firms, the larger the royalty, on the basis that the larger the number of firms, the more severely competition eliminates the opportunity for the litigating generic to benefit from its success in court. For example, there might be no royalty at all if no more than two generic firms entered the market within a year.

Addressing objections to the royalty system

There are four objections to the royalty system. First, some have objected that this system seems to imply government sponsorship of one side of commercial litigation. This isn't quite accurate. A royalty system implies government sponsorship only of the winner. If the patentee is successful in litigation, the government continues to allow it to charge a high price under the exclusivity created by the patent. If the generic firm is successful, the royalty creates a reward for it. The generic would not be rewarded for litigation in which it failed to provide meaningful benefits to society by eliminating an undeserved exclusivity. Thus, this is not a system that would encourage litigation regardless of the merits – it would only encourage litigation expected to be successful.

Second, the royalty system will create the need for a mechanism to determine eligibility for payments. While there could be a risk of litigation between generics for this in some cases, it should be possible to create rules that would limit the potential for uncertainty and conflict. I have provided a suggested set of rules for determining eligibility in Hollis (2009), Appendix 7.

Third, the royalty will increase prices for payers during the period of the royalty. However, this price increase should be put into context of the size of savings for payers achieved by litigation, the amount that is needed to incentivize generic patent challenges, and the opportunity this system would create to use more aggressive tools to push down generic prices following entry. As indicated above, generic costs in litigation would typically be less than $5m, compared to savings to payers that are in the hundreds of millions of dollars per year. A generic royalty that was related to the size of the gains created, and perhaps capped at around $20m, seems like a reasonably small price to pay for significant gains to consumers.

Fourth, the royalty regulations should ideally be a federal, not provincial, responsibility. This is problematic since the provinces are the payers and

have the greatest interest in eliminating barriers to competition; but patents are federal, and the gains from eliminating barriers to competition accrue to all payers. However, there is no reason why a coalition of major payers – specifically provincial insurers – could not collectively impose such a royalty system, and indeed there have been recent moves towards increased collaboration.[22]

4. Production costs

The second component of costs is production. I include here not only the cost of goods, wages, and capital, but also the firm-specific development costs. All of these costs vary substantially across products. Some products are simple to make, while others require extensive pre-production engineering to scale up production to commercially viable quantities. The cost of inputs also varies considerably. For many products the API (Active Pharmaceutical Ingredient) is a substantial cost factor. Added to all of this, the average cost of production varies by volume and across time. Canadian costs may sometimes be higher than international costs because of the need to satisfy Canadian regulatory requirements that require generic products to be of the same size, shape and colour as the innovator's product.

What is very clear is that Ontario's generic price ceiling of 25% (or any other randomly selected fraction) of the brand price has no relationship to the costs of production. The rule that the generic price should be a fraction of the brand price would make sense only if brands were priced at some multiple of the cost of production. However, brand pricing has no relationship to production costs in Canada or elsewhere, which is seen in the regulations in the Patent Act regarding the Patented Medicine Price Review Board (PMPRB), where the "maximum non-excessive" price for the PMPRB is never based on cost.

Biologics

An important consideration in the design of pricing policy is that it should be flexible to accommodate the variety of circumstances it will cover. One of the more important circumstances is the expected future arrival of "subsequent entry biologics" (SEBs). Small-molecule drugs, which have historically been the most important drugs in terms of expenditures, seem likely to shrink in importance. A recent report predicts that by 2016 only

[22] Karen Howlett and Rheal Seguin, Provinces join forces with plans to cut drug costs. Globe & Mail, 6 May 2010.

two of the top ten drugs by revenues will be small molecules.[23] Generic versions of these biologics, or SEBs, will have relatively high production costs and substantial development costs, and there will be few SEBs competing with any given originator product. Instituting a descending price schedule for generic SEBs, as described in the next section, provides a framework that can be effectively used to ensure gains to payers. To the extent that this mechanism helps firms considering developing an SEB to predict the price environment, they will face less risk and more willingness to invest in the costs necessary to enter the market.

5. How should we pay for production?

Ontario and some other Canadian provinces have historically based maximum generic prices on the brand price, and Ontario has set the new low standard at 25%. However, there are many products with production costs either far below or far above 25% of the brand's price. It is not clear what logic there is in setting an arbitrary price bearing no relationship to actual costs. It is, however, very clear that this approach will generate undesirable distortions in the market. First, prices will be *excessive* for many products, relative to costs. This will cause either (a) excessive, inefficient entry of generic producers into these markets, if rebates are eliminated[24] or (b) rebates to be paid by manufacturers to pharmacies. Second, prices will be *inadequate* for many other products. In this case, manufacturers will (a) not invest in challenging patents, resulting in unjustified extensions of exclusivity periods with high prices and (b) upon entry, seek special price exemptions because of high costs. This effectively results in price regulation of potentially competitive manufacturers on a case-by-case basis. Arbitrarily determined prices create distortions in markets and should be avoided.

It is clear that it is possible to improve on a system where the prices of generic drugs are unrelated to their costs. Given the same amount of total expenditure, it should be possible to improve incentives by setting more aggressive prices on drugs that have lower production costs, and more

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[23] EvaluatePharma, "Humira set to steal Avastin's crown." May 3, 2010, available at http://www.evaluatepharma.com/Universal/View.aspx?type=Story&id=211976&isEPVantage=yes

[24] One of the expected results of the Ontario ban on rebates is a reduction in the number of pharmacies, as discussed in Section 7. This will allow economies of scale within pharmacies, driving average costs down. But allowing a fixed price for generics, far above cost, while banning rebates, is likely to lead to exactly the opposite effect: more generic firms will enter the market, reducing volumes for each manufacturer, and driving average costs up.

highly rewarding both sellers of newer drugs and those that have higher production costs.

In general, it is difficult to know what the true production costs of generic drugs are, but the age of the product and number of generic competitors is certainly observable. A reasonable mechanism to encourage generic competition would be to set generic prices higher for their first year or two in the market, and then to automatically lower prices. This would provide better incentives for entry, since those firms that arrived relatively early – including the litigating firm or firms – would be better rewarded. However, this approach would, as suggested in Section 4 of the paper, still always choose the "wrong" price.

A more attractive approach, therefore, would be to make the price conditional on the number of entrants in the market, and to have the price automatically fall as entrants arrive. This is similar to, but more comprehensive than, the approach used by Ontario under the "70/90" rule until 2006. A more aggressive approach to this rule would start with a lower price and continue to reduce prices provided more firms were willing to enter. For example, prices could start at 50% of the branded product price, and fall by 10% or 5% for every additional entrant. This approach has very desirable properties, since it addresses two problems at once. First, this mechanism will drive prices down towards the cost of production, since firms will be willing to enter if prices exceed the average variable costs of supply. Thus, prices will tend towards the "right" level by relying on decisions made by firms. Second, early-entering firms will be advantaged by the opportunity to earn higher profits before later-entering firms arrive. If many firms do ultimately enter, as in the case of amlodipine, prices will be driven down quickly to very low levels.

A tender mechanism can achieve a similar result, but may also require another set of institutions to conduct the tender and manage a distribution system from the tender winner. Tender systems are less suitable in some markets, since (a) frequently there are relatively few participants, especially in the early years of the market, and (b) in some cases there may be supply security considerations that preclude reliance on a single supplier.

How have other countries achieved low generic prices?

Other countries have used different paths to achieve low prices. The most common strategy to achieve low prices is tendering, which operates especially effectively when there are many potential participants and there are significant economies of scale from producing large volumes. New Zealand, for example, has effectively used tendering to lower generic drug prices. The system in New Zealand is simplified by the fact that the

government is the insurer for all drugs in the country. However, this system creates no incentives for litigation, since there is no benefit from elimination of invalid patents or demonstration of non-infringement. This problem is somewhat mitigated by the fact that New Zealand does not have any "linkage" regulations like the PM(NOC) regulations. New Zealand has also eliminated domestic production of pharmaceuticals, which can create public health concerns for the future. If Canada attempted to duplicate the New Zealand model, without addressing the need to reward litigation separately, it would likely result in much longer exclusivity periods for patented drugs that would be safe from litigation.

The Netherlands recently adopted a tendering strategy. Their approach allows for more than one firm to supply into the market, and has significantly reduced prices and the amount of rebates paid to pharmacies. Germany and Belgium have adopted somewhat similar schemes (Kanavos et al 2009; Carradinha 2009).

A critical point to be made here is that using a mechanism that drives price down to the variable costs of production – such as tendering or the declining price schedule – is appropriate only if there is also a separate tool to address the need to incentivize litigation by generic firms. In the absence of a tool serving this purpose, aggressive pricing approaches will result in slower generic entry, undermining the ultimate goal of reducing total expenditures.

6. Pharmacy costs

Unlike generic drug manufacturers, pharmacies are in a position to exercise considerable market power, despite their apparent competitive position. This is at first perplexing; pharmacies appear similar, for example, to supermarkets, offer very similar services, and often compete with other pharmacies nearby. However, pharmacies do not compete on the basis of price, but of service. Consumers lack financial incentive to chase the lowest price for drugs since the cost of drugs is largely borne by insurance. Elimination of insurance would undoubtedly make consumers more price-sensitive. However, insurance is highly desirable for a variety of reasons, and making consumers price sensitive would ultimately result in many consumers not benefiting from drugs prescribed for them.

Pharmacies also possess very strong market power as buyers. This is because generic versions of the same molecule are perfectly substitutable, while pharmacies are not. If a generic charges a higher price, the pharmacy can simply buy an equivalent product from a different supplier. In contrast, if pharmacy A demands a larger rebate, a manufacturer cannot simply turn to pharmacy B, which serves a totally different set of patients, as a

substitute. As a result, pharmacies can be expected to capture almost all the rents available in any drug market served by multiple generics.

Thus, pharmacies occupy a position with considerable market power, which is the core consideration motivating price regulation of generic drugs. Pharmacy services are complex, and determining the true cost of these services is correspondingly difficult. Nevertheless, this is a much simpler problem than determining the total cost of drugs plus pharmacy services combined. A number of studies have analysed the cost of pharmacy services in different settings, with typical estimates of cost per prescription delivered in the range of $5 to $15 (A.T. Kearney, 2007). The average costs per prescription depend on the volume, on the types of products, and on the clientele. Fortunately, all of these are observable by a price regulator.

Given that pharmacies possess market power, price regulation can be justified. If prices are not regulated, pharmacies will be in a position to earn excess profits from exploitation of their position, which will attract more entrants into the pharmacy market. These additional entrants will reduce the average volume per pharmacy, and average costs will be driven up and returns downward. The increase in pharmacies will create extra convenience for patients. If market power is limited due to price regulation, pharmacies will face lower returns and pharmacies will exit the market. This will lead to increased volume and efficiencies at existing pharmacies. Evidently, this relationship between price regulation and the number and profitability of pharmacies requires considerable care on the part of governments.

7. How should we pay for pharmacy services?

In order to reduce complexity of price regulation, it is desirable to limit the way that pharmacies are paid. This can be done by limiting achievable costs for a desired standard of convenience to patients. Payment based on the actual costs of each pharmacy would lead only to cost inflation suffered generally in industries with price regulation based on the average costs of the firm. Fortunately, there are many pharmacies, so it should be possible to base payments to pharmacies on a benchmark model of efficiency, which can be adjusted for market size, clientele characteristics, and product characteristics. This is more or less the approach taken by the Ontario government in fixing a maximum dispensing fee with premia established for rural pharmacies. The payment for professional services other than dispensing also follows this model. Essentially, in this proposal pharmacies would be paid on a fee for service basis, similar to the reward mechanisms for physicians and other health professionals.

A fair price regulation system

Price regulation is difficult in all circumstances. However, there are many models of price regulation in Canada, and all require an independent regulatory authority that sets prices on a basis of common understanding. Independence of the regulatory authority insulates the decision-making process from political considerations.[25] This is crucial to creating a system that is perceived to be fair and sustainable, since industry can predict rates of compensation. This predictability in turn allows industry competitors to make investment decisions. A lack of predictability in the system damages the willingness of investors to invest, and requires to a higher rate of return to compensate them. Lack of predictability also leads to investments that are regretted. For example, price regulation changes in Ontario have raised concern for independent pharmacies that may be forced to close due to the new pricing model.

A fair system of price regulation should also disclose the objective of the pricing system so that all parties can make appropriate decisions. For example, the National Energy Board allows for "just and reasonable" tolls on pipelines with the explicit goal of allowing companies to earn to an appropriate rate of return on their investments. Similarly, the PMPRB allows patented drug prices to be set based on specific, non-cost criteria.

Finally, a fair price regulation system requires a fair process for decision-making. In many cases, the process is a quasi-tribunal, which allows firms and others to bring forward relevant information to allow the tribunal to make a decision on pricing. For example, in the case of regulating pharmacies, one would expect to give pharmacies, insurers, and the Minister of Health an opportunity to submit evidence on costs and quality in order to establish a fair price. Within the process, this evidence should be open to testing or verification.

Examples of this kind of system in Canada include the NEB, the PMPRB, the CRTC, and many provincial authorities. A pharmacy price-regulation authority could be constituted occasionally, at which point prices would be set prices for several years at a time, as the CRTC did under its price cap hearings for local telecom, and so it need not necessarily be a very expensive process. If prices are not set based on clear regulatory goal by an independent authority, there exists enormous uncertainty on the part of market participants and a political environment that is poisoned by mistrust and lobbying.

[25] This also insulates politicians from decisions that are politically unpopular.

In general, one should be careful about recommending a system of price regulation. However, the reality is that individual provinces have already implemented systems of price regulation on an *ad hoc* basis. If price regulation is to be continued – as seems likely – then it should operate following principles of regulation established in many jurisdictions and industries.

Rebates

Pricing at average cost implies zero rebates paid by manufacturers to pharmacies. These fees are common in distribution chains, though they are usually labeled "slotting allowances." Eliminating rebates would therefore make the pharmacy business model for prescription drugs different from its model for other non-prescription items.

Eliminating rebates works against a general principle of permitting freedom of contracting. The government has an interest only in the final product price, and not in the distribution of rents within the total chain of supply. Government limitations on contractual arrangements between manufacturers, wholesalers, and pharmacies are therefore unattractive. However, in this case, a ban on any kind of payment from manufacturer to pharmacy can be justified on the basis that pharmacies possess market power over both consumers and manufacturers. Limiting only the retail price allows the pharmacy to drive the net manufacturer price down, in which allows pharmacies to capture all rents. This in turn will create excess entry into pharmacy markets and excess costs as individual small pharmacies have higher average costs per prescription than do fewer, larger pharmacies. At the same time, a lower manufacturer net price reduces incentives for pharmaceutical manufacturers to enter and compete in the market, since rebates reduce the net price obtained by the manufacturer. With less incentive to enter, generic firms will be less willing to invest in litigation.

Can rebates be controlled?

The process of eliminating rebates is not straightforward. If the reimbursement price is above the cost of manufacturing, pharmacies with market power will attempt to extract the difference from manufacturers. Evidently, there are many ways that a pharmacy might do this.

The first is through describing the payments using other language; for example, "professional allowances" are roughly equivalent to rebates. Bill 16 in Ontario allows for "commercial terms" including volume discounts, prompt payment discounts, and distribution service fees. The proposed regulations do not limit the scale of these commercial terms, but Ontario itself has achieved volume discounts in the range of 45% of the nominal

purchase price.[26] Since estimates of the size of rebates indicated that they averaged roughly 40% to 50%, volume discounts could perfectly replace rebates if there is no restriction on the allowable scope of "commercial terms".

A second way of arranging rebates for national chain pharmacies would be for the manufacturer to pay large rebates in provinces without regulatory restriction of rebates based nominally on sales in those provinces. These rebates would depend in part, but not explicitly, on the volume of business done in Ontario and Quebec, where rebates are banned or limited. Independent pharmacies lack this opportunity, and, as a result, are at a significant disadvantage in Ontario relative to chain pharmacies. It is clear that for Ontario to restrict rebates effectively, it will need to obtain information on transactions occurring across the country. Since companies will be loathe to provide this information, it would be necessary to make the provision of this information a condition for participation in the Ontario market. Admittedly, this presents a formidable problem for restrictions on rebates. But, without addressing the reality of the business, restrictions on rebates are merely a form of discrimination against independent pharmacies.

In the absence of national standards on rebates, it will be necessary to accept that they may be paid sometimes. The right solution, then, is to use a pricing model that naturally limits rebates. The declining price system would help to limit rebates by reducing the difference between the nominal price and the actual cost of production of the product, and a tendering system would have a similar effect. Since prohibiting rebates is likely to be very difficult, if not impossible, a more sensible solution may simply be to reduce the economic incentive to pay rebates. This is achieved by reducing the reimbursed prices in a way that meaningfully relates to production costs. However, as pointed out above, this system must also take into account the importance of compensating generic firms that are successful in litigation.

8. Conclusion

This paper has offered a perspective on generic drug pricing that emphasizes the different components in the value chain, and the importance of paying for these components separately. Each of these three components has very different costs and degrees of competition, and combining the costs for each function into one fairly arbitrarily selected

[26] ORDER PO-2865, Appeal PA08-299, Ontario Ministry of Health and Long-Term Care, p. 6.

price will not achieve desired outcomes, as has been demonstrated repeatedly in Canada.

The cost components can be usefully separated into (a) litigation that enables generic competition (b) drug production costs and (c) pharmacy costs. Separating the payment for these different functions would allow governments in Canada to achieve the lowest total price. Notably, simply trying to drive down prices without addressing the litigation problem will lead to higher overall costs, since patentees will be able to obtain unwarranted extensions to their exclusivity periods. Once the litigation problem is addressed, provinces can be aggressive in trying to get the lowest price for drugs using schemes that force companies to compete on the basis of reimbursed price, rather than on the basis of rebates paid to pharmacies. Finally, pharmacy reimbursement should be regulated due to the extraordinary market power pharmacies possess. But this cannot be done on an *ad hoc* basis within the political process: there should be a recognizably fair regulatory process. This process will create a level playing field and regulatory clarity, which will enable investors to make informed and appropriate decisions.

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