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Generic Drugopoly

Why Non-patented Prescription Drugs Cost More in Canada than in the United States and Europe

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Executive summary

Studies comparing international prices of prescription pharmaceuticals have found that Canadian prices are close to the international median price for *patented drugs* but higher for *non-patented single-source* (usually brand-name) drugs, and also higher for *non-patented multiple-source* (mostly generic) drugs. Furthermore, in studies comparing Canadian to American drug prices, it has been found that Canadian prices are significantly lower overall for *patented* drugs, but are usually higher than American prices for *generic* drugs.

Given that Canadian incomes are lower than incomes in most of the countries used for drug price comparisons by the PMPRB (and much lower than incomes in the United States), economic theory would predict that in a free market the prices for drugs would also be lower in Canada, a price-to-income relationship that has also been observed for many non-pharmaceutical products. Therefore, the observation that Canadian prices for *non-patented* drugs are higher than the international median and that Canadian prices for *generic* drugs are higher than American prices, is counter-intuitive and merits investigation into the reasons for this irregular pricing pattern.

Indeed, a closer look at the structure of the market for generic pharmaceuticals in Canada and the United States shows that the American market is more competitive than the Canadian market, having a larger relative number of players and a more equal distribution of market share among producers, whereas only two major companies dominate the market for generic drugs in Canada.

The market dominance enjoyed by relatively few generic companies in Canada raises the possibility that some degree of monopoly-style power partially explains the abnormal pricing structure for generic drugs. Furthermore, until recently, the Canadian market for generic drugs has been dominated by domestically-owned companies, which may suggest that there has been some structural economic reason or set of public policies that have historically led to artificial advantages for domestic interests over foreign competitors.

A review of Canadian pharmaceutical policies suggests that the effect of government legislation, regulations, and social programs, as well as court decisions related to drug policy in Canada is to give the Canadian generic drug industry unfair advantages over its commercial rivals. The result is a high concentration of market power for only a few established companies that may allow them to enjoy *de facto* barriers to entry from potential competitors. This has a negative impact upon the interests of consumers, leading to higher prices for a large and growing portion of the most commonly prescribed drugs and creates disincentives for pharmaceutical innovation.

The special commercial advantages enjoyed by the domestic Canadian generic drug industry may be viewed as unintended consequences of public policy; however, the consistency of the outcomes in favour of one particular industrial interest suggests that there may be a pattern of favouritism being applied by governments in Canada. Evidence that such policy bias is a result of conscious government decisions can be found in the statements of elected government officials and state bureaucrats that identify two policy goals:

1. reducing the costs to social programs like healthcare by forcing lower drug prices through a variety of mechanisms that favour generic drug supply; and,

2. pursuing state-assisted industrial development by creating an artificial market for domestically owned drug makers, most of which are generic companies, at the expense of research-based companies, which are mostly foreign-owned, multinational corporations.

Evidence of bias is also apparent in the decisions of the courts, which heavily favour generic drug companies in patent disputes; something senior civil servants acknowledge and identify as a problem that justifies counter-balancing regulations.

All of this suggests that Canadian governments may be intentionally politicizing pharmaceutical policy in order to use it as a means of subsidizing the development of a domestic drug industry, a practice that is economically inefficient, costly to consumers and taxpayers, a violation of free-trade principles, and possibly challengeable under international agreements. Anecdotal evidence based on official statements implies that the research-based pharmaceutical industry may also face a court that is ideologically hostile to intellectual property rights.

This study concludes that interventionist and biased Canadian pharmaceutical policies are leading to prices for non-patented and generic drugs that are higher than would be expected under normal free-market conditions. This means a large and growing number of consumers are suffering unnecessary economic losses of significant magnitudes. Furthermore, the lack of a free market for pharmaceuticals and inconsistent protections for intellectual property rights is reducing incentives for innovation. This raises the probability that future consumer access to life-improving and life-saving medicines in Canada could be limited. Therefore, a reorientation of Canadian pharmaceutical policy toward minimizing interference in the free market and protecting intellectual property rights is required.

Highlights

- Canadian pharmaceutical policies distort prices for non-patented drugs and create conditions allowing the generic drug industry a degree of monopoly-style control over the generic drug market. This leads to Canadian prices that are higher than both international and American prices for generic drugs.
- Distorted generic drug pricing is important: This study shows that, if Canadian generic drugs had been priced at median international levels, consumers and taxpayers could save $810 million this year alone.
- The entire growth in sales of non-patented drugs between 2001 and 2002 came from generic drugs, which increased at an annual rate of 40%.
- These statistics illustrate that a large and growing number of drug consumers are paying prices for non-patented drugs that are higher than would be expected under normal free-market conditions and may, therefore, be suffering unnecessary economic losses of significant magnitudes.

Peculiarities of the Canadian market for pharmaceuticals

The Canadian market for prescription pharmaceuticals displays some intriguing peculiarities: (1) an abnormal pricing structure for non-patented drugs; (2) the absence of a competitive market in generic pharmaceuticals; and, (3) the historical dominance of the generic market by Canadian-owned companies. These peculiarities will be discussed in the first three sections of this publication.

Abnormal prices for non-patented drugs in Canada

Patented and non-patented drugs

It is important to draw a distinction between *patented* and *non-patented* drugs when conducting international price comparisons. Patented drugs enjoy a legally guaranteed period of exclusivity that protects the owner of the patent from competition in the market for sales of the protected drug compound. This means that a patent holder can charge a higher price than would be possible if others were able to sell the same drug in a competitive market. However, once a patent expires, competing drug manufacturers can copy the previously protected drug and sell it. The introduction of product competition once a drug goes off patent, means that the prices of *non-patented* drugs are usually lower than those of patented drugs. Therefore, it is important to compare the prices of patented and non-patented drugs separately because the different structure of their markets leads to different relative price levels and an aggregate price of the two is not particularly meaningful.[1]

Following is a summary of some of the research available on comparisons between the prices for patented and non-patented drugs in Canada and other jurisdictions.

Patented drugs

It has been well established that most patented drugs are cheaper in Canada than in the United States. In fact, most research indicates that prices for patented prescription drugs are higher in the United States than anywhere else in the world (Danzon, 1999). Still, in order to understand the structure of drug pricing in Canada better, it is important to make comparisons with a larger group of countries.

The Patented Medicine Prices Review Board (PMPRB) collects comparative data on the prices of patented drugs sold in Canada as well as in a set of seven comparator countries—France, Germany, Italy, Sweden, Switzerland, the United Kingdom, and the United States—that are used as a reference for imposing price controls on the Canadian market for patented pharmaceuticals. The PMPRB's analysis of international price differences for *patented* prescription drugs confirms that Canadian prices were only about 1% higher than the international median used for comparison in 2002, down from 23% higher in 1987, and between 5% and 12% higher from 1994 to 2001. However, in comparison to the United States only, the same study indicated that Canadian *patented* prescription drugs were priced 57% lower than American prices for the same drugs (PMPRB, 2003a: 23).

Non-patented drugs

The PMPRB also looked at international prices for non-patented prescription drugs separate from those for patented drugs. In 2003, two studies were released by the PMPRB that compared Canadian prices for non-patented drugs to those in the seven countries that are used as a reference by the PMPRB for imposing pharmaceutical price controls in Canada (PMPRB, 2003b, 2003c). The studies looked at prices for the 63 top-selling non-patented single-source (NPSS) and the 64 top-selling non-patented multiple-source (NPMS) drugs in Canada, France, Germany, Italy, Sweden, Switzerland, the United Kingdom, and the United States (PMPRB, 2003b: 15).[2] NPSS drugs were those with only one manufacturer, while

NPMS drugs were those with more than one manufacturer, either a brand name or generic company.[3]

Non-patented single source (NPSS) drugs Non-patented single source (NPSS) drugs are usually brand-name drugs for which a patent has expired and generic alternatives have not yet entered the market to compete for sales on that product.[4] This naturally occurring period of market exclusivity for such NPSS drugs is generally very short. Nonetheless, it is significant that Canadian consumers pay more for these drugs than would be expected under a free market, as evidenced by the fact that we find lower prices for NPSS drugs in countries with higher average incomes than Canada.

For instance, the first of the PMPRB studies mentioned above found that Canadian prices (1998/99) for the top selling NPSS drug products were, on average, 28% higher, when weighted by expenditures, than the median international prices of all of the seven other countries together. After excluding the United States, another comparison of Canadian prices to the median European price (MEP) revealed that Canadian prices were approximately 75% above the MEP on average. In fact, for 32 out of 56 cross-market equivalent drugs, or 57.1% of cases studied, Canadian drugs were priced above the median international price. The number of cases where the Canadian price was the highest among all seven countries was 12 (21.4% of cases). Canadian prices were the lowest of all countries in only 10 (17.9% of cases) drug comparisons (PMPRB, 2003b).

Non-patented multiple source (NPMS) drugs In the second of the PMPRB studies, the prices for NPMS drugs in Canada were compared to prices in nine countries: the seven countries used by the PMPRB in its first report plus Australia and New Zealand. NPMS drugs include both brand-name and generic versions of non-patented drugs. The study found that prices for both brand-name and generic versions of NPMS drugs in Canada were higher than in most of the other countries examined.

On average, Canadian prices, specifically for *brand-name* multiple source drugs, were between 39% and 49% higher than the median of prices in the other countries, depending on the source of American price information included in the sample. Similarly, Canadian prices for *generic* NPMS drugs exceeded the median of the foreign prices by 21% to 51% (PMPRB, 2003c). Figures 1a and 1b compare the lowest and median prices for all NPMS drugs including generic and brand-name drugs across the countries used for comparison by the PMPRB.

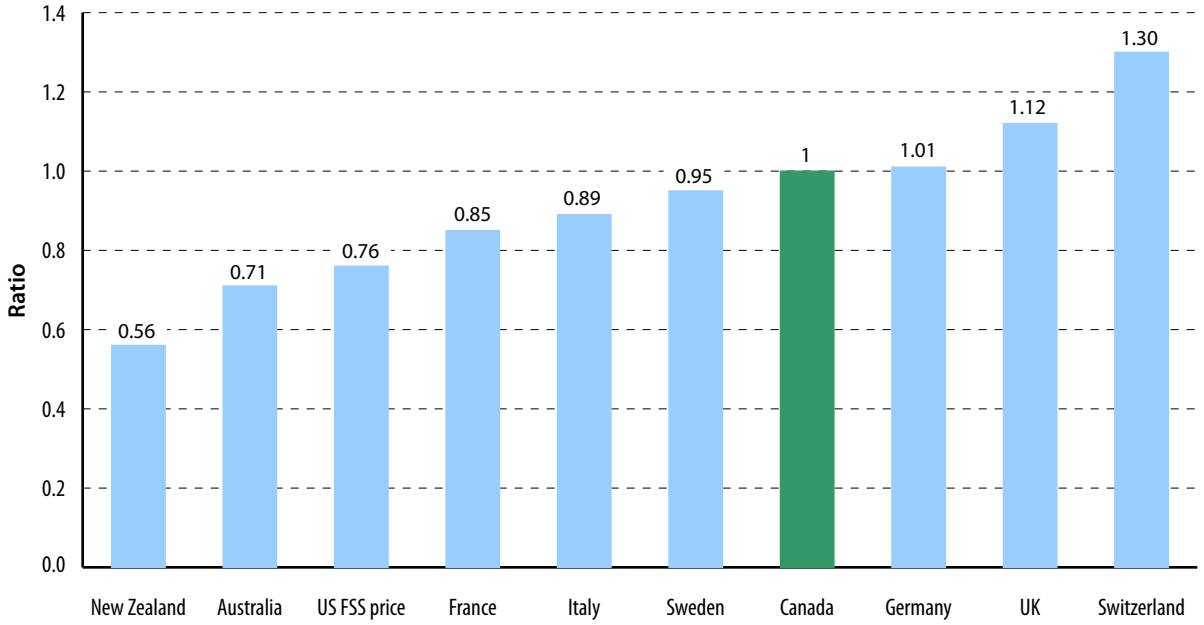
Comparisons with American data, however, are complicated by the variable definitions used to measure prices in the United States. For example, a PMPRB comparison based on published list prices for generic drugs in the United States from the *Drug Topics Red Book* showed those prices to be up to 248% higher than Canadian prices (PMPRB, 2003c). But list prices found in the Red Book are not reflective of the actual prices paid by wholesalers or pharmacies in the United States as they are only used as a basis for calculating various discounts and rebates to large government and private-sector buyers like Health Maintenance Organizations (HMOs). The detailed data on actual wholesale prices paid is not available because it is proprietary commercial information; releasing it would undermine the pharmaceutical industry's ability to differentiate prices among buyers within the American market. Therefore, the Red Book data cannot provide a realistic picture of prices for drugs in the United States.

This is confirmed by the comparison of the actual prices for NPMS drugs listed on the US Federal Supply Schedule (FSS), which match the lowest price obtainable in the American market for each of the drugs listed. Based on a comparison with the FSS prices, the PMPRB found American NPMS prices to be 69% lower than Canadian prices. The PMPRB therefore analyzes American drug prices separately, using FSS and Red Book estimates, or uses an average between the Red Book price and the FSS price for many comparisons of prices in Canada and the United States (PMPRB 2003c).[5] However, the wide range in potential prices for drugs in the American makes it difficult to calculate an accurate estimate of average prices.

Generic drugs

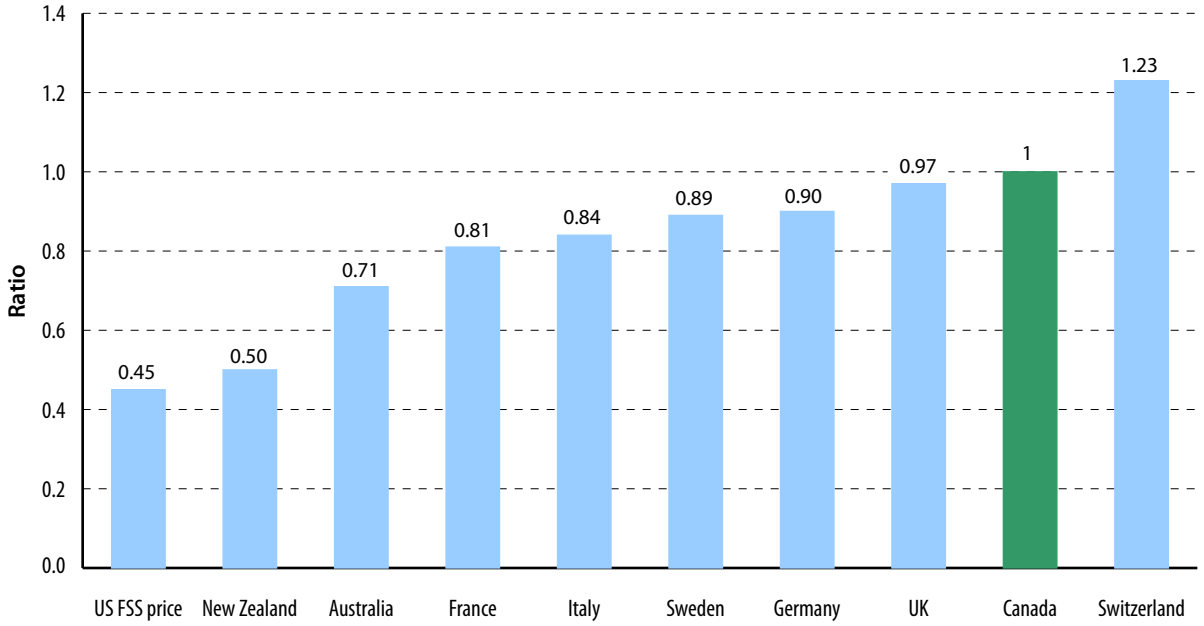
Nevertheless, there are other studies that have looked specifically at direct comparisons between prices in Canada and the United States using smaller samples of equivalent drugs and have found that, while overall drug prices tend to be higher in the United States for all

Figure 1a: Ratio of median foreign price to median Canadian price (over all NPMS products)



Source: Patented Medicines Price Review Board (PMPRB) (2003). *A Study of the Prices of the Top Selling Multiple Source Medicines in Canada*: p. 48, table 12, Bilateral Comparison—The Average Foreign to Canadian Price Ratio.

Figure 1b: Ratio of minimum foreign price to minimum Canadian price (over all NPMS products)



Source: Patented Medicines Price Review Board (PMPRB) (2003). *A Study of the Prices of the Top Selling Multiple Source Medicines in Canada*: p. 48, table 12, Bilateral Comparison—The Average Foreign to Canadian Price Ratio.

prescription drugs, the price of non-patented drugs—especially generic drugs—tends to be higher in Canada, and generic drugs account for most of the non-patented multiple-source drug products on the market.

For instance, a 2003 report by the US Food and Drug Administration (FDA) found that for six of seven of the biggest selling chronic-use drugs in the United States for which first generic entry occurred in the last ten years (alprazolam, clonazepam, enalapril, fluoxetine, lisinopril, metformin, and metoprolol), the American generic was priced lower than the brand-name versions in Canada. And according to the report, five of the seven American generic drugs were cheaper than their Canadian generic counter-parts. Of the remaining two generic drugs, one (metformin) had an American price that was 239% of the Canadian price but it did not become available generically in the United States until January 2002, so American generic prices had likely not yet fallen to normal competitive levels. The other (enalapril) was unavailable in Canada as a generic product and the price of the brand name version of enalapril in Canada was more than five times the price of the generic equivalent in the United States (US Health and Human Services, 2003).

A report prepared in 2002 by Palmer D'Angelo Consulting International (PDCI) looked at the 27 top-selling generic drugs of 2001 in Canada and compared the lowest prices available in Canada to those in the United States. The sample represented 39% of generic drug sales in Canada. Results showed that 21 of the 27 drugs studied were priced lower in the United States than in Canada (PDCI, 2002).

The pricing of Canadian generic drugs was also found to be higher than expected in an earlier study conducted by Graham and Robson in 2000 that compared the prices of the 45 most commonly prescribed drugs in the United States during 1998 with the prices of equivalent drugs in Canada at the wholesale and retail levels. The study found that the prices for patented drugs were lower in Canada overall but that Canadian prices for generic drugs, especially at the retail level, were higher than American prices (Graham and Robson, 2000).

Figures 2a and 2b below compare the lowest and median prices for generic drugs only across the countries used for comparison by the PMPRB.

Explaining abnormal pricing for non-patented drugs in Canada

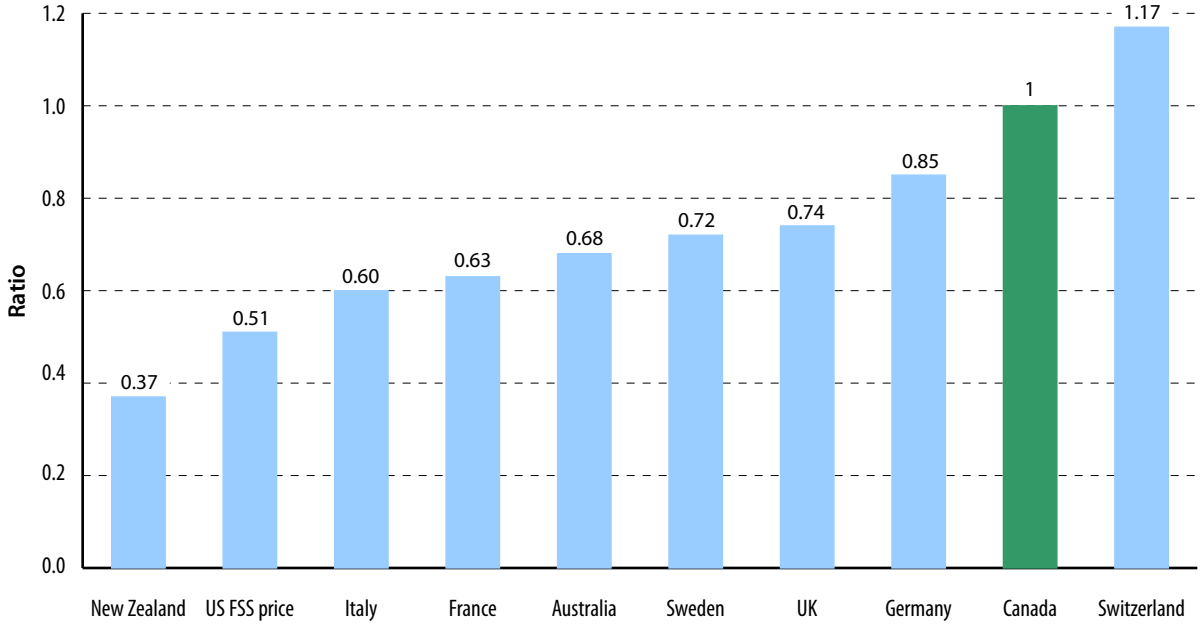
An analysis of the pricing structure for Canadian pharmaceuticals reveals irregularities that defy conventional expectations of differences between prices in Canada and those in other international markets. Previous research indicates that across free markets, the price of drugs should be positively correlated to the average incomes in each market: that is, drug prices should be higher in wealthier markets and lower in poorer markets—a pricing relationship that is consistent for many non-pharmaceutical products as well (Danzon and Furukawa, 2003; Danzon and Chao, 2000:159–95; Graham 2000).[6]

Differential pricing between markets occurs because sellers find that the profit-maximizing price in a market depends on the level and distribution of income among buyers.[7] For the seller, the best price is the one that maximizes profits through an optimal combination of supply and demand for a product within each market (Varian, 1985). Thus, countries with higher incomes will pay higher prices for goods and services as long as markets can be segmented; that is, as long as vendors can prevent customers who enjoy lower prices from re-selling their goods to customers who pay higher prices (Schweitzer, 1997).

Following this logic, one would expect that Canadian prices for pharmaceutical products would be lower than prices in countries with higher average national incomes. Yet, while Canadian prices for *patented* prescription medicines tend to be close to median international prices, prices for *non-patented* prescription medicines as a whole (including both brand-name and generic drugs) tend to be higher in Canada than in countries with higher average incomes.

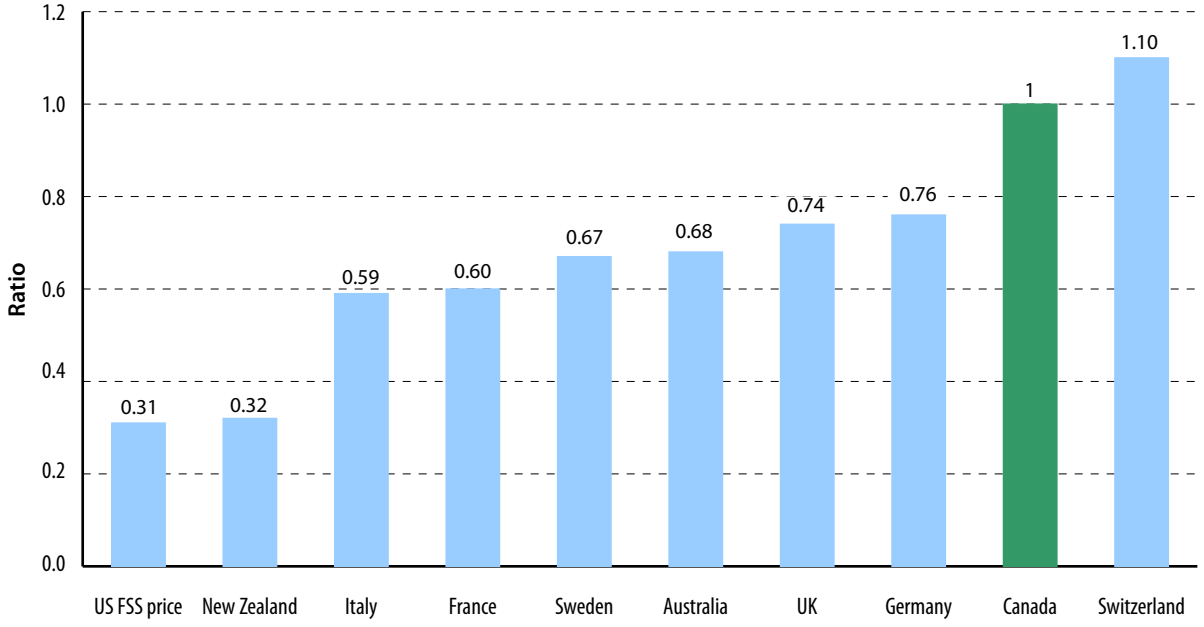
Table 1 presents a ranked comparison of the PMPRB comparison countries from highest to lowest average income based on GDP per capita at 2002 US currency exchange rates. Using currency exchange rates to compare international average incomes is preferred because the PMPRB's methodology for international drug price comparisons is also done on the basis of currency exchange rates (PMPRB 2003d: 35–36). While this data says nothing about the distribution of income in these countries, all have reasonably similar levels of industrial development and social redistributions of wealth, and are therefore fairly comparable. A comparison of the

Figure 2a: Ratio of median foreign generic price to median Canadian generic price



Source: Patented Medicines Price Review Board (PMPRB) (2003). *A Study of the Prices of the Top Selling Multiple Source Medicines in Canada*: p. 48, table 12, Bilateral Comparison—The Average Foreign to Canadian Price Ratio.

Figure 2b: Ratio of minimum foreign generic price to minimum Canadian generic price



Source: Patented Medicines Price Review Board (PMPRB) (2003). *A Study of the Prices of the Top Selling Multiple Source Medicines in Canada*: p. 48, table 12, Bilateral Comparison—The Average Foreign to Canadian Price Ratio.

Table 1: Countries used by PMPRB in comparing prices of pharmaceutical drugs ranked by GDP per capita (US$ at 2002 US currency exchange rates)

Country	GDP per capita
Switzerland	37,400
United States	36,100
Sweden	27,000
United Kingdom	26,400
Germany	24,100
France	23,400
Canada	23,100
Australia	20,700
Italy	20,400
New Zealand	14,700

Source: OECD 2004, *National Accounts of OECD countries*, Main aggregates, Volume 1 (updated May 2004).

rankings in table 1 with the rankings of countries based on various measures of drug prices in Figures 1a, 1b, 2a, and 2b confirms that prices for non-patented drugs tend to be higher in Canada than in countries with higher average incomes.

Some analyses have explained such differences among international prices for pharmaceutical drugs by differences in the use of price controls. The PMPRB, for instance, has implied that Canadian prices for patented drugs nearly match the median international price because almost all of the comparator countries impose price controls on patented medicines through regimes similar to Canada. Furthermore, because Canada uses these countries as a price reference for its own system of price controls, the PMPRB suggests that it is to be expected that patented drug prices should converge. The obvious exception is the United States, which allows relatively freer market prices for patented drugs and has higher relative price levels as a result (PMPRB, 2002: 5).

However, Graham (2000) has argued that price controls have little direct effect on drug price levels. His analysis suggests that income differences among markets explain most of the difference in prices for drugs. Graham concludes that, in the absence of Canadian price controls, income differences between the markets would still cause Canadian prices to be lower than American prices for patented drugs.[8]

Graham's analysis seems to hold the greatest weight when the PMPRB's own evidence on price inflation for pharmaceuticals is considered. The PMPRB measures the annual increase in pharmaceutical prices. According to the PMPRB, "manufacturers' prices of patented drugs fell by 1.2% in 2002. This result continues the pattern of declines and near negligible increases in the PMPI that began in 1993" (PMPRB, 2003a: 21). The PMPRB has stated that, except during 1992, pharmaceutical prices have increased less than the general rate of inflation measured by the Consumer Price Index (CPI) in every year since 1988 (PMPRB 2003a: 21).

The PMPRB's price-control regulations limit price increases for patented drugs to the expected rate of increase in the CPI over a three-year period (PMPRB, 2003a). If drug prices are rising slower than they are allowed to, this would indicate that factors other than price controls are holding the prices of patented drugs down.

Nevertheless, these competing explanations for differences in the international prices for pharmaceutical drugs only apply to observations about prices for patented prescription drugs. When it comes to non-patented drugs, there are indications that there are other factors that may partially explain irregular Canadian prices for *non-patented* pharmaceuticals.

Counter-intuitive drug pricing in Canada

Most of the European countries used for price comparisons by the PMPRB have price controls on both patented and non-patented drugs. Canada by contrast only imposes price controls on patented medicines; i.e., there are no direct price controls on *non-patented* medicines in Canada. The United States by comparison has no general price controls on either patented or non-patented drugs.

As mentioned earlier, the available evidence indicates that recent Canadian prices for patented drugs are near median prices for a set of comparable countries. This is consistent with the fact that, except for the United States, all of these countries, including Canada, have price controls for patented drugs.

In contrast to Canadian prices for patented drugs, which happen to converge with the international median, Canadian prices for non-patented drugs are significantly higher than the median in the same set of international countries. This again is consistent with the fact that,

except for the United States, those countries also impose price controls on non-patented drugs in addition to patented medicines, while Canada does not.

Finally, the United States has no direct price controls on either patented or non-patented drugs. Not surprisingly, research finds that patented drug prices are high relative to the international median of countries that do have price controls. This observation is also consistent with the explanation that the presence or absence of price controls determines price differences between countries.

In contrast to these observations, it is noteworthy that prices for non-patented drugs in the United States are lower than prices in other countries. This is counter-intuitive because, since American incomes are higher and there are no general price controls on pharmaceuticals, the American market would be expected to command higher prices for both patented and non-patented drugs (all else being equal). Yet American drug prices are only higher in the case of patented medicines. Non-patented drugs, especially generic drugs, are most often cheaper in the United States than in the other countries.

Similarly, because Canadian incomes are lower than most of the PMPRB's comparison countries, it should also have lower prices for both patented and non-patented drugs even with price controls. Instead, Canadian prices for patented drugs have converged with the median international price and Canadian prices for non-patented drugs are higher, not only than those in countries that have price controls on these drugs but also than prices in the United States, which does not have price controls at all.

When Canadian prices for non-patented prescription medicines diverge significantly from other jurisdictions, especially in a counter-intuitive fashion, it is surprising and worthy of further investigation.

Importance of distorted drug pricing in Canada

The distorted Canadian pricing structure for non-patented drugs is important to Canadians both as consumers and taxpayers. The Canadian Generic Pharmaceutical Association (CGPA) has estimated that generic drugs alone accounted for a 40.6% share of all retail prescriptions filled in Canada, or almost 145 million generic prescriptions in 2003. The growth rate in the number of generic prescriptions as of the end of 2003 was 8.4% annually compared to the previous 12-month period (CGPA, 2004a). According to the PMPRB, generic drugs reached as high as 46% of all the retail prescriptions issued in Saskatchewan in 2002 (PMPRB, 2003c: 4).

Recent data from IMS Health that measures retail sales of patented and non-patented drugs shows that generic drugs were responsible for almost 50% of the growth in the number of all Canadian retail prescriptions dispensed in 2003. Generic drugs also make up the majority of retail pharmacy prescriptions for anti-infectives, analgesics, and about 90% of diuretics (IMS Health, 2004). In terms of dollar value, generic manufacturers accounted for about 16% of the $13 billion-worth (wholesale prices) of all medications purchased by retail pharmacies, reaching $2.1 billion in 2003 and growing by 18.5% over 2002. By contrast, brand manufacturers accounted for about $11 billion of retail pharmacy drug purchases, and grew at about 11% in 2003 (IMS Health, 2004).

PMPRB data measuring manufacturers' sales of patented and non-patented drugs show that total sales of non-patented drugs reached $4.3 billion (ex-factory prices) in 2002, increasing at an annual rate of 10.3% from the year before (PMPRB, 2003a: 10). However, in 2001 and 2002, sales of branded non-patented drugs remained unchanged at $2.9 billion in each year. By contrast, sales of generic non-patented drugs increased from $1 billion in 2001 to $1.4 billion in 2002 (PMPRB, 2003a: 10). Therefore, the entire growth in sales of non-patented drugs between 2001 and 2002 came from generic drugs, which, according to PMPRB data, increased at an annual rate of 40%.

In comparison, CGPA figures measuring all sales of prescription generic drugs in drug stores and hospitals show that generic drugs grew from $1.5 billion in 2001 to $1.8 billion in 2002 and $2.2 billion (retail prices) in 2003 for an average annual growth rate of 21% (CGPA, 2004a).

Most importantly, the drugs included in one of the PMPRB's reports represented approximately 50% of all non-patented single-source drug products by volume and expenditures in the six provincial drug plans looked at during the study period. The PMPRB's analysis suggested that, had NPSS medicines been priced at median international levels, spending by the six Canadian provincial drug plans (British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, and Nova Scotia) would have been approximately $60 million or 20% less than

the $300 million these plans spent on NPSS drugs in 1999/2000 (PMPRB, 2003b).

Lost savings specifically related to higher priced *generic* drugs for consumers over the entire Canadian market are also substantial. The PDCI study cited above calculated that, if the results of the generic price differences between Canada and the United States were extrapolated to Canadian generic drug utilization levels, the potential annual savings to Canadians from paying lower American generic drug prices could reach as high as $400 million (PDCI, 2002).

Furthermore, if the CGPA's growth figures (21% annually) are used to project generic drug sales in Canada for 2004, then the value of all generic drug sales should reach at least $2.7 billion for the year. Figure 2a also shows that the average median international price among the PMPRB's group of comparison countries is nearly 70% of the median Canadian price for prescription generic drugs. This means that if Canadian generic drugs were priced at median international levels, annual consumer savings for 2004 alone could reach as high as 30%, or $810 million. This represents an enormous economic loss for consumers of generic drugs.

These statistics indicate that a large and growing number of drug consumers are paying higher prices for non-patented drugs than should be expected under normal free-market conditions and may therefore be suffering unnecessary economic losses of significant magnitudes.

Absence of a competitive market in generic pharmaceuticals

The Canadian market in generic pharmaceuticals reveals some interesting characteristics that might contribute to abnormal pricing for generic drug products in particular. According to data obtained directly from the Canadian Generic Pharmaceutical Association (CGPA), the 12 members listed on the organization's website in 2004 make up 90% of the entire Canadian generic industry, based on volume of sales (CGPA, 2004b). The total number of players in the generic drug industry is difficult to estimate; the CGPA states that the industry considers up to 49 companies in the Canadian market to be generic (CGPA, 2004b). In contrast, PMPRB reports have defined the entire Canadian generic drug industry as consisting of only 12 companies in total (PMPRB 2003c: 4) but did did not specify whether these 12 companies matched the membership list of the CGPA.

While it is significant that only 12 companies control between 90% and 100% of the generic market, it is perhaps more notable that the PMPRB has reported that the two largest generic companies accounted for 62% of the entire Canadian generic market by volume of sales in 1998/99 (PMPRB, 2003c: 4). This figure is slightly higher than the most recent CGPA data that reports the two largest companies in its membership accounted for 23.6% of the 356 million prescriptions filled in Canada during 2003, nearly 58% of the 145 million generic prescriptions dispensed in Canada (40.6 percent of 356 million) (CGPA, 2004a).

Furthermore, relatively few generic companies control almost the entire market for public spending on generic drugs in Canada. The PMPRB looked at the distribution of market share by company for public expenditures on generic drugs in selected provincial programs over the 100 top-selling products on the market during 1999/2000. Table 2 presents the PMPRB data for six provinces by company share of publicly funded drug purchases. The data indicate that one company captured 50% of all public spending for drugs in these provinces. Furthermore, the top three companies captured 82% of the market for publicly funded sales of drugs.

In contrast, markets for generic drugs in other countries are more competitive than Canada. For instance, in the United States, it took 10 of the largest companies to account for approximately 61% of the generics industry in 1998/99—equal to the percentage controlled by only two companies in Canada (PMPRB, 2003: 44–45). During the same period, in France the 10 major suppliers represented only 20% of the generic drugs market and in Germany the largest 17 major generic manufacturers represented a total market share of only 28% (PMPRB, 2003c: 43–45).

It is also interesting to look not just at the total number of companies in the generic market overall but also at the number of companies competing to supply each drug on the market. Using PMPRB data, figure 3 displays the number of generic companies competing in the market relative to the number of generic drug products

Table 2: Generic companies and their market share of provincial drug-plan expenditures in selected provinces for the PMPRB's top-selling 100 non-patented, multiple-source medicines (1999/2000)

	Percentage market share						
	British Columbia	Alberta	Saskatchewan	Manitoba	Ontario	Nova Scotia	All
Apotex	39	42	25	42	56	33	50
Novopharm	18	17	7	27	20	35	20
Genpharm	17	20	5	17	9	18	12
Altimed	10	11	12	5	6	7	7
Pharmascience	9	5	4	5	5	3	6
Nu-pharm	2	1	44	0	0	2	3
Others	5	4	4	4	3	2	3
Totals*	100	100	100	100	100	100	100

Note *: May not total 100 due to rounding.

Source: Patented Medicines Price Review Board (PMPRB) (2003). *A Study of the Prices of the Top Selling Multiple Source Medicines in Canada*. Table 5: Generic market share distribution for the sample of top 100 multiple source medicines based on provincial drug plan expenditures, 1999–2000 (page 22).

where that level of competition exists for Canada and the United States. The drug products included in this sample represent only those that matched a list of the 96 top-selling, non-patented prescription medicines in Canada for which data was available. Only 71 generic drugs in the United States matched the 96 Canadian top-selling generic products. Therefore, the data is presented as a percentage of the total number of drugs that match the 96 Canadian top-selling generics for comparability.

A comparison across those drugs that match the Canadian top-selling drugs confirms that the market for generic drugs is less competitive than it is in the United States. As figure 3 shows, Canada has a larger percentage of drugs on the market where there are few generic companies competing for sales of those particular products. In fact, the distribution of companies to products is skewed toward fewer generic companies over a larger number of drugs. The fact that Canada's market for generic drugs is less competitive than the US market is also observed in the 2002 PDCI report cited earlier in this paper.

The high concentration of commercial ownership in the Canadian market for generic drugs in the hands of relatively few companies and, especially, of the two largest generic companies may be one explanation for the abnormal pricing structure for generic pharmaceuticals witnessed here in Canada.

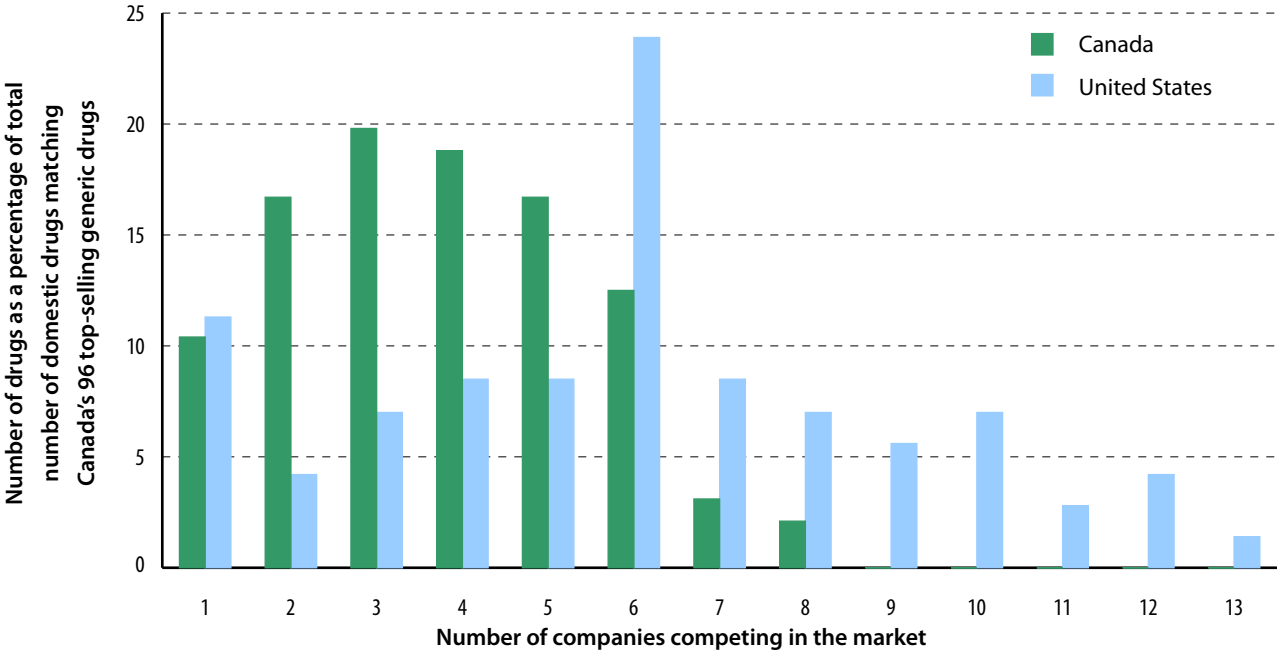
Historical dominance of the domestic generic market by Canadian-owned firms

While the Canadian market for generic drugs appears to be less competitive than other comparable international markets, until recently, it also appears that, until recently, it has been dominated by Canadian-owned firms. Both the historical patterns of national ownership in the Canadian generic drug industry as well as the relatively recent acquisition of the second largest generic company by foreign interests suggest that there may be structural economic conditions or perhaps a set of public policies that secure particular advantages for established generic companies in Canada. The fact that the largest companies have historically been Canadian-owned means that any unique advantages that accrue to generic companies in Canada in general may, in practice, result in particular advantages for Canadian-owned firms.

To verify the current national ownership of the generic and brand-name drug companies in Canada, an Internet search of pharmaceutical company websites was conducted. As well, a search was conducted on Industry Canada's Strategis business information system, which publishes company directories that contain some information about the national ownership of many countries posted in this database. In some cases, wider searches of the Internet revealed that a few of the companies listed as

Figure 3: Competition for sales of generic drugs in Canada and the United States, 2002

(number of drug products subject to various levels of competition as a percentage of the total number of domestic drugs matching Canada's 96 top-selling generic drugs)



Source: Patented Medicines Price Review Board (PMPRB) (2003). *A Study of the Prices of the Top Selling Multiple Source Medicines in Canada.*

being Canadian owned on the Industry Canada database, actually were subsidiaries of foreign-owned multinationals. (Appendix B documents the company histories and profiles of selected CGPA members).

The results of this search suggest that the largest generic company in Canada is affiliated in a group of four, separately listed, CGPA members: Apotex Inc., Apotex Fermentation Inc., Cangene-Corporation, and Nu-Pharm Inc. Recall that according to the CGPA and the PMPRB, 12 companies account for between 90% and 100% of generic prescriptions filled in Canada. If the Apotex companies are grouped together, then only nine separate business interests account for at least 90% (probably 100% based on PMPRB analysis) of generic prescriptions in Canada. Of these nine separate business interests, which claim at least 90% of generic sales as a group, this search identified five of them as having Canadian ownership.

The rest were made up of mixed foreign ownership including Israel (2) and Germany (2). Israeli-owned Teva purchased Novopharm, the second largest generic company in Canada, in 2000. In addition, Germany's Ratiopharm purchased its Canadian operations from Technilab Pharma only as recently as 2000. Therefore, up until four years ago Canadian firms controlled virtually the entire market for generic drugs.

The recent foreign acquisitions of previously Canadian-owned generic drug companies are also not a sign that there are now fewer barriers to entry for foreign generic competitors. Instead, it could be interpreted as a sign that foreign competitors believe the only way to get into the Canadian market is not to compete at the product level (an option that would increase consumer choice and lower prices) but to buy the protected advantages that established Canadian generic companies have historically enjoyed.

In comparison to the historical domestic dominance of the Canadian generic drug market, foreign ownership is much more common to the brand-name market: in 2003, nine of the top 10 largest pharmaceutical companies in Canada (by revenue from sales) were foreign-owned, brand-name companies. The only Canadian company to make the top-10 list was Apotex as the sixth largest and the only generic manufacturer (IMS Health 2004).

Explaining the high prices for generic drugs in Canada

Findings of comparatively higher Canadian prices for non-patented single-source (NPSS) and non-patented multiple-source (NPMS) brand name and generic drugs are counter-intuitive given that average incomes in the Canadian market are smaller than six of seven of the comparator countries that were examined for the PMPRB studies, including the United States (see table 1). If all of these countries had free markets, the competitive equilibrium prices of similar kinds of products would be expected to be relatively lower in Canada than they are in most of the others because, in general, prices for pharmaceuticals and other similar goods tend to be higher in wealthier markets than in those that are less wealthy. The fact that the prices for generic drugs do not follow economic theory suggests that there is some interference with the free market for non-patented drugs that is causing Canadian prices to register higher than in comparable countries.

Because all of the comparator countries except the United States have price-control regimes for patented pharmaceuticals similar to that in Canada, it is not surprising that Canadian prices do not differ from the international median for patented drugs. Nevertheless, the fact that Canadian prices for non-patented drugs, and especially for generic drugs, diverge from expected levels seems to indicate that there are particular aspects of the domestic Canadian market or of Canadian public policies that differ from those of other countries and that may be causing these counter-intuitive results. There are two main factors that explain abnormally high prices for generic drugs in Canada: the unintended effects of price controls on patented drugs; and a degree of commercial concentration in the generic market made possible by other aspects of Canadian pharmaceutical policy.

Effects of price controls for patented drugs on the prices of non-patented drugs

Graham (2000) has investigated the reasons that Canadian prices for NPSS drugs are higher in Canada than elsewhere. Looking at selected drug products that have gone off patent protection, Graham found that the unintended effect of Canadian price controls on patented drugs is to prevent brand-name companies from reducing prices on these products once a patent expires. This is because Canada's price control policy uses the highest price of the existing drugs in the same therapeutic class as a reference for establishing the maximum allowable price for new patent-protected drug formulations entering the market. Therefore, brand-name drug makers are extremely reluctant to reduce the price of the original drug when it goes off patent, for fear of inadvertently lowering the maximum allowable entry price for new drugs. In fact, even after the entry of generic competitors into the market for an off-patent drug, the price of the brand name drug tends to remain high. Thus, Canadian price controls create an artificial incentive for brand-name companies to resist competing on price for sales of NPSS drugs; resulting in lost savings for consumers of these drugs (Graham, 2000).

Looking at NPMS drugs and, more specifically, at generic drugs, an obvious explanation for the fact that Canadian prices are higher than would be expected relative to the international median is that prices for generic drug products are controlled by the state in most of the comparator countries in the PMPRB studies but are set on the market in Canada. Direct price controls of generic drug products are common in the United Kingdom, France, Italy, Sweden, and Switzerland. The United Kingdom sets a price ceiling for certain reimbursable generic products while, in France, regulations stipulate

that the price of a generic drug must be at least 30% less than the net manufacturing price of the original brand equivalent if it is to be eligible for reimbursement under public health insurance. Italy and Switzerland stipulate the same criteria but only require the generic drug to be priced respectively at 20% and 25% less than the original version (PMPRB, 2003c: 27).

In contrast, in Canada there are no comprehensive domestic price controls on non-patented drugs. However, there is indirect state intervention in generic drug pricing that occurs, for example, in the listing of drugs on the Ontario Drug Benefit Formulary, which requires first-entry generic drugs to be priced at no higher than 70% of the brand drug while subsequent entries are limited to 90% of the price of the first generic. Nevertheless, Canadian prices for generic drugs are still higher than comparable international prices even with this limited type of state intervention on pricing.

The most notable finding however, is that Canadian prices for generic drugs tend to be higher than prices for similar drugs in the United States. This aberration cannot be explained either by income differences—since incomes are higher in the United States—or by policy differences regarding price controls, as they do not exist for non-patented drugs in either the United States or Canada.

Graham (2000b) identifies price controls on patented drugs as an explanation, not just for the higher-than-expected prices of non-patented brand-name drugs but also for the high prices of generic drugs in Canada. As explained earlier, the unintended effect of the international reference mechanism used in setting Canada's price controls for patented drugs is to discourage brand companies from competing on price. Graham suggests that because brand-name companies have no incentive to reduce prices on drugs that come off patent in competition with other brand-name substitutes of the same therapeutic class, this effectively raises the competitive ceiling price for generic alternatives. It is this lack of competition from brand-name companies that creates an artificial pricing advantage for generic companies because they can demand higher prices than they would normally be able to under a free market: that is, if branded companies had incentives to compete on price. So price controls on patented drugs not only interfere directly with the market for innovative drugs—their intended effect—but also have the unintended effects of distorting the prices for non-patented single source brand drugs and giving generic companies the room to charge non-competitive, inflated prices for generic drugs as well (Graham, 2000).

How does Canadian pharmaceutical policy reduce competition in the market?

As we have noted earlier, price controls on patented pharmaceuticals in Canada can create perverse incentives for brand-name companies to resist reducing prices for older drugs in the face of competing substitutes in their therapeutic class in order to avoid undermining the maximum allowable price for new entry drugs. Therefore, price controls raise the price ceiling for generic companies by allowing them to charge higher prices than they could obtain if brand companies had incentives to compete on price. This creates economic losses for consumers.

This greater pricing room might also create significant competitive advantages for established generic manufacturers against newer generic competitors, giving them enough flexibility with profit margins to resist competitive entry into the market. Generic companies that are already established in the market enjoy both pricing and first-mover advantages. These advantages occur because an artificially high profit margin creates more room for established companies to undercut the entry prices of potential foreign competitors and still remain competitively profitable. The expectation that established companies will use price-undercutting strategies to compete with new entrants removes any incentive for potential competitors to invest resources in penetrating the market. In fact, the mere threat of undercutting prices is enough to stifle competition, meaning that established generic companies never actually have to reduce prices.

Second, existing companies have established distribution networks and contracts with wholesalers and retail pharmacies for whole product lines consisting of hundreds of products. New competitors cannot compete on a product-by-product basis because discounts offered by established generic companies could be bundled to whole product lines. Therefore, price controls that permit generic companies to charge higher than normal prices, coupled with the first-mover advantages of established companies, create barriers to entry for competing manufacturers.

Other Canadian pharmaceutical policies may likewise give special competitive pricing and first-mover advantages to generic drug manufacturers strengthening the market positions of established domestic business interests against potential competition. For instance, policies that create artificially large markets for generic products in a market with few existing players may inadvertently permit established companies to leverage the resulting economies of scale and erect barriers to entry from new competitors.

The following section outlines specific pharmaceutical policies in Canada that create artificial advantages for generic drug manufacturers over brand-name pharmaceutical companies that may also serve to reinforce the economic positions of current generic business interests, creating formidable barriers to market entry from new competitors.

Reference-based pricing

Graham (2002) has demonstrated the effect of British Columbia's use of reference pricing for its public drug benefit program in creating an artificial consumer bias that favours generic versus brand-name drugs. Reference-based pricing is a policy for containing expenditures under public-sector and private-sector drug benefit plans. It involves establishing categories of therapeutically equivalent drugs and reimbursing patients for the cost of either the cheapest drug in the category or some average price of the drugs in the same class (Lindsey and West, 1998). Under reference-based pricing, consumers who choose a drug that is more expensive than the reference drug must pay the entire difference out of pocket.

Furthermore, under reference-based pricing, the allowance for generic substitution is broader than under best-available-price or least-cost-alternative policies, which require chemical equivalence between drug products and thereby limit the range of products eligible for substitution. Reference-based pricing expands the eligibility for substitution to any drug that the payer defines as therapeutically equivalent. Such a policy encourages the substitution of generic drugs over relatively more expensive brand-name drugs because the consumer's out-of-pocket cost of obtaining the fully insured reference drug is zero at the point of purchase.

Reference-based pricing is a perfectly valid way to design a drug insurance program in a competitive market where consumers have the choice of insurer. In a free market, if consumers were unhappy with an insurance plan that only paid for the full cost of generic copies of drugs, they could shop around for others that allowed them to use branded preferences without financial penalty. A free market would permit the establishment of competing drug insurance plans that used consumer cost-sharing methods like front-end deductibles, which do not bias the decision of consumers over the choice between branded and generic drugs.

However, BC Pharmacare is a state-run, tax-subsidized, universal-eligibility insurance program. Reimbursement is designed to follow catastrophic expenses only, the definition of which is adjusted to income. Nevertheless, there is near universal catastrophic drug insurance coverage for the population, giving BC Pharmacare a *de facto* monopoly position. This is because the plan is not financed by premiums but by tax subsidy. Therefore, even if consumers dislike the reference-based-pricing design of BC Pharmacare, they have serious financial disincentives to obtain competitive private insurance because they would continue to pay for public drug insurance through their taxes even if they chose not to receive public benefits. The significant financial disincentive to opting out of public Pharmacare allows the public plan to capture the entire market.

The generic bias created by BC's Reference Drug Program, combined with the effective monopoly position of BC Pharmacare contributes to the creation of an artificially larger market for established generic companies than they would obtain in the absence of state interference. Especially in markets with few existing competitors, such a policy may inadvertently permit established companies to leverage the resulting economies of scale and erect barriers to entry from new competitors.

Finally, other Canadian research has confirmed and measured the value of first-mover advantages for generic drug manufacturers. For instance, Hollis (2002) showed that the effects of reference-based pricing for drugs listed on provincial formularies reinforce uncompetitive generic markets. According to Hollis,

> The first generic entrant in a market can expect a long-term increase of approximately 20%–35% in its share of the generic market by virtue of being first, compared to the expected market share if it does not enter first. From a policy perspective, the results of this research have a number of implications. The first is the observation that because of the nature of price competition under the reference pricing system, it appears that the first generic entrant to the market obtains a substantial competitive advantage. This is troubling in that it suggests that firms have little ability to gain market share through price-cutting, and, therefore, little incentive to cut prices. This may help to explain why generic drugs have been found to be on average more expensive in Canada than in the United States, in contrast to brand name drugs, which are considerably cheaper in Canada. The finding that delayed entry limits market share given the reference pricing system also provides another mechanism through which regulation of the pharmaceutical industry may harm post-patent competition. Although the results that apply in Canada are specific to each province, they share some characteristics not only with each other but also with formularies in many other countries, so it is possible that the implications of this study extend beyond Canada. (Hollis 2002: 723)

Formulary and off-formulary interchangeability

The public drug-benefit plans in the provinces also make use of formulary listings for the drugs that are publicly insured. Drugs that appear on the formulary list are eli-

gible for reimbursement under public benefit plans. In order to encourage lower drug expenditures, some provinces—British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, Quebec, New Brunswick, and Nova Scotia (Rx&D, 2003)—allow substitution between drugs that are considered therapeutically equivalent by the health ministry regardless of the prescribing orders of doctors. This is accomplished by relieving pharmacists of any legal liability for adverse reactions if they choose to substitute a generic drug for a branded drug, even when a physician has prescribed the branded drug. Again because generic substitutes are usually priced lower than brand-name drugs, the effect of the declaration of interchangeability is to give pharmacists incentives to favour the generic version because public reimbursement is set at fixed rates that may in practice allow retailers to keep the cost difference between the reimbursement rate and any discount they can obtain from the manufacturer.

Generic companies are in a better position to offer these discounts than brand-name companies because they do not have to recover the huge research and development costs that brand-name, research-based companies incur to develop new medicines in the first place. Generic companies merely copy the inventions of their competitors. More importantly, the artificially high price ceilings made possible by the unintended effects of price controls for patented medicines may give established generic companies a competitive pricing advantage, thus allowing them to offer larger discounts to retailers than potential competitors.

Some provinces—British Columbia, Manitoba, New Brunswick, and Novea Scotia—have issued declarations of interchangeability even for drugs that are not listed for public reimbursement in the formulary; Ontario is also considering this policy (Rx&D, 2003). Such policies are completely unnecessary because they go beyond the province's interest in reducing public drug costs and, therefore, represent a *de facto* policy of favouritism toward the commercial interests of generic drug companies. Furthermore, such policies interfere in the relationship between patients and their physicians or pharmacists. This interference undermines the market value of professional services by substituting government decree for private expert agency. In addition, state-imposed limits on direct-to-consumer advertising for pharmaceuticals in Canada do not even allow brand-name companies to respond to a declaration of interchangeability by claiming superior quality or effectiveness of their products relative to generics. The result of this policy is to reinforce further the market shares of established generic drug manufacturers through state intervention.

Double standards for drug approval

Currently, newly invented drugs must undergo lengthy and expensive approval processes required by Health Canada. According to research conducted by KPMG for the brand-name industry, the wait for approval of a patented drug was more than 2 years (KPMG, 2001). This exceeded the approval time for a generic product, which was only 1.5 years. (Health Canada 2001)

The reason for the difference in approval times is that the process is less rigorous for generic drugs than for patented drugs. Generic drugs use reverse engineering to copy the patented medicine's chemical formulation and simply submit an abbreviated application for approval based on the clinical research and testing already conducted and funded by their competitor, the brand-name patent holder. Health Canada usually does not require independent testing of the generic drug to the same extent as the original innovative drug and uses the approval of the original as equivalent for the generic.

Avoiding redundant testing for generic products makes sense from an efficiency point of view. However, the same courtesy is not extended to branded drug makers in their approval processes. By the same logic applied to generic approvals in Canada, brand-name companies should be allowed to refer to previous testing and approval for equivalent drug compounds in countries that have equally stringent testing standards like, for example, those of the US Food and Drug Administration. If such a policy were adopted, times for approving brand -name drugs would likely improve dramatically. In the meantime, established domestic generic drug companies enjoy a competitive cost (time and money) advantage that is currently denied to research-based brand-name drug makers, thus reinforcing their market position and strengthening their ability to discourage potential competition.

Compulsory licensing as industrial development policy

Canada's adoption of patent protections for pharmaceuticals is a fairly recent development. The history of intellectual-property protection for drug products in Canada suggests a long-time policy of favouring generic drug manufacturers. The first evidence of this bias dates back to 1922 when the Commissioner of Patents allowed any Canadian manufacturer to copy and produce a drug owned by another company, even if there was an existing patent.

In 1969, however, the Canadian Patent Act was amended to allow the manufacture of patented products under a policy of compulsory licensing. This explicit legal recognition meant that the government could issue a license to a generic company, allowing it to violate a drug patent in return for paying a commission to the patent holder of 4% of sales. This legally entrenched a weak regime of intellectual property rights for patent holders in Canadian law and was directly responsible for the rise of the generic drug industry in Canada. The growth of the generic industry was so rapid that within one year of the change there were already 52 generics, with such significant drugs as ampicillin and diazepam available generically (Anis, 2000).

By world standards, Canada has never had a significant domestically owned, research-based, or innovative drug industry. Until 1969, it did not even have a significant generic industry. The effect of compulsory licensing for generic drugs was to make it legally safer for domestic industrial interests to copy the research-intensive, costly inventions of foreign-owned, multinational drug companies and market them for sale in Canada.

However, this practice was generally forbidden in developed markets around the world and, thus, compulsory licensing gave Canadian companies a market, by default protected from foreign competition, within which they could compete on price with branded products because of the much lower drug-development costs associated with merely copying innovative drugs.

Canada only began to strengthen its patent protections in 1987 by introducing Bill C-22. Under Bill C-22, patent-holding firms were guaranteed a 10-year period of market exclusivity, free from competition, before a generic firm could be issued a compulsory license. However, in exchange for acknowledging these fundamental intellectual property rights of drug inventors, the government attached conditions that did not apply to other patent holders or innovative industries. For instance, the government required an increased investment from 5% to 10% of sales from the industry in Canadian research and development. Bill C-22 also led to the creation of the Patented Medicines Prices Review Board, which now would regulate patented drug prices and ensure compliance with the new 10% research and development spending rules (Anis, 2000).

In 1993, further amendments were introduced through Bill C-91 in order to bring Canadian intellectual property laws into harmony with its international trading partners. Bill C-91 finally abolished the policy of compulsory licensing and patent protections were extended to the international standard of 20 years before generic competition was allowed (Anis, 2000). Yet, in spite of this apparently reluctant turn toward protecting the commercial property rights of innovative drug makers, Canadian policy has often moved toward creatively securing further advantages for generic drug manufacturers.

Early working exceptions to patent rights

Like compulsory licensing, which gave artificial advantages to Canadian-owned generic industrial interests over foreign-owned brand-name drug makers, Canada has adopted peculiar exceptions to international patent protections since 1993 that also give the domestic generic industry artificial advantages over foreign generic competitors.

One of the ways that Canadian pharmaceutical policy has evolved to create such advantages is through early working exceptions to patent protection. This policy permits Canadian generic companies to copy, obtain marketing approval for, manufacture, and stockpile drugs protected by patent in Canada before the patent expires but does not permit these drugs to be sold in Canada until patent expiration. Under international standards for intellectual property rights, this is unacceptable because the right of property is defined as the exclusive

right to the ownership and use of the protected item. Therefore, patent holders can disallow the early working of a drug even if it does not immediately interfere with market sales.

Early working exceptions for Canadian generic companies give them a first-mover advantage over foreign competitors in preparations for entering not only the domestic market but also the global market for drugs with expiring patents. Theoretically, this allows Canadian companies to enter and capture large shares of the markets for these drugs, often operating as the only non-brand source of off-patent drugs for significant periods of time. As mentioned earlier, this may result in further long-term advantages that could allow first generic entry Canadian companies to capture around 30% of foreign markets even after other companies enter the market (Hollis 2002).

While this policy does not have a direct negative impact on consumers here in Canada, it does suggest that the Canadian government may be using pharmaceutical policy as an industrial development tool. This is a violation of international free-trade principles that prohibit state subsidies or assistance for domestic industry over foreign rivals. Additionally, early working exceptions may create strong incentives to violate patent protections before they expire in the domestic market, thus potentially undermining intellectual property rights and incentives for innovation.

Nevertheless, such an artificial commercial advantage reinforces the advantages for established Canadian-owned generic companies, allowing them to use the resulting economies of scale to resist the entry of new competitors into the Canadian generic drug market, and this may result in higher-than-expected prices for generic drugs for consumers.

Bill C-9—compulsory licensing for export to poor nations

The latest evolution in Canadian pharmaceutical policy is manifest in the adoption of Bill C-9, an act to amend the Patent Act in early 2004. This federal legislation was ostensibly drafted to make Canadian patent laws conform to international standards by relaxing the prohibitions on compulsory generic licensing of patent protected drugs. The rationale for the legislation is that access to relatively expensive patent protected drugs in countries suffering from epidemics of tuberculosis, malaria, and HIV/AIDS was limited because these countries were too economically poor to purchase these drugs in sufficient quantities. Furthermore, because these countries lack the manufacturing capacity to produce these drugs domestically, it has been argued that more developed countries should be able to violate patent laws in their own countries in order to produce the necessary drugs as generics at lower cost for export to developed countries.

However, evidence on the economics of pharmaceuticals in developing nations suggests that the rationale for C-9 is not supported by the facts. Attaran (2004) studied the patent laws of developing nations in Africa, examining patent protection in each country for the 319 medicines defined as essential by the World Health Organization (WHO) and discovered that in 98.6% of the cases studied there were no existing patent prohibitions on the generic production of the drug in question (Attaran, 2004), In an earlier study, Attaran and Gillespie-White (2001) studied the patent statuses in 53 African countries of 15 anti-retroviral drugs used to treat HIV/AIDS. The research showed that in most countries these drugs are not protected by patents and, in those countries where patents do exist, they only apply to a small subset of the drugs studied (Attaran and Gillespie-White, 2001).

These findings suggest that patent protection is not a barrier to the availability of necessary drugs in developing countries. What is suggested by the research is that poverty simply makes it unprofitable to market drugs to these countries. Therefore, brand-name drug makers find that it is not worth patenting drugs in those markets at all. In fact, the evidence clearly shows that many major brand-name companies give away drugs to poor countries or reduce prices to non-profit levels; something acknowledged gratefully by the WHO in their communications about the issue.

Another point is that allowing compulsory generic licensing in Canada for export of domestic patent protected drugs will not likely promote access to necessary drugs in Africa. As Attaran points out, "compulsory licensing is so disused that even where a country's own

citizens might benefit from it—never mind foreigners in poor countries—zero generic medicines have been manufactured in this way in the past decade, treating zero patients in any country worldwide" (Attaran, 2004: 161). In markets where the average annual spending on drugs is US$2 per person and where national health budgets average about US$8 per year in per-capita spending, it is unlikely that generic companies will have any economic incentive to distribute drugs in these countries, even at lower prices (Attaran, 2004; Attaran and Gillespie-White, 2001).

This could explain the lack of generic commercial distribution to these markets, the reluctance to seek patents, and the charitable activities of many companies in place of normal marketing. In fact, due to the lack of a basic health-care infrastructure, including the diagnosing and prescribing networks of physicians and hospitals, wholesale and retail pharmacy distribution networks, and the basic storage and transportation infrastructure needed to stockpile and move drugs to consumers, even giving drugs away will not expand access very successfully. As Attaran points out, alleviating poverty by eliminating western trade barriers against African agricultural produce would do far more to improve access to medicines than allowing generic licensing (Attaran, 2004).

So permitting generic companies to violate patents in Canada under Bill C-9 will not likely improve access to medicines in developing countries. But such a policy could benefit the generic industry. For instance, by granting a generic license, Canada is bestowing its approval for marketing of the drug. Given that Canada is used as a reference country for fast-track drug approval in most emerging markets, obtaining a generic license means that generic companies can profit from copying a patented drug before its normal expiry in Canada and also from selling it in emerging markets with accelerated approvals. This is at the expense of the patent holders' opportunities to distribute their drugs in those markets and gives a first-mover advantage for Canadian generic drug companies over foreign-owned competitors in those markets.

Competitive advantages for domestic generic drug companies

All of the above policies result in significant competitive advantages for established domestic generic drug companies over their commercial rivals that may allow them to develop a degree of monopoly-style[9] pricing power in the Canadian market. The peculiar characteristics of the pharmaceutical market that have been identified and explained throughout this study raise questions about industrial favouritism in Canadian pharmaceutical policy that advantages generic drug manufacturers at the expense of consumers and competing commercial interests.

Such policy favouritism may be related to the fact that there has historically been a higher degree of Canadian ownership over a greater share of the market in the generic industry than in the brand-name industry. As mentioned earlier, until fairly recently, about 60% of the generic drug market was controlled by two Canadian-owned companies. Yet, the fact that an Israeli-owned firm (Teva) purchased Canada's second largest generic company (Novopharm) may indicate that barriers to foreign competitive entry are formidable enough to recommend a strategy of taking over existing companies rather than attempting product competition on retail shelves. Moreover, this particular corporate takeover will not improve competition in the Canadian market for generic drugs. Teva has simply purchased the same state-imposed, monopoly-style advantages enjoyed previously by Novopharm. This is not likely to result in better prices for consumers.

Of course, domestic concentration of Canadian ownership over the generic pharmaceutical market is not necessarily a problem and, in fact, can be seen as a benefit to our national economy if achieved in a free, competitive market. Canadian pharmaceutical policy, however, interferes in the free market, advantaging one particular industrial interest, effectively granting it a degree of monopoly-style pricing power at the expense of commercial competitors and consumers.

Evidence of industrial favouritism in the policy statements of government officials

The unfair commercial advantages enjoyed by the domestic Canadian generic drug industry may be viewed as unintended consequences of public policy; however, the consistency of the outcomes in favour of one particular industrial interest suggests that there may be a pattern of favouritism being applied by governments in Canada. Evidence that such policy bias is a result of conscious government decisions can be found in the statements of government officials and state bureaucrats that identify two policy goals:

1. reducing the costs to social programs like healthcare by forcing lower drug prices through a variety of mechanisms that favour generic drug supply; and,

2. pursuing state-assisted industrial development by creating an artificial market for domestically owned drug makers, all of which are generic companies, at the expense of innovator companies, which are mostly foreign-owned, multi-national corporations.

Given that the public comments of senior government and state officials suggest political uses for pharmaceutical policy that are unrelated to ensuring consumer access to necessary medicines, protection of intellectual property, or the operation of a free market, a review of the actual comments made is warranted.

Analysis of public comments from state and government officials on pharmaceutical policy

Testimony given before the House of Commons Standing Committee on Industry, Science and Technology confirms that Canadian pharmaceutical policy gives special advantages to generic manufacturers over their brand name competitors. In 2003, the committee held hearings to discuss the notice of compliance (NOC) provisions in the regulations of the Patent Act. The regulations allow generic companies to produce and stockpile patented drugs before a patent has expired, a violation of international understandings of intellectual property rights. While the regulations allow for early working exceptions to patent, the notice of compliance rules prevent Health Canada from approving a generic drug for market until the generic company can prove that there are no patents active on the drug in question.

During those hearings, Andrei Sulzenko, Senior Assistant Deputy Minister of the Policy Sector for the Department of Industry testified about some of the peculiar Canadian pharmaceutical policies that result in special advantages for domestic generic manufacturers. The Senior ADM agreed for instance that,

> [i]nternationally, early working enables generic drug companies located in Canada to be first on the market in Europe where no such regulatory exception exists. Indeed, it is partly because of this that the European Community challenged Canada's early-working exception before the WTO recently.[10]

Under questioning by the committee, Douglas Clark, Acting Senior Project Leader of the Patent Policy Directorate in the Department of Industry echoed the Senior ADM's opinion:

> *Mr Douglas Clark:* Canada is the only industrialized country to have adopted an early-working exception system without also having adopted a patent extension system for pharmaceutical innovators. To my knowledge, we're the only ones in the world to have done that.
> *Mr. Andre Bachand:* Therefore, that's an advantage for generic drug manufacturers.

> *Mr. Douglas Clark:* Yes, I think the generic drug manufacturers see it that way.[11]

These statements from senior bureaucrats are consistent with the observations and analysis presented earlier in this paper, that Canadian pharmaceutical policy often favours Canadian-owned generic drug companies over foreign-owned rivals, granting them special competitive advantages. Other comments from committee members themselves also confirm this and indicate that Canadian-owned generic companies may benefit from a three- to six-year marketing advantage compared to manufacturers in other countries.[12]

The Senior ADM also discussed the way in which provincial government formulary and inter-changeability policies interact with peculiar Canadian court rulings to give advantages to generics over brand-name drugs. According to testimony,

> [o]nce approved, generic drugs rapidly displace the equivalent innovator products through the operation of provincial automatic substitution policies [on provincial formularies]. Then there is the fact that these substitution policies exist alongside a particular unwillingness among Canadian courts to grant preliminary injunctions to pharmaceutical patentees in conventional infringement cases, with the result that absent special rules—and I underline for the committee "absent special rules"—even the most manifestly infringing generic drug can remain on the market pending trial … Finally, there are the infringement cases themselves, which tend to be unduly protracted owing to the inherent complexity of the subject matter in dispute, and the fact that patentee wins in those cases do not always translate into recoverable damages at the end of the day.[13]

A suspicion of bias in court's decisions is suggested again in other statements of the Senior ADM. For instance, according to committee testimony, a total of 34 judicial review applications had been filed with the Federal Court on [patent] listing issues since 1993, most occurring after 1999. Of those, 27 had been dismissed or withdrawn in favour of rejecting the patent at the time of the hearings. Six were ongoing and one case was granted. Up to the time of the hearing, there were seven appeals in the Federal Court of Appeal and, of those, four had been dismissed in favour of rejecting the patent, two were ongoing, and only one had been granted.[14] According to the data presented by the Senior ADM, this meant that of the 28 cases on which the court rendered decisions over the period discussed, it rejected more than 96% of the cases brought by brand-name patent holders. These decisions directly favoured the business interests of generic companies, which were then free to copy, manufacture, and sell drugs that their competitors invented.

The Senior ADM's comments about unbalanced court rulings related to pharmaceutical intellectual property rights have been repeated by other senior federal bureaucrats. In response to questions from the committee about comparing the success rate of brand-name companies versus generic companies in the period before and after 1996, these state officials testified that, between 1993 and 1996, brands were winning approximately 66% of decided cases. However, in the period after 1996, that ratio appears to have reversed itself with generics winning two-thirds of all cases.[15] While these statistics do not indicate the substantive merit of these cases, the fact that it was raised in the context of discussions about the competing interests of research-based and generic drug companies suggests that the committee was concerned about the court's treatment of claims to intellectual property rights.

The fact that there is also a double standard in the Canadian government's approach to applying drug approval requirements that favour generic manufacturers over their brand-name competitors is again confirmed by the comments of committee members. For instance, one of the committee members, posed this question:

> Right now, the patent drug companies must prove the 100% safety and effectiveness of their medications, which can take many years. Eight to 12 years can pass between the time a patent is registered and the time a drug is put on the market.
>
> Right now, the generic drug manufacturers have the advantage of having the right to early production as well as having to prove only one bio-equivalence for their drug in order to put it on the market.

> If the generic drug manufacturers had to conduct clinical trials as is the case for patent drug companies, do you think their drugs would be put on the market as quickly?[16]

The overall bias of Canadian pharmaceutical policy in favour of generic drug companies over their brand-name competition is again shown in the response of the state officials to questioning by committee members. For example, when asked to compare Canada's regime to other international jurisdictions, a senior federal bureaucrat replied:

> I think if we compared Canada to our main competitors, the United States, the European Union, Japan, our regime is overall more pro generic than theirs … we are, relative to our competitors, more favourable to generics and less favourable to the brand-name companies in terms of our regime.[17]

Another said:

> I think that the entire intellectual property regime in Canada is relatively favourable to generic drugs, and that is reflected in quicker marketing in Canada than in the United States.[18]

In fact, the committee heard evidence that the difference in time to market for generic drugs was 22 months in favour of Canada versus the United States.[19]

The unfair commercial advantages enjoyed by the domestic Canadian generic drug industry may be viewed as unintended consequences of public policy; however, the comments of senior bureaucrats and government officials indicate that there are broader underlying political purposes behind state interventions in drug markets.

This is evident in committee hearings discussing amendments to Bill C-9, the act allowing generic drug companies to violate patent laws in order to distribute drugs to poor countries that are overcome with certain epidemic diseases. During those hearings, Pierre Pettigrew, federal Minister of Health testified that,

> you have to understand that what we are trying to do is to let Canadian industry be the first to take advantage of the fact that we have lifted certain international intellectual property obligations. That's what we are trying to do here. Globally, we have eliminated certain obligations, but not all, of course. Some obligations have been lifted. So we want Canadian industry, whether it's the patent industry or the generic drug industry—as a government we are neutral—to be able to benefit from the lifting of these international obligations.[20]

Such comments imply that one of the purposes of Bill C-9 is to create a competitive advantage for the domestic pharmaceutical industry. Given that brand-name companies already own the drugs in question, it is hard to see how compulsory generic licensing will help them. Furthermore, the earlier discussion in this paper of the absence of patents in poor African countries for necessary drugs makes the nominal purpose of the act seem doubtful. This leaves the impression that Bill C-9 is a veiled attempt to use pharmaceutical policy as a tool for industrial development.

Comments by John Manley, federal Minister of Industry in fact suggest that pharmaceutical policy in general is being used to encourage the development of the domestic generic drug industry artificially, and also as a crude means of controlling public expenditures on health-care. According to the Minister's testimony,

> It's a matter of balance, Mr. Chairman, not just balance within the industry, including the interests of the three sectors, but balance between building a competitive industry and keeping health-care costs in line. Rising health-care costs are a significant concern for Canadians … But the value of a strong generic industry in Canada isn't measured simply by the number of jobs and the increase in investment. We can see it as well in its impact on the health-care system. The use of lower-cost generic drugs helps reduce overall drug expenditures.[21]

Conclusion

This study has reviewed the literature comparing Canadian prices to international prices for prescription pharmaceuticals. It found that Canadian prices are close to the international median price for *patented* drugs but higher for *non-patented single source* (usually brand-name) drugs and also higher for *non-patented multiple source* (mostly generic) drugs. It was also found that Canadian prices are significantly lower overall for *patented* drugs but are usually higher than American prices for generic drugs.

Given that Canadian incomes are lower than those in most of the countries used for drug price comparisons, economic theory would predict that in a free market, the prices for drugs would also be lower in Canada, a price-to-income relationship that has been observed for many non-pharmaceutical products. Therefore, the observation that Canadian prices for *non-patented* drugs are higher than the international median and, especially, that Canadian *generic* drug prices are higher than American prices is counter-intuitive, inviting further investigation.

A number of explanations for the irregular pricing of non-patented drugs, and generic drugs in particular were analyzed. The unintended effect of price controls on patented drugs causing inflated generic drug prices was addressed and explained. Additionally, a comparison of the structure of the market for generic pharmaceuticals in Canada and the other countries showed that other markets are more competitive, having a larger relative number of players and a more equal distribution of market share among producers. The high degree of market power enjoyed by relatively few generic companies in Canada suggests that some degree of monopoly-style concentration partially explains the abnormal pricing structure for generic drugs observed here.

Furthermore, this study also observed that the Canadian market for generic drugs has historically been dominated by domestically owned companies, suggesting that this might be the effect of the economic structure of the industry or of public policies peculiar to Canada that create artificial advantages for domestic interests over foreign competitors.

In fact, a review of Canadian pharmaceutical policies suggested that the effect of government legislation, regulations, and drug benefit programs, as well as court decisions related to drug policy in Canada, is to give the Canadian generic drug industry an unfair advantage over its commercial rivals—both within the generic market and across the pharmaceutical industry as a whole. This has a negative impact upon the interests of consumers, leading to higher prices for a large and growing portion of the most commonly prescribed drugs and creating disincentives for pharmaceutical innovation.

This analysis also proposes that the special commercial advantages enjoyed by the domestic Canadian generic drug industry may be partially viewed as unintended consequences of public policy. However, there are serious reasons to believe that the advantages enjoyed by the Canadian generic drug companies are a result of conscious government decisions to use pharmaceutical policy for broader purposes.

The public comments of senior government and state officials indicate that pharmaceutical policy is often unrelated to ensuring consumer access to necessary medicines, protection of intellectual property, or the operation of a free market. This study identified two irregular policy goals that are evidenced by the public statements of senior elected government officials as well as appointed state bureaucrats. The goals that are identified here include: (1) reducing the total costs to social programs like health care by forcing lower drug prices through a variety of mechanisms that favour generic drug supply; and, (2) pursuing state-assisted industrial development by creating an artificial market for domes-

tically owned drug makers, most of which are generic companies. This is achieved at the expense of innovator companies, which are mostly foreign-owned multinational corporations.

All of this suggests that Canadian governments may be intentionally politicizing pharmaceutical policy in order to use it as a means of subsidizing the development of a domestic drug industry, a practice that is inefficient, costly to consumers and taxpayers, a violation of free-trade principles, and possibly challengeable under international agreements.

Anecdotal evidence based on official statements implies that the research-based pharmaceutical industry may also face a court that is ideologically hostile to intellectual property rights. Evidence of bias against research-based brand-name drug makers is apparent in the decisions of the courts, which heavily favour generic drug companies in patent disputes; something state officials acknowledge and identify as a problem that justifies counter-balancing regulations.

This study concludes that without a free market for pharmaceuticals and the consistent protection of intellectual property rights, incentives for innovation will be reduced and future access by Canadian consumers to life-improving and life-saving medicines could be limited. Therefore, a reorientation of Canadian pharmaceutical policy toward the goals of improving consumer access to the best medicines available, protecting intellectual property rights, and minimizing interference in the free market for pharmaceuticals is required.

Appendix A: An alternative explanation?

Hollis (2003) claims that first-mover advantages secured by pseudo-generic drug products are creating artificial barriers to entry for competing independent generics. He defines a pseudo-generic as a product that is produced by a brand-name company and is equivalent to the originally patented drug, but is marketed under a generic label to compete with its own branded product as well as other generic drugs.

This type of marketing strategy is commonly used for non-pharmaceutical products that sell both brand name and generic (or "no-name") versions produced under license for the same brand-name company. The courts have acknowledged that it is a legitimate practice; for instance, in a case before the Ontario Court of Appeal, the court stated that if pseudo-generic marketing was declared to be an unlawful practice under provisions of the Competition Act forbidding false product representation,

> the effect would be to stigmatize as illegal conduct what most people would not consider unlawful. It would, for example, preclude a manufacturer from marketing food products under different brand names for different prices without disclosing the fact on the label of the lower-cost product that it is identical to the other. (*Apotex Inc.* v. *Hoffman La-Roche Limited*, 2000-12-14, C33172: [Para.12])

Nonetheless, the court went on to allow a generic company to appeal a lower court ruling, which had earlier declared that pseudo-generic licensing was not anti-competitive under the meaning of the act. Therefore, an examination of Hollis's argument that pseudo-generic licensing is anti-competitive is warranted, as it may affect future court rulings.

A review of Hollis's argument that pseudo-generic entry inhibits competition suggests that his hypothesis should be rejected. It is not clear how pseudo-generics would cause prices to stay high by preventing competitive entry. Instead, it appears more likely that there is only a redistributive effect with pseudo-generic products capturing market share that would otherwise fall to generic products. To the consumer, the difference in effect is probably nil.

Moreover, pseudo-generics can only create barriers to competition by undercutting new entrants and dominating product lines in the same way as I explain generics do. If pseudo-generics were to keep their drug prices high in the face of competition, then this would create positive incentives for competitive entry into the market. Higher prices for pseudo-generic drugs are consistent with the high costs of innovation that brand-name companies face to develop the original drug. Given that pseudo-generics are affiliated with brands that have high sunk costs in research and development, they do not have the same flexibility to use undercutting as a strategy to inhibit market entry by competitors. Only generics have that advantage and so only they can achieve a first-mover advantage by threatening price-cutting as a barrier to entry. Furthermore, as explained earlier, the generic first-mover advantage is exacerbated by other policies that create artificially large markets and profit margins.

Additionally, Hollis claims that,

> In Canada, for almost every drug released for which generic competition has begun post-patent expiry in the last few years, the brand-name company has released its own "pseudo-generic" version of the drug, licensed to and marketed through a separate company, to compete in the generic market. (Hollis 2003: 21)

He also claims that "pseudo-generics now capture approximately 25% of the total generic sales in markets

in which generics began competing in the last five years" (Hollis 2003: 21).

Given that 75% of sales in new entry generic drug markets are captured by independent generic companies, and only two independent generic companies control nearly 60% of the entire market, there is simply no evidence to indicate that there are any effective barriers to competitive entry caused from the introduction of pseudo-generic products, or the scope of their market share. In fact, it appears that where they exist at all, pseudo-generic products introduce much needed competition to generic drug markets in Canada.

Finally, according to Hollis, in over two-thirds of the cases in which a pseudo-generic entered first in Canada over the period from 1994 to 1997, a generic competitor entered the market less than five months later (Hollis 2003: 26). If, in most cases, a pseudo-generic can slow the entry of competing generic companies for less than five months, this is hardly a strong argument that the introduction of these pseudo-generics is anti-competitive.

Appendix B: National ownership of generic companies in Canada

This section selectively documents those companies that are identified as having foreign ownership, or whose Canadian ownership is affiliated with another generic company, or whose ownership is unclear from public sources. The companies' history and profile information was gathered from various sources identified below and is current as of July 23, 2004.

Apotex

According to the company's website, Apotex Inc. was founded in 1974 and actually comprises a large group of companies, including:

- Apotex Inc. [North York]
- Novex Pharma [Richmond Hill]
- TorPharm [Etobicoke]
- Accucaps [Windsor and London]
- Brantford Chemicals [Brantford]
- Cangene [Mississauga and Winnipeg]
- Apotex Fermentation Inc. [Winnipeg]

Source: Apotex website: <http://www.apotex.ca/En/Default.htm>.

The list provided by the company did not include Nu-Pharm Inc., which the Canadian courts have also recognized as an Apotex affiliate. According to the court record,

> Merck & Co. Inc. initiated an action against Nu-Pharm and its officers for the infringement of the patent No. 1275349 (349 patent) for enalapril and its salt, enalapril maleate. In 1994, a Federal Court judgment upheld the validity of the patent, found that Apotex's Apo-Enalapril was infringing Merck's patent and issued an injunction accordingly. Herein, the defendants were alleged to have deliberately and willfully used Nu-Pharm, a privately held corporation, originally established by the defendant Sherman, CEO of Apotex and Apotex Pharmaceuticals, as a vehicle to circumvent and violate the injunction by allegedly manipulating the regulatory process to, in effect, reintroduce the infringing Apo-Enalapril into the market as Nu-Pharm's product under the new name Nu-Enalapril. Sherman was also alleged to control a group of corporations, including Nu-Pharm and Apotex, that were interrelated with respect to ownership, management, employees, and financing. He and his group were alleged to have consistently endeavoured to circumvent the judgment of 1994. Many decisions in this Court dismissed, on grounds of res judicata, attempts by Apotex, in conjunction with members of that group, to challenge the 349 patent.

Source: Merck & Co., Inc. and Merck Frosst Canada & Co. (*Plaintiffs*) *v.* Nu-Pharm Inc., Bernard Sherman and Richard Benyak (*Defendants*) and Nu-Pharm Inc. (*Plaintiff by Counterclaim*) (*Defendant*) *v.* Merck & Co., Inc. and Merck Frosst Canada & Co. (*Defendants by Counterclaim*) (*Plaintiffs*) *Indexed as: Merck & Co., Inc.v. Nu-Pharm Inc. (T.D.)* Trial Division, Aronovitch P. Ottawa, February 27 and July 13, 2001. The Office of the Commissioner for Judicial Affairs Canada, <http://reports.fja.gc.ca/fc/2002/pub/v1/2002fc29186.html>.

Cobalt

There was no data publicly available as to the national ownership of Cobalt. However, the address for Cobalt Pharmaceuticals Inc. listed on CGPA's website is the same address that Oryx Pharmaceuticals Inc. has posted

on its website. So it is assumed that the two are the same company. Cobalt/Oryx appear to be Canadian owned. Oryx claims to have been founded in 2001.

Source: Oryx website: <http://www.oryxpharma.com/en/contact.asp>.

Novopharm

TEVA acquired Novopharm, Canada's second largest generic company, in 2000. TEVA is a global, Israeli-based pharmaceutical company.

Source: TEVA website: <http://www.novopharm.com/corp_overview_e.asp>.

RhoxalPharma

The following information is taken directly from the company's website:

> RhoxalPharma is the Canadian subsidiary of Hexal AG, a German pharmaceutical company ranking 50th among international pharmaceutical companies. In 1997, RhoxalPharma was founded as a joint venture between Hexal AG and Rhône-Poulenc Rorer's Rhodiapharm, RPR's ultra-generic division. In 1999, Hexal took full control of RhoxalPharma with headquarters in Montreal to serve customers throughout Canada.

Source: RhoxalPharma website: <http://www.rhoxal-pharma.com/anglais/profile.htm>.

Ratiopharm

The following information is taken directly from the company's website:

> On June 29, 2000, Ratiopharm GmbH, Europe's largest generic drug company, purchased Technilab Pharma to establish Ratiopharm's generic operations in Canada. Long before being acquired by Ratiopharm GmbH, Technilab Pharma and its group of companies, enjoyed a rich history and played an important role in the evolution of the Canadian generic industry.
>
> Founded in 1974, with head office in Mirabel, Quebec, Technilab Pharma was a prominent player in the field of generic prescription drugs and over-the-counter medications. As Canada's leading manufacturer of liquid and topical generic drugs, Technilab Pharma marketed a wide range of products under the Technilab, Bio-Chimique, Charton, and Rougier brands.
>
> On February 9, 1999, Technilab Pharma acquired AltiMed Pharmaceutical Company of Mississauga, Ontario. Formed in 1996 by Hoffmann-La Roche, Pharmacia & Upjohn, and Glaxo Welcome, AltiMed was a generic industry leader and marketed over 70 generic products that generated annual sales of $100 million. With the acquisition of AltiMed, Technilab Pharma's annual sales more than doubled to $160 million. In terms of revenue generated, this acquisition moved Technilab Pharma from 6th to 3rd (among generic drug companies) and from 16th to 4th (among all drug companies) in terms of total number of prescriptions dispensed by pharmacists across Canada.
>
> On May 6, 2002, Technilab Pharma and AltiMed officially became Ratiopharm Inc. The name change effectively signaled the arrival of the world's fourth largest generic pharmaceutical manufacturer in Canada … Today, Ratiopharm Canada employs 400 people in its Mirabel and Mississauga facilities and boasts annual sales approaching $300 million.

Source: Ratiopharm website: <http://www.ratiopharm.ca/index.asp?rp=1>.

Taro

Taro is an Israeli pharmaceutical company that purchased a small Canadian manufacturer of topical medications in 1984 "allowing entry into the North American generic pharmaceutical market."

Source: Taro website: <http://www.taro.com/Content/ContentUnit.asp?CID=50&u=916&t=0&bhcp=1>.

Notes

1 There are actually many ways to measure drug prices differ from one international market to another. These various approaches each have their own set of conceptual problems. Though all may be accepted as valid, different methodologies can produced widely varying conclusions. For a discussion of these issues, see Danzon, 1996.

2 The NPMS study also included data from Australia and New Zealand.

3 However, as the PMPRB (2003b) report points out, products that were single source in Canada were not necessarily single source in other countries. If more than one bioequivalent drug product was found in a country, the product with the median unit price was used to represent the price in that country for the analysis.

4 NPSS drugs can also include drugs for which there is no competition in spite of an expiring patent because the market demand for some products is too small to support the entry of additional sellers.

5 Prices listed in the *Drug Topics Red Book* (RB) are shown as Average Wholesale Prices (AWP). However, RB prices are not accurate reflections of actual average prices. In the United States, people without drug-insurance benefits (cash customers) generally pay more than the insured (or those who belong to managed health-care organizations) for the same drugs at the point of sale. Large purchasers are able to negotiate considerable discounts off the RB prices while many cash-paying customers tend to pay prices closer to the RB's AWP. However, the proportion of cash customers has been steadily decreasing in recent years, from 63% of retail prescriptions in 1990 to only 25% by 1998. Therefore, 75% or more of retail prescriptions are sold at prices that are significantly lower than the RB prices. Furthermore, in the United States, prices paid for drugs by federal agencies are set by the Federal Supply Schedule (FSS). According to the US General Accounting Office (GAO), average FSS prices are more than 50% below the RB price. Moreover, the US Department of Veteran Affairs (VA) has been able to negotiate prices even lower than FSS prices through purchase contracts for select drugs. Also, about 75% of generic drugs are reimbursed using limits established by drug-benefit managers, based on the lowest estimated acquisition cost for any of the generic equivalents of a given drug. These prices tend to be 50% to 60% below AWP (PMPRB, 2003c: 95). Therefore, the average price for drugs in the United States is likely much lower than the Red Book price and, especially for generic drugs, may in fact be skewed toward the lower FSS price.

6 J.R. Graham (2000) discusses the characteristics of pharmaceutical products that permit price differentiation across markets. Graham explains that other products with similar characteristics also permit price differentiation.

7 A positive relationship between price and average income in a market is usually observed because average income is an important factor in determining the price elasticity of demand for a product. However, higher prices may sometimes be observed in poorer markets if a very wide income range characterizes the market. This is because average incomes are affected by the distribution of wealth in the market. For instance, a poor country may have a small minority of its population that is extremely wealthy while the bulk of the population is extremely poor. This will lower the average income (total income divided by population). If the domestic market cannot be segmented between consumer groups based on income or if the incomes of the poor are not high enough to buy at the lowest possible price, then it will only be profitable to sell to the smaller but wealthier population whose average incomes, if considered as a separate consumer group, are much higher. Furthermore, the profit-maximizing price will be set as high as the wealthier consumer group can bear. If this small group of consumers has higher average incomes than the average incomes in foreign markets, then its prices will be higher as well.

8 This conclusion is valid only so long as markets can be segmented. If cross-border parallel trade undermines the ability to segment markets through price differentiation, then in the absence of Canadian price controls, prices will converge toward the higher American price (Graham, 2000).

9 It is more accurate to describe the concentration of market share in this case as an oligopoly, or as a duopoly, as Graham (2000: 12) has. However, the term "monopoly" is used here because it is more commonly understood and I have purposely modified it by describing it in terms of degrees.

10 Comments of Andrei Sulzenko, Senior Assistant Deputy Minister, Policy Sector, Department of Industry, Canada. June 2, 2003. Appearing before the House Standing Committee on Industry, Science and Technology. Committee evidence. 37th Parliament. Second session.

11 Comments of Douglas Clark. Acting Senior Project Leader, Patent Policy Directorate, Department of Industry. June 2, 2003. Appearing before the House Standing Committee on Industry, Science and Technology. Committee evidence. 37th Parliament. Second session.

12 Comments of the Honourable Gilbert Normand. June 2, 2003. The House Standing Committee on Industry, Science and Technology. Committee evidence. 37th Parliament. Second session.

13 Comments of Andrei Sulzenko, Senior Assistant Deputy Minister, Policy Sector, Department of Industry, Canada. June 2, 2003.

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20 Comments of Hon. Pierre Pettigrew. Minister of Health. February 24, 2004. At the hearings on amendments to Bill C-9. Committee Evidence. The Standing Committee on Industry, Science and Technology. 37th Parliament. Number 002. 3rd Session.

21 Comments of Hon. John Manley. Minister of Industry. February 17, 1997. Committee Evidence. The Standing Committee on Industry, Science and Technology. 36th Parliament.

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