

The Anti-Competitive Effects of Brand-Controlled ‘Pseudo-Generics’ in the Canadian Pharmaceutical Market

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Au Canada, lorsque leur brevet arrive à expiration, les firmes pharmaceutiques qui ont une marque déposée se dotent toujours d'une filiale «pseudo-générique» afin d'entrer en concurrence directe avec les firmes de médicaments génériques. Le médicament «pseudo-générique» est identique au produit de marque mais il est commercialisé en tant que générique, et la firme pseudo-générique encaisse des frais de distribution. Cette stratégie dissuade d'entrer dans des marchés pharmaceutiques de moindre importance, du fait que la menace de la concurrence des pseudo-génériques dissuade d'autres génériques de faire l'investissement requis pour y entrer; et cela ralentit le processus d'entrée sur le marché de firmes concurrentes de produits génériques.

Brand-name pharmaceutical firms in Canada, upon the expiry of their patent, always license a “pseudo-generic” firm to compete directly against generic firms. This pseudo-generic is identical to the brand-name product, but is marketed as a generic, with the pseudo-generic firm receiving a distribution fee. This strategy deters entry into smaller drug markets, since the threat of pseudo-generic competition deters other generics from making the investment required to enter; and slows the process of entry by competing generic firms.

INTRODUCTION

Should “innovator” drug companies be permitted to compete in the generic drug market against their own branded product? Practices in this matter differ across countries. 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. Pseudo-generics now capture approximately 25 percent of the total generic sales in markets in which generics began competing in the last five years. Such cross-licensing was common in the United States in the early and mid-1990s and was effectively stopped following an investigation into the practice by the Federal Trade Commission. In most other countries, pseudo-generic drugs are treated as if they were independent

generics, just as in Canada, although their presence has considerable strategic implications.¹ In this paper, I argue that pseudo-generics harm competition.

The issue of pseudo-generics is currently before the courts in Canada, with Apotex (Canada's largest generic manufacturer) alleging that pseudo-generics, by misrepresenting their origin, are committing an offence under the *Competition Act*.² Apotex has also proposed in a submission to the Competition Bureau that the use of pseudo-generics is an abuse of dominant position under the Act.³

On the surface, pseudo-generics add competition to generic drug markets. However, I argue that the beneficial effects of the additional competition are illusory: pseudo-generics discourage any firms from competing in smaller drug markets. This pernicious effect is compounded by the fact that the brand name is able to release its pseudo-generic before other generics can enter the market, thus ensuring that it obtains the lion's share of the market. This weakens the incentive for generic firms to try to invent around the brand-name firm's patents, since no matter how much earlier they may enter than other generic firms, the pseudo-generic can always get to market first.

The issue of pseudo-generics has been attracting increasing attention recently. Liang (1996) argues that the practice of brand-name firms introducing pseudo-generics pre-patent expiration and then contracting to supply the pseudo-generic past the patent expiration date is anti-competitive. Ferrandiz (1999) shows using a model and a numerical example that it is better to have a single independent generic competitor than a single pseudo-generic only.⁴ Kamien and Zang (1999) suggest that pre-emptive pseudo-generics are a form of "virtual patent extension" which, according to their model, actually increases welfare, since the pseudo-generic takes a Stackelberg leadership position in the generic industry leading to higher generic output. The assumption of Stackelberg leadership by the first generic entrant is undesirable because capacity constraints are not important in this industry.⁵ Morton

(1999) examines whether there are complementarities of production or administration between brands and pseudo-generics in the United States and does not find any significant effects.⁶ My study is the first to consider the effect of pseudo-generics on entry. Caves, Whinston and Hurwitz (1991), Grabowski and Vernon (1992), Jambulingam and Kreling (1995), Bae (1997), Morton (1999), and Aronsson, Bergman and Rudholm (2001) examine pricing and entry decisions in generic drug markets but do not consider pseudo-generics. In a less specific context, there is a substantial literature on how licensing can be used to deter entry (Yi 1999) or to strengthen the position of the dominant firm (Rockett 1994; Eswaran 1994; Ashiya 2000).

The next section of the paper describes the operation of the pharmaceutical industry. In the third section, I argue that pseudo-generics, far from adding competition and lowering prices for consumers, are likely to increase prices of both generic and brand-name drugs in markets where they enter. The strategic impact of pseudo-generics on the rest of the generic industry is then examined in order to demonstrate that even when they do not enter, pseudo-generics can be used to deter independent generic competitors.

INDUSTRY BACKGROUND

Prescription drug expenditures are growing and currently stand at around \$13 billion in Canada.⁷ Pharmaceuticals' share of health-care expenditures has also been increasing, and currently stands at around 15 percent of total expenses. The most important form of competition in the pharmaceutical industry is from generic firms which are able to enter when all valid patents on a drug have expired or been invented around. Generic drugs are therapeutically equivalent to brand-name drugs, but differ in the non-medicinal ingredients of the drugs. Because generic drugs are typically priced between 20 percent and 90 percent of the originator drug's price, they create significant savings for private, corporate,

and public consumers: in Canada the savings are estimated to be over \$1 billion.⁸ In Canada in 1999, generics had 40.6 percent of prescriptions but only 16 percent of sales revenues at drug stores.⁹ In the United States, the proportions were respectively 41 percent and 8.5 percent.¹⁰

Brand-name drugs in Canada obtain nominal patent protection of 20 years on their product, although the effective duration of the monopoly will depend on the time taken for Health Canada to approve the product for sale, and the ability of generics to work through the “patent thicket” which firms typically employ to defend their products. The first genericized version of a drug typically faces considerable opposition, including legal challenges to the effect that the generic drug is violating one or more active patents. (For example, the manufacturer may initially obtain a patent for the use of a drug to treat depression, but discover only later that the drug can also be used to treat post-traumatic stress syndrome. The latter use would also merit a patent. If a generic company attempts to enter after the original patent expires, the brand-name firm will claim infringement of the second patent, which might or might not be valid.) Thus, generic manufacturers who attempt to enter as early as possible are certain to face considerable legal expenses when they enter; and the earlier they attempt entry, the more difficult is the entry process since the more outstanding patents there are and the more fiercely the brand-name firm will fight. Since it is desirable from a social point of view for generic competition to arrive as early as possible, in the United States the 1984 Hatch-Waxman Act guaranteed a period of 180 days without generic competition to the first generic firm to successfully challenge the incumbent’s patents. This created substantial incentives for generic firms to attempt to enter early, particularly in the largest markets. In Canada, no similar incentive exists: on the contrary, the regulations seem designed to deter generic competition.

Pseudo-generics are physically identical to brand-name drugs and manufactured on the same

production lines, but they are sold under a different trade name and priced to compete in the generic market. In some markets there is more than one pseudo-generic. The brand-name firm may use either agency or licensing arrangements with a pseudo-generic firm. While the contracts between the pseudo-generic and the brand-name firm are typically private, one recent court case forced the disclosure of the contract, which showed that the brand-name firm “controls all aspects of the manufacture, distribution, promotion, and sale” of the pseudo-generic drug.¹¹ Consumers and even some pharmacy professionals do not know that pseudo-generics are in fact identical to the brand-name drug.¹² Firms tend to keep the information concerning pseudo-generics relatively well hidden. Under an Access to Information request to Health Canada, I obtained information concerning the application for Altimed’s pseudo-generic form of diltiazem. Their submission certification states that “The product monograph and labels for Alti-Diltiazem CD are identical to the product monograph and labels for Cardizem®CD, manufactured by Hoechst Marion Roussel Inc., except for the brand name and manufacturer’s name.”¹³ So the submission certificate admits that the product is manufactured by the same firm, but claims that the manufacturer’s name differs.

Many of the companies that now sell pseudo-generic products were former competitors with the brand-name drug companies through the sale of independently developed generic products — indeed, all but one of the major generic drug companies in Canada have entered into agreements for the distribution of pseudo-generic drug products.¹⁴ These companies now distribute pseudo-generic products according to the terms set by brand companies, which ensure that they are sold only when at least one independent generic product is competing or is about to compete with the brand name.

In Canada, a significant proportion of generic sales is captured by pseudo-generics. In the 1980s, pseudo-generics constituted a tiny share of total

generic sales. However, during the 1990s, they grew substantially in their market share, following the creation of Altimed, a joint venture of three brand-name pharmaceutical firms, whose purpose from the beginning appears to have been to sell pseudo-generics. The success of the pseudo-generic strategy in capturing market share is impressive. IMS Health Canada generously provided sales data for 32 drugs in Canada for which the first generic competitor entered during the years 1994–97.¹⁵ In 1999, the total pharmacy sales of these generic drugs was approximately \$500 million, of which the pseudo-generic share was 34.6 percent.¹⁶ It appears that the brand-name firms have effectively displaced approximately one sizeable generic firm using this pseudo-generic strategy.

Regulatory Environment

In the current Canadian regulatory environment, it typically takes between three and six years to develop and obtain regulatory approval for generic drugs. No drug can be sold in Canada without first obtaining a “Notice of Compliance” or NOC from Health Canada. For an independently developed generic drug product, a submission must be filed with the minister which contains sufficient information for the ministry to assess the bio-equivalence of the drug to the brand-name product, as well as evidence of tests conducted regarding potency, purity, and stability of the new drug.¹⁷ The required studies are costly and often require several years.¹⁸ After the submission is filed with the minister, and the costs of development and bio-equivalence studies have been incurred, generic companies are required to serve a “Notice of Allegation” (NOA) on the patentee that the new product will not infringe any patent rights.¹⁹ The patentee is then permitted to apply to the court for an order prohibiting the minister from issuing an NOC. If the patentee files such an application, the minister is precluded from issuing an NOC until 24 months have passed or the application has been dismissed.²⁰ Therefore, the patentee is potentially able to prevent a generic product from entering the market for about 24 months simply by alleging that its patent has been infringed,

while simultaneously obtaining information regarding the intentions of potential competitors.²¹

In contrast, in order for a pseudo-generic to obtain an NOC, all that is required is a letter from the brand to the minister stating that the pseudo-generic is identical to the brand-name product.²² This process may take only days to complete, at no cost to the brand or pseudo-generic. Pseudo-generics sometimes obtain their NOC years in advance of when they actually enter the market, as the brand-name firm does not permit the pseudo-generic firm to sell the product until some other generic competitor has acquired an NOC.

Upon obtaining an NOC, a product can be sold anywhere in Canada. From a practical perspective, generic products are only marketed after they have been listed on the applicable provincial drug formularies. The formularies list the drug products which will be covered under various provincial insurance plans. For an independent generic, this process typically takes approximately six months from the time an NOC is issued. In contrast, it requires significantly less time from the date a submission is filed for listing on a provincial formulary for a pseudo-generic, because there are no data to be reviewed.

Because the brand receives advance notice of potential generic competition through the Notice of Allegation, it is able to predict accurately the expected date that the generic product will be listed in provincial formularies and can time the release of its pseudo-generic product to pre-empt the release of the true generic product. An important side effect of the regulations is that there is no confidentiality of business plans for generic drug manufacturers.

The provincial formularies group products that are interchangeable, such as the brand-name drug and the generics. Pharmacies may generally substitute within groups. The formulary also lists the maximum amount reimbursable for each product group, typically the lowest price listed among the

individual products. This forces all the generics to sell at the same price, since patients will be charged extra for any higher priced product. (The brand-name drug is able to charge a premium since some consumers value the brand-name product and are willing to pay extra for it, and since doctors sometimes prescribe the brand-name drug with no substitution allowed — even when one of the generic drugs is in fact actually identical to the brand-name drug. Generic drugs are completely undifferentiated and are unable to charge any significant premium over each other.)

Competition among generics is thus accurately described as repeated Bertrand competition, where firms are forced to meet the lowest price in the market or suffer a large discrete decrease in market share. The effect of this market structure in a dynamic context is that there is little point in cutting prices, since the market-share gains are likely to be minuscule, but the lower prices enduring. Provincial formularies employ various rules to generate lower prices, such as requiring generics to price at no more than 70 percent of the brand-name price.

In Canada, pharmacists are reimbursed for their dispensing fee plus the lower of the lowest-cost available alternative listed in the provincial formulary or the cost actually paid, whether the reimbursement comes from the government or a private insurance plan. The dispensing fee does not vary across different drugs within the same therapeutic category, so that pharmacies have no incentive to carry more than one generic drug: to do so would only increase their administrative costs. If a generic firm tries to gain additional business by reducing its price, the pharmacy is indifferent, since it obtains no benefit from buying a lower priced drug. Competing generic firms are reduced to using marketing schemes involving indirect payments and rewards to pharmacists. Another important way of attracting business is to make the terms of supplying particularly easy, or to have the fullest possible line of drugs so as to minimize the administrative costs of supply. However, the most important fea-

ture that a generic drug can have is that of being the first generic on the market, since then pharmacies will necessarily stock it initially, and resist switching to a different generic in the future (Hollis 2002).

Before proceeding, it is useful to consider briefly the state of competition in the pharmaceutical industry. Competition occurs within therapeutic categories to a limited extent between drugs which have similar therapeutic effects, and between generic and brand-name drugs after generics enter. As Lichtenberg and Philipson (2000) show, in many therapeutic categories, competition from similar branded drugs before patent expiry reduces brand-name profits more than post-patent competition from generics. Unfortunately, in Canada, while there may be fierce competition between branded drugs in some categories, that competition plays out through advertising to doctors (“detailing”) not through lower prices. Tracing through the history of prices in markets where therapeutically similar drugs are introduced successively is instructive here: it turns out that additional entrants appear to create no pricing discipline. For example, the market for cholesterol-fighting “statins” consisted of one drug in 1991. Five other therapeutically similar statins were introduced between 1992 and 1998. In all this time, only one firm ever reduced its prices in the Ontario formulary as new competitors were introduced and that one reduction was for less than 1 percent. Indeed, the first firm into the market raised its prices as competitors entered! Only generic competition appears to create significant price reductions in Canada.

This description of the Canadian industry is also representative of the situation in many other countries, which may differ slightly in the details but have similar structures established to protect consumers and the publicly-funded health-care provider from “excessive” pharmaceutical prices. Having provided this brief summary of the industry, I now proceed to examine why brand-name firms license other firms to compete as pseudo-generics, and what effects pseudo-generics have on prices, market shares, and welfare.

DIRECT EFFECTS OF PSEUDO-GENERIC

Pseudo-generics unambiguously reduce prices for consumers if they are the only generic available (and brand prices do not increase). Usually this is not a long-lived situation. In over two-thirds of the cases where a pseudo-generic entered first in Canada in the period 1994–97, it entered less than five months before the next generic.²³ In the few cases where the pseudo-generic lead time was longer, the price reduction compared to the brand-name drug was typically very small, on the order of 5 percent.²⁴ As we will discuss in the next section, there is reason to think that pseudo-generics may actually delay the entry of generic drugs, so that it is not clear that pseudo-generics actually accelerate the reduction in prices compared to what would happen in their absence.

Of more enduring importance is the issue of how pseudo-generics affected the prices charged by brand-name firms and of generics. Ideally, to assess this, we would compare markets with and without pseudo-generics to see what effect they had on prices. This is not possible as there was at least one pseudo-generic present in *every* national market in which generics were active. In any case, it is clear from a brief examination of pricing in formularies over time that brand prices tend to change little regardless of the degree of generic or pseudo-generic competition. It is possible that the profit-maximizing brand price is usually higher than the maximum price imposed by the Patented Medicines Prices Review Board, with or without generic competition. If anything, one would expect that the presence of pseudo-generics tends to result in higher brand prices than would be observed in their absence. The reason for this is that when a brand-name firm is considering raising prices, one of the factors holding it back from such increases is that it may lose market share; however, when a pseudo-generic obtains substantial proportion of the sales the brand loses from increasing its price, then raising prices becomes more attractive.

The effect of pseudo-generic licensing on brand-name firm profits is, of course, positive. As documented in Hollis (2002), and as is well-known in the industry, the first generic entrant into any market tends to retain a dominant position for many years. Thus, the reason that the brand-name firm will allow a pseudo-generic to enter before any other generics is that it dominates in the generic industry, and, as I describe below, significantly lessens the revenues available to independent generic firms. Indeed, as I show, the threat of pseudo-generic licensing can slow or even deter entry and eliminate competition in some markets. I conclude with a discussion of the anti-competitive implications of these arguments.

STRATEGIC EFFECTS OF PSEUDO-GENERIC

In this section, I discuss how the threat of brand-name licensing of pseudo-generics can delay or even *eliminate* competition. The reason is that pseudo-generics decrease the incentive for “independent” generic firms to invest in the fixed costs required to enter a market. This may lead to no entry at all, since without entry by independent generics, brand-name firms will not license pseudo-generics. Likewise, since a pseudo-generic can (almost) always enter a market just ahead of the first independent generic competitor, its presence reduces the incentive for independent generic firms to accelerate entry into markets. This occurs since the “prize” for being second generic in a market is relatively small and not much different from the prize for being third. This means that competition will occur later than it would otherwise. There are thus two separate ways in which pseudo-generics can decrease competition: the threat of licensing of a pseudo-generic may credibly deter entry from some markets; and will cause slower entry into other markets. These effects will not be apparent in the data since pseudo-generics enter every market where generics are present.

The strategic effects of pseudo-generics will depend on the size of the market for a particular drug

formulation in Canada. It is convenient to divide markets into three categories: small, intermediate, and large. A market is small if it is not large enough to attract generic entry even in the absence of a pseudo-generic entrant. In such markets, neither generics nor pseudo-generics will enter.

An intermediate market is one that is large enough that the present value of profits in the market is large enough to pay for the entry costs of at most one generic drug in competition with the brand-name product. In such markets, the pseudo-generic threat will entirely prevent any competition. Suppose that a generic firm decides to enter such a market. It will have to pay entry costs related to litigation, bio-equivalence studies, chemical analysis, and product manufacturing set-up. Once it has made this investment, it will finally be in a position to start sales, but just before it arrives on the market, a pseudo-generic competitor will begin sales. The pseudo-generic firm faces none of these upfront costs, and it can therefore enter profitably, even if it does not capture the entire generic market. However, the generic firm will never earn enough profits to recoup its upfront investment. A forward-looking firm will therefore decide not to invest in entry into such a market — but without entry by an independent generic firm, the brand-name firm will not license a pseudo-generic. Thus a market which was large enough to support competition between the brand name drug and a generic product will be monopolized.

Thus, in intermediate-sized markets, *the simple threat of licensing by the brand name is sufficient to deter entry*. Adding in the first mover effect — if the pseudo-generic enters first it captures a disproportionately large share of the market — increases the range of markets in which this threat is effective. It is clear that if the threat of licensing by the patentee can discourage entry, then the presence of such licensing agreements could be anti-competitive. If *many* markets could be characterized as intermediate, then there is a significant threat to competition.

Essentially, this is a case of fighting brands being used in a predatory manner to protect the monopoly held by the brand name. What distinguishes it from the usual fighting brand story is that the pseudo-generics are not temporary, though they may be entered into selective markets. The reason why they are not temporary is that almost all the costs in these markets are sunk. Thus, even if an independent generic is unable to cover its fixed costs of entry, it will stay in the market because its profits in that market make some contribution to the entry costs. Therefore, the brand name has no reason to withdraw the licence to the pseudo-generic. The second respect in which this differs from the usual fighting brand story is that this strategy of entry deterrence by the threat of pseudo-generic licensing is entirely credible and rational. The brand-name firm increases its profits by licensing a pseudo-generic if and only if it faces actual entry.

It is difficult to identify empirically how many markets are “intermediate,” since it is not possible, when no generic entry is observed, to identify whether the market is small or intermediate in size. There are many drugs being sold in Canada exclusively by the brand-name firm where all relevant patents have expired. It is likely that some of these markets could support entry by a generic firm provided it did not face the threat of pseudo-generic competition.

A large market is one that can support more than one generic competitor. While pseudo-generics cannot deter entry entirely in such markets, they can delay it. As discussed earlier, the expenses of obtaining an NOC can be considerable, but they are not necessarily fixed. There is some degree of flexibility in choosing how fast to try to get a product to market, and it is more expensive to get a product to market earlier. For example, a generic firm may choose to challenge the validity of an outstanding patent, or to develop a non-infringing process, or it may simply wait for the patent to expire. The timing of entry is thus endogenous. This effect is

amplified by the tendency of the first independent generic entrant having to bear the largest legal bills, since the brand-name company wishes to slow down the advent of competition. Thus generics have to choose whether to try to accelerate the development of a product in order to be the first independent generic and to get into the market earlier or to spend less on legal bills and development costs but be somewhat later to market with a product. It is — in the absence of these costs — socially desirable for generic competition to start as early as possible.

That there is some choice in terms of entry timing is clear from an econometric study performed by Bae (1997) who shows that generic firms in the United States tend to take longer after patent expiration to enter small markets and markets with more therapeutic substitutes (i.e., where prices are lower). That is to say, generic firms choose the optimal timing of entry; speeding up entry is costly; and so they will tend to accelerate entry only for important markets where substantial profits are available.

How does the presence of pseudo-generics change the speed at which entry takes place? Since pseudo-generics typically are the first generics to enter any market, it appears at first that they make entry happen earlier. However, this does not properly account for market dynamics. The goal of the brand-name in licensing the pseudo-generic for entry before independent generic competitors is to give the pseudo-generic a chance to establish itself in the market before the other firms. This is costly to the brand-name since it results in lost sales. So the brand-name firm will not license the pseudo-generic far in advance of expected entry of independent generics, but will typically wait until a few months before generic entry is expected to occur.²⁵ Thus the date of pseudo-generic entry is dependent on the timing of entry of the independent generic. This means that in order to determine how the presence of pseudo-generics changes the arrival of competition, we need to understand how they change the date at which the first independent generic enters.

The effect of pseudo-generic competition on the optimal entry date of the other generics is obviously to delay it. This is so because of the choice that generics face: they will want to accelerate market entry only when there is a large prize attached to early entry. (This is the result found by Bae: generics enter large markets more quickly.) However, this large prize is effectively removed by the presence of pseudo-generics. As demonstrated in Hollis (2002), the first generic into a market can expect to obtain a healthy, enduring market share, on the order of 35 percent, while the second firm can expect to obtain around 15 percent. What this means is that for a given date of entry, the expected revenues for the first independent generic are less than half of what they would have been in the absence of the pseudo-generic. This leads, when accelerating entry is expensive, to an optimal later date of entry. Suppose that the brand-name firm licenses its pseudo-generic to begin marketing two months before the independent generic. If the increase in optimal entry time for the independent generic is greater than the two months, then the pseudo-generic causes a net delay in entry.

CONCLUSIONS

This paper has shown that the practice of brand-name drug firms using pseudo-generics has the potential to eliminate competition in medium-sized markets where the potential profits are not large enough to support more than one generic; and it probably results in delayed entry in other markets. Pseudo-generic drugs can be seen as a sort of fighting brand introduced *selectively* only in cases where the brand-name firm faces competition from independent generics. Because of the nature of the market, these pseudo-generics are never temporary, since the independent generics do not withdraw from the market once they have invested the fixed costs of entry. The brand-name firms have acquired a reputation for always introducing a pseudo-generic whenever an independent generic is entering, and

making it difficult for generics to acquire a significant market share.

There are several possible solutions to the problems created by pseudo-generics. One possible solution would be to appeal to the provisions concerning Abuse of Dominant Position under the *Competition Act*. This solution would require demonstration of the following. First, that “one or more persons substantially control a class or species of business.” This is undoubtedly true of the brand-name companies in every drug market in the period following patent expiry until the first independent generic enters. Second, that licensing of pseudo-generics “has had, is having or is likely to have the effect of preventing or lessening competition substantially in a market.” The use of pseudo-generic licensing does not fit neatly into any of the examples of anti-competitive acts listed in Section 78 of the *Competition Act*. However, it does reduce competition in the ways discussed above, because it either stops competitive entry or delays it. What is more, a very reasonable (partial) remedy is available: an order that did not allow brand-name firms to license pseudo-generics until competitive entry had occurred would *reduce* the scope for entry deterrence through pseudo-generics as well as increasing the incentive for generics to enter early. This solution would substantially weaken the impact of pseudo-generics on the profitability of the generic industry, and on the incentives for generic firms to get to market early. (Note that this solution could not result in a reduction in competition, since the pseudo-generic provides no meaningful competition for the brand-name firm that controls it.)

A less intrusive remedy would be to disallow any cross-licensing by the brand-name firm only after receipt of a Notice of Allegation which the brand-name firm decided to contest. Recall that when the patent-holder of a patent listed with Health Canada receives a NOA, it may challenge the application, leading to an automatic 24-month injunction blocking entry of the generic firm. This injunction can be

lifted only after the patent is found to be invalid or not infringed by the generic drug.²⁶ When the brand-name firm claims that the generic is infringing, and then takes advantage of the period of the injunction to enter into or actuate a cross-licensing agreement with a pseudo-generic, it may be seen to be using the regulatory regime to create an unreasonable advantage for itself. In other industries, entrants are not required to give notice of entry to the incumbent, then prevented from entering for years on the basis that their design may be infringing a patent right, while the incumbent establishes a new division which exactly targets the market segment sought by the entrant. This approach would not in any sense lessen the brand-name firm’s patent rights, since the firm could still sue for patent infringement: but it would not allow the firm to use the automatic injunction provided under the regulations as an opportunity to develop and establish a competitive response to the possibility of generic entry.

A more complete and still entirely desirable remedy would be to disallow cross-licensing by pharmaceutical companies unless the licensor stopped selling the product. Note that none of these solutions would stop brand-name companies competing effectively: brand-name drug companies could always be price-competitive by lowering their price, but they would not be able to set multiple price-points.

The latter two remedies could be effected through a legislative change, or through a decision by the provincial formularies, which have authority over which drugs they will include in their benefits list. From the perspective of the formularies collectively, not listing pseudo-generics would be desirable, since the benefits of pseudo-generics are rather small compared to the costs of lost competition. However, without concerted action, no provincial formulary has a private incentive to take action to solve the pseudo-generic problem. This casts the onus for solving the problem on Health Canada, since it is federal regulations that create the opportunity for

patent-holding firms to abuse the process of the Notice of Allegation to delay and then pre-empt generic entry.

NOTES

¹In Australia, pseudo-generics have about one-quarter of the generic market. They are also in a strong position in New Zealand, Germany, the UK, and Sweden. NERA (1998) lists ownership ties and other formal affiliations between generic and brand-name firms, but does not account for licensing.

²*Apotex v. Hoffman LaRoche, Glaxo Wellcome, Pharmacia & Upjohn, and Altimed*, Court of Appeal for Ontario, 14 December 2000, Docket C33172.

³Apotex submission to the Competition Bureau on Draft Intellectual Property Enforcement Guidelines, 24 August 1999.

⁴As it happens, pseudo-generic licensing is always a response to the entry of independent generics, so the case of a single pseudo-generic with no other generic competitors is, as far as I know, never seen.

⁵Their model results in some strange implications. For example, it implies that the brand-name firm should introduce a competing pseudo-generic as soon as it enters the market, an outcome which we never actually observe.

⁶It should be noted that the US market is very different from the Canadian one: pseudo-generics have essentially vanished from the US, but have taken on increasing market share in Canada.

⁷"Prescription drugs cost Canadians \$13-billion a year," *The Globe And Mail*, 4 May 2000, p. 2.

⁸Canadian Drug Manufacturers' Association (1997). This figure represents the difference between the brand price and the generic price of generic drugs (including pseudo-generics) currently available for sale. Since the elasticity of demand is very low, it might be thought that the deadweight loss caused by high drug prices is not necessarily large, but represents a simple transfer from consumers to firms. However, governments use tax revenues to fund a large proportion of drug costs, so there is a distortion caused by the taxation.

⁹Source: IMS HEALTH Canada, Compuscript and Canadian Drugstore and Hospital Audit.

¹⁰Source: Generic Pharmaceutical Industry Association.

¹¹*Lilly v. Novopharm*, 147 DLR (4th) at 680. The case documents further record that the pseudo-generic firm was to accept deliveries "on a consignment basis." The title to the product stayed with the brand-name firm until delivery to the customer. The brand-name firm even marketed the pseudo-generic product to price-sensitive, knowledgeable buyers such as hospitals.

¹²In conversations with pharmacists I found that some did not know that there was usually a generic identical to the brand-name product; and one individual in charge of drug purchasing for a major hospital in Canada did not know which firms marketed pseudo-generics. Ordinary consumers typically have no knowledge at all of pseudo-generics.

¹³"Submission Certification" from Steve Brouitt, Manager, Regulatory affairs and Quality Assurance, Altimed; dated 14 October 1997.

¹⁴The one company that has not entered into these agreements is Apotex. This may, perhaps, explain why other generic companies have been less vocal in their disagreements with the brand-name industry.

¹⁵IMS Health Canada, "Total Estimated Prescription Dollars Dispensed in Canadian Retail Pharmacy for Selected Molecules, by Year and Province." The specific drugs were various sizes and formulations of the following molecules: Acyclovir, Beclomethasone, Benzhydramine, Bromazepam, Buspirone, Carbidopa, Cefaclor, Clonazepam, Cyclobenzaprine, Cyproterone, Diltiazem, Dobutamine, Fluoxetine, Fluvoxamine, Indapamide, Ipratropium, Isoflurane, Levobunol, Levodopa, Loperamide, Medroxyprogesterone, Megestrol, Mexiletine, Moclobemide, Orciprenaline, Oxybutynin, Pentoxifylline, Sotalol, Tenoxicam, Terazosin, Valproic Acid, Zopiclone. The brands plus pseudo-generics obtained a market share of 59.1 percent of the entire sales of those molecules, which, it should be remembered, are off patent.

¹⁶Pseudo-generic drugs were identified by staff of one of the generic manufacturers. Since pseudo-generic arrangements are private to the contracting parties, it is

possible that they may have omitted some pseudo-generics. Most pseudo-generic arrangements are through Altimed, a company apparently set up for the sole purpose of selling pseudo-generics and Linson, a subsidiary of Bristol-Myers, which acts as the pseudo-generic arm of that company.

¹⁷*Food and Drug Regulations*, C.R.C., Vol. VIII, c.870, C.08.002.

¹⁸My understanding is that the typical costs of bio-equivalence studies and associated costs are on the order of \$1 million, though there is substantial variation according to the drug.

¹⁹Source: ss. 5-7 of the *Patented Medicines (Notice of Compliance) Regulations*, as amended; and *Regulations Amending the Patented Medicines (Notice of Compliance) Regulations* SOR/98-166.

²⁰Ss. 5-7 *Patented Medicines (Notice of Compliance) Regulations*, as amended; and *Regulations Amending the Patented Medicines (Notice of Compliance) Regulations* SOR/98-166.

²¹If the patentee registers additional patents after the Notice of Allegation is filed by the generic drug manufacturer, the generic company must file an additional Notice of Allegation with the patentee. The patentee can then apply for a new order prohibiting the court from issuing an NOC for the new generic product until 24 months have passed (or the application has been dismissed) from the date that the new patent has been registered. Therefore, the brand can further delay the release of generic products by registering additional patents and alleging that those patents have been infringed by the proposed generic product.

²²*Food and Drug Regulations*, c.870, C.08.002.1(a).

²³According to IMS Health Canada data.

²⁴For example, Technilab entered the market for Diltiazem as a pseudo-generic 24 months ahead of any independent generics but offered a price just 5 percent below that of the brand-name drug.

²⁵That this is the case is obvious from the pattern of NOCs granted to pseudo-generics and their actual entry time. Many pseudo-generics obtain an NOC, or permission to begin selling in a market, long before they actually

begin selling anything. The brand does not permit them to enter until the optimal time, where the trade-off is between the loss in profits to the brand and the gain from establishing the pseudo-generic as the pre-eminent generic competitor. Without consideration of the loss in profits to the brand-name firm, the pseudo-generic would always enter immediately upon obtaining the NOC.

²⁶This is in effect like an automatic preliminary injunction. Preliminary injunctions in other patent cases are an *extraordinary* remedy granted only after a hearing in which the judge is persuaded that the balance of convenience requires the injunction to be granted.

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