

PRICE REGULATION OF PATENTED DRUGS IN CANADA: TIME FOR A POLICY CHANGE?

Since 1987, the Patented Medicines Prices Review Board (PMPRB) regulates the price that drug manufacturers can charge for patented medicines in Canada (PMPRB, 2006). The mandate of the PMPRB as defined in the *Patent Act* is to protect consumers and to promote the Canadian health care system by ensuring that prices of patented medicines are “not excessive” (PMPRB, 2006). The PMPRB has no influence over the prices of non-patented drugs, which are usually set through bargaining between pharmaceutical companies and major purchasers, such as provincially administrated drug-benefit plans (Sibbald, 2003). In contrast, most Western European countries impose price controls both in the market for patented and non-patented drugs, whilst the United States does not regulate drug prices at all. The Canadian price regulation scheme has been criticised for its arbitrary pricing rules, accused of stifling research and development, and blamed for distortions in the market for non-patented drugs. It has also been argued that the PMPRB is unnecessary on the grounds that monopsony power of the provincial health plans effectively curbs patent-holders’ price-setting freedom, and that a bargaining process in an unregulated market would yield the same or a better outcome (Blakney, 2006). The aim of this paper is to outline the rationale for price regulation of patented drugs, address recent criticisms and evaluate whether the current regulatory regime should be modified or abolished. It will be argued that regulation does indeed yield a lower price than what would be the bargaining outcome in an unregulated market, and that price-regulation of patented drugs is probably not the major reason for distortion in the market for non-patented drugs. It will be proposed that whilst there is strong justification for price-

regulation of patented drugs on *theoretical* grounds, the special features of the market for patented drugs makes determination of the optimal regulated price extremely cumbersome. It will be suggested that deregulation might be justified on the grounds of the inability of the regulator to set the appropriate price (with adverse effects on R&D as the result), but that deregulation — given the current market situation — is unlikely to benefit Canadians on the whole.

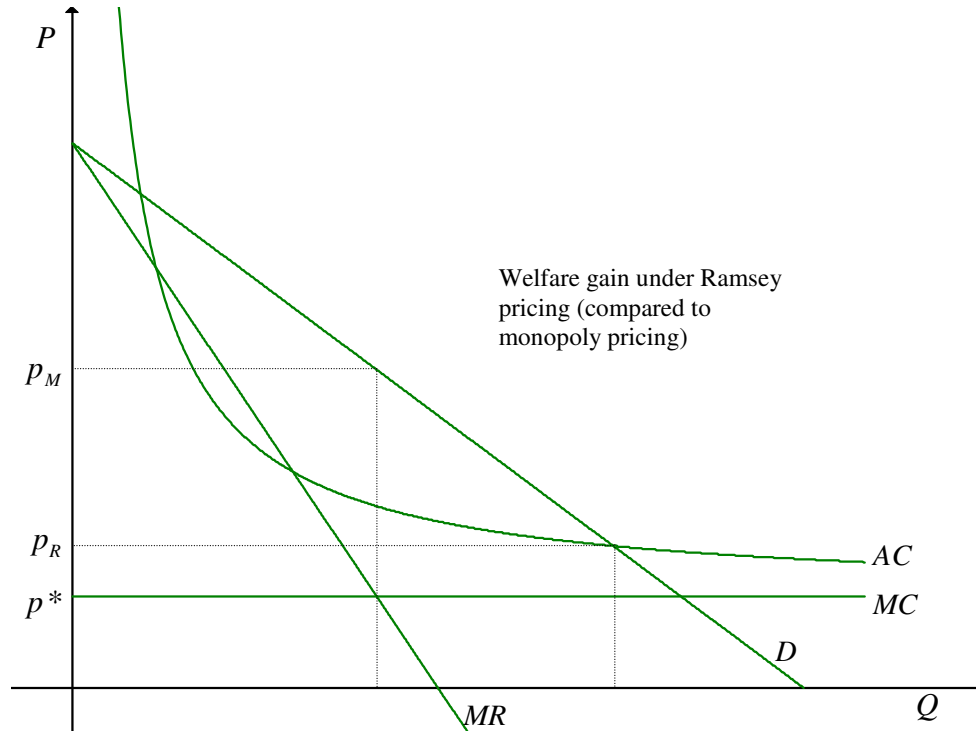
Patents provide pharmaceutical manufacturers with a time period during which they can raise supernormal profits to recover sunk costs on research and development. In Figure 1, the production of a patented drug is modelled as having considerable fixed costs (sunk expenditures on research and development) and constant marginal cost. Under first-best (marginal cost) pricing (p^*), the pharmaceutical company cannot recover sunk investments, and would — under the assumption of profit maximisation — not invest in research and development, which would be deemed undesirable from a social point of view.¹ Prior to 1987, Canada did not recognise patents on medicines, and allowed generic drug companies to import or manufacture patented medicines under a scheme of “compulsory licensing” (Anis and Wen, 1998, p.22). This policy was considered a successful way of containing public health care spending, and rationalised on the grounds that actions undertaken by Canada — comprising merely 2% of the global market — would be unlikely to have any substantial effect on the global level of research and development (Anis and Wen, 1998, p.36). Compulsory licensing was only abandoned

¹ The high level of sunk expenditures required for drug development, the relatively low marginal cost of producing a drug once it is developed, and the often limited demanded (because of specialised usage) could effectively motivate classifying the development of each particular drug as a natural monopoly, i.e., potentially more efficiently pursued in a single firm than in several. However, such a definition is quite controversial (e.g., Duffy, 2005).

after pressure from the United States during the negotiations of the Canada-United States Free Trade Agreement (FTA, later NAFTA). Today, the legislated patent term in Canada is twenty years, but because of characteristics distinctive to the pharmaceutical industry (such as time required for final testing and regulatory approval), the effective time during which a pharmaceutical company can act as a monopolist in the market is on average 10-12 years (Lexchin, 2003, p.14). Anis and Wen (1998) characterise patent-holding pharmaceutical firms as “price-discriminating international monopolies” (p.21), which — in the absence of regulation — set prices to maximise profits from each individual market (so that marginal revenue equals marginal cost), i.e., at p_M in Figure 1. Anis et al. (2003) argue that the demand-side of the Canadian market for patented drugs is peculiar because “the demanders (physicians) are not consumers, and furthermore often the demanders and consumers are not the purchasers” (p.136). Thus, since many patented drugs do not have any (good) substitutes, and since demanders are unlikely to change their behaviour in response to price changes, the demand for patented drugs in the Canadian market is arguably price inelastic. The more price inelastic the demand, the higher the profit-maximising price of the monopolist, and the greater the distortions caused by tax collections in other markets required to fund public drug plans (in 1995, 35.4% of Canadian drug expenditures was from public funds (CIHI, 2006, p.15)). It is arguable that this scenario justifies price regulation, which potentially could bring down prices to the second-best (Ramsey) level (p_R), where pharmaceutical companies can recover their fixed costs with a reasonable return to investment (so that incentives for continued research and development are sustained), but without draining public funds or making excessive profits from the ill. Thus, optimal price regulation in the market for patented

drugs might not only improve allocative efficiency in the market for pharmaceuticals (reduce deadweight loss as indicated in Figure 1), but could also alleviate distortions in other markets by reducing the need for tax collection.

Figure 1: Monopoly and Ramsey Pricing of a drug with high fixed cost and constant marginal cost



The current regulatory regime in Canada makes no attempt to determine Ramsey prices from first principles (i.e., by evaluating relevant cost and demand functions). Instead, regulators use a set of ‘rules of thumb’, hoping that these will result in a more desirable outcome than that of the unregulated market. Every patented drug is classified into one of three categories, in each of which different pricing rules apply. Category 1 drugs are “line extensions of existing medicines” (i.e., the same molecule), and the proposed price is deemed excessive if it does “bear a reasonable relationship” with that of other dosages

marketed by the patentee (Anis and Wen, 1998, p.23). Category 2 drugs are designated “breakthrough” or offering “substantial improvement” on older therapies, and the price of a Category 2 drug “is presumed excessive if it exceeds (i) the prices of all the medicines in the same therapeutic class and (ii) the median of the prices in seven countries²” (Anis and Wen, 1998, p.23). Category 3 drugs are new substances which offer “moderate, little or no therapeutic improvement”, for which prices are considered excessive if they exceed all other medicines in the same therapeutic class (Anis and Wen, 1997, p.21). Once a patented drug has been introduced to the market, the supplier cannot increase its price at a higher rate than the change in consumer price index. Cross-country price comparisons between the Canada and United States (lacking price regulation) usually show that Canadians — unsurprisingly — enjoy lower prices than Americans for most patented drugs.³ For instance, Graham (2000) quotes a PMPRB report which found that prices of patented drugs were on average 60% higher in the US than in Canada, whilst the corresponding difference in income was only 46% (p.7). Hence, whilst it seems fair to argue that price regulation has been successful in curbing public expenditure, this does not imply that the regulatory process yields Ramsey pricing, or that it causes an improvement in overall efficiency.

Blakney (2006) argues that because patent-holding pharmaceutical companies do not face price-taking consumers, but a highly monopsonistic market dominated by the provincial drug plans, they do not have the power to act as price-setting monopolists. He contends

² France, Germany, Italy, Sweden, Switzerland, the UK and the USA

³ Note, however, that there is substantial disagreement about how to conduct cross-country price comparisons of patented drugs, since the exact form of the product (dosage, packaging, etc.) as well as common practice concerned with which drug to prescribe for which indication may differ between different countries.

that prices in an unregulated market would be determined through a bargaining process between the drug company and the provincial drug plans, and could potentially be more efficient than prices set by the PMPRB (p.5). In practice, provinces compile lists on what drug will be covered at what price (based on their estimated cost-effectiveness), which frequently come to dictate the coverage offered by private insurers as well. Since provinces can trade medicines between each other, it could be argued that patent-holding companies only need to bargain with a single buyer for the entire Canadian market. However, as Enthoven and Fong (2006) point out, having large *market* power by virtue of being a large (or the only) purchaser does not necessarily imply large *bargaining* power in the market for patented medicines. Since there are usually no (or only poor) substitutes for the product offered by the patent-holding company, “a party’s bargaining power is determined simply by the ability to say no — to walk away from the table without an agreement”. Whilst Blakney (2006) seems to assume that the provincial health administration will ‘walk away’ when the offered price exceeds the benefit calculated by its pharmacoeconomic experts, this need not necessarily be the case. In reality, interest groups often create considerable pressure for including particular drugs on publicly funded drug plans.⁴ If patent-holders anticipate that there will be external pressure to cover a particular drug, they will be unwilling to lower prices during negotiation (knowing that they can always get the higher price at the end).⁵ In other words, political pressure could prevent provincial drug plans from posing a credible ‘walk-away’ threat when bargaining with pharmaceutical companies. Hence, it is arguable that a patent-

⁴ For instance, breast cancer treatment using Herceptin (Trastuzumab) in the UK was initially deemed cost inefficient and not funded by the National Health Service. However, after substantial political pressure, this decision was revoked (e.g., Enthoven and Fong, 2006).

⁵ The precise bargaining power would thus depend on the nature of the particular drug, and in particular, the level of organisation of the potential patient group.

holder can exert substantial monopoly power even when bargaining with a monopsonistic province, and that it will enjoy more price setting freedom the stronger the organised interests of the potential patient group. Under strict price regulation (i.e., where the patent holder knows that it cannot influence the price set by the regulator), on the other hand, the drug company will take the regulated price as given and supply each market as long as the regulated price exceeds variable costs, assuming that fixed costs can be recovered in other markets (i.e., as long as the regulated price $p > p^*$ in Figure 1).

It has been demonstrated that Ramsey pricing would be more efficient than unrestrained (or insufficiently restrained) monopoly pricing in the market for patented drugs, since it could reduce the deadweight loss associated with monopoly power. In addition, Ramsey pricing would be preferable to first-best pricing, since it would allow pharmaceutical companies to recover sunk costs, and provide sufficient incentives for research and development. However, it is highly unlikely that the current regulatory regime — under which prices in the Canadian are determined by a set of rules — actually yields Ramsey prices. As argued above, a patent-holding drug company taking the regulated price as given will enter a particular market if it can price slightly higher than variable cost, even without the prospects of recovering fixed costs. Thus, a single regulated economy could enjoy the desirable level of supply of a patented drug even if the regulated price is set *below* the average cost (note, however, that this is a beggar-thy-neighbour policy, which would be unsustainable if adopted by all economies). Consequently, there is a theoretical possibility that consumers in regulated markets (e.g., Canada, Western Europe) are subsidised by (or free-ride on) consumers in unregulated markets (e.g., the US, Japan).

Whether this is indeed the case — i.e., whether the regulated price is set below average cost — is a widely debated issue. Light and Lexchin (2005) present figures showing that pharmaceutical companies in Europe and Canada are no less innovative than their American counterparts, arguing that regulated prices in these countries are sufficient to cover R&D expenditures (i.e., they are not too low), and that price regulation has not had a negative impact on innovation. However, under the assumption that pharmaceutical companies act in the global rather than in national markets, this comparison is flawed: the level of investment (R&D) need not reflect the pricing regime in the location where laboratories or headquarters are located (presumably determined by the relative cost of hiring skilled staff), since fixed costs may be recovered from other markets (e.g., the American). Arguably, the peculiar current structure of the international market for patented drugs makes it nearly impossible to determine how regulated prices relate to Ramsey prices.⁶

Price regulation of patented drugs in Canada has also been accused for distorting the market for generic drugs (e.g., Skinner, 2004). If regulation of one market causes considerable distortions in related markets, it could be argued that these markets should be regulated as well, or that the initially regulated market should be deregulated. When a drug patent expires, generic drug companies usually enter the market and start supplying the previously patented drug at a lower price. Since generic drug companies do not conduct research and development, their fixed costs (which depend on production alone)

⁶ Note that if the currently unregulated markets were to introduce price controls equivalent to those imposed in regulated markets, it would become obvious whether the regulated prices actually correspond to the average cost (if they do not, R&D would be unprofitable and cease). Nonetheless, such an experiment would indeed be very costly if this turned out to be the case.

are considerably lower than those of pharmaceutical companies engaged in research. Thus, as long as demand is sufficiently large, the market for generic drugs appears to be “inherently competitive” (Anis et al., 2003, p.138). In 2000, generic drugs accounted for about 11% of pharmaceutical sales in Canada (Sibbald, 2003); the three largest generic suppliers accounted for 82% of total sales (Skinner, 2004, p.13), indicating considerable market concentration. Studies have found that prices of generic drugs in Canada are not only higher than in countries imposing price controls (most Western European countries) (Elgie, 2002, p.10), but on average, also exceed those in the US (Graham and Robson, 2000, pp.11-13). Although some of the discrepancy between Canadian and US conditions must be attributed to differences in market size, it has also been suggested that price regulation of patented drugs has put an upwards pressure on prices of generic drugs. For instance, Skinner (2004) contends that the current pricing rules for patented drugs—which frequently take the form of a price ceiling based on the prices of existing drugs—create disincentives for pharmaceutical companies to reduce the price of brand-name drugs once patents expire, as they want to “avoid undermining the maximum allowable price for new entry drugs” (p.17). This increases the price at which the first generic company can competitively enter the market, allowing the first entrant to raise supernormal profits. He proposes that this gives established companies a “first mover advantage”: as long as the first entrant can raise some excessive profits, it will have ‘deeper pockets’ than potential competitors and be able to pose a credible threat of undercutting prices to undermine additional entrants (p.15). The high level of market concentration in the generic drug market would lend support to this hypothesis. Anis et al. (2003) attribute the lack of competition in the market for generic drugs to the 70/90 and

Best Available Price (BAP) regulations instituted in 1993 by the Ontario government, rather than to the price regulation of patented drugs. They argue that “[b]ecause Ontario is the largest market in Canada, Ontario generic prices were likely to be applicable to the rest of the country as well” (p.140). Essentially, the 70/90 regulations condition the price that can be charged by generic drug companies (assuming that they want to enter the list of coverage by the provincial drug plan): the first entrant cannot charge more than 70% of the price of the branded drug, and the second entrant cannot charge more than 90% of the price offered by the first generic entrant (p.136). The BAP regulation states that Ontario will only buy at the lowest (best) available price, and is supposed to induce suppliers of multiple-source drugs to compete by price-bidding (p.136). However, once the BAP has been established, the lowest bidder does not get the exclusive right to serve the market; instead, all suppliers are allowed to supply at the BAP (p.139). This means that there is *de facto* little incentive for generic firms to bid down prices at all (since competition on price can only be a profit-maximising strategy if it has the potential to increase the firm’s market share). On the contrary, there seems to be strong incentives for generic suppliers to collude (even if implicitly) to share markets at a higher price, or to serve separate markets. Anis et al. (2003) compare the price dispersion for multiple-source generics, noting that the price spread in prices offered by generic firms was more compressed around the target price levels (90/70) for patents expiring 1993-1998 than 1987-1993 (before instituting the 90/70 regulations) (p.139). Hence, the market for generic drugs seems to be uncompetitive for a range of reasons unrelated to the price of patented drugs, e.g., the small number of competing generic suppliers and Ontario provincial regulations. Arguably, these problems must be addressed before it can be firmly established that

distortion caused by regulation in the market for patented drugs is so substantial that it justifies deregulation.

To set the Ramsey price of a patented drug, the regulator would in theory not only need to determine the already incurred costs of the pharmaceutical company, but also make a decision about what rate of return to capital is sufficient to induce future innovations. Since only a small fraction of substances investigated by research teams end up being marketable, products that actually reach the market need not only cover the costs of their own development and clinical testing, but also the costs of research projects that turned out not to be marketable. Consequently, attributing fixed costs in this uncertain environment would — if even possible — pose a major challenge to the regulator. It also seems very difficult for a regulator with limited knowledge about the internal structure of private corporations to decide on what level of return to capital that would be required to induce innovative research. Because of the high level of risk-taking involved in medicinal research, it is arguable that for drug development to be efficient in a free market environment, pharmaceutical companies must be allowed to maintain ‘deep pockets’ by raising substantial supernormal profits. Following, Lexchin (2003) suggests that it might even be preferable to disregard patents altogether and finance pharmaceutical R&D through public funds (p.23): if fixed costs are covered by a subsidy, then first-best (marginal cost) pricing can be applied to yield full allocative efficiency in the market. However, as argued by Enthoven and Fong (2006), the government’s ability to allocate such funds under imperfect information to provide the right incentives for appropriately

innovative research is debatable. In addition, such a policy would be likely to create substantial tension in the trading relationship with the United States.

This paper has argued that patent-holding pharmaceutical companies would essentially be free to set monopoly prices in the Canadian market the absence of price regulation. Since the demand for patented drugs is inelastic in demand, monopoly pricing would not necessarily yield large output distortions, but high prices, deadweight loss and be a drain on public finances. It has been suggested that the lack of competition in the market for generic drugs cannot convincingly be attributed to regulation in the market for patented drugs, and does not in itself motivate deregulation. It has been proposed that determination of optimal Ramsey prices in the market for patented medicines is extremely difficult, and that the current structure of the international market for patented drugs allows for sustainable pricing *below* the efficient level (allowing for potential international free-riding). However, as long as there is no threat of external sanctions for imposing price regulation, and the global level of research and development is maintained, Canadians would have little to gain from deregulating prices of patented drugs.⁷

⁷ Whether it is *ethically* justifiable that affluent countries (such as Canada) impose price controls on patented drugs, whilst not allowing developing economies to consume patented medicines at marginal cost, is another discussion.

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