



# Compulsory Licensing and Canadian Pharmaceutical Policy

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## Introduction

Seldom have Canadians seen such acrimonious debate as in the recent controversy over compulsory licensing of pharmaceuticals, which resulted in the passage of Bill C-22 in the fall of 1987. Canadian policy towards the drug industry,<sup>1</sup> an industry dominated by foreign multinationals (MNEs), has been markedly different from policies elsewhere. Since 1969, under section 41(4) of the Patent Act, Canada has allowed domestic firms to apply for licenses to manufacture and/or import patented drugs, paying 4 percent of sales to the patent holders in license fees. The policy has been strongly opposed by the MNEs and the U.S. government on the grounds that Canada is not paying its fair share of development costs for drugs.<sup>2</sup> In the wake of several studies and MNE lobbying, the federal government has recently passed Bill C-22, which weakens the licensing provisions in return for industry promises of more jobs and investment.

This paper uses the OLI-internalization model of foreign direct investment (FDI) to analyze the pharmaceutical industry and the compulsory licensing debate.<sup>3</sup> There is a large literature on compulsory licensing; however, none of it squarely places the debate within the context of the internalization model.<sup>4</sup> The purpose of the paper is to fill this gap.

We first describe the industry and review the debate. The paper then shows how the drug industry fits into internalization theory in terms of firm and country-specific advantages, and motives for internalization. We analyze the effects of patents and transfer pricing on this industry. The model is then used to assess the impacts of section 41(4) and its replacement, Bill C-22. We also discuss the possible impacts of Canada-U.S. bilateral free trade on this industry.

We conclude that the domestic economic effects of compulsory licensing were beneficial, but the international political effects were severe. The new legislation reduces both the economic gains and political costs to Canada. However, under Canada-U.S. free trade, Bill C-22 opens up the possibility for larger gains, along with the potential for development of a Canadian pharmaceutical multinational.

# The Pharmaceutical Industry as an International Oligopoly

## The Global Drug Industry

The pharmaceutical industry is an example, par excellence, of a knowledge-intensive, vertically-integrated international oligopoly. There are four stages in the industry: the R&D stage (which includes basic and applied research and clinical testing), the production of fine chemicals, preparation and packaging into dosage form, and marketing and sales.<sup>5</sup> The research stage is usually carried out near the parent's headquarters, where products are developed for sale on the world market. Clinical testing is usually done in the final sales market, unless the country accepts clinical results from elsewhere. The production of fine chemicals is characterized by substantial economies of scale such that one or two plants can satisfy the global demand for a particular active ingredient. It is the most capital-intensive stage, located usually in the home country and in one or two others, depending on costs and available materials. The preparation (blending the fine chemicals with other ingredients and production in dosage form) and packaging stage is footloose since it has few economies of scale. Preparation/packaging is usually done in the least-cost location or in the domestic market, depending on the content policy of the local government. Marketing and sales are domestic functions which are located near the final consumers. Thus, of the four stages, all but the last can be imported. In most host countries, at least the research and chemical stages are imported.

The major drug MNEs are headquartered in six countries: the United States, West Germany, Britain, France, Switzerland and Japan. In 1982, over 50 percent of world sales were made by 25 firms, of which half were U.S. MNEs. The industry could therefore be classified globally as a loose oligopoly. However, since most drugs are used to treat specific illnesses, competition is better measured by the number of firms producing within a prescription class. This number is small, with one firm often controlling the majority of sales. Thus effective concentration is much higher than industry concentration measures would imply.

Competition is typically oligopolistic (i.e., non-price), usually through R&D expenditures and brand-name advertising. Advertising expenditures concentrate on physicians because a doctor's prescription is necessary in order to purchase drugs in most developed countries. Thus demand is based on the doctor's preferences and knowledge, not on the consumer's. Because the public

demand for health care is price inelastic, so is the demand for drugs. This encourages oligopolistic behaviour such as market segmentation and price discrimination.

Government policies towards the drug industry vary substantially among countries. Home countries generally offer 17 to 20 years of patent protection. Patents can be on products (the drug itself is patented) and/or on processes (only the process is patented). Home countries actively subsidize R&D expenditures at home and encourage national treatment for their subsidiaries abroad. The United States, in particular, has lobbied for increased patent protection in host countries, e.g., threatening to withdraw preferential tariffs from the NICs unless they alter patent laws, linking elimination of Canada's compulsory licensing with the bilateral Canada-U.S. Free Trade Agreement, and including patent protection in its list of services in the GATT Uruguay Round.<sup>6</sup>

Host countries, on the other hand, generally treat foreign drug subsidiaries less generously than do home countries.<sup>7</sup> Patent protection varies from non-existent, particularly in LDCs, to 20 years in other countries. Most countries require clinical testing prior to granting patents. They may force joint ventures on the drug MNEs as a prerequisite to entry in the domestic market (e.g., Japan). The state may organize a central purchasing function (e.g., Britain and Norway), or simply control drug prices (e.g., France and Belgium). Canada's compulsory licensing policy is, however, unique.

## The Pharmaceutical Industry in Canada

The Canadian drug industry has the same general characteristics as its international counterpart. However, there are three major government policies—compulsory licensing, public insurance coverage, and provincial equivalency and/or price regulations—which have had marked effects on the industry.<sup>8</sup>

Canada gives a 17-year patent life on drug products by process. Compulsory licensing legislation has existed since 1923; however, the small Canadian market, coupled with the restriction that licensees must manufacture the drug (this rule encompassed the fine chemical stage), meant that licenses were unprofitable and few existed. Thus, each prescription class consisted of one single-source drug, with effective competition restricted to close substitutes. Firms competed via advertising and promotional expenditures, not by price. As a result, the 1965 Hall Commission concluded that Canadian drug prices in the 1960s were among the world's highest.

In response, the Patent Act was amended in 1969 to allow

licensees to import and/or manufacture the patented drug upon demonstration of equivalency and payment of a 4 percent royalty to the patentee. Effectively, section 41(4) reduced patent life to six to seven years, since a generic copy needed about five years to meet clinical test requirements and two years to gear up production. As a result, in some prescription classes multiple sources now exist for drugs. This has created competition between brand-name and generic drugs (and lower manufacturer's prices).

The second difference is that a high percent of the market is covered by government and private insurance plans. The Canadian market is split into 80 percent retail (of which 43 percent is paid by provincial governments, 47 percent by private plans, and 10 percent by uncovered individuals) and 20 percent hospitals (covered by government). Thus only about 8 percent of consumers pay the full cost of their drugs. This tends to make the demand for drugs in Canada even more inelastic due to the moral hazard problem associated with insurance.

Lastly, all provincial governments, except P.E.I., have product selection laws. Each province publishes a formulary, available to wholesale buyers, that lists equivalent drugs and gives the maximum price payable by the government. The laws are designed to encourage substitution of cheaper generic drugs for brand-name ones; however, by writing "no substitution" on the prescription, the doctor can still ensure that the pharmacist supplies the brand-name drug.<sup>9</sup> There is some controversy as to how successful the formularies have been at reducing prices.<sup>10</sup>

As a result of these policies, there are now in Canada about 130 firms in the drug industry: nearly 100 foreign-owned subsidiaries (FOSCs), 30 generic, mostly Canadian, firms, and a few genetic/organic manufacturers (e.g., Connaught Laboratories).<sup>11</sup> Canadian sales represent 2 percent (\$1.3 billion) of the global drug market. The industry is almost wholly located around Toronto and Montreal, with only 3 percent of employees working outside of Ontario and Quebec. Minimal R&D work is done here; only 3-5 percent of employees are involved in R&D while 33-34 percent are in sales. R&D expenditures are approximately distributed as 15 percent basic and 25 percent applied research, and 60 percent clinical testing. Most fine chemicals are imported; and the preparation/packaging stage is evenly distributed between imports and domestic production. Almost half of all imports are from the United States, on which the average duty paid was about 6 percent. The FOSCs are mainly U.S.-owned and buy substantial intrafirm imports of chemicals and finished drugs from their affiliates. There is strong evidence of over-invoicing of these imports from low-tax countries.<sup>12</sup>

The generic segment of the market is dominated by four firms, Novopharm and Apotex (both Canadian-owned and located in Toronto) and Horner and ICN (U.S.-owned and located in Montreal). These four firms represent about 85 percent of all generic drug sales and about 8.5 percent of the total market. They also hold about 47 percent of all licenses and 79 percent of all working licenses.

### The Compulsory Licensing Debate

The effects of section 41(4) have been studied by several Canadian economists and government bodies, with sharply conflicting results. Gordon and Fowler concluded that compulsory licensing had caused FOSCs to shift production and R&D work outside of Canada and to over-invoice imports, thereby shifting out profits too.<sup>13</sup> Although a developing generic industry had succeeded in reducing the prices of a few drugs, Gordon and Fowler noted that the vast majority of drugs were not licensed and that those prices had risen, leaving overall prices basically unchanged. Eastman found quite different results. The report argued that licensing had few harmful effects on the drug FOSCs; had created an active, mainly Canadian, generic component; and lowered drug costs by about \$211 million annually.<sup>14</sup> There have also been several papers arguing for and against compulsory licensing.<sup>15</sup>

The industry itself has been actively involved in the debate. The PMAC (Pharmaceutical Manufacturers Association of Canada), an alliance of 64 MNEs, has strenuously lobbied for a return to the pre-1969 policy. It views compulsory licensing as a dangerous precedent that other countries might follow. The PMAC has argued that generic drugs are less safe than brand names and that R&D in the industry has significantly declined. The alliance has also blamed compulsory licensing for the closure of the Ayerst and Hoffman-LaRoche plants in 1982-83. A second group, the CDMA (Canadian Drug Manufacturers' Association), a much smaller group of 17 Canadian generic companies, has lobbied for the retention of compulsory licensing and disputes the PMAC findings.

## An Internalization Perspective on the Canadian Pharmaceutical Industry

In this section, we use the internalization paradigm to isolate the key characteristics of the pharmaceutical industry. In the model, foreign direct investment depends on three factors: firm specific advantages (FSAs, the O variable), country specific or locational advantages (CSAs, the L variable), and internalization advantages

(the I variable). The model is described in Table 15.1 which is loosely based on Dunning<sup>16</sup> and Rugman, Lecraw and Booth.<sup>17</sup>

## Ownership Advantages

FSAs are unique, intangible, wholly-owned advantages that are readily transferable within the affiliates of a multinational. FSAs allow the MNE to compete in foreign markets where domestic firms have the advantage of better knowledge of local conditions, lower communication costs, and no cultural or language impediments. Examples of FSAs are technological advantages, economies of scale, product differentiation, access to cheaper capital, international diversification of risk, and access to raw materials (see Table 15.1).

**Table 15.1**

The OLI-Internalization Model: Motives for Foreign Direct Investment

### *Ownership/Firm-specific Advantages*

Knowledge — new products, processes, marketing/management skills

Oligopolistic market structure and behaviour — patents, product differentiation, economies of scale

Excess managerial and/or entrepreneurial capacity

Financial and monetary advantages — access to capital, international diversification

Access to raw materials

### *Internalization Advantages*

Exogenous market imperfections

Natural market imperfections

The pricing of knowledge — impactedness, opportunism, uncertainty, public goods characteristic of knowledge

Transactions costs — domestic and international market-making costs

Government-imposed market imperfections — taxes, tariffs, NTBs

Endogenous market imperfections — monopoly pricing, market segmentation, erection of barriers to entry, truncation of subsidiaries, supranationality, exertion of bargaining power over small countries

### *Location/Country-specific Advantages*

Economic advantages — factor endowments, production costs, size of market, income, transportation and communication costs

Non-economic advantages — political stability, psychic distance, social factors

Government factors — trade barriers, government regulations, attitude to MNEs

The most important FSA possessed by the drug MNEs is technological knowledge. The industry is among the most R&D-intensive of all manufacturing industries. It has been estimated that a new drug takes upwards of \$100 million and 10 years to develop. Knowledge in this industry includes the discovery of new drugs and production processes, superior marketing and distribution networks, and expertise in product differentiation via advertising. Other FSAs include brand names, patents, and the ability to price-discriminate between markets. Patents are of particular importance, as is access to raw materials (e.g., chemicals). Firm-level economies of scale (e.g., in R&D and other management functions) lead to centralization at the head office; little R&D is done outside the parent firm. This is typical of most FOSCs.<sup>18</sup>

It is therefore logical to ask what country characteristics are likely to generate FSAs and thus lead to the development of home MNEs. In the drug industry, home countries tend to be large and wealthy, with well-developed chemical industries and highly-skilled labour forces. Their governments usually offer full patent protection, tax incentives, and subsidies to R&D. Canada's potential as a home country for drug MNEs is mixed. It is wealthy and has a skilled labour force; however, it is handicapped by a small market. Weak patent laws (due to compulsory licensing plus patents by process) and limited R&D effort also discourage domestic MNEs. A 1977 OECD study ranked its members according to the capacity for indigenous development of their drug industry.<sup>19</sup> The study ranked Canada as a low-capacity country due to its small market, small chemical industry, and poor innovation record.

### Internalization Advantages

The existence of a special know-how, or core skill, is an asset that can generate economic rents for the firm. These rents can be earned by licensing the FSA to another firm, exporting products using this FSA as an input, or setting up subsidiaries abroad. Market imperfections can be reduced if the MNE chooses the internal market over exporting and/or licensing. Imperfections are of two types: exogenous and endogenous (see Table 15.1). Exogenous imperfections are caused by failures in, or the lack of, private markets. These can arise naturally or be induced by government policies. There are two kinds of natural imperfections: failure in the market for knowledge, and the existence of transaction costs. Government-induced market imperfections are created by trade barriers. Endogenous market imperfections are due to MNE oligopolistic behaviour and market structure.



**Natural Market Imperfections: The Pricing of Knowledge** The market for knowledge fails because of three inherent characteristics: 1) transactions in knowledge suffer from impactedness and opportunism; 2) uncertainty plagues this market; and, most importantly, 3) knowledge is an intermediate good with strong elements of a public good. Because technology is intangible and firm-specific, it is difficult for either the owner or the potential buyer to assess its value. The seller must explain to the buyer how it can be used without telling enough that the buyer could replicate the knowledge, hence, knowledge is impacted. Opportunistic behaviour may result, as each party attempts to shift the terms in his or her favour. Impactedness and opportunism are worsened by uncertainty, leading the buyer to underestimate the benefits. If both parties are risk-averse, the private market underproduces knowledge.

Most markets in intangibles are faced with these problems. However, it is the publicness quality of knowledge that poses a rarer and more serious problem. Knowledge, once created, is easily disseminated and jointly consumed; thus the marginal cost of provision to an additional consumer is low. Once produced, individuals cannot be excluded from consumption via the price mechanism since no one has property rights to this knowledge. Thus consumers "free ride", and cannot be forced to pay. Publicness, the combination of jointness and non-excludability, implies that firms cannot profitably produce knowledge, and so the private market fails. This phenomenon is illustrated in Figure 15.1.

The  $D_A$  curve in Figure 15.1 represents the demand by consumer A (the highest demander), and  $D$  represents the total demand for this knowledge.  $MC$  is the marginal cost of production, assumed constant for simplicity. The marginal cost of provision to an additional consumer is zero. The socially-optimal level of investment occurs where social benefit equals social cost, at  $Q_s$ , where  $D$  intersects  $MC$ . The social value of knowledge is measured by areas 1 + 2 + 3 (the excess of consumer willingness to pay over production costs). However, the private market only produces  $Q_A$  where  $D_A$  intersects  $MC$ , since once produced by A, other consumers free ride. In Figure 15.1, this quantity is zero, since  $D_A$  lies below  $MC$ . Thus the private market fails to invest enough in knowledge.

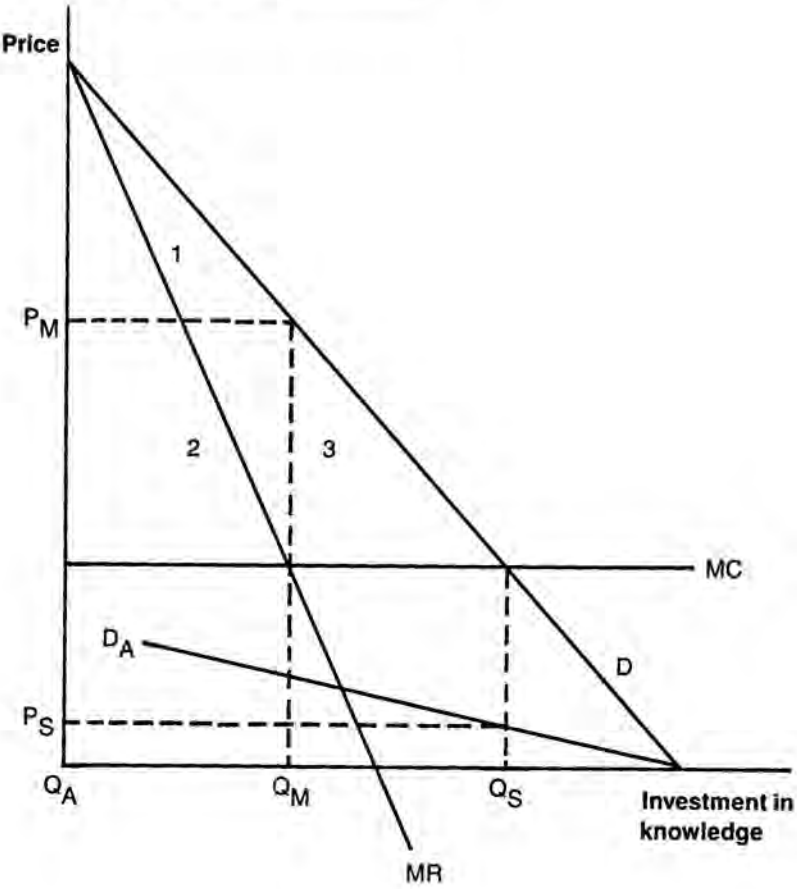
One government remedy for this market failure is a production subsidy (e.g., tax incentive, R&D subsidy) that would cause the producer price to fall to  $P_s$  and raise output to  $Q_s$ . A second policy is government production (e.g., federal agricultural research) at  $Q_s$ . The most common policy, however, is patenting.

A patent confers a property right on the patentee that eliminates free riding, allowing its holder to earn monopoly rents in exchange

for increased investment in knowledge. In Figure 15.1, a patent allows this firm to set marginal revenue (MR) equal to marginal cost, and raise price above MC. The new private equilibrium occurs where  $MR = MC$ , with a quantity of  $Q_M$  and price of  $P_M$ . The social value created at  $Q_M$  is area 1 + 2 (i.e., consumer surplus plus monopoly rent), which is smaller than at  $Q_S$  due to the lower output level.

The problems associated with knowledge, as outlined above, characterize the R&D-intensive pharmaceutical industry. Appropriation of rents is essential, owing to the uncertainty involved in

**Figure 15.1**  
The Pricing of Technological Knowledge



R&D projects. Few investments produce saleable products that pass health regulations, are patentable, and earn large profits. Thus these products must generate sufficient returns to recoup earlier investments and fund ongoing research projects. Hence, average cost is higher than marginal cost and estimates of monopoly rents are likely to be deceptive.

Secrecy, lead time, and investments in marketing are alternatives to patents as methods of appropriating the rents from knowledge. Secrecy is particularly important for drug processes, due to difficulties in obtaining patents for many processes, and fear that competitors will "invent around" the patent. Secrecy is much harder to maintain for products. Because confidentiality is better protected through wholly-owned subsidiaries, it is not surprising that internalization is the preferred investment form. In Canada, since our patent laws are for products by process only, investments in products may be discouraged. Also, patents for a process, as compared with a new product, offer a smaller gain in social welfare. The gain in the process case is restricted to the decrease in costs due to the new process, whereas a new product (the case illustrated by Figure 15.1) creates a new market, generating consumer and producer gains.<sup>20</sup>

**Natural Market Imperfections: The Existence of Transactions Costs** Transactions costs are incurred in overcoming market imperfections or obstacles to trade. The higher the costs, the smaller the volume of trade. All markets are faced with the costs of search, communication, specification of details, negotiation, monitoring of quality, transport, payment of taxes, and enforcement of contracts. Casson stresses that all firms can reduce these costs by making an internal market and then improving the quality of service by backwards integration.<sup>21</sup> Such vertically-integrated firms are most likely to be found in the high-quality, high-priced end of the market. However, he argues that only certain types of transactions are likely to lead to investment across borders by MNEs: 1) economies of scale at an upstream stage that encourage servicing several downstream national markets from the same plant; 2) internationally mobile buyers; 3) consumers ordering products in one country for delivery in another; and 4) firms with an international absolute advantage in market-making.

Several of these points apply to the global drug market. Costs of ensuring quality are high since most governments have strict regulations about quality. Economies of scale in fine chemicals, the

upstream stage, are significant. Drug MNEs also have a strong international advantage in market-making skills due to brand images, patents, and product differentiation. In the Canadian case, controls over the safety and efficacy of drugs have encouraged local backwards integration into the clinical testing stage.<sup>22</sup>

**Government-Imposed Market Imperfections** When governments levy taxes, tariffs, and other forms of trade barriers, they reduce firm profits. Unrelated firms trading across international borders must pay these taxes; however, MNEs can, through transfer pricing and other financial manoeuvres, at least partly arbitrage these exogenous imperfections.<sup>23</sup> For example, *ad valorem* tariffs can be avoided by under-invoicing imports. If the profit tax rate is higher in one country than another, tax payments can be reduced by over-invoicing intrafirm imports to, and under-invoicing exports from, that country. The amount and timing of head office fees, dividends, and royalties can all be manipulated to reduce tax payments.

These incentives exist for pharmaceutical MNEs, as they do for other MNEs. The three Canadian drug policies—compulsory licensing, insurance, and provincial formularies—all offer potential for arbitrage. For example, MNEs use advertising to link brand name with high quality, in order to offset the price advantage of generic drugs. The inelastic nature of demand due to high insurance coverage encourages price discrimination (although compulsory licensing works against this). Offering bulk discounts to pharmacists and encouraging “no substitution” prescriptions lessen the price-dampening effects of provincial formularies. Over-invoicing of chemicals and drugs in bulk form imported from MNE affiliates has two arbitrage effects: it reduces tax payments, and increases the profits shifted out of Canada through trade flows (thus partly offsetting the lower rents yielded by compulsory licensing; see Appendix).

**Endogenous Market Imperfections** Endogenous market imperfections are created by the MNE as it exploits its monopoly power in domestic markets. As an international oligopoly, MNEs can raise global profits by segmenting markets and price-discriminating; erecting entry barriers to limit competition from domestic firms; restricting high-level decision-making in the MNE to headquarters, and truncating subsidiaries; setting up inefficient miniature replicas in host countries; and using transfer pricing to shift rents out of host countries.<sup>24</sup> The drug industry in Canada has been accused of all of these practices, especially in the pre-1969 time period.<sup>25</sup> Since then, compulsory licensing and provincial formularies have

reduced barriers to entry to the Canadian market, lessening the potential for exploitive MNE behaviour.

## Locational Advantages

The third component of the OLI-internalization model is location. Once a firm has decided to internalize its FSAs through wholly-owned subsidiaries, the decision to go abroad depends on the location attractions of potential host countries. These Country Specific Advantages (CSAs) are of three types: economic, non-economic, and governmental advantages (see Table 15.1). Economic advantages include factor endowments, production costs, marketing factors such as size and growth of the market and income levels, and transportation and communication costs. Non-economic factors include the degree of political stability, psychic distance, and public attitudes towards foreigners. Governmental factors include various barriers to commodity and investment flows, along with regulations specifically aimed at foreign MNEs. An attractive CSA package would include a large, growing, high-income market, low production costs, a large endowment of factors scarce in the home country, and an economy that is politically stable, welcomes FDI, and is culturally and geographically close to the home country.

Canada offers many locational advantages and, as a result, has attracted large investments by pharmaceutical MNEs. The labour force is well educated, income levels are high, and labour costs are similar to those in the United States.<sup>26</sup> The economy is politically stable and close to the United States (home to over half the drug MNEs). As a result, foreign MNEs dominate over 90 percent of the Canadian drug market. FOSCs in this industry, however, are truncated subsidiaries; investments are concentrated at the preparation/packaging and marketing stages. A small domestic market, small chemical sector, and low levels of indigenous R&D have inhibited development of the R&D and chemical stages.

The third CSA affecting location of pharmaceutical subsidiaries is government policy. The chief policy influences in the Canadian case have been tariffs, corporate taxes and R&D incentives, the Foreign Investment Review Agency, compulsory licensing, provincial formularies, and government involvement in insurance. Canadian policy has been traditionally welcoming of FDI in the pharmaceutical industry. In the early 1900s, U.S. drug firms jumped the Canadian tariff wall to set up branch plants. Tax and patent policies were similar to U.S. levels. No screening of FDI existed. In MNE eyes, Canada was regarded as a good host country. Government policies since 1969, however, have been interpreted as unfriendly and may have discouraged pharmaceutical FDI.

# Compulsory Licensing: Implications of the Internalization Model

## Implications for the Compulsory Licensing Debate

To sum up, the major ownership advantage of the pharmaceutical industry is knowledge. This is partly protected by patent laws, but secrecy is also important. The imperfect market for knowledge leads to its internalization through wholly-owned subsidiaries. Applied research and clinical testing may be decentralized to host countries with large markets and strict regulatory requirements, but key technologies are developed at home. Through horizontal integration at the packaging and marketing stages, MNEs can maximize the stream of rents earned on knowledge by selling their products in the global marketplace. Patents give property rights that ensure a stream of rents sufficient to cover previous investments and fund the new ones necessary to stay at the leading edge of the product life cycle. Vertical integration ensures quality control and takes advantage of economies of scale. Both types of integration allow the MNE to arbitrage government imperfections such as tariffs and tax differentials.

Compulsory licensing negatively affects MNE advantages in Canada. Licensing shortens the length of patent protection, reducing the potential stream of rents that can be earned here. It generates competition within prescription classes between branded products and generic substitutes. In response, the MNEs raise their rent share by over-invoicing inputs, increasing royalty and service payments, and using market segmentation techniques. They can also price-discriminate and raise prices in single-source prescription classes to offset losses in multiple-source classes.

The common perception is that compulsory licensing has also discouraged R&D investment in Canada. However, Canada represents less than 2 percent of the world market and no drug MNEs are headquartered here. Effectively, Canada is a small open economy in the international drug market. Because we are so small, our patent laws are unlikely to affect the total amount of MNE investment in R&D. Whether we offer patents for products or for process should have no impact on global investments. Similarly, neither the length of time provided by our patent legislation nor the existence of compulsory licensing of drugs is likely to affect global R&D expenditures.<sup>27</sup>

Such legislation, however, does affect the revenues MNEs can appropriate on their investments in Canada. The share of R&D allocated to Canada is not likely to be affected since horizontally-

integrated MNEs allocate production to low-cost plants, and sales to high-revenue markets. Thus production costs, taxes, and health regulations determine the location of R&D production, not sales revenue. Reduced rents, however, may deter promotional activities by FOSCs, causing the MNEs to cut back expenditures on advertising and promotion.

In summary, in international eyes, Canada is a drug importer that free rides, gives little patent protection, and pays little towards global R&D costs.<sup>28</sup> This is, of course, the accusation the MNEs and the U.S. government have made with respect to compulsory licensing. We conclude that, although the domestic economic effects have been positive for Canada, the international political effects have been strongly negative. The second has been of more concern to the federal government than the first, particularly during the Canada-U.S. free trade negotiations.

### Implications for Bill C-22

While the new patent legislation does not eliminate compulsory licensing, it substantially weakens it.<sup>29</sup> Bill C-22 was passed only after strong criticism from the Senate, which advocated the 1985 Eastman proposals (four years plus a 14 percent royalty paid according to R&D performance). The final version raises the pre-license period to ten years in return for MNE promises to create 3000 jobs and spend \$1.4 billion in investment over the next ten years.

The federal government claims that consumer prices will not rise, but has given the provinces extra funds to offset expected higher drug costs for hospitals. The bill also establishes a Drug Price Review Board, headed by Harry Eastman, to monitor drug prices. The penalty for overpricing is to be revocation of up to two patents held by the offending firm. Skeptics have argued that the Board will be ineffective and that the R&D commitments will not be met; the government has strongly argued that the bill is in Canada's best interests. The big winners from the new legislation are expected to be the members of the PMAC and Quebec (where most of the investment is promised); the big losers are members of the CDMA, consumers, and taxpayers (since health costs are expected to rise).<sup>30</sup>

Based on our application of the internalization model to this industry, we make the following predictions for Bill C-22. First, by conferring a longer patent life on new drugs, while grandfathering licenses on existing drugs, the policy offers more protection to the knowledge FSA of the MNEs. It allows larger rents to be earned on new drugs, and manufacturers' prices should rise. To the extent that provincial governments are paying for these drugs through

hospitals and government plans, MNE-provincial government conflicts should be exacerbated, particularly as government deficits increase. A widening between brand-name prices available to hospitals and consumers (where demand is less elastic) may occur. Higher rents should induce more promotional expenditures in Canada directed at doctors and pharmacists. Sales activity should increase.

Second, provincial formularies over time should become less and less useful as fewer drugs are licensed by the generics. The effective period before a new generic comes on stream has been raised from seven to eight years to seventeen to eighteen. Given the short product life cycle of most drugs, generics will be less profitable under the new legislation, and this segment of the industry should decline.

Third, the FOSCs are committed to increasing investment and employment. The internalization model suggests that these commitments are likely to be met at the clinical testing, packaging, and marketing stages. Some applied R&D may be decentralized, but no key technology is likely to be allocated to Canada. No enforcement provisions are built into the legislation to ensure that commitments are met through basic and applied research, and with internalization of the market by the MNEs, it would be difficult to determine how these commitments would be actually satisfied. Given the aging Canadian population and high degree of insurance coverage, substantial assembly and marketing investments would be made anyway. These commitments may therefore be easily satisfied by the MNEs.

Fourth, the Drug Prices Review Board is a government-imposed market imperfection. The internalization model suggests that the MNEs can manipulate transfer prices and financial flows to neutralize the Board. Given the number of drugs and variety of prices that exist within and outside Canada, the Board is unlikely to function successfully, even with an enormous staff (which it does not have). Due to the difficulty of establishing prices, the Board is apt to follow the U.S. Internal Revenue Service under section 482, using full-cost estimates of prices. However, the true costs of chemical production and R&D overhead, and their allocation from the global level to the Canadian subsidiary, are carefully guarded MNE secrets. The Board has the right to subpoena information from the FOSCs, but not from MNE parents. Thus it would be difficult to ascertain full costs. The Board may be reduced to using MNE-provided data based on U.S. prices, which are higher than ours. We conclude that the Board's effectiveness as a price monitoring agency should be limited, given the internal market structure and arbitrage opportunities of the pharmaceutical MNEs.



Overall, Bill C-22 reduces the political damage caused by compulsory licensing and removes one irritant from the Canada-U.S. free trade negotiations. However, it effectively moves the industry back to pre-1969 days, generating economic costs for consumers, generic firms, and provincial government purses.

## Bill C-22 and Canada-U.S. Bilateral Free Trade

If the bilateral Free Trade Agreement goes into effect, the main features affecting the pharmaceutical industry are the following: the tariff on chemicals is to be eliminated in five steps, the tariff on drugs in ten steps, both starting January 1, 1989. No agreement was reached on intellectual property rights, so that Canadian and U.S. patents laws are not harmonized. Each country is to apply its health and safety standards in a non-discriminatory fashion. Each government is to ease government procurement access for the other's firms. R&D, marketing, and sales personnel are to have temporary access to the other market.

The major change for this industry is the increase in market size: in ten years the North American market will no longer be segmented by tariffs. As a result, drug prices at the manufacturer's level should move together. Since Canadian prices are below U.S. levels, this should put further pressure on Canadian prices in addition to Bill C-22. From the buyer's side, the absence of search and lack of price information on drugs may allow consumer price differentials to persist. However, the large, retail drug chainstores are likely to arbitrage prices, creating additional pressure for harmonization. The Canadian Drug Prices Review Board, in all probability, will end up taking U.S. prices as its benchmark, and find little evidence of price gouging by the MNEs.

Since clinical testing is cheaper here than in the United States, if the U.S. Food and Drug Administration accepts Canadian tests in lieu of U.S. tests (under loosened health regulations, but still an unlikely prospect), more of this stage could be shifted to Canada. The assembly/packaging stage, located here initially to avoid the tariff on inputs, is unlikely to shift back to the United States. The industry has few economies of scale and is footloose. As long as Canadian costs are reasonable, plants should remain close to the Quebec and Ontario markets. Rationalization may occur, with longer production runs and fewer product varieties being produced in Canada; however, the scale gains are apt to be small. There should be more movement of R&D and marketing personnel across the border, most in a South-North direction. The pressure to

eliminate compulsory licensing altogether may grow stronger, especially if intellectual property rights are codified under GATT.

The large North American market removes one major obstacle, identified by the OECD study and the internalization model, to an indigenous Canadian pharmaceutical MNE. The lengthening of patents removes another. Federal and provincial commitments to increased spending on R&D also improve the picture. The firms most likely to exploit this opportunity are the Canadian generics. Whether they can break into the international oligopoly and develop products for the North American market is unclear. The generics have developed some technological capability and fill a soon-to-shrink market niche. They must develop a strategy or face decline in the long run. The greatest potential may lie in the biogenetic engineering firms.

Another opportunity lies with the Japanese. If the federal government encourages international joint ventures with Japanese drug MNEs (currently a small, but growing competitor in the global industry), the potential market benefits may be large. We assess the third possibility, that the drug MNEs locate basic R&D here, as improbable. However, if the Ontario and Quebec governments press for world product mandates (which they may do as *quid pro quo* for paying higher drug prices), some indigenous technology may develop.

Overall, bilateral free trade should have little effect on the Canadian drug industry. The elimination of tariffs may lead to some rationalization of production. More clinical testing may be done here. The basic R&D and chemical stages are unlikely to move. The agreement opens up opportunities for Canadian firms and FOSCs with world product mandates to penetrate the U.S. market. The potential for a Canadian pharmaceutical MNE is there; whether an entrant exists that can break into the international drug oligopoly remains to be seen.

## Conclusion

We have shown how the OLI-internalization model can be used to analyze the international drug industry and the compulsory licensing debate. We conclude that in a knowledge-intensive, foreign-owned industry like Canadian pharmaceuticals, compulsory licensing offers economic benefits at a high political cost. Bill C-22 reduces the economic benefits and political risks. The wild card in the deck is Canada-U.S. free trade, which offers the potential for an indigenous drug MNE—if a Canadian firm is willing and able to take advantage of the opportunity.

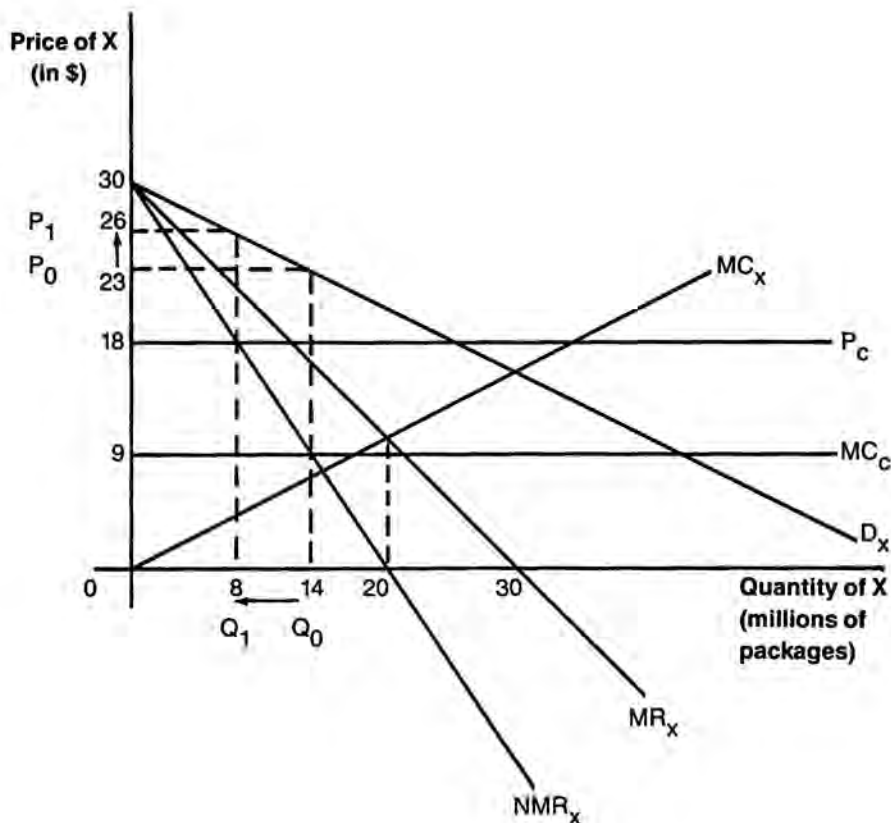
### Appendix The Over-invoicing of Pharmaceutical Imports

Figure 15.2 pictures a MNE consisting of a chemical affiliate located in a low-tax country (Switzerland) and a drug manufacturer located in a high-tax country (Canada). Assume one unit of C, the chemical, is used to produce one package of X, the drug. The MNE holds the sole patent on X and behaves like a monopoly, maximizing global profits net of taxes. This means that, at the margin, the last unit of X sold should add as much to revenue as it does to costs; i.e., the marginal revenue from sales of X should equal the marginal costs of producing the chemical and of processing it into X:

$$MR_x = MC_c + MC_x \text{ or } MR_x - MC_x = NMR_x = MC_c$$

**Figure 15.2**

Transfer Pricing in a Vertically-Integrated Multinational



The MNE therefore maximizes global profits by equating the marginal cost of the C input,  $MC_c$ , to the net marginal revenue from sales of X,  $NMR_x$ . For simplicity, assume  $MC_c$  is \$9; marginal and average costs are the same; and the transfer price is set equal to  $MC_c$ .  $NMR_x$  is determined by vertically subtracting  $MC_x$  from  $MR_x$ . Thus the initial profit maximum occurs where  $NMR_x$  and  $MC_c$  intersect. Output is 14 million packages at \$23 per unit.<sup>31</sup> Gross profit, measured as the area under the  $NMR_x$  curve and over the  $MC_c$  curve, is \$147 million. Assuming Canada levies a 40 percent tax, while Switzerland has no tax, net profit is \$88.2 million.

By over-invoicing chemical imports, the MNE can shift profits to the Swiss affiliate. This distorts output but raises net profit.<sup>32</sup> For example, assume the transfer price is doubled to  $P_c = \$18$ . Final output falls to 8 million units and the product price rises to \$26. Gross profit of \$48 million is declared by the Canadian affiliate, \$72 million by the Swiss affiliate. Total gross profit falls from \$147 million to \$120 million. Net profit, however, rises from \$88.2 million to \$100.8 million, an increase of \$20 million! Hence, over-invoicing of imports is a profitable activity for the pharmaceutical MNEs.

## ENDNOTES

1. The drug market is segmented into two categories: prescription/ethical drugs and over-the-counter drugs. The categories differ in that a physician's prescription is necessary only to buy prescription drugs. The major share of drug sales and the majority of compulsory licenses are in the prescription category. In this paper the term drugs refers only to prescription drugs.
2. See R. Davidson, "The Scope of Patents", *Policy Options* (December 1986), pp. 3-6, and "Ottawa Rebuked over Drug Patent Delay", *The Globe and Mail*, April 8; and "Intellectual Property", November 18, 1986.
3. The OLI (Ownership-Location-Internalization) model is an eclectic model of FDI, drawing together work on MNEs in the industrial organization, international trade, and market failure fields. The model was developed by Dunning (see *International Production and the Multinational Enterprise* (London: George Allen and Unwin, 1981)). In the OLI framework, all three elements are necessary to generate FDI. The internalization model (see A.M. Rugman, "New Theories of Multinational Enterprise: An Assessment of Internalization Theory", *Bulletin of Economic Research* (May 1986), pp. 101-118) also discusses the three elements, but emphasizes market failure (the I variable) as the key (and perhaps the only necessary) requirement for FDI.

4. See, however, the short analysis in Rugman, Lecraw and Booth (full reference in note 17).
5. Harry C. Eastman (Commissioner), *The Report of the Commission of Inquiry on the Pharmaceutical Industry* (Ottawa: Supply and Services Canada, 1985).
6. "Trade Ministers to Consider Placing Intellectual Property Rights on GATT Agenda", *The Globe and Mail*, April 6, 1986.
7. Eastman, *Ibid*; Roy Davidson, "The Scope of Patents", *Policy Options* (December 1986), pp. 3-6.
8. See P. K. Gorecki *Compulsory Patent Licensing of Drugs in Canada: Have the Full Price Benefits Been Realized?* (Ottawa: Supply and Services Canada, 1986), and G.F. Mathewson and R.A. Winter, *Market Structure and Performance in the Pharmaceutical Industry* (Ottawa: Supply and Services Canada, 1986) for more detail.
9. For example, *The Globe and Mail*, July 2, 1985, in "Limits on Generic Drugs Likely after Cut-throat Lobbying War", reported that the drug MNEs in 1984 mailed prescription pads to doctors with no-substitution preprinted on the pads.
10. For example, P.K. Gorecki, (*Compulsory Patient Licensing of Drugs in Canada: Have the Full Price Benefits Been Realized?* (Ottawa: Supply and Services Canada, 1986)) estimates that generic prices at the manufacturer's level in 1983 were 35 percent of brand name prices (i.e., a 65 point differential; however, at the retail level this price gap varied by province from a zero price differential (in New Brunswick) to a 33 percent differential (in Ontario and British Columbia). He attributes the failure to pass cost savings from the manufacturer to the consumer to differences in provincial formularies establishing drug equivalencies and setting reimbursable prices.
11. Data are taken from Eastman (1985), Gorecki (1986), and D.G. Quirin, *Transfer Pricing of Drugs and Pharmaceutical Intermediate Products* (Ottawa: Supply and Services Canada, 1986).
12. *The Globe and Mail* (January 23, 1986), in "Multinationals Lobby Tirelessly against Licensing Generic Drugs" reported that an industry-wide audit by Revenue Canada found that 40 drug MNEs had understated their Canadian profits by \$80 million between 1975 and 1978. The MNEs had over-invoiced imports in order to shift profits to lower-taxed affiliates. *The Globe and Mail* (August 21, 1987) in "Transferring Money Helps Multinationals Increase Profits" reported a 1983 study that showed intrafirm prices for drug imports were more than three times higher than the same drugs on the open market. The ten MNEs studied paid \$60 million in dividends, \$20 million in royalties, head office fees of \$9.5 million, and bought intrafirm imports of over \$250 million over 1983 and 1984, for a total outflow of \$340 million. The ten MNEs reported an average return on shareholder's equity of 24 percent. This compared to R&D by the whole industry of \$250 million on close to \$1.3 billion sales. (See also M. Gordon and D.J.

- Fowler, *The Drug Industry: A Case Study of the Effects of Foreign Control on the Canadian Economy* (Toronto: Canadian Institute for Economic Policy, 1981), and Quirin, 1986).
13. Myron Gordon and David J. Fowler, *The Drug Industry: A Case Study of the Effects of Foreign Control on the Canadian Economy* (Toronto: Canadian Institute for Economic Policy, 1981).
  14. Eastman, *Ibid.*
  15. P. K. Gorecki and Ida Henderson, "Compulsory Licensing of Drugs in Canada: A Comment on the Debate", *Canadian Public Policy* (1981), pp. 559-568; James J. McRae and Francis Tapon, "Compulsory Licensing as a Policy Instrument", *Canadian Public Policy* (1984), pp. 74-77; P. K. Gorecki, "Changing Canada's Drug Patent Law: The Minister's Proposals", *Canadian Public Policy* (1984), pp. 77-82; Douglas G. Hartle, "Federal Proposals to Restrict Competition in the Canadian Pharmaceutical Industry", *Canadian Public Policy* (1984), pp. 83-89. Davidson, *Ibid.*
  16. John H. Dunning, *International Production and the Multinational Enterprise* (London: George Allen and Unwin, 1981).
  17. Alan M. Rugman, Donald J. Lecraw, and Lawrence D. Booth, *International Business: Firm and Environment* (New York: McGraw-Hill Book Company, 1985).
  18. Alan M. Rugman, "Research and Development by Multinational and Domestic Firms in Canada", *Canadian Public Policy* (Autumn 1981), pp. 604-616.
  19. Bruce Richard Warley, *The Canadian Experience with Compulsory Licensing of Pharmaceuticals: Its Relevance for LDCs*, M.A. research essay (Ottawa: Paterson School of International Affairs, Carleton University, 1987).
  20. Y. Kotowitz, *Issues in Patent Policy with Respect to the Pharmaceutical Industry* (Ottawa: Supply and Services Canada, 1986).
  21. Mark C. Casson, "Transaction Costs and the Theory of the Multinational Enterprise", in Alan M. Rugman, ed., *New Theories of the Multinational Enterprise* (New York: St. Martin's Press, 1982).
  22. Bohumir Pazderka, *Multinational R&D Activity in the Pharmaceutical Industry* (Ottawa: Supply and Services Canada, 1986).
  23. Alan M. Rugman and Lorraine Eden, *Multinationals and Transfer Pricing* (London: Croom Helm; New York: St. Martin's Press, 1985).
  24. Stephen Hymer, "The Efficiency (Contradictions) of Multinational Corporations", in Gilles Paquet, ed., *The Multinational Firm and the Nation State* (Don Mills, Ontario: Collier-MacMillan, 1972); Robin Murray, ed., *Multinationals Beyond the Market: Intra-firm Trade and the Control of Transfer Pricing* (New York, London: John Wiley and Sons, 1981).
  25. Eastman, *Ibid.*

26. Gordon and Fowler, *Ibid.*
27. G. F. Mathewson and R. A. Winter, *Market Structure and Performance in the Pharmaceutical Industry* (Ottawa: Supply and Services Canada, 1986).
28. In fact, an eminent Canadian economist (and staunch free trader), Harry Johnson, recommended just such a policy, on the grounds that the "quid didn't justify the pro." That is, importing SOEs with little chance of developing indigenous MNEs should free ride by offering little or no patent protection. Johnson was the first economist to develop the public goods aspect of knowledge argument. See H.G. Johnson, "The Efficiency and Welfare Implications of the International Corporation", in C.P. Kindleberger, ed., *The International Corporation* (Cambridge: MIT Press, 1970). M.K. Berkowitz and Y. Kotowitz ("Patent Policy in an Open Economy", *The Canadian Journal of Economics* (February 1982), pp. 1-17) also note that if the R&D stage were located in the SOE host country, the costs would be incurred in the SOE while the rents on this investment would be recouped in the home country. If the expenses were tax deductible, the host country would receive even less benefit.
29. For a good review of the political background surrounding the development of the bill, see Warley (1987).
30. See "Drug R&D Plans Doubted", *The Globe and Mail*, December 8, 1986, and "Review Board Will Judge the Prices of 3,000 Drugs", *The Toronto Star*, December 21, 1986.
31. Noting that demand is  $PX = 30 - 1/2 X$  and  $MC_x = 1/2 X$ , the reader can verify that  $NMR_x = 30 - 3/2 X$ , and then solve for price and output data.
33. The incentive to over-invoice could be offset by the Canadian tariff on pharmaceutical imports, which is 10 percent. However, if the final product is manufactured in Canada, fine chemicals and bulk drugs enter duty free (see Warley, 1987). The MNE thus arbitrages another government-imposed market imperfection by trading off the tariff saving against the cost of domestic production. This complication is ignored here. However, note that Appendix B in Quirin (1986) lists drug imports and duty paid by country for 1983. If we total these columns we find imports of \$477.9 million and tariff revenue of \$31.033 million, for an average tariff rate of 6.5 percent. Thus, the effective tariff rate is well below 10 percent, implying that many imports enter duty free.