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Technical Report No. 8

REGULATING THE PRICE OF PRESCRIPTION DRUGS IN CANADA: COMPULSORY LICENSING, PRODUCT SELECTION, AND GOVERNMENT REIMBURSEMENT PROGRAMMES

Paul K. Gorecki
Economic Council of Canada

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by

Paul K. Gorecki
Economic Council of Canada

The findings of this Technical Report are the personal responsibility of the author, and, as such, have not been endorsed by members of the Economic Council of Canada.

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RÉSUMÉ

Au cours des années 60, les administrations fédérale et provinciales se sont beaucoup préoccupées du prix élevé des médicaments d'ordonnance au Canada. Après la parution de toute une série de rapports et les travaux de plusieurs commissions, un certain nombre de réformes ont été amorçées. Par exemple, au niveau fédéral, la Loi sur les brevets a été modifiée en 1969 pour permettre l'attribution d'une licence autorisant l'importation de médicaments encore protégés par un brevet. Une redevance a été établie à 4 % du prix de vente demandé par le détenteur de la licence. À des degrés divers, les gouvernements provinciaux ont mis en oeuvre des mesures législatives et des programmes pour encourager l'utilisation des produits généralement meilleur marché offerts par les bénéficiaires de licences. Les médecins ont été avisés des prix de différentes marques du même médicament ainsi que du fait qu'elles étaient certifiées comme équivalents thérapeutiques par les provinces. Il fut permis aux pharmaciens, dans certaines conditions, de choisir une marque moins chère que celle prescrite par le médecin, le médecin et le pharmacien étant protégés contre tout recours en loi. Dans le cadre de leurs programmes d'assurance-médicaments, les gouvernements ont établi, pour la détermination des prix, des règles qui favorisaient l'utilisation de marques meilleur marché. La présente étude tente d'évaluer l'effet de ces mesures sur le prix des médicaments et sur la performance de l'industrie des produits pharmaceutiques, en mettant l'accent plus particulièrement sur la modification de 1969 à la Loi sur les brevets, qui portait sur les licences obligatoires. En outre, l'auteur accorde une attention particulière à la vente au détail en Colombie-Britannique, en Ontario, au Québec et en Saskatchewan.

Voici, en résumé, les principales conclusions de l'étude. Les prix à la production ont diminué, souvent de beaucoup, dans le cas des produits pharmaceutiques soumis à la concurrence des médicaments vendus sous licence. Ces réductions de prix ont été "refilées" au consommateur, sur le marché hospitalier, et se sont répercutées aussi, à des degrés divers, sur les marchés provinciaux de vente au détail. Il n'est pas rare que des dépenses pour un médicament particulier vendu sous licence soient inférieures de 50 % à ce qu'elles auraient été sans la licence obligatoire et autres applications connexes de la politique pertinente. Cela n'empêche pas d'ailleurs la réalisation d'autres gains, souvent considérables, sur presque tous les marchés.

L'auteur évalue la performance de l'industrie des produits pharmaceutiques en vue d'étudier les effets du principe

de la licence obligatoire sur certaines variables clés, comme le niveau de la recherche et du développement, le moment de l'introduction de nouveaux médicaments sur le marché, le prix des produits pharmaceutiques auxquels la licence obligatoire ne s'applique pas, la conjoncture relative aux investissements, la balance commerciale et la publicité. Malgré un certain nombre de difficultés liées à la méthode utilisée et aux données, les renseignements recueillis indiquent que les licences obligatoires pour l'utilisation des brevets n'ont eu qu'une incidence très faible ou même nulle sur la performance des indicateurs, choisis aux fins de la présente étude, de l'industrie des médicaments.

Étant donné ces constatations, l'étude recommande que le principe de la licence obligatoire soit retenu tel quel. D'autres recommandations portent sur les moyens d'abaisser les prix de détail des médicaments. Le montant d'une ordonnance comprend les frais de préparation payés au pharmacien et le coût des ingrédients ou des médicaments, qui représentent respectivement environ 50 % du total (bien que dans le cas des médicaments commercialisés sous plusieurs marques, la part des premiers soit beaucoup plus élevée). Les modifications recommandées au système des prix de détail permettraient au marché de fixer lui-même ces frais, ce qui forcerait les gouvernements provinciaux à se retirer de ce genre de négociations. Les coûts des médicaments (c'est-à-dire des ingrédients) continueraient, d'autre part, à être établis en grande partie par le gouvernement. Cependant, l'étude recommande un certain nombre d'améliorations qui, bien qu'elles laissent au marché un rôle plus étendu, quoique encore limité, devraient favoriser un meilleur contrôle des coûts des ordonnances par les gouvernements provinciaux, les avantages allant au consommateur, sous forme de prix plus faibles, et au contribuable, sous forme de réduction d'impôt. Vu le vieillissement de la population et les contraintes qui pèsent actuellement sur les budgets de tous les gouvernements, ces recommandations sont particulièrement opportunes.

SUMMARY

Throughout the 1960's there was considerable concern at both the federal and provincial levels of government about the high price of prescription drugs in Canada. After a series of reports and commissions a number of reforms were introduced. At the federal level the Patent Act was amended in 1969 to allow licences to be granted for the importation of drugs still subject to patent protection. A royalty level of 4 percent of the selling price of the licensee was set. Provincial governments, in varying degrees, introduced legislation and programmes to encourage the use of the generally lower priced licensee brands: physicians were informed of the prices of different brands of the same drug and of the fact that the province certified these brands as therapeutically equivalent; the pharmacist, under certain conditions, was allowed to select a lower priced brand than that prescribed by the physician; both physician and pharmacist were exempted from legal liability where such selection took place; pricing rules were established as part of government drug reimbursement programmes which promoted the use of lower priced brands. This study attempts to evaluate the impact of these measures on the price of drugs and on performance of the drug industry, with particular emphasis on the 1969 amendment to the Patent Act - compulsory licensing. In the retail sector special attention is paid to the situation in British Columbia, Ontario, Quebec and Saskatchewan.

The major findings of the study can be summarized as follows: prices have fallen, often substantially, at the level of the manufacturer for those drugs subject to licensee competition. These price reductions have been passed on to the consumer in the hospital market and, in varying degrees, in the provincial retail drug markets. It is not uncommon for expenditure on a particular licensed drug to be reduced by 50 percent from what it would have been without compulsory licensing and associated policy measures. Nevertheless further gains, often of considerable magnitude, can be achieved in virtually all markets.

The performance of the drug industry is assessed with a view to examining the impact of compulsory licensing on such key variables as the level of R & D, the date of introduction of new drugs, the price of drugs not subject to compulsory licensing, the investment climate, the balance of trade and advertising. Despite a number of methodological and data problems the accumulated evidence suggests that compulsory patent licensing has had very little, if any, impact on the industry performance indicators selected for study.

In view of these findings, the study recommends that compulsory licensing be retained in its present form. Other recommendations concern methods for lowering of drug prices at the retail level. The price of a prescription consists of the

dispensing fee paid to the pharmacist for his professional services and the ingredient or drug cost, with each accounting for approximately 50 percent (although for drugs with several brands the dispensing fee is a much higher proportion of the total prescription price). Changes recommended in the retail pricing system would allow the dispensing fee to be set by market forces thus extricating provincial governments from negotiation in the fee setting process. Drug (i.e., ingredient) costs, on the other hand, would continue to be set largely by government, although a number of suggested improvements are recommended, but with a limited, though expanded, role for the market. The proposals should enable better control over the prescription costs to be exercised by the provincial governments, with benefits accruing both consumers in the form of lower prices and taxpayers in reduced tax bills. Given the aging of the population, and the fiscal restraint at all levels of government, these proposals are particularly relevant at this time.

INTRODUCTION

Throughout the 1960's there was considerable concern, at both the federal and provincial levels, over the "high" price of drugs in Canada. This concern manifested itself in a series of federal government reports, starting in 1961 with that of the Director of Investigation and Research, Combines Investigation Act, followed by the Restrictive Trade Practices Commission, 1963, the Royal Commission on Health Services, 1964, and finally, in 1967, the report of a Parliamentary committee under the chairmanship of Mr. Harry C. Harley. There was substantial agreement as to the facts, the problem and its resolution among these reports. Briefly, prices were considered high both in relation to production costs and to prices in other advanced western industrialized countries. It was believed that the chief culprit facilitating this state of affairs was the 17 year patent protection afforded drugs. The suggested solution was a substantial reduction in such patent protection, ranging from outright abolition of patents to some form of compulsory licensing.

In June, 1969 the Parliament of Canada passed section 41(4) of the Patent Act, with the intention of stimulating competition in the supply of patented drugs. In essence, this amendment has meant that upon payment of a four percent royalty a licence can be obtained to manufacture and/or sell a patented drug. Among OECD countries, with the exception of Italy which does not allow patents on drugs, the compulsory licensing provision in section 41(4) of the Canadian Patent Act is unique.

The federal and provincial governments also introduced measures designed in part or in whole to facilitate the success of section 41(4): virtually all provinces passed laws allowing the pharmacist to select a cheaper for a more expensive brand of the same drug; information on the therapeutic equivalence and price of patentee and licensee drugs were provided (initially by the federal government and subsequently some of the provinces) in order to encourage the physician to prescribe and the pharmacist to dispense the lower priced brand; and provincial governments began to provide drugs free of charge, in whole or in part, to certain sections of the population, particularly those over 65 years of age and/or on welfare. In several instances specific measures were introduced which, in effect, resulted in mandatory selection of the lowest priced brand of a particular drug. While such schemes were limited to the public provision of drugs they may, nevertheless, have an effect on the entire retail market.

The objective of this paper is to assess the impact of section 41(4), and concomitant measures, not only in terms of lowering drug prices but in the wider context of the performance of the drug industry. Since compulsory licensing is now 10 years old enough experience should be available to judge its success. Furthermore policy questions at both levels of government make such an investigation timely. Provincial governments can antici-

pate increases in their drug bills as persons over 65 years of age, who typically have their drugs supplied free of charge, increase in number. Thus, pressures will build up to reduce drug costs. By studying and evaluating several existing provincial programmes, in the context of compulsory licensing, those measures that are most effective in reducing drug costs can be isolated and perhaps refined in the future.

At the present time the federal government is considering revisions to the Patent Act. In 1976 the federal Department of Consumer and Corporate Affairs issued its Working Paper on Patent Law Revision, which considered the compulsory licensing question. In response to this a number of briefs were submitted by a variety of groups. More recently, in 1980, the federal Department of Industry Trade and Commerce has released a discussion paper and five background papers on the domestic health products industry which touched on the subject of compulsory licensing. Hence this study, which concentrates exclusively on compulsory licensing and concomitant measures, should provide additional information for policy-makers considering prospective changes in the law.

The study is divided into eight chapters and a number of appendices. Chapter I provides an overview of the present legal, institutional and economic framework and environment within which drugs are manufactured, prescribed and dispensed. The legislation, history and interpretation of compulsory licensing is discussed in Chapter II. Although the legislation dates back to 1923 the focus of attention is on the 1969 amendments to the Patent Act allowing a compulsory licence to be granted for the importation of either the raw material or the final dosage form. The purpose of Chapter III is to look into the patterns and determinants of compulsory licensing: What factors determine which drugs are licensed? In which pharmacologic - therapeutic categories are most licensed drugs classified? How many licensed drugs actually result in a product on the market? The next two chapters, IV and V, are concerned with the identification, characteristics and marketing strategy of the firms which have acquired compulsory licences (the licensees) and those firms which own the patents subject to licensing (the patentees). The impact of compulsory patent licensing on drug prices and expenditure is discussed in Chapter VI. Particular attention is paid to a large buying group of hospitals, Hospital Purchasing Incorporated of Toronto, and the retail markets in British Columbia, Ontario, Quebec and Saskatchewan. The effect of compulsory licensing on R & D, the balance of trade, the rate of introduction of new drugs, the investment climate and advertising is studied in Chapter VII. The final chapter, VIII, provides an overall assessment of the impact and success or failure of compulsory licensing and concomitant measures. Some possible suggestions for future policy are also presented and critically examined.

CHAPTER I

THE LEGAL, ECONOMIC AND INSTITUTIONAL FRAMEWORK: AN OVERVIEW

1.1 Introduction

In order to be able to assess and comprehend the impact of compulsory patent licensing, an understanding is needed of the legal, institutional and economic framework or environment within which prescription drugs are manufactured, prescribed and dispensed. A comprehensive analysis and discussion of this environment is both unnecessary and impractical. Instead, the object here is much more modest - to present an overview of the environment sufficient that the skeleton of the system can be understood. Detail will be added to those parts which are particularly relevant to this study.

This chapter is divided into several sections. Section 1.2 outlines the delivery system for prescription drugs, from the manufacturers to the consumer (i.e., patient). The remaining sections consider issues which relate to the delivery system, but generally refer to more than one participant and are of particular relevance to compulsory patent licensing: interchangeability; product selection; government reimbursement programmes. The final section, 1.5, presents a brief summary and some inferences.

1.2 The Delivery System For Drugs

1.2.1 Introduction

There are five main participants in the delivery system: manufacturer; physician; pharmacist; patient; and governments, both at the federal and provincial levels. The role of each is briefly described as well as the economic and other factors that are likely to influence their behaviour with respect to prescription drugs. A final section, 1.2.7, distinguishes between the hospital and retail prescription drug markets.

1.2.2 Manufacturer[1]

The manufacturer is responsible for the preparation of the final dosage form of a prescription drug suitable to be administered to the patient. This usually takes place in Canada. In contrast, the drug's raw material (i.e., bulk active ingredient) is imported from a small number of plants which supply the worldwide needs of the industry. This pattern of production and location reflects the low absolute volume of worldwide production and the relatively small size of the Canadian market. The value added in final product preparation in Canada, however, is often substantial.[2]

The number of manufacturers of prescription drugs in Canada is (depending upon the source) between 66 and 120 for

1979 [3] The actual number is probably toward the upper limit of the range. Manufacturers typically specialize in groups of drugs in a particular therapeutic category or categories. Most of the larger manufacturers are foreign-owned and fully integrated, owning both the raw material and final dosage preparation production facilities.

Manufacturers of drugs can be divided into three categories for the purposes of this study: licensees (i.e., those firms that have taken out compulsory licences under section 41(4) of the Patent Act); patentees (i.e., those firms that own patents for which a compulsory licence has been issued by the Commissioner of Patents); and other (i.e., neither licensee nor patentee). An indication of the relative importance of these three groups can be gained from an estimate of their respective shares of the Saskatchewan prescription drug market in 1977-1978,[4]

Category	%
Patentee	71
Licensee	8
Other[5]	21

As can be readily observed, patentees and licensees together account for 79 percent of sales of prescription drugs, with the patentees clearly predominating. In other words, the study of compulsory licensing has relevance to virtually the whole industry. Even those firms which account for 21 percent of industry sales and are neither patentee nor licensee may own patents for which licences will be issued. For example, Fisons Ltd. is a U.K. multinational firm which has a subsidiary in Canada and owns patents relating to several drugs, but the Commissioner of Patents has not issued a compulsory licence for any of these drugs to date. Chapter IV discusses the licensees in some detail, while the patentees are the subject of Chapter V.

1.2.3 The Physician[6]

The physician's role in the delivery system is that of prescribing a particular drug as treatment for the diagnosed illness of the patient. Only a qualified medical practitioner (i.e., physician or dentist) can write a prescription, defined as, "...an order [or authorization] given by a practitioner directing that a stated amount of any drug be dispensed for the person named in the order" (Canada, Department of National Health and Welfare, 1979a, p. 8). The prescription can fall into one of three categories.

(1) Open Prescription: the physician writes the generic or proper name of the drug. For example, instead of Valium (i.e., the brand name) the physician writes diazepam. The choice of brand, in the case of a multisource drug, is then delegated to the pharmacist,

constrained by whatever provinicial regulations have been enacted.

(2) No Substitution: the physician writes a specific brand name (e.g., Valium) and the words "no substitution" in which case the pharmacist must dispense the brand named.

(3) Brand Name: the physician writes a specific brand name (e.g., "Valium") but the words "no substitution" do not appear on the prescription. In such instances, as with an open prescription, the pharmacist has discretion, subject to provincial regulations, to select a different brand from that named in the prescription.

Physicians at the time of the introduction of compulsory licensing typically wrote brand name prescriptions with the brand being specified that of the patentee. Only one province, Alberta, allowed the pharmacist to product select. In the 1970's the federal and some of the provincial governments attempted to influence the prescribing habits of doctors such that the lower priced brands became prescribed more frequently. These efforts are discussed in section 1.3 below.

1.2.4 The Pharmacist[7]

Only a registered pharmacist may dispense a prescription drug upon receipt of a physician's prescription. Less than one percent of all prescriptions require the pharmacist to compound different chemicals to meet the requirements of the prescription. In most instances, the pharmacist takes the dosage form (e.g., tablets, ointment) from a large container and places it in a smaller container for the patient's use. The compounding that was originally virtually all conducted by the pharmacist is now done by the manufacturer. However, the pharmacist may (must in Quebec) keep patient's records which can be used to assess actual or potential adverse drug interactions. The pharmacist may also provide advice and information that the patient may require in administering the prescription drug.

The total number of licensed pharmacists in Canada has increased steadily since the mid-1960's, from 10,147 in 1967, to 11,629 in 1972 and 15,328 in 1977. However, because the rate of increase of the total population has been smaller, the population served per pharmacist has declined steadily from 2,028 in 1967 to 1,529 in 1977. There are, however, noticeable provincial differences, with one pharmacist on average in 1977 serving 2,173 people in Quebec, 1,609 in Ontario, but 712 in Saskatchewan.

The pharmacist, in the role of a dispenser of drugs, is a health professional, in the same sense as the physician in a prescribing role. As such, a professional body, created under provincial law, is normally responsible for overseeing the dis-

cipline and conduct of pharmacists on behalf and in the interests of the public. This body can make rules and regulations which relate not only to matters such as standards of ethics, qualification, knowledge and skill, but also ownership of a pharmacy, and price disclosure or similar devices such as gifts, rebates, and bonuses. The professional body, which in many cases is referred to as a College of Pharmacists or a Pharmaceutical Association, is responsible for enforcing these rules and regulations by the use of fines and by revoking or suspending the pharmacist's licence.

The pharmacist is not only a health professional, but also, frequently, a small businessman selling such items as sunglasses, toiletries, over-the-counter drugs (i.e., drugs which can be advertised to the general public and require no physician's prescription) and newspapers. The dispensing of prescriptions is therefore seen in strict profit and loss terms by the pharmacist in his role as a businessman, especially in view of the increasing significance of prescription drugs in overall pharmacy operations, as the following figures demonstrate:

Year	Percentage of prescription to total pharmacy sales
1954	19.8
1964	27.4
1974	35.0

Note: This information should be interpreted with some care as a result of the low response rate to the survey.

Source: Canadian Pharmaceutical Association, (1975, Table 32, p. 43).

Frequently an association exists, again organized on a provincial basis, to take account of and represent the pharmacist's economic interest, e.g., the Ontario Pharmacists' Association, the B.C. Pharmacists' Society and the Independent Retail Druggists Association of Quebec Inc. In the case of pharmacists in B.C. an agreement in 1969 to charge $1.00 for filling welfare prescriptions resulted in a conviction and fine under the conspiracy provisions of the Combines Investigation Act. These associations usually negotiate the remuneration for dispensing a prescription with the relevant government agencies in those provinces which operate drug reimbursement programmes. Section 1.4 below discusses and describes these programmes.

The pharmacist has traditionally priced the prescription drug by following the recommended price of the manufacturer, with little or no price disclosure by the pharmacist. However, with the advent of many multisource drugs and provincial involvement in drug reimbursement programmes and also on the initiative of pharmacists, the compensation to the pharmacist for dispensing a prescription drug has been divided into two parts:

a dispensing fee for the professional service of the pharmacist and an ingredient cost, representing the cost of the drug to the pharmacist. This method of pricing was intended to remove the incentive present under a mark-up system, to dispense higher priced drugs. Again, there is little or no price disclosure by the pharmacist. In the late 1970's, depending upon the province, the dispensing fee accounted for between, on average, 40 and 50 percent of the price of a prescription. In some instances, particularly for multisource drugs, the ingredient cost contains a mark-up for the pharmacist, depending upon the province. Hence, the 40-50 percent range is, on average, the minimum that the pharmacist receives of the prescription dollar. The issue of dispensing and ingredient cost is discussed further in Chapters VI and VIII below, while the discussion in sections 1.3 and 1.4 below addresses the rules and regulations concerning the choice of brands of a drug to which a pharmacist is subject, both in general and under government reimbursement programmes, respectively.

1.2.5 The Patient[8]

The patient is the final consumer of prescription drugs. There are several characteristics of the patient's demand for drugs which should be noted. Most of these are generally well accepted both inside and outside the health care sector. First, the demand for drugs is highly price inelastic. In other words, for wide variations in the price of drugs, total consumption changes only marginally. This is not at all a surprising statement. Drugs are often a matter of life and death, or, at least, the difference between good and bad health. The consumer is often in no position to question the judgement of the physician to whom, implicitly at least, the decision as to whether a drug is an appropriate therapy is delegated. Second, those people in the older age categories have a greater demand for drugs measured in terms of the average number of prescriptions. Such prescriptions are usually higher priced. For example, for the U.S. in 1973 the following variation of demand with age was observed:

Age Group	Prescriptions per Capita	Average Price per Prescription ($)
0-16	3.2	3.39
17-24	4.2	3.77
25-44	5.6	4.33
45-64	8.7	5.09
65 and over	14.4	5.09

The limited evidence available for Canada is consistent with this finding. For example, in Ontario, for 1979, while those over 65 constitute 9.5 percent of the province's population, they accounted for approximately 20 percent of total expenditures on prescriptions. As the age structure of the population of Canada

changes in the next 50 years or so, such that the age group over 65 increases substantially in importance, the demand for drugs is likely to increase considerably. Third, the patient in purchasing a prescription drug can fall into one of several categories. At one extreme the patient bears the full cost of the prescription (i.e., cash-paying customer) while at the other the patient bears none or only a portion of the cost of the prescription. For example, persons over 65 typically receive drugs free of charge or at a substantial discount under provincial drug reimbursement programmes. The cash-paying customer has an incentive, given the physician has prescribed a certain number of drugs, to minimize his expenditures on such drugs. However, as already noted, there is little or no disclosure of either the dispensing fee or the price of the most popular selling drugs. On the other hand, the non-cash paying customer will minimize things such as walking distance to the pharmacist. Government reimbursement programmes, in part, are an attempt to stimulate market prices which are then used as a method of reimbursement to the pharmacist. These programmes are considered in section 1.4 below, together with some of the pricing rules.

1.2.6 Governments

Governments, at both the federal and provincial levels, have a number of important roles to play in the delivery system for drugs. The federal government's major function is to certify that all new drugs introduced in the Canadian market are safe and efficacious with respect to the claims made by the manufacturer. In addition, the federal government inspects manufacturing facilities, conducts continuing surveillance once a drug is marketed, and prohibits the advertising of the therapeutic properties of prescription drugs to consumers while controlling the content of any such advertising directed at the physician and pharmacist. However, in the mid-1970's some measure of price disclosure was permitted by pharmacists, under the Food and Drugs Act, when regulation C.0.1.044 was amended to read, in part, "No person shall advertise to the general public a Schedule F [i.e., prescription drugs] except in respect of the name, price and quantity of the drug...." The federal government derives its legal authority from the Food and Drugs Act, which is administered by the Department of National Health and Welfare.

The provincial governments are responsible for the professions of pharmacy and medicine, and attendent regulations and laws. For example, although regulation C.01.044 permits price disclosure by pharmacists, it is within the authority of provincial governments to agree or disagree. Other laws include the product selection laws discussed in section 1.3 below. The various programmes to reimburse patients and/or pharmacists for prescription drugs, detailed in section 1.4 below, are organized, operated and controlled at the provincial level. In a few instances, however, this may be contracted out to a third-party, as occurs in Alberta.

1.2.7 Retail vs. Hospital Market[9]

The retail market refers to prescription drugs purchased by individual or groups of pharmacists from manufacturers for resale through a pharmacy to members of the general public upon presentation of a valid prescription. Most of the discussion in sections 1.2.4 (the pharmacist) and the latter part of 1.2.5 (the patient) were concerned with the retail market. The hospital market refers to prescription drugs purchased by hospitals, either individually or frequently as members of a buying group, from manufacturers, for administering to patients in the care of the hospital. Although estimates vary, it would appear that between 10 and 20 percent of the prescription drug market is accounted for by the hospital market. However, for individual drugs this can vary considerably. The major difference between the two markets is that the hospital market is much more price sensitive. Buying groups of hospitals operate tendering systems which, other things equal, select the lowest price brand amongst a group of interchangeable brands. Physicians in the hospital are often required to delegate brand selection to a Drugs and Therapeutic Committee to facilitate the successful operation of the tendering system. In view of the greater significance of the retail market, most attention is paid to it in this study.

1.3 Interchangeability, Formularies and Product Selection Laws

1.3.1 Introduction

One of the topics in the pharmaceutical industry which has generated considerable debate is the question of whether two brands of the same drug are therapeutically equivalent. In other words, if the patient is given firm A's brand of diazepam instead of firm B's, or vice versa, will the effects be exactly the same? Equivalence implies that different brands of the same drug are interchangeable.

The following, somewhat stylized account, shows why the issue of drug equivalence and interchangeability has been and continues to be of significance in the context of compulsory licensing. The account refers to the 1960's, although it would appear to be equally applicable to the period from World War II until 1960, and discusses government attempts to change the situation.

The first firm to sell a drug is generally the originator or inventor, armed with patent protection. Such firms are usually large, well-established multinationals with a good reputation amongst both physicians and pharmacists. The new drug is introduced and promoted via a brand name to the medical profession. On the other hand, there are sellers of the "same" drug that can be characterized as small, conducting relatively little research into new drug therapy, perhaps not very well established and without the ability to engage in extensive promotion to phy-

sicians and pharmacists. The smaller firm will typically launch its brand some years after the originator has been selling the drug. However, the smaller firm's price will usually be substantially lower than the originator. Under such conditions the physician, in the words of the Harley Committee (1967, p. 16) "...prescribes those drugs he has heard of, has read of, and has some knowledge of - he is a cautious man and prescribes the drug manufactured by a company known to him." This is as a rule, not surprisingly, the originator.[10]

The problem of devising ways and methods of encouraging physicians to prescribe and pharmacists to dispense lower priced brands of the same drug was addressed in the various federal inquiries into the price of drugs in the 1960's, and subsequently in a number of provincial reports and legislative moves. One method was the provision of information to physicians and pharmacists concerning the quality and price of different brands of the same drug, eventually leading some provinces to certify interchangeability for a list of brands of the same drug. This list is published in a formulary. A second method was the authority, under certain circumstances, given to pharmacists to select, for the benefit of the patient, a lower priced brand of the drug named in the prescription. In section 1.3.2 information, formularies and interchangeability are considered, while in section 1.3.3 product selection laws are outlined and discussed.

1.3.2 Information, Interchangeability and Formularies

One of the major recommendations of the Harley Committee (1967, p. 17) was that the federal government publish and distribute free "... an information bulletin to the medical profession giving complete details on drugs and their actions and reviewing major drug uses in Canada." Such a review would detail, among other things, the proper or generic name of the drug, all manufacturers of the drug, comparative costs and clinical equivalency of these various manufacturer's brands, as well as any problems associated with the manufacturer's product, including toxicity, impurity and court actions. The Harley Committee was convinced such a programme would pay for itself in more frequent prescribing and dispensing of lower priced drugs. Although the recommendations of the Harley Committee were aimed primarily at the federal level, both levels of government responded. This section outlines, briefly, the initial response of the federal government and the subsequent action of the various provinces.

Federal Response[11] The federal Department of National Health and Welfare in direct response to the Harley Committee's recommendations introduced the Drug Quality Assurance Programme, commonly referred to as QUAD, in 1971. (This was preceded by a publication called the R_x Bulletin, which provided information on drug price and quality very soon after the Harley Committee's report was published). Information on

drug quality, standards of manufacturer, prices and clinical tests were provided in a publication entitled QUAD REVIEW, which was distributed free to pharmacists and physicians on four occasions between 1972 and 1975. No QUAD REVIEWS were issued subsequently, partly because this function has largely been conducted by the provincial governments. The QUAD programme has instead evolved into a central co-ordinating and information gathering agency, in which the provinces have an important role in ranking and selecting, for example, those drugs upon which comparative bioavailability studies should be conducted. The information is then distributed to provincial governments.

In sum, the QUAD programme has provided information initially to physicians and pharmacists and subsequently to provincial governments, on drug quality and comparability. It is important to note that QUAD did not certify that two brands of the same drug were interchangeable, nor did it empower pharmacists to select a different brand from that specified in the physician's prescription, since neither was part of the QUAD mandate. The programme administrators recognized these limitations. In a statement at the time the QUAD programme was launched, the federal Minister of National Health and Welfare stated,

> I am fully aware of the fact that many physicians and pharmacists are reluctant to prescribe and dispense generic or other lower-cost drugs, unless they can be assured that low-cost drugs are of acceptable quality. Any program aimed at reducing drug costs must, therefore, recognize the need to provide objective information on drug quality to the professions of medicine and pharmacy. (Munro, 1971, p. 2).

In other words, with the provision of information the relevant professions would prescribe and dispense the lower priced drugs.

Provincial Response[12] Provincial governments have responded differently with respect to the provision of information on drug quality, equivalence and prices to physicians and pharmacists. These responses are briefly described with some, albeit minimal, attention paid the provincial variations of each.

The provinces of Manitoba, New Brunswick, Ontario, Quebec and Saskatchewan have elected to publish information on prices and different brands of the same drug similar to that contained in a QUAD REVIEW, but on a more frequent basis, in the context of a provincial drug reimbursement programme (see section 1.4 below) and product selection legislation (see section 1.3.3 below). The information, contained in a publication referred to as a formulary, is issued semi-annually, usually on January 1st and July 1st. The first issues by the various provinces were dated as follows:

Province	Date First Formulary Introduced
Manitoba	1974
New Brunswick	1975
Ontario	1970
Quebec	1972
Saskatchewan	1975

A word of explanation is required with respect to the date specified for New Brunswick and Ontario. New Brunswick published a Prescription Drug Program Common Usage Drug Schedule in 1975 for the purposes of drug reimbursement. In 1977 this publication was combined with the Product Selection Formulary, which certified various brands of the same drug as interchangeable pharmaceutical products. Ontario had a publication which listed price and different brands of the same drug, the PARCOST Comparative Drug Index, which was published semi-annually starting in 1970. This publication did not certify the various brands of the same drug as interchangeable until 1972, when the province's product selection legislation was introduced. In 1974 a formulary was issued, coincidentally with the introduction of a drug benefit programme (ODB), and this was merged in 1975 with the PARCOST Comparative Drug Index.

The drugs in a formulary are classified into a series of pharmacologic-therapeutic categories such as cardiovascular drugs or eye, ear, nose and throat preparations. For each drug, by dosage form and strength, the price per unit will be listed and, in the case of a drug for which several manufacturers exist, some or all of the brands will be listed. Inclusion in the formulary signifies that the particular brand has met the required provincial quality considerations as well as a number of other criteria, usually printed in each edition of the formulary. It is usual for a Drugs and Therapeutics Committee to evaluate each drug, based on QUAD material and, in some instances, information provided directly by the manufacturer. In the case of different manufacturers of the same drug, inclusion in the formulary signifies that all the brands are certified as interchangeable by the provincial government, with the exception of Quebec. In other words, the pharmacist can select any of the brands of a particular drug, since a formulary is usually linked with a product selection law, described below. In this respect most provincial formularies differed radically from QUAD REVIEWS.

It should be noted that provincial formularies typically do not provide a list of every drug on the market and all brands of multisource drugs. New Brunswick and Manitoba have relatively small formularies while those of Ontario, Quebec and Saskatchewan are much more extensive. The differences are substantial. For example, the number of drugs (i.e., all dosage forms and strengths as well as brands of a given drug are treated

as a single entry) listed in the July 1979 formulary of these provinces was as follows:

Manitoba	33
New Brunswick	37
Ontario	511
Quebec	896
Saskatchewan	433

These differences are a reflection of the fact that formularies are used as an integral part of provincial drug programmes in that they may be used to list all these drugs eligible for reimbursement, and/or those which are high selling and for which a number of suppliers exist. Provinces also vary in their policy of how many suppliers of a given drug they will include in a formulary, an issue discussed in Chapter IV, section 4.4 below.

The other governments, that is Alberta, British Columbia, Nova Scotia, Newfoundland and Prince Edward Island, do not provide any information concerning quality and interchangeability of drugs to physicians and pharmacists, although Newfoundland hopes to issue a formulary in late 1980. The absence of a formulary or a similar publication, such as a QUAD REVIEW, reflects the lack of provincial drug reimbursement programmes with the exception of British Columbia and, to a lesser extent, Alberta, which contracts out to Blue Cross the payment of drugs to certain segments of the population. A second factor is that some of these provinces, again with the exception of Alberta and British Columbia, do not have (i.e., Nova Scotia and Prince Edward Island) or only recently have passed, but not proclaimed (i.e., Newfoundland), product selection legislation. The gap is partially filled for these provinces by the annual publication of the Canadian Pharmaceutical Association, the Compendium of Pharmaceutical Specialties, which besides listing information concerning the drugs' uses and side-effects also names the various firms which sell the drug. However, no prices are included.

In sum, then, following the Harley Committee recommendations the federal government introduced the QUAD programme in 1971. Information on drug quality, comparability and prices were presented in a series of QUAD REVIEWS issued between 1972 and 1975. As the provincial governments began to pass product selection legislation and introduce drug reimbursement schemes, responsibility for issuing such information, in a somewhat different format and context, passed to the provinces. As of July 1980 five provinces, representing, in 1973, 76.6 percent of all retail prescription drug sales in Canada, issued formularies that list drugs of acceptable quality and four of them certified that different brands of the same drug, by dosage form and strength, were interchangeable. Five provinces did not replace the vaccuum left at the end of the QUAD REVIEWS although Newfoundland intends to publish a formulary in late 1980.

TABLE 1-1

PROVINCIAL PRODUCT SELECTION LAWS: A SUMMARY, 1980

Province	Date Product Selection Legislation Introduced	Permissive or Mandatory[a]	Rules for Selection[b]	Determination of Cost	Determination of Interchangeability	Legal Protection for Pharmacist and physician
Alberta	1962	Permissive	None specified[c]	None specified	Pharmacist; no formulary	Not provided
British Columbia	1974	Permissive	Equal or lower priced than brand prescribed[d]	None specified	Pharmacist; no formulary	Not provided
Manitoba	1974	Permissive	Lowest price brand[e]	Formulary[e]	Formulary	No legal liability
New Brunswick	1975	Permissive	Lower priced brand to that prescribed[f]	Lowest price brand in pharmacist's inventory[f]	Formulary	No legal liability
Newfoundland	Expect to proclaim permissive and, after six months, a system similar to Manitoba will be introduced, probably in late 1980. No legislation to permit product selection until this change.					
Nova Scotia	No product selection legislation.					
Ontario	1972	Permissive	Lower priced brand to that prescribed[g]	Lowest price brand in pharmacist's inventory[g]	Formulary	No legal liability
Prince Edward Island	No product selection legislation.					
Quebec	1974	Permissive	None specified[h]	None specified	Formulary[j]	Not clear
Saskatchewan	1971	Permissive	None specified[i]	None specified	Pharmacist (1971-1974); formulary (1975 onwards)	No legal liability

a. All provinces do not allow product selection where the prescription is marked "no substitution" by the physician. In some instances the legislation specifies that the words "no substitution" be in the physician's handwriting. This reflects the provision of prescription pages by some drug firms with the words "no substitution" already printed across the prescription.
b. Emphasis added in all footnotes to entries in this column.
c. "Where a prescription refers to a drug ... by a brand name [the pharmacist] ... may use a drug that is the generic or brand name equivalent of that named in the prescription...."
d. "... a pharmacist may use an interchangeable pharmaceutical product where its price to the purchaser is no more than the price of the prescribed drug."
e. "Every person who dispenses a prescription for a drug ... shall ... dispense an interchangeable pharmaceutical product other than the one prescribed ...[if it] is lower in cost than the drug prescribed." This is qualified by, "No person shall knowingly supply an interchangeable pharmaceutical product ... at a price in excess of the cost of the lowest priced interchangeable pharmaceutical product ... in the [formulary]."
f. "Every person who dispenses a prescription may ... dispense an interchangeable pharmaceutical product other than the one prescribed, provided [it] ... is lower in cost than the drug prescribed." This is qualified by, "No person shall knowingly supply an interchangeable pharmaceutical product ... at a price in excess of the lowest price interchangeable pharmaceutical product in his inventory ...." Hence, no matter which brand is dispensed, the lowest priced brand in the pharmacist's inventory determines the priced charged.
g. Language same as New Brunswick. See footnote f, above.
h. "A pharmacist ... may ... substitute for the prescribed medication a medication whose generic name is the same ...."
i. "... the pharmacist about to dispense a drug pursuant to the prescription may select and dispense an interchangeable pharmaceutical product other than the one prescribed."
j. As mentioned in the text, the Quebec formulary only lists drugs of acceptable quality.

Source: Provincial Pharmacy Acts, as well as rules and regulations made pursuant to such Acts. Information supplied by various provincial and federal officials through the QUAD programme.

1.3.3 Product Selection Legislation[13]

Drugs can be divided into two categories for the purposes of the discussion of product selection legislation. First are those drugs for which there is only one supplier. These are referred to as single source drugs. For example, the drug cimetidine is manufactured and sold in Canada by only one firm, Smith Kline and French. Hence whether a physician writes the generic or proper name (i.e., cimetidine) or the brand name (i.e., Tagamet) the pharmacist has no alternative but to dispense the Smith Kline and French product. The second category of drugs are those for which there are a number of manufacturers. These are referred to as multisource drugs. For example, the July, 1979 Ontario formulary lists three manufacturers of the drug perphenazine, as well as detailing their prices and respective brand names in the following way, for 16 mg. tabs;

Brand Name	Manufacturer	Unit Price ($)
Phenazine	ICN Canada Ltd.	0.0737
Apo-Perphenazine	Apotex Inc.	0.0853
Trilafon	Schering Corp. Inc	0.1384

Source: Ontario, Minister of Health (1979b, p. 41).

Inclusion in the formulary means that all these brands of perphenazine are, to use the jargon of the product selection laws, interchangeable pharmaceutical products. Since different brands have typically widely varying prices, as shown above, the issue arises as to what rule the pharmacist should adopt upon receipt of the physician's prescription in selecting which brand to dispense. Product selection legislation attempts to provide the pharmacist with guidelines in resolving this problem.

Product selection laws vary considerably in their detail and substance, province by province. Hence, only the broad outlines and generalities will be presented here. Table 1-1 provides a summary of the various provincial product selection legislation. As can readily be observed all provinces, except Newfoundland, Nova Scotia and Prince Edward Island, passed product selection legislation in the period 1971-1975, with the exception of Alberta (1962). Newfoundland, although it passed such legislation in December 1979 has, as yet, to proclaim the Act. This is expected in late 1980. In discussing these laws it should be remembered that the major purpose, subject to objections and qualifications by physicians and pharmacists, is to promote the use of lower priced drugs.[14] It is primarily in this light that their failure or success should be judged.

Earlier, in section 1.2.3 above, the prescription that the physician writes was divided into three categories: open; no substitution; brand name. A no substitution prescription consists of the physician writing a specific brand name (e.g., Valium) and the words "no substitution" across the prescription. Under such circumstances, under all product selection laws in

Canada, the pharmacist has to dispense the brand named by the physician. In effect a no substitution prescription is equivalent to a single source drug.

The second type of prescription is one for which the physician writes the brand name but does not specify "no substitution". Under all the product selection laws the pharmacist is then permitted to select a different brand from that named. Two particular aspects of this are worthy of note. First, is the pharmacist compelled to select (i.e., mandatory product selection) or is it left to his judgement and discretion (i.e., permissive product selection)? In all provinces, product selection is permissive. Second, if the pharmacist does product select what rule is specified with respect to the cost of the selected drug vis-à-vis the brand named in the physician's prescription? A variety of approaches have been used. Alberta, Quebec, and Saskatchewan do not specify a rule in the legislation. In other words, the pharmacist can select a lower or higher priced brand than that prescribed. A second group of provinces New Brunswick and Ontario, specify that the pharmacist must select a lower priced brand than that prescribed in product selection.[15] In these two provinces there is a paragraph in the legislation which constrains this choice,

> No person shall knowingly supply an interchangeable product ... at a price in excess of the cost of the lowest priced interchangeable pharmaceutical product in his inventory.... [emphasis supplied]

For Manitoba, in contrast, the legislation says the pharmacist should not knowingly supply an interchangeable pharmaceutical product in excess of the lowest priced in the formulary.[16] The final approach is that of British Columbia which specifies that the pharmacist, if he product selects, must choose a brand equal in price to or less than the price of the brand prescribed.

The third type of prescription is referred to as "open". In such instances the physician, instead of writing a particular brand name uses the generic or proper name. For example, rather than prescribing Tegopen, Cloxapen, Bactopen, Cloxilean, Orbenin, etc., the physician writes cloxacillin. The product selection legislation does not always deal specifically with the open prescription case, although it is clearly covered for both Manitoba and Ontario. This may reflect the fact that historically most physicians prescribed by brand name and the chief purpose of the legislation is to encourage selection at this level. However, the legislation with respect to open prescriptions would appear to be reasonably straightforward. Obviously, under such circumstances, the physician has delegated to the pharmacist the decision as to brand choice. The terms mandatory or permissive are irrelevant. Hence column 3 of Table 1-1 refers mainly to brand name prescriptions.[17] The critical question is therefore what rules, with respect to cost, are specified in product selection legislation for open prescriptions. Two

categories would appear to cover all the provinces having product selection legislation. First, the pharmacist is granted complete discretion to dispense the highest, lowest or some intermediate priced brand. Alberta, British Columbia, New Brunswick and Saskatchewan would appear to fall into this category. The second rule specifies that the pharmacist can charge no more than either the lowest priced brand in his inventory (Ontario) or in the formulary (Manitoba) no matter which brand is dispensed.

As can be readily surmised from the discussion of the various product selection laws and the summary in Table 1-1, there is likely to be a considerable variation in their impact when viewed from the vantage point of their contribution to the prescribing and dispensing of lower priced drugs. At one extreme are provinces such as Quebec which grant complete discretion to the pharmacist in selection, while, on the other hand, Manitoba compels the pharmacist to charge the price of the lowest priced interchangeable pharmaceutical product, as specified in a formulary. The net result is, other things equal, that lower priced brands are likely to hold a higher share of the market in Manitoba than Quebec. Some attention is paid to the impact of product selection laws for compulsorily licensed drugs in Chapter IV, section 4.5 below.

This discussion of product selection legislation refers to the general framework within which such selection takes place. Provincially funded drug reimbursement programmes, discussed in the next section 1.4, can, in some instances, substantially alter the product selection rules for drugs dispensed under such programmes compared with the general product selection legislation. Perhaps the best example is Saskatchewan, which on a reading of the product selection legislation would appear to be fairly permissive. However, the universal drug programme introduces, in essence, mandatory product selection of the lowest priced interchangeable pharmaceutical product. Hence the impact of product selection legislation should be considered in conjunction with provincial drug reimbursement programmes, to which attention is now turned.

1.4 Provincial Drug Reimbursement Programmes, Product and Price Selection[18]

The purpose of this section is to furnish a brief overview of provincial drug reimbursement programmes, and to provide an exposition of the pricing rules which such plans follow in order to reimburse the pharmacist for dispensing the government funded prescription, particularly whether product selection is mandatory or permissive. Little attention is paid to private third-party programmes such as those run by Blue Cross and Green Shield or associated with an insurance firm, or to those prescriptions for which the patient or consumer bears the full cost. This is a reflection of the fact that the rules and regulations set by the provincial reimbursement programmes interact and affect the rest of the market, rather than vice

versa. Indeed, as mentioned below, the government programme in some provinces is universal and hence is likely to set the pricing rules for all prescriptions.

Table 1-2 summarizes the coverage of the provincial drug reimbursement programmes. Overall, the provinces of Canada cover 30 percent of the population under such programmes, the remainder being covered by private third party programmes or bearing the full cost themselves. However, government coverage varies considerably, province by province. Three provinces, British Columbia, Manitoba and Saskatchewan, provide universal coverage, while all other provinces cover 10-20 percent of their populations, except Newfoundland (6 percent) and Prince Edward Island (also 6 percent). Every province provides coverage for those on welfare and often for those over 65 years of age. However, the nature of the coverage varies considerably, with some forms of patient co-payment in all provinces except Newfoundland, Nova Scotia, Ontario, Quebec and Prince Edward Island. While the dates of introduction of the provincial reimbursement programmes varied, the present population coverage, almost without exception, dates from the mid-1970's. Hence, although the table is dated 1979/80, apart from minor details, such as the amount of co-payment for some provinces, the table is valid for the mid-1970's onwards.

Details of the methods by which provincial drug reimbursement programmes establish the cost of a drug for the purposes of payment to the pharmacist, either directly or indirectly, and whether product selection is mandatory or not under the programme are presented in Table 1-3. The details concerning product selection in the table do not differ from those in Table 1-1 referring to the general product selection laws, except for Saskatchewan. For this province, product selection is mandatory under the reimbursement programme, except of course, for no substitution prescriptions. However, the Ontario and Manitoba schemes, with respect to selection, there is, what might be termed mandatory price selection. The formulary for both provinces lists the unit prices of all brands of multisource drugs, as in the Ontario example of perphenazine, cited in section 1.3.3 above. Mandatory product selection would imply the lowest priced brand should always be dispensed. In the example of perphenazine this would be ICN's Phenazine. The twist to Manitoba and Ontario schemes is that no matter which brand of a multisource product is dispensed, the government will only reimburse the pharmacist for the lowest priced brand in the formulary. In the perphenazine example no matter whether Phenazine, Apo-Perphenazine or Trilafon is dispensed the pharmacist only receives the price for Phenazine. This is analoguous to mandatory price, rather than product, selection. Hence, Ontario and Manitoba combine mandatory price selection with permissive product selection.

As the percentages in Table 1-2 indicate, the Saskatchewan programme covers the whole of the population while

TABLE 1-2

THE COVERAGE OF PROVINCIAL DRUG REIMBURSEMENT PROGRAMMES: A SUMMARY, 1979/1980[a]

Province	Percentage of population covered[b]	Class of population covered and any patient payment[c]	Date original programme introduced and extended to present coverage
Alberta	12	welfare, nil; over 65, 20 percent of the prescription.	at least 1950's, present coverage since 1973.
British Columbia	100	welfare and over 65, nil; others, $100 plus 20 percent in excess of this sum for any calendar year per individual or family unit.	1974, extended to "others" in 1977.
Manitoba	100	welfare, nil; over 65, $50 plus 20 percent in excess of this sum for any calendar year per family unit; under 65, $75 plus 20 percent in excess of this sum for any calendar year per family unit.	1950's, present coverage since 1975.
Newfoundland	6	welfare, nil.	1960's.
New Brunswick	20	welfare under 18, $1.00 payment per prescription; welfare over 18, $2.00 payment per prescription; over 65, nil.	not known, present coverage since 1976.
Nova Scotia	10	welfare; over 65; nil for both categories.	not known, present coverage since 1976.
Ontario	14	welfare; over 65; those under Family Benefit Act, Extended Care Services and Homecare; nil for all categories.	1974, present coverage since 1976.
Prince Edward Island	6	welfare; special disease states; nil for both categories	not known, present coverage since at least early 1970's.
Quebec	16	welfare; over 65; nil for both groups.	1972, present coverage since 1977.
Saskatchewan	100	certain welfare recipients and special beneficiaries, nil; all others (including over 65) payment per prescription up to a maximum of $2.80.	1948, present coverage since 1975.
Canada	30	----------	------

a. Refers to financial year ending in 1979 or 1980, depending upon the most recent for which information is available.
b. This refers to the total eligible population, not those receiving benefits. In Saskatchewan, for example, the total eligible population was 922,536 in 1977/78 but the number of beneficiaries was 605,326. (See Saskatchewan, Department of Health, 1978, Table II, p. 16 for details).
c. Often referred to as co-payent.

Note: A drug reimbursement programme is defined as a scheme whereby government pays in whole or in part the drug costs of a certain category or categories of the population.

Source: Badgley and Smith (1979, pp. 79-91) and information provided by provincial and federal officials through the QUAD program.

for Ontario, only 14 percent are covered. However, due to the presence of those over 65, who, as pointed out in section 1.2.5 above, are the heaviest per capita consumers of drugs, the actual percentage of prescriptions in Ontario covered by the government scheme is not 14 percent but, according to estimates provided by the provincial government, 28-30 percent for the 1977-1979 period. It is likely that a similar finding holds for Alberta, New Brunswick, Nova Scotia, and Quebec all of whose plans cover far less than the total provincial population, but include those over 65.

As mentioned in the previous section, other things being equal, in a province with mandatory product selection, the average price per unit of a drug should be less than where only permissive selection is allowed. However, things are not equal. Table 1-3 provides details of how government reimbursement programmes define drug cost for the purposes of payment to the pharmacist. Several methods of defining cost are used, varying from actual acquisition cost to the pharmacist (British Columbia, Newfoundland, Prince Edward Island) cost of smallest package sizes purchased by the pharmacist (New Brunswick, Nova Scotia, Ontario), a tendering system for supplying the whole province (Saskatchewan), to the cost of the most frequently purchased package size by pharmacists (Manitoba and Quebec). Even within the same definition of cost there may be a difference because of the way in which product selection works, the length of time for which a prescription can supply a patient without a refill, the co-payment features of the programme, the number of brands of a drug allowed in the formulary, and the way in which the public officials administer the scheme. As a result the price of a given brand and the average price paid for a given drug as reimbursed by the province, will differ across the country.[19]

A final factor which should be remembered in comparing the cost of provincial drug reimbursement plans is that the price of a prescription has two components, as discussed in section 1.2.4 above: an ingredient cost (i.e., the drug cost) and a dispensing fee (i.e., the professional service of the pharmacist). Attention here has concentrated on the former, but differences exist in the dispensing fee, compounding the difficulties that are yielded by drug costs. In most instances fees are negotiated between the province and the pharmacists' trade association, and differ province by province. In Chapters VI and VIII further discussion of the dispensing fee is presented. However, at this stage, noting that it exists and is, as pointed out in section 1.2.4 above, a significant percentage of the price of a prescription, will suffice.

1.5 Summary and Overview

In this chapter the framework within which compulsory licensing legislation can be placed has been sketched. This entailed outlining the role and responsibility of the manu-

TABLE 1-3

DRUG PRICING UNDER PROVINCIAL DRUG REIMBURSEMENT PROGRAMMES: A SUMMARY, MID-1970's [a]

Province	Drug Cost Definition for Reimbursement	Formulary	Maximum Supply per Prescription	Product Selection
Alberta	Cost to wholesaler plus 25 percent	None	100 days	Permissive
British Columbia	Actual pharmacy cost[b]	None	100 days	Permissive
Manitoba	Drugs listed in formulary, price based on package size most commonly purchased by pharmacist; other drugs, price based on smallest package size available	Limited formulary for high selling multisource drugs.	None	Permissive (mandatory price selection)[c]
New Brunswick	Cost of smallest package size	Limited formulary for high selling multisource drugs.	100 days (prior approval for up to 180 days)	Permissive
Newfoundland	Cost to pharmacist	Pending	30 days, 90 permissible in some instances	Permissive for for first six months after formulary introduced, then a system similar to Manitoba
Nova Scotia	Cost of smallest package size to pharmacist	None	100 days	None
Ontario	Cost to pharmacist of smaller package sizes (100's) except for a small number of high selling drugs where larger package size (1000's) used[d]	Formulary	One month under normal circumstances, not to exceed 6 months in any event[e]	Permissive (mandatory price selection)[c]
Prince Edward Island	Actual acquisition cost to provincial dispensary[f]	None	60 days	None
Quebec	Cost of most popular selling package size purchased by pharmacist	Formulary	None	Permissive
Saskatchewan	Provincial government tender system for high selling drugs (standing-offer-contracts); for other drugs pharmacists' customary replacement cost.[g]	Formulary	Six months[h]	Mandatory

a. Most of the provincial drug reimbursement programmes have had the same rules for drug reimbursement to pharmacists since at least the mid-1970's to the present. In some instances, small changes have taken place in the intervening period. For example, it was only in 1979 that Ontario moved to price high selling drugs based on larger package sizes.

b. B.C. government looks at average true acquisition cost in any given area or city and demands to see invoices if store claims reimbursement above local average price. There are only a small number of wholesalers in B.C. and the prices they charge to the pharmacist are also monitored by the government.

c. See text for an explanation of this term.

d. Pharmacist's costs from wholesaler, unless data has proven 50 percent of a manufacturer's sales of these drug products in Ontario are via direct channels, in which case latter source is used.

e. This policy is currently under review.

f. For Prince Edward Island the provincial government operates a central dispensary from which drugs are distributed to the eligible categories mentioned in Table 1-2 above.

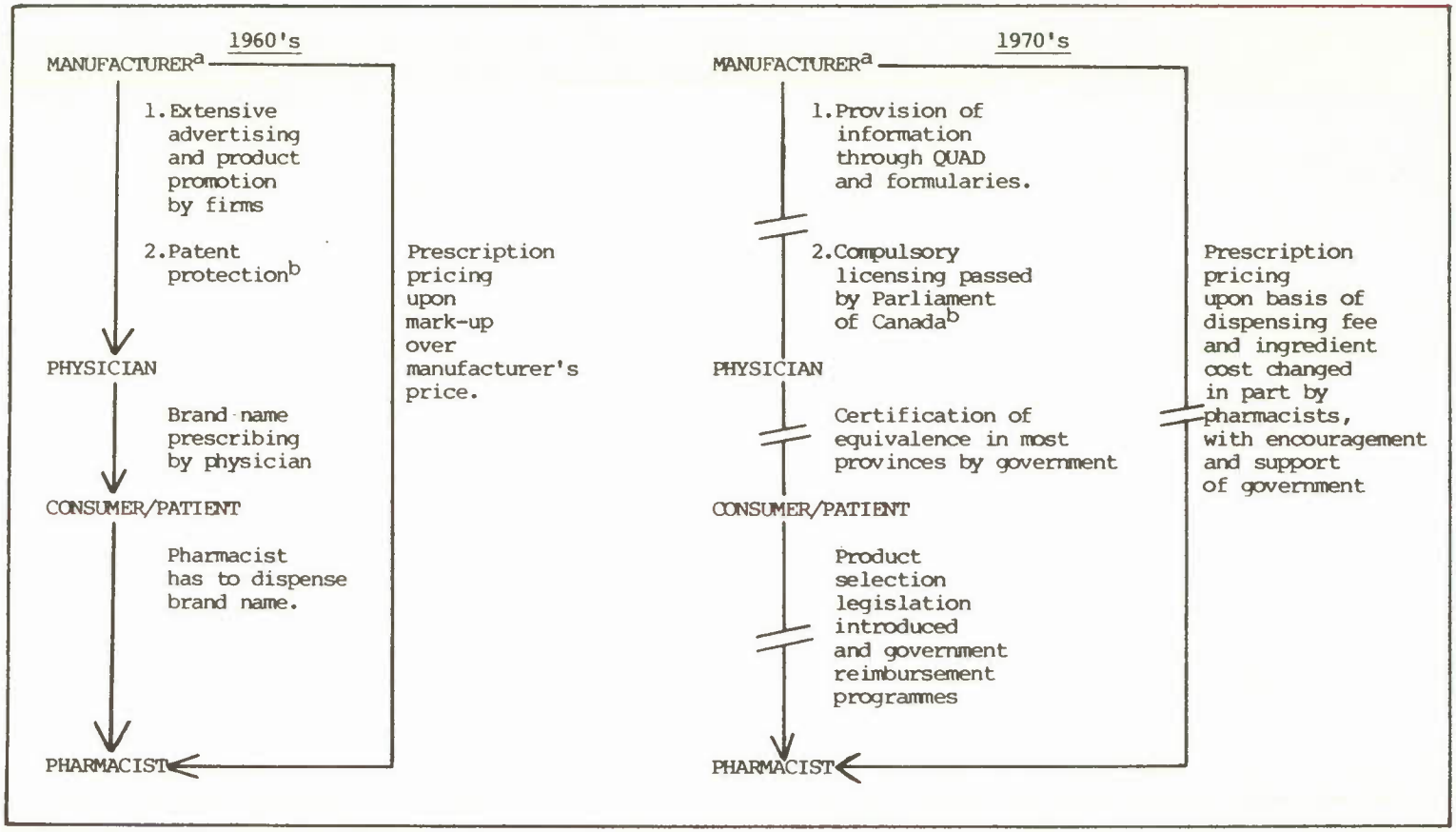
g. For non S.O.C. drugs manufacturers provide firm price quotations for a six month period. Pharmacists must charge acquisition cost to a maximum of the price listed in the formulary for all drugs. Although the formulary price for low volume products may be based on smaller package sizes, pharmacists who buy these products in larger package sizes, at lower prices, must submit and are paid actual acquisition cost.

h. For most drugs the pharmacist is entitled to one dispensing fee for each 34 day supply of medication. A pharmacist is entitled to one dispensing fee for each 100 day supply for certain maintenance drugs (thyroid, digoxin, anticonvulsants, oral hypoglycemics) and one dispensing fee for each two month supply of oral contraceptives.

Source: Information provided by various provincial and federal officials through the QUAD programme.

FIGURE 1-1

CHANGING THE LINKS IN THE DRUG DELIVERY SYSTEM: GOVERNMENT POLICY
THE 1960's and 1970's



a. Refers to major, usually multinational, firms which dominate the industry.
b. Prior to 1969, compulsory licensing existed only for manufacture in Canada. This had little impact. See Chapter II below, for details of the change to import and/or manufacture.

Note: This Table applies primarily to multisource drugs. The 1960's model still exists for single source drugs, except for the method of pricing a prescription, which accords with the 1970's model.

Source: See text.

facturer, pharmacist, physician and patient in the drug delivery system and government policy toward each of those groups. Figure 1-1 depicts the links between these groups as they existed in the 1960's and government policies introduced in the 1970's designed to change the nature of these links, with a view to promoting the use of lower priced drugs of acceptable quality. The major thrust of the policies was, essentially, to break the decisive influence of the larger, usually multinational, drug firms over the drug delivery system. As such the policies applied to all drugs, but with particular emphasis on multisource drugs.

These general policies, depicted in Figure 1-1, were essential, indeed necessary, with perhaps the exception of the hospital market, for the success of compulsory licensing. Indeed, all of these policies were part of the same concern over the "high" price of drugs. Compulsory licensing applies, however, only to those drugs for which the patent is still extant and hence for which the owner of the patent can legally exclude potential competitors from manufacturing and selling the same product, albeit with a different brand name. In terms of Figure 1-1 compulsory licensing leads to, potentially at least, a number of competitors with the original manufacturer. The remainder of this study is an examination of the success or failure of compulsory licensing within the framework of Figure 1-1.

CHAPTER II

PATENTS AND COMPULSORY PATENT LICENCES

2.1 Introduction

A compulsory patent licence can be defined, generally, as the granting to a third party (the licensee) the right to use a patent, against the wishes of the patent owner (the patentee). The granting authority is usually a quasi-judicial official (i.e., the Commissioner of Patents) whose decision can be appealed to the courts (i.e., the Federal Court[1] and then the Supreme Court of Canada). In other words, a compulsory patent licence is an involuntary contract between a willing buyer (the licensee) and an unwilling seller (the patentee) imposed and enforced by the state.

Several aspects of compulsory licences need to be clarified in order to be able to evaluate their impact. These include some or all of the following: the determination of the level of financial or other compensation[2] that the licensee must pay the patentee; the criteria upon which a licence may be awarded;[3] the qualifications that a licensee is required to satisfy; the coverage, in terms of the class or classes of patents, subject to compulsory licensing; the use of the patent, that may restrict the right to manufacture (or process) domestically or include the right to import goods and services which would otherwise infringe the patent. These issues are the topic of this chapter. Most of the emphasis will be placed on those issues of particular relevance to compulsory patent licensing of drugs.

The chapter is organized as follows. The definition of a patent and the method by which it is granted is very briefly outlined in 2.2. The smaller degree of patent protection afforded food and medicines is noted. There exist certain general provisions which relate to compulsory patent licensing in both the Patent Act and the Combines Investigation Act, which are the subject of 2.3. Specific provisions in the Patent Act for the issuing of compulsory licenses to manufacture or import drugs are the concern of sections 2.4 and 2.5, respectively. A brief summary is presented in section 2.6.

2.2 Definition of a Patent[4]

A patent is defined under the Patent Act[5] as letters patent for an "invention", which is said to be,

> ...any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art process, machine manufacture or composition of matter.... (Section 2)

The patent owner has "the exclusive right, privilege and liberty of making, constructing, using and vending to others" goods and services embodying the invention.[6] This right is limited to a period of 17 years from the date the application of the patent is allowed. A patent is granted only to the inventor, or his legal representative. The invention cannot be patented if it was previously known or used by others, or was in public use or on sale for more than two years prior to application being made in Canada. In return for the granting of the patent, the owner discloses the substance of the invention to the public.

Most patents issued in Canada are to foreign inventors or corporations.[7] For example, between 1960 and 1969 the annual percentage of patents issued to Canadian residents varied between 4.7 and 5.7 (Economic Council of Canada, 1971, Table 4-3, p. 54). The corresponding percentage in 1974 was 5.7, the lowest of a group of advanced Western countries including Australia and Spain (Canada, Department of Consumer and Corporate Affairs, 1976, Table 4, p. 64). In the opinion of the Harley Committee (1967, p. 37) the percentage of drug patents held by Canadian residents would appear to be as small, if not smaller, than that for all patents. Evidence collected by the Director of Investigation and Research supports this view. In 1958, of the 372 patents held on antibiotics for which information was available, "only nine [were held] by Canadian residents" (RTPC, 1963, p.100). With respect to tranquillizers, the corresponding numbers were seven and zero.

The official responsible for the administration and enforcement of the Patent Act is the Commissioner of Patents, presently part of the Department of Consumer and Corporate Affairs. All applications for a patent are made to the Commissioner, who determines whether the invention is "new and useful" and arbitrates in situations where more than one person claims responsibility for an invention. The decision of the Commissioner to grant a patent is appealable to the Federal Court and, ultimately, to the Supreme Court of Canada.

The definition and procedure for granting a drug patent is no different from that for any other class of patent except in one important respect.[8] Section 41(1) of the Patent Act specifies that inventions "relating to substances prepared or produced by chemical processes and intended for...medicine, the specification shall not include claims for the substance itself...." (emphasis added).[9] Instead, the inventor can only patent the invention in a process-dependent form - i.e., "when defining such an invention, the inventor must describe it in terms of the process which produces his product" (Canada, Department of Consumer and Corporate Affairs, 1976, p. 121).

The implication of the process-dependent patent for drugs has been described as follows:

> The result is an artificial loophole or excision in the exclusivity of the patentee's rights in the case of new substances of this type. Any person who conceives of a process, unclaimed by the patentee which leads to the same...medicine, may use it with immunity from infringement. (Canada, Department of Consumer and Corporate Affairs, 1976, p. 121).

The impact of section 41(1) of the Patent Act, originally enacted in 1923,[10] has been two-fold. First, according to a former Commissioner, compared to all, a much higher proportion of drug patents contested are invalidated in the courts. This was attributed,

> ...to the fact that a patent is obtainable only on the process of manufacture of the drug and the patent examiner might be more lenient than would be the case if a patent could be obtained on the product itself. (RTPC, 1963, p. 100)

The second effect is that "importers are marketing drugs in Canada which may or may not be infringements of Canadian patents, and they pay no royalties," according to a brief of Cyanamid of Canada Limited (cited in RTPC, 1963, p.100). However, the potential for importation is mitigated somewhat, since "section 41(2)[11] of the Patent Act...puts the onus probandi [i.e., the burden of proof] on the shoulders of the defendant [i.e., the importer] in an infringement suit" (RTPC, 1963, p. 101) to show that the process used is different from that of the patentee. In view of the substantial lessening of protection afforded drug patents by the introduction of compulsory licences to import in 1969, discussed in section 2.5 below, it is probable that the process-dependent form of drug patents had only a marginal effect in reducing the protection afforded the drug patentee, at least in the period subsequent to 1969.

2.3 Compulsory Licensing: General Provisions

2.3.1 Introduction

Compulsory licences may be issued on any patents, including those relating to drugs, under certain provisions of the Combines Investigation Act and the Patent Act.[12] Both statutes apply varying criteria to the issuing of such licences, which reflect their differing objectives. However, in neither case have the compulsory licence procedures been extensively used since their respective inception.

2.3.2 The Patent Act

The Patent Act provides under section 67(1) that either the Attorney General of Canada or a private citizen may,

> ...at any time after the expiration of three years from the date of the grant of a patent apply to the Commissioner [of Patents] alleging in the case of that patent that there has been an abuse of the exclusive rights thereunder and asking for relief under this Act.

The Act, under section 67(2),[13] specifies six grounds or circumstances under which a patent may be deemed to have been abused, such as "the patented invention...is not being worked within Canada on a commercial scale." In determining whether there has been an abuse, section 67(3) says that

> ...patents for new inventions are granted not only to encourage invention but also to secure that new inventions shall so far as possible be worked on a commercial scale in Canada without undue delay.

Taking the provisions of section 67 together, the Ilsley Commission (1960, p.78) commented that the primary intention was "directed against failure to work in Canada." This is consistent with Neumeyer's (1959, p.15) view that Canadian patent legislation "from the beginning, distinctly and unmistakably emphasized...practical working of inventions."

The Commissioner of Patents is charged with (a) deciding whether there has been abuse, as defined in section 67, and (b) granting relief, in accordance with the powers granted in sections 68 and 69.[14] One form of relief is the granting "of a license [to the applicant] on such terms as the Commissioner may think expedient...." However, the statute provides some, not altogether unambiguous, considerations which the Commissioner should take into account in setting the terms of the licence.[15] For example, the Commissioner should "endeavour to secure the widest possible use of the invention in Canada consistent with the patentee deriving a reasonable advantage from his patent rights." No royalty figure is set in the legislation. The patentee is allowed to contest, under section 71, the application of the potential licensee.

The provisions relating to the abuse of patents and compulsory licences have existed since 1923; prior to that, the only relief from abuse was the revocation of the patent.[16] However, despite its long history, little use has been made of section 67. For example, between 1935 and January 1970, the details are as follows:[17]

Licences granted	11
Applications refused	9
Applications abandoned or withdrawn	32
Applications pending	1
Total	53

As can be readily observed, by far the largest proportion of applications was unsuccessful.

The Economic Council of Canada (1971, pp.93-94) has adduced that the reason for the lack of use of the compulsory licence provisions is as follows:

> Experience, both in Canada and abroad, points to the conclusion that if a system of compulsory licensing is to work well - to encourage full technological transfer and invention-embodying production in Canada where this is economically justified, while at the same time keeping within just and reasonable bounds Canada's contribution to the economic cost of the world patent system as a whole - it must operate with a fair degree of certainty and speed....Lack of certainty and speed is believed to be a major reason why the present compulsory licensing provisions in the Patent Act, although in principle broad in their scope and applicability, have been relatively little used.[18]

This view is consistent with the experience with the compulsory licence provisions relating to the importation of drugs, which are characterized by certainty, speed and, at the same time, heavily used.

2.3.3 The Combines Investigation Act[19]

The primary objective of the Combines Investigation Act, as stated by the official with major responsibility for its administration and enforcement, is "to assist in maintaining effective competition as a prime stimulus to the achievement of maximum production, distribution and employment...." (Canada, Director of Investigation and Research, 1977, p. 7.) Patents, which consist of the awarding of a monopoly right for a 17 year period, may conflict with the objective of maintaining effective competition. This is recognized in section 29 of the Combines Investigation Act[20] which states, broadly speaking, that if patents are used to unduly limit competition, then they can be declared void, a licence issued, or the conditions changed concerning an existing voluntary licence agreement. Only the Attorney General of Canada can undertake proceedings under section 29, there being no provision for private action, unlike section 67(1) of the Patent Act. The legal proceedings are

commenced in the Federal Court. The Combines Investigation Act specifies no criteria which the court should follow in awarding a licence.[21] A provision similar to section 29 has existed, intermittently, since 1919 and, in its present form, continuously since 1946.[22]

In sharp contrast to the United States, where the equivalent of the Combines Investigation Act has been used as a vehicle to issue numerous compulsory licences,[23] there have been only four recorded instances since 1919 of legal proceedings concerned with patents.[24] In two instances, the patentee was required to issue licences[25] to applicants. There is no evidence available as to whether any licensees came forward. In one case the patent had less than two years to expiration, so that applicants would have been unlikely.

The lack of use of the patent provisions reflects two factors. First, the proceedings take such a long time that the contested patents have either expired or only have a short term left to run. This creates little incentive for businessmen to complain to the Director of Investigation and Research.[26] Second, the Patent Act contains, as outlined above, provision for private application for compulsory licences and, although there are shortcomings from the applicants' view, it nevertheless seems to have been a better option than complaining to the Director.

2.4 Compulsory Licensing: The Right to Manufacture Drugs in Canada[27]

2.4.1 Introduction

Since 1923, a provision has existed in the Canadian Patent Act for individuals and corporations to apply to the Commissioner of Patents for a compulsory licence to manufacture a drug (or food) in Canada. The relevant section, 41(3), reads as follows:

> In the case of any patent for an invention intended for or capable of being used for the preparation or production of food or medicine, the Commissioner shall, unless he sees good reason to the contrary, grant to any person applying for the same, a licence limited to the use of the invention for the purposes of the preparation or production of food or medicine but not otherwise; and, in settling the terms of such licence and fixing the amount of royalty or other consideration payable the Commissioner shall have regard to the desirability of making the food or medicine available to the public at the lowest possible price consistent with

> giving to the inventor due reward for the research leading to the invention.[28]

In 1969, section 41(3) was amended to permit the issuing of compulsory licences to import as well as manufacture. The section was also renumbered: 41(4).

Attention here is confined solely to section 41(3). This should provide a useful background to the understanding of section 41(4), since there is a considerable degree of overlap and continuity between the two sections. The judicial interpretation of 41(3) is discussed and presented in 2.4.2 together with the conditions attached to the use of a 41(3) compulsory licence to manufacture. The penultimate section is concerned with the use of 41(3) by licensees. The final section attempts, in a cursory fashion, to evaluate the effectiveness of the compulsory licence provisions.

2.4.2 The Interpretation of Section 41(3)

In interpreting section 41(3),[29] the overall approach has been set down by Abbott, J., in delivering the judgement of the Supreme Court:[30]

> In my view, the purpose of s. 41 (3) is clear. Shortly stated it is this. No absolute monopoly can be obtained in a process for the production of food or medicine. On the contrary, Parliament intended that, in the public interest, there should be competition in the production and marketing of such products produced by a patented process, in order that as the section states, they may be 'available to the public at the lowest possible price consistent with giving to the inventor due reward for the research leading to the invention'.[31]

This agreed with a similar statement made by Jackett, J., of the Federal Court, in the same case:

> In my view, the objective of the provision is to bring about competition. On balance, in most fields, competition is regarded by Parliament as being in the public interest...and also because competition tends to bring about greater efficiency, better service, and further research. The monopoly granted to an inventor is an exception to this general principle in our law. Section 41(3) was passed because, in the field to which it applies, 'the specific public interest in free competition' was deemed to be more important than the

> maintenance of the patentee's monopoly rights....[32]

Given this general background and underlying philosophy as a guideline, the specific details of the scope, royalty and other conditions attached to compulsory licences to manufacture were as follows.

First, the application of 41(3) applied to both product and process patents.[33] Second, an applicant may apply for a licence as soon as a patent is granted.[34] Third, the "royalty has been fixed at 15% of the net selling price of the bulk material made by the licensee and sold to others at arm's length with percentages varying on expiry of patents involved."[35] This would appear to be primarily a rule of thumb.[36] Fourth, the onus has been placed on the patentee to show the Commissioner "good reason to the contrary" as to why a licence should not be awarded. On this point the RTPC (1963, p.104) has stated:

> The Commissioner has not yet been convinced that an applicant was not qualified either financially or professionally, and he has rejected all arguments to the effect that the applicant had previously infringed the patent or could not produce economically in commercial quantities or that the market was already adequately supplied In this respect, the Commissioner of Patents gave the following evidence to the Commission:
>
> > "Reasons to the contrary being such as the patentee already manufacturing in Canada, public demand being fully supplied, prices being reasonable, the applicant intending to produce only the bulk material leaving to others the tableting, capsuling, compounding, etc., have all been rejected by the Commissioner of Patents in Canada and by the Comptroller General in the United Kingdom (where the law is similar to ours) and the courts have concurred where appeals have been made."

In only one instance[37] has the Commissioner found good reason to refuse a licence - the applicant appeared not to wish to manufacture, but rather to import.[38]

In sum, then, once an application for a compulsory licence to manufacture has been made to the Commissioner of Patents under section 41(3), the onus is on the patentee to justify the royalty[39] and show "good reason" why the licence

should not be awarded. In most instances the royalty would appear to be 15 percent.

2.4.3 Use of Section 41(3)

Applications for licences under 41(3) over the period 1923-1969, together with their final disposition, were as follows:[40]

Licences Granted	22
Applications Refused	4
Applications Abandoned	23
Total	49

The distribution of licence applications over the period 1923-1969 was as follows:[41]

1923-1949	0
1949-1961	14
1961-1969	35

Hence, only a few applications for a licence have been received in the 46 year period in which 41(3) was in force, mostly in the period subsequent to 1961. Less than 50 per cent of the 49 applications eventually resulted in a licence, largely because of withdrawal by the applicant.

Several reasons for the paucity of applications and the pattern over time have been suggested. The reason for no applications prior to 1949 was, according to the Harley Committee (1967, p. 38) that, "there were no drug 'winners', i.e., drugs which were 'breakthroughs' in the industry and which forecast volume sales with record profits." A similar view is also held by a commission which examined pharmacy.[42] However, although there may have been an incentive in the post-war period to apply for compulsory licences to manufacture, there were certain supply-side constraints. First, the licensee had to manufacture the drug in Canada, which has a relatively small market size.[43] The patentee, on the other hand, typically imported the active ingredient in bulk form and then prepared the dosage form in Canada. As the Harley Committee (1967, p. 8) commented:

> ...Canada, economically, is not sufficiently populated to be able to support particular raw material plants of this type; and, in consequence, a large percentage [80 percent] of the active ingredients... require importation from the United States, the United Kingdom and other countries.

The likely difference in manufacturing costs clearly placed the licensee at a disadvantage. Second, there were "many delays encountered"[44] in the granting of a licence. Of the 14 licences that were granted as of September 1966, "the shortest

period of time for the licence to issue was 5½ months with the longest taking 2½ years" (Harley Committee, 1967, pp.40-41). These delays had important potential disincentive effects. They made planning production difficult, involved expense if court proceedings were necessary and allowed the patentee that much longer to establish his brand name and hence consolidate his market position.[45] Third, in the sale of prescription drugs, the major determinant of market share is advertising expenditures rather than price competition.[46] The comparative advantage of the licensee is probably in the area of price, since the patentee will have 4 or 5 years at minimum to establish his product in the minds of doctors and pharmacists. Fourth, there was no allowance in provincial legislation, with the exception of Alberta, for product selection by the pharmacist, nor was data provided on therapeutic equivalence of the patentee's and licensee's product. Fifth, the licensees were typically smaller enterprises, not the larger multi-national pharmaceutical corporations, which would clearly have a much greater ability to overcome some of the above problems.

These reasons would appear to explain the small number of compulsory licences issued. Of particular importance is probably the first, since in the 16 months following the introduction of compulsory licences to import, in June 1969, the disposition of the 90 applications was as follows:[47]

Licences Granted	46
Applications Refused	1
Applications Abandoned or Withdrawn	17
Applications Pending as at October 30, 1970	26

None of the other four conditions had changed materially in that sixteen month period.[48]

Although only a few compulsory licences have been issued under section 41(3), it has been argued that the section led to a much greater issuing of voluntary licences.[49] The Ilsley Commission (1960, p. 95) expressed the following view, with no supporting evidence:

> It is probable that the number of compulsory licences ordered under our present section 41 is not indicative of its significance. It is generally considered that the mere existence of such provisions leads to voluntary licensing which otherwise would not take place.

The Canadian Pharmaceutical Manufacturers Association took a similar view in its brief to the RTPC and provided some evidence of voluntary licensing. However, the RTPC (1963, p. 115) interpreted this evidence as follows: "the results... do not indicate that voluntary licences are granted on a substantial

scale." In addition, the RTPC (1963, pp. 115-116) examined voluntary licensing with respect to five broad spectrum antibiotics and concluded that "no licence for any of these five products has been issued to a competitor on a truly voluntary basis" (RTPC, 1963, p. 116). Hence, voluntary licensing would not appear to have been increased significantly because of the compulsory licensing provisions of 41(3).

In sum, section 41(3) of the Patent Act, which between 1923 and 1969 allowed the Commissioner of Patents to issue compulsory licences to manufacture pharmaceuticals, has received little use. What use has occurred was concentrated in the 1949-1969 period. The reasons for the lack of utilization of 41(3) include the small size of the Canadian market, the delays encountered in the issuing of the licences, and the non-participation of existing patent owners. The first reason was felt to be the most significant.

2.4.4 Impact of Section 41(3)

It is beyond the scope of this report to go into the effectiveness of 41(3) in reducing the price of drugs. However, the available evidence suggests the impact was not of major proportions. First, only a few licences were actually taken out. No evidence has been produced as to how many were actually worked. Hence, the small number probably meant, at a minimum, the impact could only have been limited. Second, the RTPC (1963, p. 512) concluded that,

> It is the Commission's opinion that close control exercised by patents has made it possible to maintain prices at levels higher than would otherwise have obtained. The meagre use made of the compulsory licensing provision in section 41(3) of the Patent Act has meant that competition from rival producers of the same patented product has seldom occurred and thus has had little or no effect on prices.[50]

Third, drug prices in Canada were considered by the various enquiries which looked into the question in the 1960's to be too high when compared to other countries. The Harley Committee (1967, p. 15), for example, came to the "...inescapable conclusion that drug prices in Canada are in fact high and that every fair and reasonable step should be taken to reduce these prices." In other words, the prices of drugs in Canada in the 1950's and 1960's were high by international standards, and in the opinion of several Commissions, too high. Existing compulsory licence provisions had little impact.

2.5 Compulsory Licensing: The Right to Manufacture and/or Import Drugs into Canada

2.5.1 Introduction

In June 1969 the compulsory licence provisions, which had existed in the Patent Act since 1923, were amended to allow the Commissioner of Patents to grant compulsory licence applications not only to manufacture but also to import. The amended section, 41(4), read as follows:

> Where, in the case of any patent for an invention intended or capable of being used for medicine or for the preparation or production of medicine, an application is made by any person for a licence to do one or more of the following things as specified in the application, namely:
>
> > (a) where the invention is a process, to use the invention for the preparation or production of medicine, import any medicine in the preparation or production of which the invention has been used or sell any medicine in the preparation or production of which the invention has been used, or
> >
> > (b) where the invention is other than a process, to import, make, use or sell the invention for medicine or for the preparation or production of medicine,
>
> the Commissioner shall grant to the applicant a licence to do the things specified in the application except such, if any, of those things in respect of which he sees good reason not to grant such a licence; and, in settling the terms of the licence and fixing the amount of royalty or other consideration payable, the Commissioner shall have regard to the desirability of making the medicine available to the public at the lowest possible price consistent with giving to the patentee due reward for the research leading to the invention and for such other factors as may be prescribed.

The procedure for licence applications, the criteria for granting a licence, the determination of the licensee's royalty

payment, conditions of issuance, and the number of licences granted, are all addressed in this section. The rest of this study examines the impact of compulsory licences granted since 1969.

The decisions of the Commissioner and the judgements of the Federal Court show that the principles established in the 1923-1969 period applied, equally well, to the interpretation of section 41(4). In his first decision on an application, the Commissioner made the following remarks on 41(4):

> The basic change to s.41 was to enable the Commissioner of Patents to issue compulsory licences for the importation of medicines produced by patented processes or substances produced by patented processes used in the preparation of production of medicines, whereas prior to the new enactment the Commissioner had authority only to issue to applicants compulsory licences to manufacture under the patent affected....
>
> In my view, and in spite of the amendments, the direction to the Commissioner of Patents relating to the fixing of the royalty or other consideration and in settling the terms of the licence has not in fact fundamentally been changed; and hence the principles determined by the Courts in the interpretation of the former s.41(3) still remain applicable.[51]

In particular, the general intent or philosophy behind 41(3) would appear to apply equally well to 41(4). Indeed, the two quotations cited at the beginning of section 2.4.2 above on this point were introduced, approvingly, by the Commissioner in his first decision under 41(4).[52] The Commissioner then went on to remark,

> A basic issue before the Commissioner of Patents in any application for compulsory licence under s.41(4) of the Patent Act is, then, as to whether or not the grant of that licence will result in the provision of effective competition by the applicant with the patentee so that the patentee's former legal monopoly is made available to the public at the "lowest possible price" within the meaning of the subsection.[53]

In the light of these remarks, no separate consideration is given here to the general intent of 41(4).

2.5.2 Procedure for Licence Application

The procedure to be followed by the applicant for a licence, the patentee(s), and the Commissioner of Patents in administering section 41(4) of the Patent Act, is specified in a set of regulations or rules,[54] which are reproduced as Appendix A below. The regulations were issued by the Governor in Council, on the recommendation of the Minister of Consumer and Corporate Affairs, who is responsible to Parliament for the administration of the Act. Section 12 of the Act provides authority to the Governor in Council to make regulations "ensuring...due administration" of the Act. The regulations were issued in June 1969, contemporaneously with the coming into force of section 41(4).

Figure 2-1 is a schematic representation of the procedure that constrains the applicant, patentee, Commissioner and other participants under section 41(4). Since not all of the steps and time intervals are mandatory, reference to actual practice[55] under rules outlined in Figure 2-1 is necessary to determine the extent of participation of the Commissioner, applicant, patentee, and others, as well as the time taken to award a licence by the Commissioner.

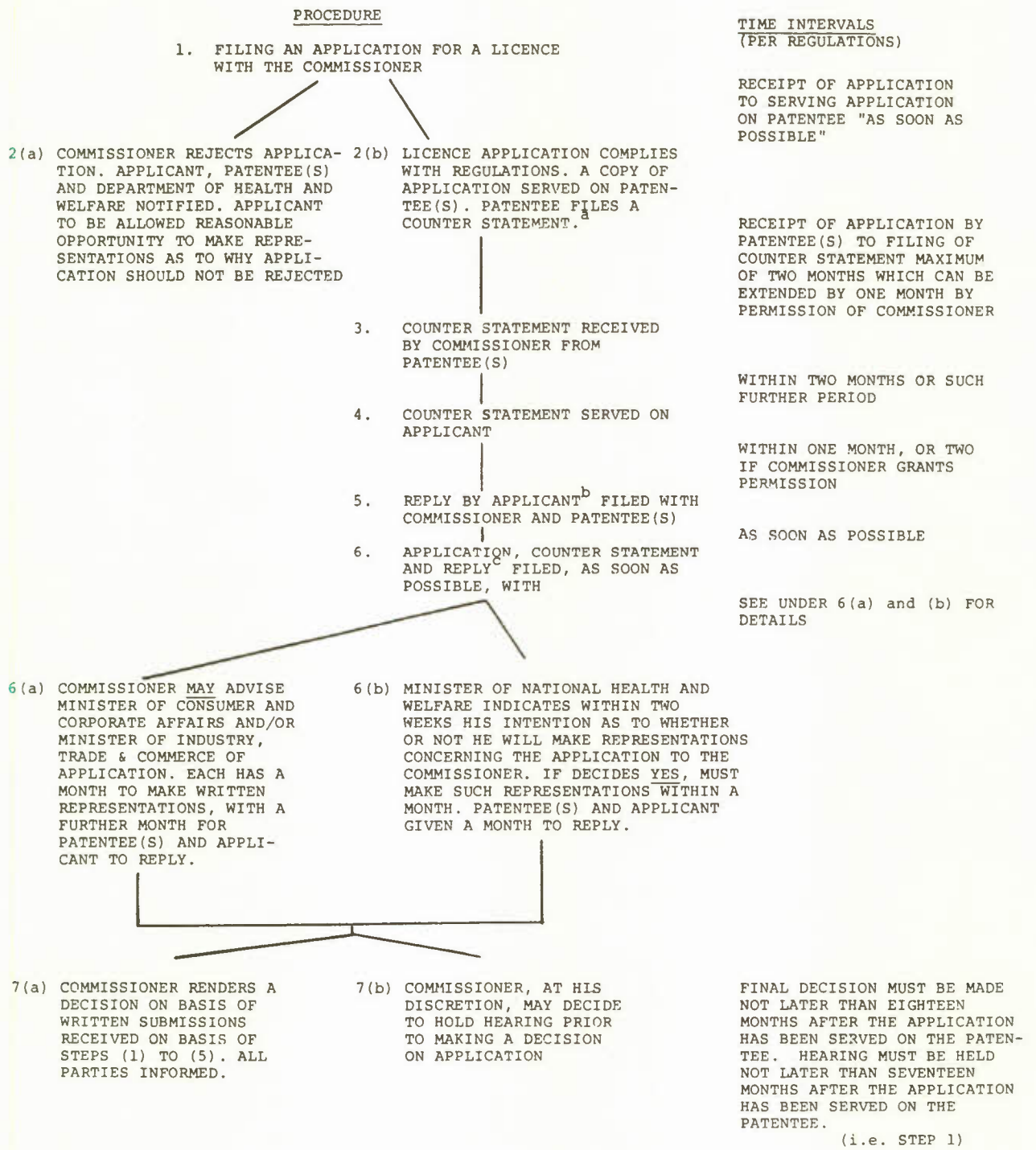
The step which starts the process is the filing of an application by the applicant for a compulsory licence. The regulations specify in some detail the information that should be included in the application:[56] the patent and patent owner; applicant's address, business, skills concerning the manufacture, importation and distribution of drugs; proposed price structure; source of supply of the imported drug; applicant's view as to appropriate royalty; previous applications of the applicant. The Commissioner rejected a small number of applications in 1969 and 1970, on the ground that the applicant did not conform to the regulations with respect to the filing of an application. However, once experience and familiarity with the process was gained, the Commissioner rarely rejected an application.

The patentee, on receipt of an application which the Commissioner has approved as complying with the regulations, usually files a counter statement, with the applicant making reply. Although the Commissioner is required to send copies of the application, counter statement and reply to the Minister of National Health and Welfare, the Minister is not required to make a representation and usually does not. The final two participants are the Minister of Consumer and Corporate Affairs and Minister of Industry, Trade and Commerce, whom the Commissioner may advise of the application and invite to make representations. However, with few exceptions, neither Minister is consulted by the Commissioner.[57]

The Commissioner, on the basis of steps 1 to 6, has a set of written statements from the applicant and, usually, the

FIGURE 2.1

STEPS REQUIRED TO OBTAIN A
COMPULSORY LICENCE UNDER SECTION 41(4)
OF THE PATENT ACT



a. Patentee(s) need not file counter statement in which case would proceed directly to step 6.
b. Applicant need not file a reply.
c. See footnotes (a) and (b).

SOURCE: See Appendix A below.

patentee. The decision as to whether to award a licence can be made by the Commissioner either on the basis of these written representations or, in addition, evidence submitted during a hearing. The decision is at the discretion of the Commissioner.[58] Apart from some early decisions[59] involving important principles that would be applied to subsequent applications, the Commissioner usually has not held a hearing, but has rendered a decision on the basis of the written submissions.[60] Almost without exception, the Commissioner has granted the application for a licence. This prompted the Canadian Patent Reporter (1970, p. 94) to remark that, "As a practical matter, the licence will be granted almost as a matter of course."

The regulations specify the maximum time allowed for completion of most of the steps in the procedure under 41(4), as well as a global maximum of 18 months from the time the application is served on the patentee. Since, typically, some of the optional steps are not included and the applicant has an incentive to complete steps solely his responsibility in less than the allotted time,[61] it is likely the time taken to complete proceedings under 41(4) will be substantially less than 18 months, the upper limit specified in the regulations. This is supported by the evidence presented in Table 2-1 which shows that 82.3 percent of licences issued on applications made between 1969 and 1977 took less than 12 months from the date of the application being received by the Commissioner and that official issuing the licence. The average time taken was 9.6 months. Hence, the applications are usually processed much more quickly than the statutory maximum of 18 months.

Although the Commissioner has the power and authority under the Patent Act to issue compulsory licences under section 41(4), his decision can be appealed, in the first instance, to the Federal Court and, eventually, to the Supreme Court of Canada. The patentee or the applicant can appeal the Commissioner's decision, although almost without exception, it is the patentee who appeals. The small number of appeals[62] from the decision of the Commissioner has never resulted in that official's decision being overturned, although in two instances, some minor clarification of the Commissioner's terms of a licence did take place.[63] The lack of success in appeals by the patentee reflects two factors. First, the view of the courts, as expressed by King, J., that,

> ...the Court should not interfere with the manner in...which the Commissioner performs his licensing unless it is apparent that he is wrong in exercising jurisdiction and unless it is shown that the right of appeal to the [Federal Court] would be an inadequate remedy.[64]

Table 2-1

FREQUENCY DISTRIBUTION[a] OF TIME TAKEN IN MONTHS FOR A COMPULSORY LICENCE TO BE ISSUED FROM THE DATE OF APPLICATION TO THE COMMISSIONER 1969-1977[b]

Number of Months	Frequency	
	Percentage	Cumulative Percentage
1	0.0	0.0
2	0.0	0.0
3	2.2	2.2
4	4.4	6.6
5	15.6	22.2
6	4.4	26.6
7	0.0	26.6
8	8.9	35.5
9	8.9	44.4
10	15.6	60.0
11	15.6	75.6
12	6.7	82.3
13	6.7	89.0
14	4.4	93.4
15	2.2	95.6
16	0.0	95.6
17	0.0	95.6
18	0.0	95.6
19[c]	2.2	97.8
20[c]	2.2	100.0

a. Based on a 20 percent sample.
b. Sample refers to licence applications which were successful and made in the period 1969 to 1977. Later years are not included, since all applications are not processed and hence the inclusion of completed applications would bias the time taken downwards.
c. As reported in the text, the regulations specify an upper limit of 18 months. In some instances the application received by the Commissioner of Patents may not have been completed correctly, requiring some modification by the applicant. Hence, the actual date a completed application is received may be different from the receipt of the initial application.

Source: Public Files of the Commissioner of Patents, Department of Consumer and Corporate Affairs, Ottawa, 1979.

Second, a number of appeals would seem to be made by the patentee purely for the sake of an appeal (i.e., without merit). For example, Jackett, C.J., remarked that,

> ...there is...some ground for thinking that many appeals under s.41 of the Patent Act are brought regardless of any considered opinion that there is, under the authorities, any valid ground for attacking the Commissioner's decision.[65]

Hence, to all intents and purposes, the final word on a licence application is the Commissioner's decision.

2.5.3 Criteria for Granting a Compulsory Licence

In deciding whether or not to grant a licence under section 41(4), the Act specifies that,

> ...the Commissioner shall grant to the applicant a licence to do the things specified in the application except such, if any, of those things in respect of which he sees good reason not to grant such a licence...

The Commissioner's interpretation is as follows:

> In short, compulsory licences applied for under s.41 of the Patent Act leave little discretion to the Commissioner of Patents. These licences, in fact, amount almost to licences of right. What the Commissioner of Patents is required to do is mandatory unless he sees good reason not to grant the licence applied for [emphasis in original].[66]

The issue, then, in granting a compulsory licence, is the meaning of "good reason." Apart from the applicant not filing an application complying with the regulations, which is determined by the Commissioner, the onus is on the patentee to provide good reason to the Commissioner.

The decisions of the Commissioner and the courts provide several instances of attempts by the patentee to demonstrate the existence of good reason: that the application related to a product which was issued prior to section 41(4), and that this section is not retroactive;[67] that the applicant has not been shown to be capable of processing final dosage forms, from the imported bulk active ingredient, which produce clinically effective blood levels;[68] that the applicant made false material representations in the application for a licence;[69] that the applicant is requesting licences on patents for which the patentee is charging a

reasonable price.[70] In all instances,[71] the patentee was judged not to have provided good reason. Hence, it would appear virtually impossible for the patentee to provide "good reason" for the Commissioner not to grant a licence to an applicant, who had completed an application in conformity with the regulations.

2.5.4 Determination of Level of Royalty

In fixing the royalty which the licensee or applicant should pay the patentee, the Act provides the following guidelines to the Commissioner:

> ...the Commissioner shall have regard to the desirability of making the medicine available to the public at the lowest possible price consistent with giving to the patentee due reward for the research leading to the invention and for such other factors as may be prescribed.

No other factors have been prescribed to aid the Commissioner in determining the royalty, although there has been at least one suggestion as to what they might be.[72]

The Commissioner, in his first decision under section 41(4), set out at some length the reasons and criteria used to determine the royalty level.[73] At one point in his decision the Commissioner summarized the determination of the royalty figure thus,

> The percentage chosen must, after full consideration, attempt to balance the statutory requirement of "giving to the patentee due reward for the research leading to the invention", as interpreted by the Courts, against "making the medicine available to the public at the lowest possible price". It is a decision that involves the public interest as an over-riding factor but which also recognizes that part of such interest relates to the maintenance of research incentive and the importance of process and substance.
>
> Were the product involved not subject to compulsory licensing under the provisions of s.41, it would be reasonable to assume that a willing patentee and a willing licensee, bargaining under equal terms, would fix a royalty at 10% of the net selling price to customers at arm's length. Indeed, this might even be considered a generous royalty. In applications for compulsory licences falling within s.41,

> however, such a high figure cannot be used. The percentage figure of net sales should be substantially lower to eliminate consideration of those expenses incurred by the opponent after those that led to the invention.
>
> Taking all these factors into account, therefore, I fix the royalty payable to the patentee at 4% of the net selling price of the drug in its final dosage form or forms to purchasers at arm's length.[74]

The four percent royalty became the standard which the Commissioner used as a yardstick to judge all other applications.[75] The onus was on the patentee or applicant to demonstrate that four percent was the incorrect royalty. Almost without exception such attempts were unsuccessful.[76] The royalty level of four percent was usually disputed on appeal from the Commissioner's decision by the patentee rather than the applicant.[77]

In setting the royalty, two complicating factors occurred: the application usually covered multiple patents owned by a single patentee;[78] occasionally the drug applied for was covered by patents held by more than one corporation. In both instances the Commissioner designed rules of thumb to facilitate quick processing of the application. Where there was more than one patentee involved, the Commissioner followed the rule of thumb of dividing the four percent royalty equally among the patentees.[79] In these instances where there are several patents at issue, the four percent royalty was payable until the last patent expired. The Commissioner remarked as follows:

> Whether one or more patents are included in the licence is not of consequence: the royalty is based on the "package" of those patents claimed to be required to produce the invention, i.e., the medicine, and represents an average assessment over the term of that patent within the "package" which expires last.[80]

The Commissioner felt too much uncertainty and arbitrariness would result if an attempt was made to assign royalties by patent.[81]

2.5.5 Conditions of Issuance

The main terms and conditions attached to a compulsory licence issued by the Commissioner may be summarized as follows: procedures to settle disputes between the patentee and licensee; methods for the patentee to verify the actual royalty paid is correct; the sale of the drug is not restricted to Canada; the licence is non-exclusive (i.e., the same licence can be issued by

the Commissioner to other applicants); the licence holder cannot grant a sublicence; if the Governor in Council prescribes any factors to be taken into account by the Commissioner in assessing the royalty, then either the patentee or licensee can request a reassessment. Appendix C reproduces a typical example of a compulsory licence.

It should be noted that patentees have requested, at various times, the Commissioner to place restrictions and constraints on the licensees' use of the patent. For example, Hoffmann-La Roche Ltd. wanted the licensee to sell "Diazepam under its generic name, and not under a trade name of its own,"[82] and be restricted to the source of supply mentioned in the application.[83] These attempts have been unsuccessful. In one instance, Thurlow, J., gave the following reasons for denying the restriction requested by the patentee,

> I cannot think it likely that such a system [i.e., restriction requested] would be helpful in achieving the objective of the section to provide effective competition in the Canadian market and in my opinion no such restrictive effect on the licence is intended by the requirement of the rule.[84]

A similar motive may have been responsible for the denial of other restrictions requested by the patentee.

2.5.6 Number of Licences Issued

Table 2-2 shows that over the period 1970 to 1978, 227 compulsory licences were issued, an average of 25 per year. The distribution over the period has been quite uniform, but there have been noticeable peaks in 1970 and 1977. Compulsory licences under section 41(4) can be either to import and/or to manufacture in Canada. Most of the licences taken out were either to import and manufacture (57.7 percent) or to import (37.4 percent). Only 4.9 percent of all compulsory licences were to manufacture in Canada. The combining of the right to import and manufacture probably reflects the fact that many applicants will import the active ingredient of the drug and prepare the final dosage form and strength in Canada.

Table 2-2 refers only to those instances in which a licence was issued by the Commissioner. It excludes from consideration licence applications which were abandoned, withdrawn or cancelled by the applicant, and instances in which the Commissioner refused to issue a licence. The relative frequency of such occurrences over the period 1969-1977 was as follows:[85]

Table 2-2

NUMBER OF COMPULSORY PATENT LICENCES ISSUED UNDER SECTION 41(4): 1970[a]-1978

Year	NUMBER of LICENCES			
	Total	To Manufacture	To Import	To Import and Manufacture
1970	52	4	4	44
1971	24	1	12	11
1972	21	2	15	4
1973	19	2	11	6
1974	19	1	13	5
1975	17	0	9	8
1976	26	1	12	13
1977	33	0	9	24
1978	16	0	0	16
Total	227	11	85	131

a No licences were issued in the period June 1969, when Section 41(4) came into force, and the end of 1969.

Source: Bureau of Intellectual Property, Department of Consumer and Corporate Affairs. See Appendix D below for further details.

Abandoned, withdrawn or cancelled	23
Refused	5
Total	28

These numbers should be interpreted with some caution: in over half of the instances, the applicant successfully re-applied for a licence; 18 of the 28 unsuccessful applications referred to the period June 1969 to December 1970 and undoubtedly reflect a trial and error learning process by applicants. For example, although a licence is only issued for a single drug entity, Rocke William Cie. Ltée. applied for nine drug entities in one application, including such big sellers as diazepam, chlordiazepoxide and ampicillin, in September 30, 1969.

In sum, a large absolute number of licences have been issued over the period 1970-1978. However, about 10 percent of all applications were unsuccessful. This is a considerable overstatement, since successful re-applications were made in over half of the cases.

2.6 Summary and Overview

The discussion in this chapter has shown that the protection afforded the drug patent owner has progressively declined over the period 1923 to the present: the definition of a drug patent was made process dependent (i.e., anybody who could make the drug by a different process to that patented was free to take out a patent on that process and sell the drug[86]) and remains unchanged since 1923; compulsory licences to manufacture have been available since 1923, while importation was added in 1969. This gradual lessening of protection of drug patents has not been part of coherent, consistent government strategy, but rather the result of a series of ad hoc steps. The 1923 definition of a drug patent was taken from a British patent of 1919, the "intention...[of which] was to provide some relief to the British chemical industry from the domination by German chemical industrialists" (Canada, Department of Consumer and Corporate Affairs, 1976, pp. 121-122), while the 1969 compulsory licence to import provisions were a reflection of concern over the high price of drugs.

The main objective of this study is an evaluation of the success and impact of the 1969 compulsory licence provisions. In terms of the number of such licences issued and the time taken to process the application, the 1969 provisions would appear to be very successful compared to the 1923-1969 compulsory licence provisions, which related to manufacturing only. For example, in the 1970-1978 period, 227 licences were issued, while between 1923 and 1969 only 22 licences were issued. Hence, if the 1969 compulsory licence provisions failed to achieve their primary objective - reduced drug prices - it would not appear to be for lack of licences or the administration of the amendments and their regulations by the Commissioner.

CHAPTER III

COMPULSORY LICENSING: PATTERNS AND DETERMINANTS

3.1 Introduction

This chapter is principally concerned with an examination of the pattern of compulsory patent licensing and the determinants of the incidence of licensing. However, before these patterns and determinants can be addressed, a number of definitional and sample selection issues need to be discussed. Section 3.2.1 defines a compulsory licence for this and all the succeeding parts of the study. It builds on the material introduced earlier. Only a sample of all licensed drugs, that is, prescription drugs, are considered in this study. The reasons for this choice and significance of prescribed, rather than all licensed drugs are discussed in section 3.2.2. The next section, 3.3, details the number of licences issued by drug and by pharmacologic-therapeutic classification. The incidence of the working of the licences (i.e., the licensee marketed the drug) is also presented. The penultimate section attempts to estimate, empirically, the major determinants of the incidence of licensing. Finally, the implications of the results are discussed and described in section 3.5.

3.2 Some Preliminaries: Definition and Sample Selection

3.2.1 Definition of Compulsory Licence

The previous chapter showed that over the period 1970 to 1978, 227 compulsory licences were issued by the Commissioner of Patents under section 41(4) of the Patent Act. The figure of 227 should not, however, be interpreted as x number of firms have taken out, on average, separate licences on y number of drugs, where xy=227, since multi-licences were taken out against the same drug. Three reasons may be cited for this practice. First, in some instances, the patents on a drug may be held by more than one patentee. In such instances the applicant makes a separate compulsory licence application for the patents held by each patentee. For example, on Dec. 1, 1971 the Commissioner of Patents issued four compulsory licences to Frank W. Horner Ltd. to manufacture and import ampicillin, each being for a separate patent holder.[1] Second, a patentee may have taken out a set of patents for a drug in, say, 1964 and then introduced some patented improvements in 1974. A compulsory licence may have been issued against the original set of patents in 1971 and then a subsequent compulsory licence issued in 1974 to include the improvements.[2] Third, a licensee may apply separately, at different times, for a licence to import and manufacture, rather than, as is usual, in a single licence application.[3] In order to focus attention on the number of drugs per firm for which compulsory licences have been issued, the following convention is adopted: when a firm holds more than one compulsory licence on any given drug, for any of the three reasons cited above, all of the compulsory licences will be treated as though one application was made. Unless otherwise expressly stated this convention is followed throughout the remainder of the text and tables.

3.2.2 Sample Selection of Licensed Drugs

The Commissioner of Patents has issued, over the period 1970 to 1978, a total of 152 licences under section 41(4) covering 55 drugs. The Patent Act does not restrict the category or classification of drugs for which a compulsory licence application may be granted. As a result not all of the licensed drugs can be classified as "prescription." The breakdown is as follows:

Drug Category	Licences	
	Drugs	Number
Human		
Ethical		
Prescription	47	142
Non-prescription	5	6
Other	2	2
Non-Human		
Veterinary	1	2
Total	55	152

Source: Appendix F below.

This study concentrates upon prescription drugs in examining the impact and effects of compulsory licensing. This choice was made for several reasons. First, the various government inquiries conducted into the price of drugs in the 1960's, which led to section 41(4) being enacted, appeared to be principally concerned with prescription drug prices.[4] For example, the Hall Commission's (1964, pp. 39-45) recommendation that compulsory licensing to import be introduced, is made under the section entitled, "Prescription Drug Services." Second, as the above tabulation shows, of the 152 licences issued, 142 (or 93.4 percent) were for prescription drugs, while of the 55 licensed drugs, 47 (or 85.5 percent) were classified as prescription. Hence, it would appear that the main impact of compulsory licensing is likely to be on the prescription drug market, not veterinary drugs or those that can be purchased by the patient, without a prescription, from the pharmacist (i.e., non-prescription drugs in the above tabulation). In other words, ignoring licensed drugs that fall into categories other than "prescription" would not appear to seriously underestimate the effects and impact of compulsory licensing. Third, it has been recently estimated that of the various categories of drugs delineated above, prescription drugs are by far the most significant in terms of sales. The relative proportions are 100:56:13, as between prescription, non-prescription and veterinary, respectively. (See Canada, Department of Industry, Trade and Commerce, 1980, p. 8). Thus, the prescription drug market is not only the most important in terms of licences, but also in terms of economic size. Since attention is being confined solely to prescription drugs, unless otherwise stated, the term "drugs" will be understood to refer to prescription drugs throughout the remainder of the text and tables.

3.3 The Pattern of Compulsory Licences

Over the period 1970 to 1978 there were a total of 47 drugs against which 142 compulsory licences were issued by the Commissioner of Patents. In other words, an average 3.0 compulsory licences were issued on each drug. In terms of individual drugs the five most significant were as follows:

Drug (Patentee Brand)	Number of Licences Issued
chlordiazepoxide (Librium)	11
diazepam (Valium)	11
furosemide (Lasix)	11
ampicillin (Penbritin)	8
thioridazine (Mellaril)	7
Total	48

The remaining 42 drugs accounted for 94 licences. In 16 instances the Commissioner issued only a single licence. In other words, the distribution of the number of licences issued by drug is moderately skewed with 10.6 percent of the drugs (5/47) accounting for 33.8 percent of the licences (48/142).

An alternative method of examining the drugs against which licences were issued and the frequency of licensing is to categorize by pharmacologic-therapeutic classification. This classification system groups drugs which are concerned with similar human medical problems or treatments such as cardio-vascular drugs or cough preparations.[5] The results are presented in Table 3-1 for the period 1970-78 (subdivided into 1970-72 and 1973-78) by number of drugs for which compulsory licences have been issued and the frequency of issuance.[6] The table shows a small number of categories account for a very large percentage of compulsory licences issued. In particular, for the period 1970 to 1978, 80.9 percent of all drugs for which a compulsory licence was issued and 85.9 percent of all compulsory licences belonged to the anti-infective, cardiovascular and central nervous system groupings. A similar concentration was recorded for both of the sub-periods in Table 3-1. Twelve of the nineteen [7] categories in Table 3-1 contained no drugs against which a compulsory licence was issued. Hence, the distribution of compulsory licences by pharmacologic-therapeutic classification is heavily skewed when measured either by the number of drugs for which a licence has been issued or the total number of licences.

During the two sub-periods 1970-72 and 1973-78, Table 3-1 shows an equal number of compulsory licences were issued (71 vs. 71), despite the fact that the latter period is twice the length of the former. In other words, the issuing of licences was concentrated in the period immediately following the introduction of section 41(4) in June 1969. Licences taken out

TABLE 3-1

DRUGS FOR WHICH COMPULSORY LICENCES HAVE BEEN ISSUED, CLASSIFIED BY PHARMACOLOGIC-THERAPEUTIC GROUPINGS AND YEAR: CANADA, 1970-1978

Pharmacologic-Therapeutic Classification	Significance of Each Classification[a]		Drugs For Which Licences Were Issued[b]					
	Number of Prescriptions	Total Sales	1970-1972[c]		1973-1978[c]		1970-1978[c]	
			Drugs	Frequency	Drugs	Frequency	Drugs	Frequency
	Percentage		Number					
4:00 Antihistamines	0.2	0.1	0	0	0	0	0	0
8:00 Anti-Infectives	22.5	18.3	5	18	8	13	11	31
12.00 Autonomic Drugs	3.3	4.3	0	0	0	0	0	0
20:00 Blood Formation and Coagulation	0.3	0.3	0	0	0	0	0	0
24:00 Cardiovascular Drugs	11.2	13.3	5	7	6	21	8	28
28:00 Central Nervous System Drugs	26.2	24.7	14	39	14	24	19	63
36:00 Diagnostic Agents	0.5	0.3	0	0	0	0	0	0
40:00 Electrolytic, Caloric and Water Balance	7.2	4.7	0	0	0	0	0	0
48:00 Cough Preparations	2.1	1.7	0	0	0	0	0	0
52:00 Eye, Ear, Nose and Throat Preparations	2.5	1.8	0	0	0	0	0	0
56:00 Gastrointestinal Drugs	0.6	0.6	1	1	1	1	2	2
60:00 Gold Compounds	0.02	0.5	0	0	0	0	0	0
64:00 Metal Antagonists	0.03	0.2	0	0	0	0	0	0
68:00 Hormones and Substitutes	13.6	15.1	3	5	1	1	3	6
76:00 Oxytocics	0.01	0.004	0	0	0	0	0	0
84:00 Skin and Mucous Membrane Preparations	6.4	7.5	1	1	3	7	3	8
86:00 Spasmolytics	0.6	0.6	0	0	0	0	0	0
88:00 Vitamins	0.8	0.5	0	0	0	0	0	0
92:00 Unclassified	1.5	5.2	0	0	1	4	1	4
Extemporaneous Preparations	0.5	0.7	0	0	0	0	0	0
Total	100	100	29	71	34	71	47	142

a. Based upon data for Saskatchewan for 1977/78 (see Saskatchewan, Department of Health, 1978, Table V, p. 18). The relative significance of the categories would appear to have remained stable over the period 1975/76 - 1977/78 (see Saskatchewan, Department of Health, 1978, Figure 3, p. 14). Saskatchewan accounts for approximately 4 per cent of the drug market in Canada (see Scrip, 1979, p. 3). While differences are likely to exist between Saskatchewan and Canada, it is believed the relative importance of pharmacologic-therapeutic classifications for Saskatchewan are broadly representative of Canada.

b. Multiple licences issued on the same drug to the same firm are treated as a single licence in this table.

c. Licences are dated by the year they were issued by the Commissioner of Patents.

Source: Appendix D below; Saskatchewan, Department of Health (1978); Scrip (1979); and various provincial government drug formularies.

in the period 1973-78 reflect two factors: new licensees, such as Apotex Ltd., Canada Packers Ltd., and K-Line Pharmaceuticals Ltd; and existing (i.e., 1970-72) licensees taking out compulsory licences on hitherto unlicensed drugs such as flurazepam, haloperidol and amoxicillin.

The application for a compulsory licence indicates an intention, almost certainly serious, by the applicant to market the drug. However, this intention may not be realized. The lag between the application and issuance of the licence by the Commissioner as reported in Chapter II, is, on average, 9.6 months. In such a time span the factors and assumptions upon which the application was based may change, thus causing the applicant to revise his decision to market the drug: a new and improved product may be launched, substantially reducing the demand for the patentee's (and hence licensee's) product; the patentee may reduce the price of the drug to an unprofitable level in anticipation of the licensee's entry; the patentee's drug may not be removed from "New Drug Status" as the licensee had expected, thereby increasing the cost to the licensee of marketing the drug, for reasons explained below.

Even if the licensee actually offers the drug for sale, there is the possibility that sales will not be satisfactory thereby causing the licensee to withdraw it from the market. This failure could be the result of factors similar to those mentioned above. In addition, the licensee may fail to get the drug listed in the provincial formularies.

In considering whether a licence has been worked (i.e., the licensee has marketed the drug), licences are divided into three categories: those for which there is no evidence that the licence resulted in a drug being marketed by the licensee; instances in which the licensee marketed the drug and subsequently withdrew it from sale; and, finally, licensees which marketed the drug and still offer the drug for sale. The relevant information is provided in Table 3-2. This table should be read as follows: for, say, 1970 there were 48 licences issued and, of these, there is no evidence 14 were ever worked; in 6 cases a drug was marketed but was subsequently withdrawn; and for the remaining 28 licences, a drug was marketed and, as of August 1979, is still being dispensed by pharmacists.

Table 3-2 shows a considerable shortfall in the use of licences by the licensees. Over the period 1970-78, of the 142 licences issued, 86 or 60.6 percent were worked and of these 72 or 50.7 percent are presently being worked. The licences that were not worked are clustered in the periods 1970-72 and, to a lesser extent, 1976-77. In addition to the reasons listed above, three others may be cited to account for licences not being worked. First, for some of the licences taken out in the period 1976-77, the licensees may still be in the process of bringing the drug on the market. Second, because of concern among licensees in the middle and late 1970's that changes (i.e., abolition or severe restriction) might be made in section 41(4)

TABLE 3-2

INCIDENCE OF WORKING[a] OF COMPULSORY PATENT LICENCES ISSUED UNDER SECTION 41(4): 1970-1978[b]

Year[c]	Total Number Issued[c]	Licences Not Worked		Licences Worked But Drug No Longer Sold		Licences Worked and Drug Currently[d] on the Market	
		No.	%	No.	%	No.	%
1970	48	14	(25.0)	6	(42.9)	28	(38.9)
1971	11	4	(7.1)	4	(28.6)	3	(4.2)
1972	13	6	(10.7)	2	(14.3)	5	(6.9)
1973	12	4	(7.1)	0	(0)	8	(11.1)
1974	11	7	(12.5)	0	(0)	4	(5.6)
1975	11	3	(5.4)	0	(0)	8	(11.1)
1976	12	8	(14.3)	0	(0)	4	(5.6)
1977	18	7	(12.5)	0	(0)	11	(15.3)
1978	6	3	(5.4)	2	(14.3)	1	(1.4)
Total	142	56	(100)	14	(100)	72	(100)

a. Working is defined as the licensee has marketed the drug for which a licence was issued.
b. No licences were issued between June 1969, when section 41(4) of the Patent Act came into force, and the end of 1969.
c. Licences are dated by the year they were issued by the Commissioner of Patents.
d. As of August 1979.

Source: Print-out of current (i.e., August 1979) drugs on the market supplied by the Bureau of Drugs, Department of National Health and Welfare; various provincial government formularies (Ontario and Quebec); Canada, Department of National Health and Welfare (1972, 1974, 1975c, 1975d).

of the Patent Act, more applications for licences may have been made as an "insurance" policy against legislative change. Third, Table 3-2 measures the working of a licence by whether the licensee marketed the licensed drug. In a very small number of instances, almost exclusively in the period 1970-72, licences were taken out to manufacture the active ingredient, with often no intention on the part of the licensees of marketing the drug in final dosage form.[8] Those would have been counted here as not worked. Nevertheless, in spite of these qualifications there is a large disparity between the number of licences which have been issued and the number worked.[9]

An alternative method of examining the discrepancy between licences issued and worked is presented in Table 3-3. The pharmacologic-therapeutic classification is the same as that used in Table 3-1 above. Columns 1 and 2 refer to the number of licences issued by drug and frequency respectively, while columns 3 and 4 provide the corresponding frequency distribution for licences which were worked. The last two columns refer to licences which were not worked.

The table shows that the distribution, by pharmacologic-therapeutic classification, is very similar for licences issued, worked or not worked. For example, the three most important categories (i.e., anti-infectives, cardiovascular drugs and central nervous system drugs) accounted for 85.9 percent of the number of licences issued, 88.4 percent of those worked, and 82.1 percent of those not worked respectively. In terms of the numbers of drugs, these three categories accounted for 80.9 percent of the drugs for which licences were issued, 81.2 percent of the drugs for which licences were worked and 80.0 percent of those for which licences were not worked. The shortfall of 56 licences not worked consisted of 23 attributable to 15 drugs that were never marketed by a licensee, and 33 to drugs that were marketed by licensees, but not to the extent indicated by the number of licences issued (that is, some firms did not work their licences for these drugs).[10]

In sum, this section began with an initial benchmark, the number of licences issued, as a gauge with which to start to measure the impact of compulsory patent licensing. The data showed that over the period 1970-78, 142 licences were issued against 47 drugs. However, the application and issuing of a licence is only an indication of an intention to work the licence. For example, of the 142 licences issued, only 86 were worked. Hence, any consideration of the impact of compulsory patent licensing must take into account the discrepancy between licences issued and worked. The next section considers some of the determinants of the incidence of compulsory patent licensing and, as such, may provide useful clues into their impact.

TABLE 3-3

DRUGS FOR WHICH COMPULSORY LICENCES[a] HAVE BEEN ISSUED, CLASSIFIED BY PHARMACOLOGIC-THERAPEUTIC GROUPINGS AND WHETHER WORKED.[b] CANADA, 1970-1978.[c]

Pharmacologic-Therapeutic Classification	Drugs for Which Licences Were Issued[d]				Drugs for Which Licences Were Worked				Drugs For Which Licences Were Not Worked			
	Drugs		Frequency		Drugs		Frequency		Drugs		Frequency	
	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	%	No.	%
4:00 Antihistamines	0	(-)	0	(-)	0	(-)	0	(-)	0	(-)	0	(-)
8:00 Anti-Infectives	11	(23.4)	31	(21.8)	8	(25.0)	20	(23.3)	3	(20.0)	11	(19.6)
12.00 Autonomic Drugs	0	(-)	0	(-)	0	(-)	0	(-)	0	(-)	0	(-)
20:00 Blood Formation and Coagulation	0	(-)	0	(-)	0	(-)	0	(-)	0	(-)	0	(-)
24:00 Cardiovascular Drugs	8	(17.0)	28	(19.7)	5	(15.6)	16	(18.6)	3	(20.0)	12	(21.4)
28:00 Central Nervous System Drugs	19	(40.4)	63	(44.4)	13	(40.6)	40	(46.5)	6	(40.0)	23	(41.1)
36:00 Diagnostic Agents	0	(-)	0	(-)	0	(-)	0	(-)	0	(-)	0	(-)
40:00 Electrolytic, Caloric and Water Balance	0	(-)	0	(-)	0	(-)	0	(-)	0	(-)	0	(-)
48:00 Cough Preparations	0	(-)	0	(-)	0	(-)	0	(-)	0	(-)	0	(-)
52:00 Eye, Ear, Nose and Throat Preparations	0	(-)	0	(-)	0	(-)	0	(-)	0	(-)	0	(-)
56:00 Gastrointestinal Drugs	2	(4.3)	2	(1.4)	0	(-)	0	(-)	2	(13.3)	2	(3.6)
60:00 Gold Compounds	0	(-)	0	(-)	0	(-)	0	(-)	0	(-)	0	(-)
64:00 Metal Antagonists	0	(-)	0	(-)	0	(-)	0	(-)	0	(-)	0	(-)
68:00 Hormones and Substitutes	3	(6.4)	6	(4.2)	2	(6.3)	2	(2.3)	1	(6.7)	4	(7.1)
76:00 Oxytocics	0	(-)	0	(-)	0	(-)	0	(-)	0	(-)	0	(-)
84:00 Skin and Mucous Membrane Preparations	3	(6.4)	8	(5.6)	3	(9.4)	7	(8.1)	0	(-)	1	(1.8)
86:00 Spasmolytics	0	(-)	0	(-)	0	(-)	0	(-)	0	(-)	0	(-)
88:00 Vitamins	0	(-)	0	(-)	0	(-)	0	(-)	0	(-)	0	(-)
92:00 Unclassified	1	(2.1)	4	(2.8)	1	(3.1)	1	(1.2)	0	(-)	3	(5.4)
Extemporaneous Preparations	0	(-)	0	(-)	0	(-)	0	(-)	0	(-)	0	(-)
Total	47	(100)	142	(100)	32	(100)	86	(100)	15	(100)	56	(100)

a. Multiple licences issued for the same drug to the same firm are treated as a single licence in this table.
b. Working is defined as the licensee having marketed the drug, for which a licence has been issued, by August 1979.
c. No licences were issued between June 1969, when section 41 (4) of the Patent Act came into force, and the end of 1969.
d. Licences are dated by the year they were issued by the Commissioner of Patents.

Source: Table 3-1, above; print-out of current (i.e., August, 1979) drugs on the market supplied by the Bureau of Drugs, Department of National Health & Welfare; various provincial government formularies (Ontario and Quebec); and Canada, Department of Health and Welfare (1972, 1974, 1975c, 1975d).

3.4 The Determinants of the Pattern of Compulsory Patent Licences

3.4.1 The Determinants

It is usual in neo-classical economics to assume that the objective of the firm is to maximize profits in present value terms, which is defined simply as total revenue minus total cost. Revenue represents the demand side while costs are the reflection of the supply side. This is a perfectly general framework into which can be fitted the decision to apply for a compulsory patent licence and subsequently market the drug. On the demand side are factors such as the size of the market, the rate of growth, and the acceptance of the licencee's product and the price of substitutes. The supply side factors include the status of drug (i.e., "New" or "Old" drug), the significance of economies of scale in production, and the availability and cost of the active ingredient. In this section each of these factors is considered separately, and with empirical evidence where it is available. In addition, multiple regression analysis is presented in order to quantify the influence of demand and supply side factors. However, due to data limitations, the equations estimated are limited in scope.

Size of Market. For a given investment in obtaining a compulsory patent licence and subsequently marketing the drug, the return is likely to be higher the larger the size of the market for several reasons: any scale economies have a greater chance of being realized; the fixed investment can be spread over a greater number of units; it is precisely in the large volume multiple service drug categories that provincial drug programmes desire to lower costs and hence are willing to encourage the use of the licensee's product[11]; and, finally, the patentee may be willing to "tolerate" a number of fringe firms with relatively small market shares, so long as they pose no significant threat to his position. Hence the incidence of compulsory patent licensing is likely to be positively related to the size of the market for the drug.

Several possible measures of market size could be utilized: the total market value of drug sales, the total number of prescriptions dispensed, and volume of tablets or capsules (or their equivalents) dispensed. If all tablets and capsules of similar weight and size were the same price and dispensed in similar quantities then it would be irrelevant which measure of market size was selected. However, this is typically not the case. Size and number of prescriptions across drugs differ, thus making comparisons difficult. Even for a given type of drug, licensee and patentee prices differ considerably, despite the fact that they may be considered perfect substitutes by the provincial drug quality committees. For example, the ratio of the patentee/ licensee price for diazepam 5 mg. tablets varied between 2.97 and 1.51 in one provincial formulary in 1977.[12] (Diazepam was one of three drugs each having eleven licences issued for it). This price differential probably reflects a

degree of product differentiation, at least on the demand side. Nevertheless, despite these disadvantages, value of sales or number of prescriptions dispensed are likely to indicate fairly accurately differences between large, small and medium sized markets.[13]

Table 3-1, presented above, provides the starting point for considering the significance of market size as a determinant of the pattern of compulsory patent licensing. The table records the percentage of prescriptions and sales by drug manufacturers for each pharmacologic-therapeutic classification. As can be readily observed, there would appear to be a close similarity between categories ranked by prescriptions and sales, on the one hand, and drugs and frequency, on the other. For example, details of the most important categories, ranked by prescriptions and sales, are as follows.

Classification	All Drugs		Licensed Drugs	
	Prescriptions	Sales	Drugs	Frequency
	(Rank)		Percentage	
Central Nervous System Drugs	(1) 26.2	(1) 24.7	(1) 40.4	(1) 44.4
Anti-Infectives	(2) 22.5	(2) 18.3	(2) 23.4	(2) 21.8
Hormones and Substitutes	(3) 13.6	(3) 15.1	(4) 6.4	(4) 4.2
Cardiovascular Drugs	(4) 11.2	(4) 13.3	(3) 17.0	(3) 19.7
Total	73.5	71.4	87.2	90.1

Source: Tables 3-1 and 3-3, above.

The columns headed "drugs" and "frequency" refer to the period 1970-78. This result is in accordance with *a priori* expectations.[14]

The correspondence between pharmacologic-therapeutic categories ranked by number of compulsory patent licences (either drugs or frequency) and relative importance in terms of number of prescriptions or sales, although similar, is not exact. For example, as shown above, Hormones and Substitutes ranked third in terms of prescriptions (13.6 per cent) but fourth in terms of number of compulsory patent licences issued (frequency, 4.2 percent). In other words, the level of sales is not the only determinant of compulsory licencing.

Market Growth. An investment decision by a licensee will depend not only on market size at a particular point in time, but also on the expected rate of growth (i.e., the degree to which the demand curve is shifting to the right or left). A positive

relationship is to be expected between the incidence of compulsory patent licensing and the rate of market growth. The reasoning is exactly analogous to that discussed above under market size.[15]

Patentees' Advantage. Most of the drugs for which compulsory patent licences have been issued have been on the market (i.e., available to the physician to prescribe for the use of the general public) for a number of years prior to the Commissioner issuing a licence and the licensee marketing the drug. On average the lag between the introduction of the drug by the patentee and the issuing of the licence was 10.1 years,[16] while the lag from patentee introduction to the licensee marketing the drug was, not surprisingly, a little longer - 11.6 years.[17] The long lag reflects the fact that compulsory patent licensing was introduced in 1969 and many of the drugs for which licences were issued had been introduced a number of years prior to 1969. Table 3-4 provides a frequency distribution which takes this factor into account. As can readily be observed, of the 45 out of the 47 licensed drugs for which information is available, in all but eight instances, the patentee marketed the drug prior to 1969. The average lag between the patentee marketing the drug and issuing the licence for the pre-1969 set of 37 was 11.3 years, for the post-1969 set of eight, 4.4 years. The same pattern is observed in Table 3-4 for the corresponding lag for those drugs which were licensed and worked. Finally, Table 3-5 demonstrates the lag between the marketing of the drug by the patentee and by the licensee exhibits similar patterns to those described above for the lag between patentee marketing and the issuing of a compulsory licence.

Recent research has demonstrated that the first firm to market a particular drug has significant sales advantage over subsequent sellers of the "same" drug (i.e., same or very similar).[18] In other words, the length of time a drug is on the market is positively related to its sales, among a group of substitute drugs. Bond and Lean (1977, p. vi) summarize their findings in this respect as follows:

> In each of the markets here under study, the first firm to offer and promote a new type of product received a substantial and enduring sales advantage. Moreover, although the promotional dollars spent by the first firms were absolutely large, the first firms nonetheless devoted a smaller percentage of their sales dollars to promotion than did their competitors. In each market the success of the first brand did stimulate other firms to enter with therapeutically substitutable products. Yet such follow-on brands failed to dislodge the early entrant

TABLE 3-4

FREQUENCY DISTRIBUTION OF THE TIME LAG BETWEEN PATENTEE MARKETING THE DRUG[a] AND THE COMMISSIONER OF PATENTS ISSUING A LICENCE.[b] LICENCES ISSUED 1970-1978[c]

Difference Between Date Patentee Marketed Drug And Date Licence Issued	All Drugs		Date Patentee Marketed Drug			
			Pre-1969		Post-1969[e]	
Number of Years[d]	Licensed	Licensed and Marketed by Licensee	Licensed	Licensed and Marketed by Licensee	Licensed	Licensed and Marketed by Licensee
1	0	0	0	0	0	0
2	0	0	0	0	0	0
3	2	2	0	0	2	2
4	3	2	1	1	2	1
5	4	0	1	0	3	0
6	3	1	2	1	1	0
7	2	2	2	2	0	0
8	1	1	1	1	0	0
9	3	3	3	3	0	0
10	5	4	5	4	0	0
11	7	5	7	5	0	0
12	2	2	2	2	0	0
13	2	2	2	2	0	0
14	4	3	4	3	0	0
15	3	3	3	3	0	0
16	0	0	0	0	0	0
17	1	0	1	0	0	0
18	3	2	3	2	0	0
Total	45	32	37	29	8	3
Average Number of Years	10.1	10.5	11.3	11.3	4.4	3.3

a. Dated by when patentee first marketed the drug in Canada. In those instances of several patentees, first patentee to market is used.
b. Under section 41(4) of the Patent Act. In those instances of several licensees, date of first licence issued is used.
c. No licences were issued between June 1969, when section 41(4) of the Patent Act came into force, and the end of 1969.
d. Lags are calculated by subtracting year of licence issuance from year patentee marketed drug. Data on month patentee marketed drugs not available.
e. Post-1969 includes patentee drugs marketed in 1969.

Note: To appear in the print-out of current drugs on the market (see below), a drug product must still be marketed; the possibility exists that an earlier product containing the drug is no longer marketed and the time lag thus may be biased on the low side.

Source: Appendix D below; print-out of current (i.e. August, 1979) drugs on the market supplied by the Bureau of Drugs, Department of National Health and Welfare; various provincial government formularies (Ontario and Quebec); Canada, Department of National Health and Welfare (1972, 1974, 1975c, 1975d); and information supplied by the Pharmaceutical Manufacturers Association of Canada.

> from a dominant position. Neither heavy promotion nor low price appears to have been sufficient to persuade prescribing physicians to select in great volume the substitute brands of late entrants.

Although Bond's and Lean's conclusions are based on two drug groups (i.e., oral diuretics and antianginals) for the U.S., not Canada, nevertheless it is likely that the general theory is also applicable to Canada and the specific instances of compulsory patent licensing. In other words the greater the length of time the patentee has had the drug on the market prior to either a licence being issued or worked, the less will be the incidence of compulsory patent licensing.

These are the three major factors which, a priori, were considered to be major determinants, on the demand side, of the incidence of compulsory patent licensing and for which the data is available on a fairly systematic and consistent basis. Attention is now turned to the supply side factors.

"New" vs "Old" Drug Status. In order for the patentee to market[19] a new drug in Canada for the first time the approval of the Health Protection Branch of the Department of National Health and Welfare must be received. This federal government department derives its authority in this regard by virtue of administering the Food and Drugs Act and its attendant regulations.[20] These specify the information required to be submitted, the tests (animal and human) to be performed and the stages of approval with respect to the safety and efficacy of a new drug. These requirements can be, and frequently are, very costly and take a number of years to complete. For example, "the number of pages of documentation required to satisfy the requirements for Ketamine was 67,128" (Sellers and Sellers, 1978, p. 70), while the lag between the first testing of a drug in the laboratory and the approval of regulatory authorities would appear to be seven to nine years.[21] The purpose here is not to describe this process since it has more than adequately been done elsewhere,[22] but rather show how the regulations which control the introduction of new drugs by the patentee affect the licensee.

After the Health Protection Branch is satisfied as to safety and efficacy of the drug, the Notice of Compliance is issued to the patentee who can then, "place his new drug on the Canadian market" (Canada, Department of National Health and Welfare, 1973, p. 4). However, the interest of the regulatory agency does not cease at this point. For one thing, when a new drug is first released on the market it is usually accorded New Drug Status. In general, this status requires the patentee to:

> ...report any new information he receives either through his tests or from users concerning unexpected

TABLE 3-5

FREQUENCY DISTRIBUTION OF THE TIME LAG BETWEEN PATENTEE MARKETING THE DRUG[a] AND THE LICENSEE MARKETING THE DRUG:[b] LICENCES ISSUED 1970-1978.[c]

Difference Between Date Patentee Marketed Drug And Date Licensee Marketed Drug	All Licensee Marketed Drugs	Date Patentee Marketed Drug	
Number of Years[d]		Pre-1969	Post-1969[e]
1	0	0	0
2	1	0	1
3	0	0	0
4	1[f]	0	1
5	1	0	1
6	1	1	0
7	1	1	0
8	1	1	0
9	4[g]	4	0
10	1	1	0
11	3	3	0
12	6	6	0
13	1	1	0
14	5	5	0
15	0	0	0
16	2	2	0
17	1	1	0
18	2	2	0
19	0	0	0
20	1	1	0
Total	32	29	3
Average Number of Years	11.6	12.4	3.7

a. See footnote a, Table 3-4, above.
b. Dated by when licensee first marketed the drug. In those instances of several licensees, first licensee to market is used. Refers to licensee drugs marketed by August, 1979.
c. See footnote c, Table 3-4.
d. See footnote d, Table 3-4.
e. See footnote e, Table 3-4.
f. This drug was produced by the licensee before the licence was taken out. In this instance, the "Date Licensee Marketed Drug" was taken as the same year the licence was first granted.
g. Two of the four drugs were produced by the licensees before the licences were taken out. In these instances, "Date Licensee Marketed Drug" was taken as the same year the licence was first granted.

Note: In four cases, "licensee" firms without licences for a particular drug, produced the drug prior to the firm that actually took out the licence. Calculations using date of earlier production by the firm without the licence made little difference to the results; average number of years for all licensee marketed drugs was 12.0 and for pre-1969 patentee marketed drugs, 12.5.

Source: See Table 3-4, above.

> reactions to the drug such as side effects or failure to produce desired effect. (Canada, Department of National Health and Welfare, 1973, p. 5).

Once sufficient information has been collected to confirm the safety and efficacy of the drug, then it is accorded Old Drug Status. However, the requirements under New Drug Status, "and the basis for such continued surveillance are not clearly defined" (Sellers and Sellers, 1978, p. 76). A similar statement applies to the line between New and Old Drug Status.[23] For example, diazepam, although one of Canada's largest selling drugs and prescribed for more than ten years, is still accorded New Drug Status. In other words, a degree of discretion is accorded to the officials administering the legislation.

The firm which obtains a compulsory patent licence does not have to replicate all of the safety and efficacy tests that the patentee conducted in order to market the drug. However, some of these tests may have to be conducted by the licensee and this depends critically upon whether the drug has New or Old Drug Status. Put crudely, if the drug retains New Drug Status then the licensee usually has to undertake a number of tests, performed to the satisfaction of the Health Protection Branch, before a Notice of Compliance is issued.[24] On the other hand, if the drug is accorded Old Drug Status, no pre-market clearance (i.e., approval) is required to meet Health Protection Branch requirements. All that the licensee is required to do is to notify the regulatory agency that it intends to market the drug.[25] Hence, if a drug is accorded New, rather than Old, Drug Status the cost to the licensee of bringing the drug to market is greater and hence the incidence of compulsory patentee licensing is expected to be less. In short, while New Drug Status may be justified from a safety and efficacy viewpoint, it nevertheless may constitute a "barrier to entry."[26]

Of the 45 drugs for which licences were issued, 16 had New, and 29 had Old Drug Status. (No data was available for two drugs). This is not surprising since, as reported above, most of the drugs had been on the market a number of years prior to 1969 and hence were likely to have reached Old Drug Status.

In the introduction to this section several other supply side factors were mentioned, including the significance of economies of scale in production and the availability of the active ingredient to the licensee. Unfortunately, the information on these two factors is somewhat sketchy. However, some fragmentary information is available on the first factor. Economies of scale would appear to be of most significance in the production of the active ingredient, rather than the preparation of the final dosage form. However, most of the licensees import the active ingredient and only participate in the preparation of final dosage forms. In other words, economies of scale are of

little consequence with respect to the licensee.[27]

3.4.2 Empirical Results

Ideally, in order to test the relative significance of the variables outlined above as determinants of the incidence of compulsory patent licensing, data should be gathered on all drugs for which licences have been issued as well as a sample for which no licences have been issued. However, data is available only for licensed drugs. While this falls short of the ideal, it nevertheless does provide for at least a partial evaluation of the determinants.

The definition of the variables are presented below. They closely follow the discussion above and hence the attention paid to each will be brief.

Variable Name	Definition
LICENCES	Number of licences issued per drug over the period 1970-1978.
WORKED	Number of licences worked per drug by August, 1979.
MARKET SIZE	Total Canadian sales of the drug (licensee and patentee) for 1969. Sales expressed in $000's.
GROWTH	Percentage change in sales between 1969 and 1975.[28]
LAGLIC	Number of years between patentee first marketing the drug and licence first issued.
STATUS	1 = Old Drug Status 0 = New Drug Status

Table 3-6 presents the statistical findings on the determinants of the number of licences issued and worked under section 41(4) of the Patent Act. The regression equations were estimated using ordinary least squares. Although data are available for the two dependent variables (i.e., licences and worked) for all of the 47 licensed drugs this is not the case for

any of the independent variables: the maximum number of observations for market size and laglic was 45,[29] status 43 and growth 39.[30] These shortfalls mean that the maximum number of licensed drugs for which all of the independent variables were defined was not 47, but 37. As a result Table 3-6 presents estimated equations for this sample only. In those instances where an equation in the table could be estimated for more than 37 observations and the result is at variance with that reported then this is discussed. However, in general, the results are not sensitive to the sample size within this range.

The four explanatory variables - market size, growth, laglic and status - account for 65 percent of the variation of licences (equation 1) and 67 percent for worked (equation 2). Of the four independent variables the most important is market size, as a comparison of R^2 for equations 1 and 3 (for licences) and 2 and 4 (for worked) demonstrates.[31] The expected signs on the regression coefficients on the four explanatory variables are positive for market size and growth and negative for laglic and status. In general, for equations 1 through 8 the actual signs are the same as those predicted, with the exception of growth and status, when worked is the dependent variable (i.e., equations 2, 6 and 8). However, in terms of statistical significance, only market size is consistently significant across equations 1 to 8, with laglic significant for only equation 7, although this variable is nearly significant at the 10 percent level for equation 1 (for licences in both cases). The close conformity of the results of the odd and even numbered equations in Table 3-6 reflects the high correlation, 0.8779, between the two dependent variables, licences and worked. The importance of market size is consistent with the view of informed observers of compulsory licensing. For example, the trade association of the patentees has commented "... compulsory licenses are sought and issued on the high volume, successful drug products..." (PMAC, 1979, p. 11).

The correlation coefficients among the four independent variables are as follows:

Variable Pair	Correlation Coefficient
Market size/Status	-0.0243
Market size/Growth	-0.2802
Market size/Laglic	-0.1292
Growth/Status	-0.4448
Status/Laglic	+0.4835
Growth/Laglic	-0.2087

The correlations are sufficiently "low" to suggest that multicollinearity is not a serious problem, with the possible exception of status, which is quite high correlated with two of the other independent variables, growth and laglic.[32] Equations 4 through 8 of Table 3-6 would suggest, however, that

TABLE 3-6

THE DETERMINANTS OF THE NUMBER OF LICENCES ISSUED AND WORKED UNDER SECTION 41(4) OF THE PATENT ACT: 1970-1978

Equation Number	Dependent Variable	Constant	Market Size	Growth	Laglic	Status	R^2	F Ratio
		Regression Coefficients and t-Values[a]						
1	Licences	3.31 (3.15)***	0.0013 (6.69)***	0.00003 (0.02)	-0.13 (-1.65)	-0.25 (-0.30)	0.6488	14.8***
2	Worked	1.16 (1.47)	0.0011 (7.29)***	-0.0001 (-0.11)	-0.07 (-1.19)	0.48 (0.77)	0.6705	16.3***
3	Licences	1.66 (4.25)***	0.0014 (7.25)***	---	---	---	0.6003	52.6***
4	Worked	0.70 (2.48)**	0.0011 (8.14)***	---	---	---	0.6545	66.3***
5	Licences	4.20 (4.66)***	---	---	---	-0.98 (-0.93)	0.0240	0.86
6	Worked	2.10 (2.99)***	---	---	---	0.09 (0.10)	0.0003	0.01
7	Licences	3.20 (3.28)***	0.0014 (6.85)***	0.0002 (0.17)	-0.14 (-1.99)*	---	0.6478	20.2***
8	Worked	1.36 (1.85)*	0.0011 (7.29)***	-0.0005 (-0.47)	-0.05 (-0.96)	---	0.6644	21.8***

a. t-values in parenthesis, R tested by an F-test; all t-tests are one-tailed; all regression equations estimated for 37 observations.

*** significant at 0.01 level.
** significant at 0.05 level.
* significant at 0.10 level.

Note: Variables are defined in the text.

Source: IMS data provided by the Bureau of Intellectual Property, Department of Consumer and Corporate Affairs; PMAC (1979, Appendix 7); print-out of current (i.e., August, 1979) drugs on the market, from the Bureau of Drugs, Department of National Health and Welfare; and information on the status of drugs (i.e., Old or New) also provided by the Bureau of Drugs, Department of National Health and Welfare.

collinearity amongst the independent variables would not appear to be a serious problem.

In sum, the regression results suggest market size is the major determinant of both the number of compulsory licences issued and worked, accounting for approximately 60-65 percent of the variation in the dependent variables. Laglic was statistically significantly related to licences but not worked. The two remaining explanatory variables, growth and status, were not statistically significantly related to either of the dependent variables. In the case of status this can be explained in either of two ways. First, the licensee only applies for licences on those drugs for which there is a reasonable expectation that the status will be changed from New Drug to Old Drug. In those instances where there is no such expectation, application is not made.[33] Since the sample for which the estimated regression expectations in Table 3-6 are estimated refer only to licensed drugs, the effect of the distinction between New and Old Drug Status is not detected. Second, the effect of Old vs. New Drug Status is captured by a 1:0 dummy variable. Such an approach is quite proper and feasible if the costs of the safety and efficacy tests required by the Health Protection Branch, Department of National Health and Welfare are uniform across all licensed drugs on New Drug Status. However, this would not appear to be the case. One licensee estimates that such costs can vary from $10,000 to $400,000 with an average in the region of $25,000 to $50,000.[34] Under such circumstances the dummy variable technique may be inappropriate, hence yielding the statistically insignificant coefficient in Table 3-6. The lack of significance for growth may be the result of misspecification: the dependent variables refer to 1970-1978 and 1970-August 1979, but growth is measured for 1969-1975. Unfortunately growth data to 1978 and 1979 is not available for this study.

3.5 Summary and Overview

Over the period 1970 to 1978 the Commissioner of Patents issued 152 licences which referred to 55 separate drugs. (It should be noted that where a licensee made several applications concerning one drug, for whatever reason, all such applications were treated as a single licence application in this and all remaining chapters. This explains the difference between the much larger total recorded in Table 2-2 of 227 and the figure of 152 mentioned above). The licensed drugs included not only prescription, but veterinary and ethical non-prescription drugs. The vast majority of licences (93.4 percent) and the principal focus of the government inquiries in the 1960's were accounted for by prescription drugs. Hence this study is confined to the 142 compulsory licences accounted for by the 47 prescription drugs. In view of this, the term "drugs" will be understood to refer to prescription drugs throughout the remainder of the text and tables, unless otherwise specified.

The maximum number of licences issued for a particular drug was 11. Three such drugs, chlordiazepoxide, diazepam and furosemide, were in this category. Eighty-one percent of all drugs for which compulsory licences have been issued and 85.9 percent of all licences belong to three pharmacologic-therapeutic classifications - anti-infective, cardiovascular and central nervous system. Licences were not issued evenly over the period 1970-1978, but rather concentrated in the period 1970-1972 (50.0 percent of the 142 issued). Of the 142 licences, 60.6 percent or 86 were worked (i.e., licensee marketed the licensed drug) by August 1979, and of these 83.7 percent or 72 are presently being worked.[35]

A number of determinants of the number of licences issued or worked were identified: market size; the status of the drug Old vs. New; growth of market size; the patentee's advantage in being first to market the drug. Regression equations were estimated using these four explanatory variables. Taken as a group they accounted for approximately 60 percent in the variation of both the number of licences issued and worked, per licensed drug. The major explanatory variable was market size, a result that agrees with the view of informed observers of compulsory licensing.

This chapter has two findings that should be taken into account when studying the impact of compulsory licensing on drug prices. First, there is a difference between the number of licences issued and worked. Over the period 1970-1978, of the 142 licences issued, only 86 were worked by August, 1979. Second, market size is, not surprisingly, the major determinant of the number of licences issued or worked. Hence, the impact of compulsory licensing is likely to affect the largest markets and hence, potentially at least, could lead to substantial reductions in the prescription drug bill.

CHAPTER IV

THE LICENSEES

4.1 Introduction

The object of this chapter is to present an overview of the firms which have taken out compulsory patent licences under section 41(4) of the Patent Act. The outline is, of necessity, somewhat sketchy. Most of the information available on the prescription drug industry refers to the patentees, which are usually subsidiaries of large multinational pharmaceutical firms. In contrast, the licensee is usually part of a much smaller entity, on which there is relatively little data publicly available. Hence, gaps will appear in the description of the licensees.

The chapter is divided into three major parts and one minor one. Section 4.2 presents the identity of the compulsory patent licensees together with some of their more salient characteristics, such as the number of licences acquired and worked, size, ownership, and nationality. An attempt will be made to account for several of the characteristics of the licensees in Section 4.3. Section 4.4 is concerned with the marketing strategy that the licensees have used in competition with the patentees. Attention will be paid to pricing patterns, the significance of formulary listings and promotional activities. The success of these activities, in terms of market share penetration, is discussed in section 4.5. Finally, a brief summary and some inferences are drawn in section 4.6.

4.2 Licensee Characteristics: A Description

Incidence Of Licensing. Twenty-six firms took out a total of 142 compulsory patent licences against 47 drugs over the period 1969 to 1978. Table 4-1 identifies the licensee firms, the number of drugs for which licences were issued and whether or not the licence was worked.[1] In terms of either the frequency of the number of drugs for which licences were issued or issued and worked, by licensee, a small number of firms are very important. For example, five licensees account for 90 (or 63.4 percent) of 142 licences issued and 56 (or 77.8 percent) of the 72 licences being worked as of August, 1979. In particular two were of considerable significance; ICN Canada Ltd. and Novopharm Ltd., which, together, accounted for 38 (or 52.8 percent) of the licences being worked as of August, 1979. In contrast, 14 of the 26 licensees which took out licences against only one or two drugs accounted for 21 (or 14.8 percent) of all licences issued and 7 (or 9.7 percent) of the 72 licences being worked as of August, 1979. In sum, a large percentage of both the total number of licences issued and worked are accounted for by a small number of licensees.

Nationality, Ownership Characteristics and Size. Table 4-2 details various ownership characteristics of the licensees, such as nationality, as well as size and date of establishment in Canada. The table divides the licensees into two groups: those that were working their licences as of August, 1979 and those that were not. More information is generally available for the former group than the latter. In any event, the division might yield some clues as to the reasons for the non-working of licences.

Of the 26 licensees in Table 4-2 the relative importance of the various countries of ownership was as follows:

	No.	Percentage
Canada	16	61.5
U.S.A.	8	30.8
U.K.	1	3.9
Kuwait	1	3.9
	26	100

In the period 1975/76 - 1978/79 a number of foreign acquisitions of Canadian licensees were made, thus reducing the importance of Canadian ownership.[2] In 1975/76, for example, 20 or 76.9 percent of the 26 licensees were Canadian owned. Within the two groups of licensees the significance of Canadian ownership was of approximately the same magnitude. The 16 Canadian licensees accounted for only 35 or 48.6 percent of licences worked as of August 1979 and only two of the five licensees, mentioned above, that accounted for 77.8 percent of all licences worked. In sum, although, despite a recent decline, the vast majority of licensees are Canadian owned, in terms of licences worked, foreign owned firms are of more significance.

In some instances the licensee firm is a subsidiary of another firm, rather than privately owned, with the principals or their nominees responsible for the management and conduct of the firm. Of the 26 licensees in Table 4-2, a parent firm is identified in exactly one-half of the instances. Since a parent firm may own more than one subsidiary, the actual number of private firms is 11 not 13. The parent firms can be categorized as follows:

TABLE 4-1

LICENSEES, LICENCES ISSUED AND WORKED UNDER SECTION 41(4) OF THE PATENT ACT: 1970-1978

Licensee Firms[a]	Drugs Licensed[b]		Licences Not Worked[c]		Licences Worked, But Drug No Longer on the Market[d]		Licences Worked and Drug Currently on the Market[d]	
	No.	(%)	No.	(%)	No.	(%)	No.	(%)
1. ICN Canada Ltd.[e]	31	(21.8)	5	(8.9)	4	(28.8)	22	(30.6)
2. Novopharm Ltd.[f]	30	(21.1)	12	(21.4)	2	(14.3)	16	(22.2)
3. Frank W. Horner Ltd.	11	(7.8)	5	(8.9)	1	(7.1)	5	(6.9)
4. Jerram Pharmaceuticals Ltd.[g]	11	(7.8)	5	(8.9)	-	-	6	(8.3)
5. Apotex Inc.	7	(4.9)	-	-	-[v]	-	7	(9.7)
6. K-Line Pharmaceuticals Ltd.	5	(3.5)	1	(1.8)	2[v]	(14.3)	2	(2.8)
7. Sterilab Corporation Ltd.[h]	6	(4.2)	4	(7.1)	2	(14.3)	-	-
8. Gilcross Ltd.[i]	4	(2.8)	3	(5.4)	1	(7.1)	-	-
9. Mowatt and Moore Ltd.[j]	5	(3.5)	3	(5.4)	-	-	2[t]	(2.8)
10. Harris Laboratories[k]	4	(2.8)	1	(1.8)	-	-	3	(4.2)
11. Neo Drug Co.[l]	4	(2.8)	2	(3.6)	-	-	2	(2.8)
12. Delmar Chemicals Ltd.[m]	3	(2.1)	3	(5.4)	-	-	-	-
13. Paul Maney Laboratories[n]	2	(1.4)	1	(1.8)	-	-	1	(1.4)
14. Dymond Drugs Ltd.	2	(1.4)	-	-	2	(14.3)	-	-
15. ERI Pharmaceuticals Ltd.[o]	2	(1.4)	-	-	-	-	2	(2.8)
16. International Medication Systems Ltd.	2	(1.4)	2	(3.6)	-	-	-	-
17. Micro Chemicals Ltd.[p]	2	(1.4)	2	(3.6)	-	-	-	-
18. P.V.U. Inc.[q]	2	(1.4)	2	(3.6)	-	-	-	-
19. W.E. Saunders Ltd.	2	(1.4)	2	(3.6)	-	-	-	-
20. Ethica Ltée[r]	1	(0.7)	1	(1.8)	-	-	-	-
21. Laboratoire Medic Ltée	1	(0.7)	-	-	-	-	1	(1.4)
22. Medivet Products Inc.[q]	1	(0.7)	1	(1.8)	-	-	-	-
23. Nadeau Laboratory Ltd.[s]	1	(0.7)	-	-	-	-	1	(1.4)
24. Noco Drugs Ltd.	1	(0.7)	1	(1.8)	-	-	-[u]	-
25. Compagnie Pharmaceutique Vita Ltée[r]	1	(0.7)	-	-	-	-	1	(1.4)
26. Trans-Canada Dermapeutics Ltd.	1	(0.7)	-	-	-	-	1	(1.4)
Total	142	(100)	56	(100)	14	(100)	72	(100)

a. Licensees having common ownership are treated as a single licensee firm. Thus, if a subsidiary and parent had each taken out a licence for the same drug, these were counted as only one licence. If a licensee firm changed its name, the most recent name appears in the table. Finally, if licensees were independent for most of the period 1970-1978, having been acquired by another licensee or patentee or other third party only in the last two years, they are listed separately. Ownership details are provided in footnotes following.

b. Between 1970 and 1978. No licences issued between June and December 1969. Licence dated by the year it was issued by the Commissioner of Patents.

c. "Worked" is defined as the licensee has marketed the drug for which the licence was issued.

d. As of August, 1979.

e. S & U Chemicals Ltd. and Sabra Pharmaceuticals Ltd. also took out licences and are included with ICN due to common ownership.

f. Stanley Drug Products Ltd. is owned by Novopharm.

g. Sands Pharmaceuticals is a division of Jerram.

h. 1977/78 acquired by Abbott Laboratories Ltd.

i. Firm went out of business; previously Jules R. Gilbert Ltd.; equipment and formulations acquired by Jerram Pharmaceuticals Ltd.

j. 1976/77 acquired by Beecham Canada Ltd. Owned Neo Drug Co. See footnote l below.

k. Previously M.T.C. Pharmaceuticals Ltd. Parent company: Canada Packers Ltd. Licences taken out by both Canada Packers and M.T.C.

l. Previously owned by Mowatt and Moore Ltd. Listed separately from Mowatt and Moore Ltd., and Beecham Laboratories Ltd. in current drug print-out, Bureau of Drugs, Department of National Health & Welfare.

m. Bulk pharmaceutical products, fine chemical manufacturing.

n. Division of Canapharm Industries Inc. Licences taken out by Canapharm.

o. Acquired by ICN Canada Ltd. in 1978/79.

p. 1969, had same ownership as Paul Maney Labs.; now owned by Generics Corporation of America, U.S.A. Fine chemicals manufacturer.

q. Veterinary products.

r. Part of Sabex International Ltd. Not known when acquired by Sabex International Ltd.

s. Parent: Desbergers Ltd.

t. One of products is listed under Beecham Laboratories Ltd.

u. Product listed under Sabex International Ltd.

v. Were produced prior to licences granted. Both 1978 licences.

Source: Canadian Manufacturer's Association (1979); Canada, Department of National Health & Welfare (1972, 1974, 1975c, 1975d, 1978, 1979a); Dun and Bradstreet (1979a, 1979b); Drug Merchandising (1975, 1979); Foreign Investment Review Agency (1976, 1977, 1978, 1979); Penstock Directories (1979); Canada, Statistics Canada (1971, 1974a, 1978b); the print-out of current drugs on the market (i.e. August, 1979) supplied by Bureau of Drugs, Department of National Health and Welfare; and various provincial government formularies.

TABLE 4-2
SIZE, OWNERSHIP, NATIONALITY AND ESTABLISHMENT OF LICENSEES IN CANADA

LICENSEE FIRM	OWNERSHIP CHARACTERISTICS NATIONALITY	IDENTITY	OTHER	LICENSEE SIZE[a] ($000,000's sales)	ESTABLISHED (MANUFACTURING) IN CANADA
LICENSEES[b] WORKING[c] LICENCES AS OF AUGUST 1979[d]					
ICN CANADA LTD.	U.S.A.	ICN Pharmaceuticals, Inc.	Major[e] multinational pharmaceutical firm	10-15	1956 (1971)
NOVOPHARM LTD.	Canadian	Individuals	-	15-20	1965 (1969)
FRANK W. HORNER LTD.	U.S.A.	Carter-Wallace	Minor[f] multinational pharmaceutical firm	15-20	1912 (1912)
JERRAM PHARMACEUTICALS LTD.	Kuwait (Canadian until 1977/78)	Individuals	-	1-2½[g]	1971 (1972)
APOTEX INC.	Canadian	Individuals	-	2½-5	1974 (1974)
K-LINE PHARMACEUTICALS LTD.	Canadian	Private	-	n.a.	n.a.
MOWATT AND MOORE LTD.	U.K. (Canadian until 1976/77)	Beecham Group Ltd.[h]	Major[e] multinational pharmaceutical firm	2½-5[g]	1920 (1920)
HARRIS LABORATORIES LTD.	Canadian	Canada Packers Ltd.	Large food processor	1-2½	1942 (1945)
NEO DRUG CO.	Canadian[i]	Private	-	½-1	1945 (n.a.)
PAUL MANEY LABORATORIES LTD.	Canadian[i]	Private	-	½-1	1942 (1957)
ERI PHARMACEUTICALS LTD.	U.S.A. (Canadian[i] until 1978/79)	ICN Pharmaceuticals Inc.[j]	Major[e] multinational pharmaceutical firm	n.a.	n.a.
LABORATOIRE MEDIC LTEE.	Canadian[i]	Private	-	n.a.	n.a.
NADEAU LABORATORY LTD.	Canadian	Desbergers Ltd.	-	1-2½[g]	1920 (1920)
COMPAGNIE PHARMACEUTIQUE VITA LTEE.	Canadian[i]	Sabex International[l]	Pharmaceutical firm formed by merger of several small Canadian firms in mid-1970s.	n.a.	1973 (1973)[k]
TRANS-CANADA DERMAPEUTICS LTD.	Canadian[i]	-	-	1-2½	1957 (1962)
LICENSEES[b] NOT WORKING[c] LICENCES AS OF AUGUST 1979[d]					
STERILAB CORPORATION LTD.	U.S.A.	Abbott Laboratories Ltd. Acquired in 1977/78 from Damon Corp. U.S.A.	Major[e] multinational pharmaceutical firm	1-2½[g]	1963 (1965)
GILCROSS LTD. (Formerly Jules R. Gilbert Ltd.)	Canadian	Private	Bankrupt		
DELMAR CHEMICALS LTD.	Canadian	John Labatt Ltd.	Food and Drink conglomerate	½-1	1941 (1941)
DYMOND DRUGS LTD.	Canadian[i]	-	-	1-2½[g]	1930 (1930)
INTERNATIONAL MEDICATION SYSTEMS LTD.	U.S.A.	-	-	n.a.	n.a.
MICRO CHEMICALS LTD.	U.S.A. (Canadian until 1975/76)	Generics Corporation of America, U.S.A.	Large multinational	n.a.	n.a.
P.V.U. INC.	Canadian[i]	-	Veterinary company	n.a.	n.a.
W.E. SAUNDERS LTD.	U.S.A.	Chromalloy American Corp.	Large multinational	½-1[g]	1856 (1856)
ETHICA LTEE.	Canadian[i]	Sabex International Ltd.[l]	Pharmaceutical firm formed by merger of several small Canadian firms in mid-1970s.	n.a.	1973 (1973)[k]
MEDIVET PRODUCTS INC.	Canadian[i]	-	Veterinary company	n.a.	n.a.
NOCO DRUGS LTD.	Canadian[i]	Pharmo Products Ltd.	-	less than ½[g]	n.a.

a. Size refers to dollar sales in Canada for the year 1978, unless otherwise stated. Sales include non-prescription drugs.
b. Ranked by number of licences issued (see Table 4-1, above for details).
c. "Working" defined as licensee marketing drug for which licence issued as of August 1979. The converse applies to "non-working."
d. Latest data available.
e. Major as defined by James (1977, Appendix 1, pp. 248-250), that is, a firm ranked by sales volume as one of the world's fifty largest ethical drug firms in 1973.
f. Minor as defined by James (1977, Appendix 3, pp. 253-254), that is, a firm ranked by sales volume between fifty-first and eightieth among the world's largest ethical drug firms in 1973.
g. Sales data refers to 1974.
h. Acquired via the Canadian subidiary, Beecham Canada Ltd.
i. No evidence owned by a foreign firm, therefore assumed Canadian.
j. Acquired via the Canadian subsidiary, ICN Canada Ltd. (See table for details).
k. Date parent established.
l. Sabex International Ltd. had sales of $2½-5 million.

Source: See Table 4-1 above.

	Number of Parent Firms	No. of Licensees
Multinational pharmaceutical firm	4	5
Large Canadian food/drink firm	2	2
Other	5	6
Total	11	13

In the "other" category are included a number of multinational firms for which no data is available and several Canadian firms or groups of firms which are primarily ownership shells rather than separate operating entities in their own right. The five licensees owned by the four multinational pharmaceutical firms include the first and third ranked licensees.[3] Together, these five licensees account for 31 (or 43.1 percent) of the 72 licences worked as of August 1979. We shall return to the apparent paradox of multinational pharmaceutical firms owning firms that take out licences against the patented products of fellow multinational pharmaceutical firms in section 4.3 below.

Table 4-2 also presents data on the relative importance of the licensees, measured in terms of sales for 1978. The sales figures include not only licensed drugs, but also prescription drugs for which the patent has effectively expired (e.g., tetracycline), as well as non-prescription drugs. Sales figures are not available for all licensees, especially for what is believed to be the smaller sized licensees. The three leading licensees, measured in terms of licences worked as of August 1979, were the only firms in Table 4-2 with annual sales in excess of $10 million. All the remaining licensees for which data is available, with the exception of Mowatt and Moore Ltd. and Apotex Inc., had annual sales of less than $2.5 million. Given that the total prescription drug market is several hundred million dollars a year it can be readily appreciated that the licensees are relatively small in relation to total market size and, as will be shown in Chapter V below, to the patentees. Finally, the table shows that most of the licensees have been long established and manufacturing in Canada. However, the leading five licensees, with the exception of Frank W. Horner Ltd., are all of relatively recent origin.

Profitability, Research and Development, and Advertising. Unfortunately, little information is available on either the research and development and advertising activities of the licensees or their profit performance.[4] Nevertheless, a number of general statements can be made with a reasonable degree of confidence. First, the licensees conduct little or no research into new drugs, this being done almost exclusively by the patentees. It is for this reason that the licensees are

referred to, somewhat pejoratively, as "copiers" and "imitators" by the patentees. The licensees do, however, conduct bioavailability and toxicity tests in meeting Health Protection Branch standards for licensed drugs still on "New Drug" status.[5] Such tests are usually classified as R & D activity. Second, some of the licensees do advertise in trade magazines such as Drug Merchandising. It is not possible to specify though, whether such expenditures constitute 5 or 10 percent as a proportion of sales for the average licensee. However, some "advertising" of the licensee's product is undertaken, at zero cost to the licensee,[6] by provincial governments, through inclusion in a formulary.[7] The formularies are distributed widely to physicians and pharmacists. Finally, no data is available on profitability. In any event, such data would be difficult to interpret for a number of licensees are now merged, some are foreign owned so the problem of transfer pricing may arise and, finally, for the smaller entrepreneur/manager firm the issue of how to separate his services from those of capital occurs. Nevertheless, the leading licensees are probably making at least a normal rate of return on capital, especially ICN Canada Ltd., and Frank W. Horner Ltd., both owned by multinationals, which are likely to be especially sensitive to activities earning "low" rates of return.[8] It is difficult to make any statements about the profitability of the remaining licences, except that it would appear some at least have trouble in making a normal rate of return, as evidenced by the bankruptcy of Gilcross Ltd.

Trade Associations. There is one major trade association of licensee firms, the Canadian Drug Manufacturers Association (CDMA). This association dates back to at least the early mid-1960's and restricts its membership to Canadian owned and controlled firms. Four licensee firms are members: Novopharm Ltd., Apotex Inc., K-Line Pharmaceuticals Ltd., and Harris Laboratories Ltd.[9] The CDMA does not have a permanent research staff and chairman solely concerned with the association. Indeed, its current chairman, V.J. Parks, is also Manager, Research, Development and Government Affairs for the pharmaceutical segment of Canada Packers Ltd., Harris Laboratories Ltd. There is a second, minor[10] trade association, Association des Fabricants du Quebéc de Produits Pharmaceutiques (AFQPP) which "represents a tightly knit group of about 10 Quebec manufacturers" (Scrip, 1979, p. 2). However only Neo Drug Co. of the licensees in Table 4-2 would appear to be a member of AFQPP. Hence, most of the licensees do not belong to either the CDMA or the AFQPP. In particular, three of the leading five licensees, as measured by the number of licences worked as of August, 1979, did not belong to a trade association: ICN Canada Ltd., Frank W. Horner Ltd., and Jerram Pharmaceuticals Ltd. However, ICN Canada Ltd. had belonged to the PMAC, discussed in section 5.2 below, until 1977. Hence, it would appear the licensees are not a well organized coherent group in presenting their views to government on compulsory licensing and

related issues. Indeed, only 5 of the 26 licensees belong to the CDMA or AFQPP.

Summary. In the period 1970-1978 the Commissioner of Patents issued 142 licences to 26 firms. The licensees, both in terms of firm size and number of licences owned, are dominated by a small group of firms. Three licensees accounted for 50.7 percent of all licences issued and 59.7 percent of all licences worked as of August, 1979, while all three had annual sales in 1978 in the $10-20 million range. Two of the three are subsidiaries of U.S. firms while the third is Canadian owned. Eleven of the 26 licensees were not working any of their licences as of August, 1979. The licensees conducted little, if any, research into the discovery of new drugs. Information on profitability and advertising was not available. Finally, the licensees are poorly organized and publicly represented, in that only five belonged either to the CDMA or AFQPP and these five do not include two of the leading three licensees.

4.3 Licensee Characteristics: An Analysis

The primary objective of this paper is to analyze the impact of compulsory patent licensing. Viewed in that light two characteristics of the licensees seem particularly pertinent. First, not one of the patentees discussed in Chapter V below is a licensee.[11] The patentees, with their knowledge of the industry and large size would seem the most obvious candidates to make compulsory licensing work. Second, what inferences can be drawn from the fact that many firms took out licences and appear to be quite successful at selling the same drug as the patentee?

A consensus emerged out of the various government reports into the drug industry in the 1960's[12] about the relation of costs to prices, the level of prices and profitability. Broadly stated the propositions were as follows. The price of drugs in Canada was high by both international standards and in relation to the cost of production. The rate of profits in the drug industry was among the highest in the manufacturing sector. Under such circumstances standard micro-economic analysis would predict, in the absence of barriers to entry, that firms would enter the industry with lower priced substitutes. The net result would be a fall in price and levels of profitability. Such behaviour was not observed in the 1960's. This suggests that barriers to entry existed, such as capital requirements, patents, advertising expenditures or research and development, which successfully prevented or discouraged new entrants.

Although the analysis of the various government inquiries was not cast in the above framework, the inference was essentially the same: barriers to entry existed in the prescription drug industry which discouraged new entrants and price competition.[13] The barrier which was singled out as of prime

significance was the patent protection afforded drugs.[14] Hence, the recommendation most commonly made was that the patent protection afforded drugs should be severely weakened.[15] The passage of 41(4) saw the implementation of that suggestion.

In the period 1969 to 1979, as detailed in the previous section, 26 firms were granted one or more compulsory patent licences by the Commissioner of Patents and attempted to compete with the patentees, as detailed below, on the basis of price. Hence, the events subsequent to the passage of 41(4) are consistent with the implied predictions of the various government inquiries and reports. The more general subject of the significance of price competition amongst the patentees is left to the discussion in the next chapter.

The economic self interest of the patentees explains their absence from the list of firms to which the Commissioner of Patents has issued compulsory patent licences. The patentees, as a group, have a strong economic interest in the maintenance of the patent system, as the analyses and conclusions of the various government reports and inquiries attest - higher prices and profits than would otherwise be the case. Should each patentee decide to take out a licence against all the remaining patentees then price competition,[16] much greater than currently exists between licensee and patentee,[17] would result. Given the extreme insensitivity of the demand for drugs to price changes, the price and profit margins of the patentees would fall. Hence, as a group, patentees would experience considerable adverse economic consequences from a policy of acquiring compulsory patent licences.

Although it is in the economic self interest of patentees, as a group, not to become licensees, this is not to deny that it may be profitable for a patentee to become a licensee. However, there are several factors discouraging such a course of action. First, it is a risky proposition. Not only is it difficult to forecast the final outcome but the remaining patentees are likely to react by, for example, acquiring licences on the "renegade" patentee's products and attempting to bankrupt the firm. Second, while there are undoubtedly risks to such a strategy the potential benefits may not be that large, considering that most of the patentees are multinational firms and Canada represents only two per cent of world drug sales.[18] Hence, for these reasons, it is unlikely that any of the patentees will become a licensee.

A constant theme of the literature on the drug industry is the importance of non-price competition.[19] Much research effort by the pharmaceutical industry is directed toward producing substitutable or new products which offer some therapeutic advantage over existing drugs on the market: safer; treats a different segment of the population; is slightly more efficacious. Such advances, via advertising, can be promoted to physicians in order to secure sales. However, it is unlikely

that the physician will switch from prescribing a long established patentee's product to a licensee substitute which involves no therapeutic advantage, only a lower price. Such an explanation of patentees not acquiring compulsory patent licences was presented in the early 1960's by an official of Cyanamid of Canada Limited, a firm that was to become a patentee under section 41(4):

> The larger company [i.e., patentee] would far rather develop its own product than go into the market with someone else's product. Cyanamid, for example, could undoubtedly obtain a compulsory licence on a number of patent protected products. But in order to take business away from the patentee, we would have to detail the product to doctors, this is not easy when the products are identical or very similar, and we would have to pay a royalty. We are in a far better position with our own product. It is simply not profitable to market a product developed by a competitor who has fully established himself in that market. (Restrictive Trade Practices Commission, 1963, p. 118).

This explanation is likely to carry somewhat less force today with the introduction of section 41(4), and the attendant federal and provincial government programs, some of which attempted to directly influence the prescribing habits of the physician, such that price would become an important factor in deciding which brand of a drug to prescribe.

4.4 Marketing Strategy Of Licensees

In evaluating the "success" or "failure" of compulsory patent licensing and in suggesting any consequent recommendations to better achieve the policy objectives of compulsory patent licensing, knowledge is needed of the strategy followed by the licensees in competing with the patentees. This section outlines the main thrusts of licensee marketing strategy and demonstrates the essential role played by government policies in securing licensee penetration of patentee markets. The reader will recall that some of the issues, such as government reimbursement programmes and product selection legislation, are discussed in Chapter 1 above.

Acceptance Of Licensee Product. A necessary condition for the licensee to be able to penetrate the patentees' market is the acceptance by physicians, pharmacists and, to a much lesser extent, patients, that the licensee brand of any drug X is therapeutically equivalent to the patentee brand of the same drug. In other words, it has to be established that the

licensee's product is a perfect substitute for that of the patentee's.

The issue of acceptance comes from the perception of the patentees as large well-established firms with a record of producing and marketing the licensed drugs for a number of years prior to the appearance on the market of the licensees' substitute products. On the other hand, the perception of the licensee is likely to be that of a much smaller firm than the patentee, perhaps in a somewhat shaky financial position and somewhat of an unknown when it comes to providing a substitute product of a consistently good quality. Given such perceptions, health care officials such as physicians and pharmacists are naturally concerned about ensuring the quality and equivalence of the licensee product.[20]

The federal and provincial governments have played a very important part in certifying quality and therapeutic equivalence of licensee drug products. Two policies are of particular importance; first, the passage of product selection legislation by almost every province. Such legislation allows the pharmacist to dispense the licensee product instead of the patentee product, often without incurring any legal liability for damages should the user of the licensee product suffer adverse effects due to poor quality. Second, the certification by provincial governments[21] that the licensee and patentee brands of the same generic drug are therapeutically equivalent or, to use a common phrase, interchangeable pharmaceutical products. The list of licensee drugs, together with the patentees', that are considered interchangeable are published in a formulary and distributed to physicians and pharmacists by the provincial government. Formularies are currently used by five provinces[22] which, in 1973, accounted for 76.6 per cent of all prescribed drugs by sales.[23] Chapter 1 discusses formularies and product selection legislation in more detail.

In assessing the acceptance of licensee drugs, attention will be concentrated upon the success of licensee products being listed as interchangeable with the patentees' in provincial government formularies. (It should be noted, however, that the Quebec formulary only lists brands of acceptable quality and does not certify interchangeability.) Inclusion in a formulary is not normally automatic, except for Quebec, once the federal regulatory authorities have approved the licensee's drug for sale and are satisfied with the manufacturing facilities. Usually a provincial Drug Quality and Therapeutics Committee will decide which licensee products will be included. There is no question that the patentee drug will secure a listing in the formulary. In order to satisfy the Committee, however, the licensee may be required to conduct tests in addition to those already submitted to the federal regulatory authorities.[24] Although quality and equivalence are the major criteria for

inclusion, the Committee also has to be satisfied that the licensee can supply the drug in sufficient quantity to meet market demand.[25]

The federal regulatory authorities provided a list of all drugs on the market, as of August, 1979. Table 4-1 shows that of the 26 firms which had obtained at least one licence from the Commissioner of Patents, between 1970 and 1978, only 15 had licensed drugs on the market as of August, 1979. Provincial government formularies, which for all provinces are issued twice a year (January and July), provide a list of all brands considered interchangeable for each drug. A comparison of the federal regulatory authority's list of different brands of a given drug on the market with the corresponding provincial listings provides an indication of how successful each licensee is in gaining acceptance for its licensed drugs. The results are presented in Table 4-3.[26]

Licensees, treated as a group, (i.e., the line marked "total" in Table 4-3) have met varying success in obtaining listings for their products in the five provincial formularies. Quebec lists virtually every licensee drug (i.e., 70/72 or 97.2 percent) while all the other provinces fall well short of listing 100 percent of licensee brands, varying from Ontario (52/72 or 72.2 percent) to New Brunswick (26/72 or 36.1 percent). While not being listed in the formularies for such relatively small markets as Saskatchewan, New Brunswick, and Manitoba[27] may not be a serious economic impediment to the licensee, failure to gain access to the Ontario market (which accounts for 37.6 percent of drug sales in Canada) is clearly likely to be a significant barrier to the licensee in selling a particular licensed drug. Hence, gaining acceptance would appear to be a problem for a significant number of licensed drugs in the economically important market of Ontario.

Before turning to a discussion of the success of individual licensees in obtaining listings in provincial formularies, a slight word of caution is appropriate with regard to interpreting Table 4-3. One of the reasons why licensee drugs fail to appear in a provincial formulary is that a particular drug is not listed at all; that is, neither the patentee nor the licensee(s) brand is listed.[28] For example, furosemide is included in all provincial drug formularies except New Brunswick's. In Chapter 1, the criteria for whether or not a drug is included in a provincial formulary is discussed. In an attempt to eliminate this influence, the line marked "total" in Table 4-3 was re-estimated excluding from the denominator licensed drugs that are never referred to in the formulary. The results are as follows:

PROVINCE	UNADJUSTED		ADJUSTED[29]	
	Ratio	%	Ratio	%
QUEBEC	70/72	97.2	70/72	97.2
ONTARIO	52/72	72.2	52/70	74.3
SASKATCHEWAN	47/72	65.3	47/68	69.1
NEW BRUNSWICK	26/72	36.1	27/42	64.3
MANITOBA	42/72	58.3	42/60	70.0

These adjustments make no substantive difference with respect to Ontario, Quebec and Saskatchewan. However, for New Brunswick and Manitoba the lack of success of licensees in obtaining listings as recorded in Table 4-3, appears, especially for the former province, to be due to the relatively small number of the licensed drugs listed in the formulary. Also the problem, mentioned above, of an important number of licensees being omitted from the Ontario formulary is not due to that province listing relatively few of the licensed drugs.

In terms of individual licensees only Mowatt and Moore Ltd. is successful in obtaining a listing in every province for all of its compulsorily licensed, currently marketed drugs. Other licensees which fare well across all the provinces include Novopharm Ltd., Frank W. Horner Ltd., Apotex Inc., and Harris Laboratories Ltd. If the fact that some provinces do not list the licensed drug at all is taken into account, then K-Line Pharmaceuticals Ltd. could also be considered successful in this respect.

The licensees that were unsuccessful in obtaining listings across all provinces can be divided into three categories. First, Jerram Pharmaceuticals Ltd., while very successful in the major markets of Ontario and Quebec, failed to obtain a listing in any other province. This reflects the fact that Jerram, due to problems with production facilities, was delisted from all provincial formularies in late 1977/early 1978, and has as yet to be relisted by New Brunswick, Manitoba and Saskatchewan.[30] Second, a group of small licensees, mostly Quebec based, ranked 9th to 15th in Table 4-3. All of these licensees were successful in obtaining listings in Quebec but completely unsuccessful outside. This may reflect the fact the licensed drugs marketed by these licensees included such high selling items as diazepam, chlordiazepoxide, furosemide, and amitriptyline, for which there were usually several licensees already listed. The various provincial formulary committees may have simply decided that there were typically enough licensees to ensure the full benefits of price competition. However, in a Quebec government report the failure of these smaller licensees to secure a listing in the Ontario formulary was felt, in part, to reflect the discretionary use of quality and inspection standards against such firms.[31] Third, ICN Canada Ltd., a Quebec-based licensee, with 100 percent of its drugs appearing in the Quebec formulary, has only 14 of 22 drugs (or 63.6 percent) listed in Ontario. ICN's lack of success in the remaining

TABLE 4-3

LICENSEE SUCCESS IN OBTAINING LISTING OF LICENSED DRUGS IN PROVINCIAL GOVERNMENT FORMULARIES: JULY 1979

LICENSEE \ PROVINCE	(Ratio of no. of licensed drugs listed in formulary to total no. of licensed drugs worked and currently on the market as of August 1979) Quebec	Ontario	Saskatchewan	New Brunswick	Manitoba
1. ICN Canada Ltd.	22/22	14/22[a]	15/22[b]	12/22[c,d]	15/22[d]
2. Novopharm Ltd.	15/16	15/16	15/16	9/16[e]	14/16
3. Frank W. Horner Ltd.	5/5[f]	5/5	5/5	3/5[a]	4/5[a]
4. Jerram Pharmaceuticals Ltd.	5/6[f]	5/6	0/6[g]	0/6[a,h]	0/6
5. Apotex Inc.	7/7	7/7	6/7	0/7[l]	5/7[a,l]
6. K-Line Pharmaceuticals Ltd.[i]	2/2	2/2	2/2	0/2	0/2
7. Mowatt and Moore Ltd.	2/2	2/2	2/2	2/2[a,j]	2/2
8. Harris Laboratories Ltd.	3/3	2/3	2/3	0/3[a]	2/3
9. Neo Drug Co.	2/2	0/2	0/2	0/2[l]	0/2
10. Paul Maney Laboratories Ltd.	1/1[k]	0/1	0/1	0/1[a]	0/1
11. ERI Pharmaceuticals Ltd.	2/2	0/2	0/2	0/2	0/2
12. Laboratoire Medic Ltd.	1/1[m]	0/1[l]	0/1[l]	0/1[l]	0/1[l]
13. Nadeau Laboratory Ltd.	1/1	0/1	0/1	0/1	0/1
14. Compagnie Pharmaceutique Vita Ltée.	1/1	0/1	0/1	0/1	0/1
15. Trans-Canada Dermapeutics Ltd.	1/1	0/1	0/1	0/1[l]	0/1[l]
Total	70/72	52/72	47/72	26/72	42/72
Percentage of Canada's Retail Market[n]	28.5	37.6	3.2	3.5	3.8

a. One of the drugs was not listed in this formulary at any time, for either patentee or licensee.
b. One drug was counted that was listed July 1975-July 1978. Three of the drugs were not listed in this formulary.
c. Ten of the drugs were not listed in this formulary, at any time, for either patentee or licensee.
d. Six of the drugs were not listed in this formulary, at any time, for either patentee or licensee.
e. Two drugs were not listed in this formulary at any time, for either patentee or licensee.
f. The unlisted drug was in the formulary from July 1973 to July 1975.
g. Three of these drugs were listed January 1976 to January 1977.
h. Three of the drugs were not listed in this formulary, at any time, for either patentee or licensee.
i. This licensee is listed in recent formularies as Beecham Labs.
j. One of the drugs was listed January and July 1977.
k. In the latest two formularies listed with ICN Canada Ltd. This licensee had to be listed in formularies previous to that, separately from ICN Canada Ltd. to be counted.
l. The(se) drug(s) was(were) not listed in this formulary, at any time, for either patentee or licensee.
m. Listed July 1974-July 1978.
n. Excludes sales of prescription drugs to hospitals. Percentages refer to 1973.

Note: The formulary used for New Brunswick referred to January, not July, 1979.

Source: Canada, Department of National Health and Welfare (1975a, Table 47, p. 57); Appendix D, Table D-1, below; and various provincial government formularies.

provinces is accounted for by the licensed drugs not being listed at all. An examination of the eight instances in which ICN failed to obtain a listing in Ontario revealed the following: in one instance the drug is not listed at all;[32] in four instances only the patentee's brand is listed;[33] in three only one licensee is listed: Novopharm Ltd. (1)[34] and K-Line Pharmaceuticals (2).[35] For the latter seven drugs, ICN has not obtained a listing for five of them because of the delay due to the extra tests required by Ontario but not by Quebec;[36] for another[37] the licensee has decided not to acquire a listing; and in the final case[38] the drug was listed in the Ontario formulary for January 1980.[39]

In sum, of those firms that were unsuccessful in obtaining listings for their products, either in part or in whole, the reasons were as follows: the drug was not included in the formulary at all; the drug is relatively new and hence there is a time-lag before it becomes listed in the formulary; a number of brands of the licensed drug were already listed.

An important aspect that is not revealed by Table 4-3, but which was touched upon in the text above, concerns the speed with which licensees are successful in obtaining a listing in the provincial formularies, once the federal authorities have allowed the licensee's drug to be sold in Canada. In compiling Table 4-3 it became apparent that Quebec listed drugs much more quickly than any other province. In order to illustrate this, a case study was made of Apotex Inc., a recent licensee managed by an experienced entrepreneur in the industry.[40] The details are outlined below.

Drug	Date Certified By Federal Authorities[41]	Date Listed in Quebec	Date Listed in Ontario	Difference Between Ontario and Quebec Listings (months)
thioridazine	1976	July '76	Jan. '78	18
perphenazine	1976	July '76	Jan. '77	6
furosemide	1976	Jan. '77	Jan. '77	0
chlorthalidone	1976	July '76	Jan. '78	18
amitriptyline	1975	Jan. '76	July '77	18
diazepam	1977	July '77	July '77	0
methyldopa	1976	July '76	Jan. '78	18
Average:	--	--	--	11

Other provinces are not reported since the lag was as long, if not longer, than Ontario. For example, Saskatchewan, which lists six of the seven licensed drugs marketed by Apotex Inc. took, on average, 2 years longer than Quebec to list Apotex's brands in its formularies.[42] This reflects at least two factors: an administrative procedure that results in somewhat longer time periods to review submissions and, because of the difficulties experienced by Jerram Pharmaceuticals Ltd., noted above, Saskatchewan was reluctant to accept a large number of products from another "unproven" manufacturer and chose to accept Apotex

products gradually, as confidence grew in this licensee. Hence it would appear that Quebec usually lists a licensee's drug as soon as the federal authorities have approved the drug for sale,[43] whereas Ontario and the other provinces wait a year or two more before listing. In the case of Ontario this reflects the fact that they may require some additional tests to those provided for the federal government as well as inspecting the licensee production facilities in order to ascertain equivalence. It would appear that the remaining provinces usually wait until Ontario has listed the licensee's drug. In addition, some of these provinces also examine the production facilities of the licensees.

Thus, the two most important provinces for a licensee to be listed in the formularies are Ontario and Quebec, which together accounted for 66.1 percent of retail sales in Canada (see Table 4-3). Quebec has listed almost every licensee product as soon as the federal authorities have approved the drug for sale. In contrast, Ontario has listed only 72.2 percent of all licensee brands, usually with a considerable lag after the federal authorities have approved the drug, probably reflecting interchangeability requirements not present in Quebec. This lag partly accounts for the shortfall of licensee products listed in Ontario. Since other provinces[44] follow the Ontario lead, this delay may be a costly barrier to the licensee.

Pricing Policy of Licensees. The pricing policy for the licensee can only be considered within the wider framework of the appropriate marketing strategy for the licensee, once the necessary condition of obtaining a listing in the various provincial formularies has been satisfied.[45] The licensee is selling a product that is therapeutically and chemically the equivalent of the patentee product. Hence, the usual method of competition in the drug industry used by the patentees, the discovery of drugs via research and development offering therapeutic advantages over existing products, promoted to physician and pharmacist, cannot be used by the licensee in promoting his substitute product.[46] Under such conditions the only strategy for the licensee would appear to be to use price as the major competitive instrument combined with limited promotion to advertise the quality and interchangeability with the patentee's product, where this has been certified by a provincial government formulary listing. This indeed appears to be the path followed by the licensees.

If price is the main competitive variable used by the licensee in order to attract "customers" from the patentee then the licensee will charge a lower price in order to offset the successful product differentiation of the patentee. Such a pattern is confirmed by examination of provincial government formularies which list the prices of interchangeable brands of the same drug. For example, the pricing pattern for one of the most important compulsorily licensed drugs, diazepam, a tranquilizer in the central nervous system pharmacologic-therapeutic classification, is, as follows,

PATENTEE	BRAND	INDEX OF PRICE PER UNIT
Hoffman-LaRoche Ltd.	Valium	100
LICENSEES		
Apotex Inc.	Apo-Diazepam	3.0
ICN	E-Pam	3.3
Mowatt and Moore Ltd.	D-Tran	31.9
Novopharm Ltd.	Novodipam	35.7
Frank W. Horner	Vivol	66.9

The price refers to 5 mg tablets of diazepam, the most popular dosage form, for the second half of 1979 for the province of Saskatchewan.[47] As expected the licensee prices are below those of the patentee. However, there is substantial variation of prices among the licensees. This reflects, in part, the fact that firms have been more successful in penetrating the patentee's market and, at the same time, achieving a degree of product differentiation which is reflected in a higher price. For instance, Frank W. Horner Ltd. first marketed Vivol in 1970, three years before Novopharm Ltd. and ICN Canada Ltd., and was thus able to capitalize on an early lead. In contrast, Apotex Inc., first marketed Apo-Diazepam in 1977, later than any of the other licensees by three years. The relative newness of Apotex Inc. is no doubt reflected, in part, in the low price for its brand of diazepam.

The success of the licensees in penetrating the market of the patentees clearly depends upon the price sensitivity of pharmacists and physicians in their dispensing and prescribing roles. As explained in Chapter 1 the importance in price competition is likely to vary considerably by provincial drug program, the class of patient (i.e., private or public third parties, cash paying) and the segment of the market (i.e., hospital vs. retail outlet) served. At the very least, the large price differentials between licensee and patentee brands of the same drug, observed in virtually all provincial formularies, suggest that serious limitations on price competition remain. We will return to this in section 4.5 below.

Brand Names. A drug can be described by its generic or proper name,[48] that is, "the name recognized in the Food and Drug Regulations, in a licence issued under section 12 of the Food and Drugs Act or in any of the official reference books on drugs." (Restrictive Trade Practices Commission, 1963, p. 7). The generic name is usually multi-syllabic and difficult to pronounce; e.g., chlordiazepoxide, perphenazine, amitriptyline, chlorthalidone, furosemide. A drug firm usually identifies its particular synthesis of a generic drug by the use of a brand name which is almost always shorter and easier to remember for the physician and pharmacist. For example, the brand names Zyloprim and Purinol are used, respectively, by Burroughs Wellcome Ltd.,

and Hoffman-La Roche Ltd., to refer to the same generic drug, allopurinol. The generic name cannot be protected by a trademark, whereas the converse applies to the brand name.[49] Hence, drug firms typically use brand names in promoting their products.[50]

An examination of the brand names selected by the licensees shows that although in many instances they have followed the lead of the patentee and used brand names, there has been a marked tendency to make greater use of the generic name. This has been done in a number of different ways. Apotex Inc., for example, uses the prefix "Apo-" before the generic name to form the brand name. A similar approach is used by Novopharm Ltd. which uses the prefix "Novo" but sometimes uses only part of the generic name. Finally, Jerram Pharmaceuticals Ltd. and, to a large extent, ICN Canada Ltd. use the generic name as their brand name. The greater use of generic names by the licensees may suggest that the various attempts by provincial governments to encourage physicians to prescribe using the generic name of the drug have met with some success.

Summary. The marketing strategy of the licensees has consisted of first gaining acceptance of their product in the five provinces which publish and distribute formularies. These five provinces account for 76.6 percent of all retail sales of prescription drugs in Canada. Of particular importance is a listing in Ontario and Quebec. The licensees have no problem with respect to Quebec. However, Ontario takes longer to list products which accounts in part for the fact that only 72.2 percent of the licensees' drugs are listed. In addition, the smaller licensees are not listed at all in Ontario. The remaining three provinces generally follow Ontario's lead. The main instrument used by the licensee to compete with the patentee is price. The licensee has, in fact, little choice but to use price.

4.5 Market Penetration by Licensees

In this section the success with which the licensees have been able to penetrate the market of the patentees, for those drugs subject to compulsory licensing, is explored. Attention is focussed not only on Canada as a whole but also on the provinces of Ontario, Quebec and Saskatchewan, and the retail as well as hospital market. Data availability is not uniform across all of these provinces and markets. The reader should therefore bear these differences in mind when making comparisons.

Table 4-4 shows patentee and licensee market shares for a sample of 20 licensed drugs for 1978 for both the retail and hospital market in Canada. The market shares are measured by patentee and licensee sales to the retail and hospital markets. For each drug the sales refer to all dosage forms and strengths even though patentee and licensee may compete on less than the complete range of available dosage forms. The sample of 20 drugs

TABLE 4-4

PATENTEE[a] AND LICENSEE MARKET SHARE OF SALES OF 20[b] LICENSED DRUGS, CANADA,[c] 1978

Generic Name of Drug	Market Share[d]	
	Patentee	Licensee
amitriptyline	75.2	24.8
amoxicillin	81.9	18.1
ampicillin	74.8	25.2
betamethasone[e]	100	0
chlordiazepoxide	67.2	32.8
chlorthalidone	76.8	23.2
clofibrate	98.4	1.6
cloxicillin	92.2	7.8
diazepam	71.7	28.3
erythromycin estolate	86.7	13.3
methyldopa	84.4	15.6
ethambutol	53.8	46.2
fluocinolone acetonide	100	0
furosemide	86.8	13.2
hydrochlorothiazide	82.5	17.5
perphenazine	79.8	20.2
rifampin	51.4	48.6
thioridazine	71.9	28.1
trifluoperazine	84.8	15.2
triamcinolone acetonide	94.7	5.3
Average		
Unweighted	80.8	19.3
Weighted	82.2	17.8

a. And/or voluntary licensed user.
b. See text for details of sample selection.
c. Both retail and hospital market.
d. Refers to sales of all dosage forms, not just those for which licensee competition exists.
e. Only bethamethasone-17-valerate.

Source: PMAC (1979, Appendix 6, Attachment B) based upon IMS data.

was selected from those drugs for which a compulsory licence had been issued over the period June 1969 to June 1979.[51] However, where patents had expired, were invalid, or not used, where none of the licensees had marketed the drug or, finally, where neither patentee nor licensee were marketing the drug, then such licensed drugs were excluded from consideration.

The market share data in Table 4-4 suggests that the patentees have been, on average, extremely successful in retaining a very substantial (i.e., 80 percent) share of the market for licensed drugs, despite the presence of licensee competition, facilitated by various federal and provincial government programmes and legislation outlined in Chapter 1, above. In only three instances did the licensees account for more than 30 percent of the sales of the licensed drug. For most of the licensed drugs in Table 4-4, licensee penetration fell in the range of 10-30 percent (i.e., for 12 of the 20, or 60 percent). The licensees were less successful in gaining market shares of the highest compared to the lowest selling drugs; for those four[52] licensed drugs with total sales in excess of $5.0 million, the average market share held by licensees was 21.8 percent, while for the four[53] drugs with sales of less than $1.0 million the corresponding average was 32.6. This is reflected in the overall average market share of the licensees, when measured using the weighted compared to unweighted average. Finally, it might be noted that, not surprisingly, above average licensee market shares are recorded for those drugs for which licences have been issued most frequently.[54]

While the information contained in Table 4-4 is undoubtedly a useful beginning in examining patentee and licensee market shares it does not enable a number of issues to be addressed. First, the success of the licensees on those dosage forms and strengths with which they compete with the patentee - Table 4-4 refers to all dosage forms and strengths. Second, patentees typically charge higher prices than licensees for the same quantity of a given dosage form and strength. As a result market shares measured in terms of (say) number of 5 mg. tabs. rather than the value of such tabs. may yield quite different results. Third, the success of individual licensees cannot be measured from Table 4-4. These three issues need to be considered so a fuller understanding of patentee and licensee competition can be gained, which can then be used in policy discussions and recommendations.

A popular selling dosage form and strength for a sample of ten high selling licensed drugs,[55] from a number of different therapeutic categories, was selected to explore the above three issues. Of these ten drugs all but one, chlorpropamide, were also included in Table 4-4.[56] Information on the number of units and their value for both licensees and patentees were available for the hospital market (for Hospital Purchasing Incorporated, a large buying group of Toronto hospitals) and the retail market in the provinces of Ontario,

(for the Ontario Drug Benefit which accounted for 28-30 percent of all prescriptions dispensed in Ontario in the period 1977-1979) Quebec, (for the Programme de medicaments du Quebec, which accounts for approximately 25 percent of the Quebec market) and Saskatchewan (for the Saskatchewan Drug Prescription Plan, which accounts for all of the province's prescription drugs). Further information on most of these markets can be found in Chapter 1, especially section 1.3. The information has been provided on the understanding that individual firms' sales and market shares will not be revealed.

Table 4-5 provides a summary of the patentee and licensee market share, measured in physical units of the dosage form and strength as well as the dollar value (i.e., sales). Information in the table is presented only on the licensee market share, the patentee's share being the residual. Market share data is presented for all four markets in Table 4-5 for two years (in part, or in whole) several years apart, in the second half of the 1970's.

Table 4-5 shows that the licensees have been very successful in penetrating all of the markets with the exception of Quebec. The most successful licensees correspond closely with those in Table 4-3, with ICN Canada Ltd., and Novopharm Ltd. being particularly significant in every market. In all instances licensee market share increased over time, reflecting a rise in the number of licensees and the presence of licensee competition for virutally every drug by the second of the two dates in Table 4-5 for each market. In Saskatchewan the extension of the standing offer contract system (i.e., tendering) from five to nine of the ten drugs between 1976 and 1979 also played an important role in the success of the licensees. The market share of the licensees were usually less measured in terms of value than quantity reflecting the lower price charged by licensees. The disparity is particularly noticeable for Saskatchewan, which can be explained by a competitive tendering system which results in lower prices, but for the "no substitution" prescriptions the patentee can receive a markedly higher price. In contrast the hospital market "no substitution" prescriptions do not exist so that licensee quantity and value market shares for individual drugs are the same (i.e., 0 or 100, depending upon whether a licensee is successful or not in securing the contract).

A major factor accounting for the difference in licensee market shares across the various markets in Table 4-5 is the degree to which the rules of the marketplace, outlined in Chapter 1 above, encourage the prescribing and dispensing of the typically lower priced licensee brand. In the hospital and Saskatchewan markets, both of which operate tendering systems, and Ontario, with mandatory price selection, there is a clear incentive encouraging the use of lower priced brands. In contrast, the Quebec system, with permissive product selection[57] and payment for the brand dispensed, no matter what the cost, does not provide incentives for the use of lower priced

TABLE 4-5

AVERAGE LICENSEE MARKET SHARE FOR 10 LICENSED DRUGS, SELECTED DOSAGE FORMS AND STRENGTHS,[a] VARIOUS MARKETS, 1976-1981

HOSPITAL		RETAIL[b]					
Hospital Purchasing Inc., Toronto		Ontario (Ontario Drug Benefit)		Quebec (Programme de medicaments du Quebec		Saskatchewan (Saskatchewan Prescription Drug Plan)	
Year[c]	%	Year[d]	%	Year	%	Year[e]	%
Market Share Measured in Units of Output (i.e., quantity)							
1978/79	62.5	1977	55.0	1976	9.4	1976	26.9
1980/81	66.7	1980	64.4	1978	12.3	1979	61.2
Market Share Measured in Sales (i.e., prices)							
1978/79	62.5[f]	1977	54.2	1976	8.4	1976	19.9
1980/81	66.7[f]	1980	62.1	1978	10.6	1979	37.3

a. The licensed drugs and the high selling dosage form and strength selected, covering a variety of therapeutic categories, were as follows: amitriptyline 25 mg. tabs.; diazepam 5 mg. tabs.; clofibrate 500 mg. caps.; furosemide 40 mg. tabs.; methyldopa 250 mg. tabs.; ampicillin 250 mg. caps.; amoxicillin 250 mg. caps.; cloxacillin 250 mg. caps.; erythromycin estolate 25 mg. susp.; and chlorpropamide 250 mg. tabs.

b. In all instances the retail market refers to provincial government drug reimbursement programmes. For full details see Chapter 1, section 1.4 above, for details.

c. Should be read as year ending June 1979 or June 1981, although this did vary by drug somewhat.

d. Refers to May of 1977 and 1980.

e. Refers to the first quarter of 1976 and 1979.

f. For one of the ten drugs HPI did not let a contract in either year, while for another, information was not available on the firm which was awarded the contract in 1978/79.

Source: Information provided by Hospital Purchasing Inc., Ontario Drug Benefit, Programme de medicaments du Quebec, and the Saskatchewan Prescription Drug Plan.

licensee products. Hence, provinces, by setting the rules of the game, are able to encourage or retard licensee competition, with resultant differences in drug prices for a given drug dosage form and strength, other things equal.[58]

The disparity between the results in Tables 4-4 and 4-5, which show that licensees command a lower market share for Canada compared to a number of sub-markets can be accounted for by a number of factors such as differences in dosage form and strengths, market coverage and data sources.[59] Nevertheless, whatever the reasons for the disparity between the two tables, the important point in comparing the two is that substantial differences exist in the success of licensees depending upon the sub market. Such differences reflect, in considerable part, the rules of the marketplace which are set by the provinces.

4.6 Summary and Overview

Since the introduction of compulsory patent licensing to import in 1969, twenty-six firms took out a total of 142 licences on 47 drugs up to and including 1978. However, as of August 1979 not all 142 licences were being worked, only 72. A small number of licensees accounted for the vast majority of the licences issued or worked. For example, five licensees accounted for 63.4 per cent of 142 licensees issued, 77.8 per cent of those worked. While most of the licensees appeared to be relatively small, the three leading licensees all had sales in excess of $10 million. None of the licensees were also patentees, a finding explained by the self-interest of the patentees: an all-out price war with each other is likely to lead to lower prices and profits. In terms of marketing their drugs the licensees generally obtained provincial certification that their brands were equivalent and interchangeable with the patentees. However, the Quebec formulary only lists brands of acceptable quality and does not certify interchangeability. Ontario usually took longer than Quebec and listed somewhat fewer licensee drugs than Quebec. The other provinces followed Ontario's "lead". The licensees competed on the basis of price with the patentees. Not surprisingly in those markets where price competition is encouraged (e.g., hospital, Ontario, Saskatchewan) the licensees commanded substantial market shares, whereas in Quebec, where much less incentive is provided, the patentees retained, on average, in excess of 80 percent of the market.

The major object of compulsory patent licensing was to stimulate price competition with the result that prices would decline. This chapter has shown that a large number of firms have acquired licences, entered various provincial markets and competed on the basis of price. Hence, if the objects of compulsory licensing have not been realized it is not for lack of licensees vigorously competing on the basis of price, when given the opportunity. We now turn to the patentees and their competitive reaction to the licensees' entry.

CHAPTER V

THE PATENTEES

5.1 Introduction

In construction and broad outline, this chapter parallels that of the previous chapter on the licensees. As remarked above, however, data on the patentees is more readily available and plentiful. This chapter therefore describes characteristics of the patentees for which corresponding data is not available for all of the licensees (e.g., profitability). Hence, comparisons are not always possible between the material presented in the two chapters.

Section 5.2 details the major characteristics of the patentees, such as the number of licensed drugs owned by the patentee, size, ownership and nationality, research and development activity, and profitability. No attempt will be made to account for the characteristics of the patentees, as was done for the licensees. It is beyond the scope of this study. In any event numerous studies of the drug industry are readily available, although they often do not refer specifically to Canada.[1]

In the previous chapter an attempt was made to discuss and describe the strategy used by the licensees to penetrate the market for the patentees' drugs. The corresponding section in this chapter, 5.3, presents details on the patentee's competitive reaction to the licensee entry into the market. In particular, attention will be paid to price cutting, contesting applications for compulsory patent licence applications, the use of a portfolio of "indications" for the patentee's drug, and acquisitions as methods of neutralizing, if not eliminating, the influence of the licensees in any given market. The final section, 5.4, brings together the various strands of the chapter in a summary with some inferences drawn.

5.2 Characteristics of Patentees

Patentees. In Chapter III details were provided of the 47 drugs against which at least one compulsory patent licence had been issued over the period 1970 to 1978. In several instances the patents on a particular drug may be owned by more than one firm. For example, there may be several intermediate processes which have to be used in order to manufacture the active ingredient. Each process patent may be held by a different firm.[2] The patents on approximately one in five of the licensed drugs were owned by two or more firms. (i.e., 13 of 47 or 27.7 percent). The frequency is as follows:[3]

Table 5-1

PATENTEES RANK IN WORLD DRUG INDUSTRY, CANADIAN SUBSIDIARY, COUNTRY OF OWNERSHIP AND NUMBER OF DRUGS AGAINST WHICH LICENCES ISSUED

Patentee	Country of Patentee[a]	Rank in World Drug Sales[a]	No. of Compulsorily Licensed Drugs[b] (No. currently marketed by licensees)		Canadian Subsidiary
			Sole Patentee	Several Patentees	
Hoffman La Roche	Switzerland	1	3(2)	1(0)	Hoffman-La Roche Ltd.
Merck and Co.	U.S.A.	2	4(2)	2(2)	Merck, Sharp and Dohme Canada Ltd.; Charles Frosst and Co.
Warner Lambert/Parke Davis	U.S.A.	3	0(-)	1(1)	Warner-Chilcott Laboratories Co. Ltd. (Warner Lambert Canada Ltd.); Parke, Davis and Co. Ltd.
Hoechst	Germany	4	1(1)[f]	0(-)	Hoechst Pharmaceuticals
Ciba-Geigy	Switzerland	5	6(3)	2(2)	Ciba-Geigy Canada Ltd.
American Home Products	U.S.A.	6	1(0)	1(1)	Ayerst Laboratories (Ayerst, Mckenna and Harrison Ltd.); Wyeth Ltd.; Elliott-Marion Co. Ltd.,
Pfizer	U.S.A.	7	1(0)[g]	1(0)	Pfizer Co. Ltd.
Bayer	Germany	8	0(-)	1(1)	Bayer (Canada) Inc.[c]
Bristol-Myers	U.S.A.	9	0(-)	2(2)	Bristol Laboratories of Canada; Mead Johnson Canada; Will Pharmaceuticals
Sandoz-Wander	Switzerland	10	0(-)	1(1)	Sandoz (Canada) Ltd.
Eli Lilly and Co.	U.S.A.	11	1(1)	1(0)	Eli Lilly & Co. (Canada) Ltd.
E.R. Squibb & Sons	U.S.A.	13	1(1)	1(1)	E.R. Squibb & Sons Ltd.
Schering-Plough	U.S.A.	15	1(1)	1(1)	Schering Corporation Ltd.
Upjohn	U.S.A.	17	1(0)	0(-)	The Upjohn Co. of Canada
Rhône-Poulenc	France	18	3(1)	1(1)	Poulenc Ltd.
Glaxo	U.K.	22	0(-)	2(1)	Glaxo Laboratories; Allen and Hanburys
American Cyanamid	U.S.A.	25	0(-)	3(2)	Cyanamid of Canada (Lederle)
Beecham	U.K.	26	0(-)	4(3)	Beecham Laboratories (Mowatt & Moore Ltd.)[d]
Imperial Chemical Industries	U.K.	28	2(1)	1(1)	ICI Pharmaceuticals[d]
Smith, Kline	U.S.A.	31	1(1)	0(-)	Smith, Kline & French Canada Ltd.
Wellcome	U.K.	32	0(-)	2(1)	Burroughs Wellcome Ltd.; Calmic Ltd.
G.D. Searle	U.S.A.	33	1(0)	0(-)	G.D. Searle & Co. of Canada.
Dow	U.S.A.	34	0(-)	1(1)	Dow Chemical of Canada
Morton-Norwich	U.S.A.	46	1(1)	0(-)	Norwich/Eaton Pharmaceuticals (Norwich Parmacal Co Ltd.); Eaton Laboratories
Boots	U.K.	54	1(1)[h]	0(-)	----
12 other companies[e]			5(1)	11(10)	----
Total			34(17)	40(32)	

a. James (1977, Appendix 1, pp. 248-50 and 3, pp. 253-54). The ranking is by sales volume of drugs, 1973.
b. For the 47 drugs of Table 3-1 above.
c. Canadian subsidiary is not directly involved in prescription drug market.
d. The three drugs are produced by Ayerst Ltd. in Canada, not by ICI Pharmaceuticals Ltd., under a voluntary licensing agreement.
e. Twelve firms ranking below the top 80 companies (in terms of worldwide drug sales). No data on their rank is available.
f. Hydrochlorothiazide is not produced by licensee, Micro Chemicals, but about 11 other "licensees" without licences are currantly producing it. Patent expires 1984 (PMAC), but is apparently not enforced. Thus, did not include it in the count.
g. Chlorpropamide: the licence was taken out by Dymond Drugs and they did produce it, at least for the period June 1974-August 1977, but this drug is currently produced by at least 5 "licensee" firms without a licence. Since the patent has either expired or is not enforced, did not include it in the count.
h. Ibuprofen: Frank W. Horner Ltd. produces this, but not Novopharm, the licensee. However, since Horner began producing this only in 1979, a compulsory license may have been obtained this past year or it may have a private licensing arrangement for this drug and thus the drug was included in the count.

Source: Appendix D, Table D-1 below; Drug Merchandising (1975, 1979); Canadian Manufacturers' Association (1979); James (1977); Canada, Statistics Canada (1978b); Quebec, Regie de l'assurance-maladie du Québec (1979a, 1979b); and the print-out of current (i.e., August 1979) drugs on the market, from the Bureau of Drugs, Department of National Health and Welfare.

Number of Patentholders of the Licensed Drug	Frequency
1	34
2	7
3	1
4	3
5	1
6	1
Total	47

Most of the licensed drugs with multi-patentholders were in the anti-infective agents therapeutic category (i.e., eight of the 13 or 61.5 per cent). The drug with the largest number of patentholders was ampicillin (i.e., six).

The maximum number of potential firms with a patent on the 47 compulsorily licensed drugs is, due to the presence of multi-patentholders on each of 13 drugs, not 47, but 74.[4] However, since some of the patentees hold patents on more than one drug the actual total number of patentholders is 37, substantially less than 74. For example, Hoffman-La Roche Ltd. is the sole patentholder for three drugs - chlordiazepoxide (brand name,[5] Librium) diazepam (brand name, Valium) flurazepam (brand name, Dalmane) and one of two patentees on another drug, trimethoprim (brand name, Bactrim).

Table 5-1 provides an overview of the patentees and their significance in terms of rank in worldwide sales. In the first column the patentee is identified. It is this firm against which the licensee applies to the Commissioner of Patents in seeking a compulsory licence.[6] The patentee usually holds the worldwide rights to the patent. The second column of the table specifies the country where the patentee is domiciled. The rank of the patentee in terms of worldwide ethical drug sales for 1973 is presented in column 3. The next two columns detail the number of compulsorily licensed drugs for which the patentee is either sole owner or one of several patentholders. The numbers in parentheses indicate the corresponding totals of licensed drugs, either owned partly or wholly by the patentee, which are currently (i.e., August 1979) being worked by one or more licensees. Finally, the column on the extreme right lists the name of the Canadian subsidiary of the patentee.[7] In several instances the patentee has more than one Canadian subsidiary.

Thirty-seven firms owned patents relating to 47 drugs for which compulsory licensees were issued by the Commissioner of Patents between 1970 and 1978. Of the 37 firms, however, only 31 owned patents relating to drugs for which the licensees were marketing the licensed drug as of August, 1979. In other words, six of the 37 patentees, or 16.2 percent, owned patents relating to drugs for which there were licences extant, but no licensee competition in the form of a substitute product.

These six included such drug firms as Upjohn and G.D. Searle. The reasons for non-working of the compulsory licence are discussed in Chapter III above.

The ownership of patents relating to compulsory licensed drugs is not concentrated in the hands of one or two patentees, as evidenced by Table 5-1. In terms of the 34 single patentee licensed drugs the size distribution is as follows:

Total number of licensed drugs owned by the patentee		Total number of licensed drugs owned by patentee for which licensees are marketing the licensed drug	
No.	Frequency	No.	Frequency
6	1	6	0
5	0	5	0
4	1	4	0
3	2	3	1
2	1	2	2
1	16	1	11

There is only a moderate degree of concentration in both distributions. For example, the leading four patentee firms account for 47.1 percent (i.e., 16/34) of all licensed drugs with a single patentholder. Both distributions are heavily skewed toward the lower values. A similar conclusion is reached by examining the size distribution of licensed drugs for which there are multi-patentholders.[8] The ownership concentration on the patentee side contrasts sharply with that of the licensees, where the two leading licensees owned 52.8 per cent of all licences worked as of August, 1979.

Nationality, Ownership Characteristics and Size. In considering the ownership characteristics, nationality and size, attention will be confined to the patentees listed among the largest 80 drug firms in the world (see Table 5-1 for details). This approach is used for three reasons. First, as a group the patentees among the leading 80 drug firms account for 29/34 or 85.3 percent of all licensed drugs for which there is a single patentee and 79.4 of all multiple patentee drugs.[9] These drugs include such leading sellers as diazepam and chlordiazepoxide. Second, few of the 12 patentees outside the leading 80 world drug firms sell their drugs in Canada directly. It would appear, in most instances, they are licensed to a third party. Third, much more information is available on the patentees among the leading 80 world drug firms than those ranked lower. Reference will, however, be made to the 12 patentees outside the largest 80 world drug firms where appropriate.

The patentees among the world's leading 80 drug firms, as detailed in Table 5-1, are all foreign owned.[10] The composition is as follows:

Country	Number	Percentage
U.S.A.	14	56.0
U.K.	5	20.0
Switzerland	3	12.0
Germany	2	8.0
France	1	4.0
Total	25	100

Among the seven countries from which the patentees originate, the U.S.A., U.K. and Switzerland are clearly the most significant, accounting for 88.0 percent of all patentees among the leading 80 world drug firms. The importance of foreign-owned firms is not surprising. Although the percentage of prescription drug sales accounted for by foreign-owned firms is not published, 85.1 percent of industry 374 (Manufacturers of Pharmaceuticals and Medicines), which includes prescription drugs, is accounted for by foreign-owned firms.[11]

The patentees, in addition to being foreign-owned, are among the leading drug firms in the world. Table 5-1 records that compulsory licences have been issued by the Commissioner of Patents on drug patents owned by all of the world's leading 10 drug firms and 15 of the leading 20. Many of the names of the patentees, for various reasons, are commonly known - Hoffman-La Roche, Ciba-Geigy, Bayer and Imperial Chemical Industries (ICI).

The patentees make their drugs available to the public in Canada in one of two ways; first, through a wholly owned subsidiary, often bearing a name the same or similar to that of the patentee, with the addition of the word "Canada" in the title. Most (i.e., 20 out of 25) patentees among the world's leading 80 drug firms used this method to sell their drugs in Canada. In several instances the patentee has more than one subsidiary listed in Table 5-1. Second, the patentee can enter a voluntary licensing arrangement with a third party, which is usually the Canadian subsidiary of a fellow patentee. This would appear to be the policy of five[12] of the patentees among the leading 80 drug firms in the world and most of the patentees ranked less than 80th. Voluntary licensing would seem primarily to reflect the fact that the patentee is either small in size and/or one of several patentholders of the drug, combined with the relatively small size of the Canadian market for prescription drugs.

In considering the patentee operations in Canada attention will be confined mainly to the subsidiaries of those 20 patentees among the world's leading 80 drug firms which marketed licensed drugs, for which they owned the patents,

through wholly owned subsidiaries. It is recognized, of course, that subsidiaries of these 20 patentees will often market, under a voluntary licence arrangement, patented drugs owned by other patentees, not directly represented in the prescription drug market. The size distribution of the 20 patentees' subsidiary operations in Canada are as follows:[13]

Size (1978) $million, sales	Subsidiaries No.	%
20 and over	8	40.0
15-20	6	30.0
10-15	2	10.0
5-10	3	15.0
2½-5	1	5.0
Total	20	100

The sales figures refer not only to the patentee subsidiary sales of licensed drugs but also to all other prescription and non-prescription drugs.

The patentee subsidiaries in Canada are much larger than the licensees described in the previous chapter. For example, 14 of the 20 or 70.0 percent of the patentee subsidiaries had sales in excess of $15 million, only 2 of the 16 or 12.5 percent of the licensees for which data are available had sales in excess of $15 million.[14] No licensee fell into the category of $20 million and over. Although patentee subsidiaries are large in relation to the licensees they are comparatively small in relation to the total world-wide ethical sales of the patentee. For example, in 1973 the world-wide drug sales of each of the largest 11 patentees exceeded the total retail prescription drug market for Canada, Hoffman-La Roche's worldwide sales alone were more than double the size of the Canadian market.[15]

Another method of presenting the relative size of the patentee subsidiaries in Canada is to estimate their percentage of the prescription drug market. These data are detailed in Table 5-2, on the basis of the sales of prescription drugs in the province of Saskatchewan. The table shows that patentees, taken as a whole, account for a very significant share of the prescription drug market - 71.2 percent in 1977-78. In 1976-77 the corresponding percentage was 72.0. In terms of individual patentees, the two most important were American Home Products and Merck & Co. with, respectively, 14.1 and 11.7 percent of the market. Most of the remaining patentees had less than five percent of the market. The four most important patentees accounted for 35.5 per cent of the total prescription market.[16] Since individual firms tend to specialize in particular therapeutic categories, concentration at the level of such categories is usually higher than indicated by such global industry figures.[17] Evidence similar to Table 5-2 is not

TABLE 5-2

THE SIGNIFICANCE OF PATENTEES IN THE PRESCRIPTION DRUG MARKET OF THE PROVINCE OF SASKATCHEWAN:[a] 1977-78

Patentee[b] (Ranked by Worldwide Drug Sales)	Percentage of Prescription Drug Sales
Hoffman-La Roche	3.9
Merck & Co.	11.7
Warner Lambert/Parke Davis	3.0
Hoechst	1.5
Ciba-Geigy	4.5
American Home Products	14.1
Pfizer	1.0
Bristol-Myers	0.7
Sandoz-Wander	1.6
Eli Lilly & Co.	5.1
E.R. Squibb & Sons	2.3
Schering-Plough	1.8
Upjohn	3.3
Rhône-Poulenc	1.8
Glaxo	4.6
American Cyanamid	0.9
Smith, Kline	3.3
Wellcome	4.3
G.D. Searle	1.8
Morton-Norwich	<0.1
Total[c]	71.2

a. Includes all prescription drugs sold by the patentee in Saskatchewan, except those sold to hospitals.
b. The patentee and/or its subsidiaries, which are identified in Table 5-1 above. Note, as discussed in the text, a patentee may sell prescription drugs in Canada for a fellow patentee under a voluntary licence arrangement. These sales would be included in the estimation of the percentages.
c. Note five of the 25 patentees among the world's leading 80 drug firms are excluded from this table, but included in Table 5-1. The reasons for this sub-sample of the 25 is discussed in the text. Three of the excluded patentees sold no drugs in Saskatchewan, while Dow and Beecham both recorded very low sales volumes: 0.7 per cent and 0.2 per cent, respectively.

Source: Saskatchewan, Department of Health (1978, Table XIII, pp. 21-22); James (1977, Appendix 1, pp. 248-250, and 3, pp. 253-254.)

available for Canada. Nevertheless the fragmentary material that is available[18] is consistent with the main inference drawn from this table: while the patentees appear to be significant, measured in terms of the percentage of drug sales they account for, individual patentees account for fairly small overall market shares.

Most of the patentees, through their subsidiaries, have been present in Canada for a long period of time. For example, the majority of patentees were established prior to the Second World War and manufacturing in Canada by the 1950's.[19] Among the acquisitions of Canadian owned drug firms since 1960 by the patentees, the most significant has been the purchase, in 1966, of Charles E. Frosst Ltd. by Merck & Co.

Profitability, Research and Development and Advertising. Research and development expenditures, as well as those devoted to advertising (including promotion), are not available on an individual basis, but only for the industry as a whole or for PMAC members. However, since the patentees account for the overwhelming proportion of total prescription drug sales, figures derived from these studies are likely to be representative of the patentees behaviour in regard to these two dimensions. Profitability data is available for not only the industry as a whole, but also for some individual patentee subsidiaries operating in Canada.

The research and development (R & D)[20] activity of the patentees results in the drug industry being among the most R & D intensive industry Canada, as measured by the ratio of scientists and engineers per 1,000 employees or the ratio of R & D expenditures to total sales.[21] According to a survey of PMAC members,

> Canadian ethical pharmaceutical firms spent over $21 million in 1975 (5% of their total Canadian sales) on research. This ratio of research expense to sales has been relatively constant over the last decade (PMAC, 1978b, p. 18).

Among the patentees which conduct research and development in Canada, perhaps the most significant is American Home Products which, through its subsidiary Ayerst, currently employs approximately 300 persons in this program.[22] Virtually all of the research conducted by the patentees is financed from company sources,[23] rather than via government grants.[24] Finally, it should be noted that a very large percentage of research and development expenditures in Canada is not directed toward producing or discovering new drugs,[25] but rather conducting clinical tests to meet regulatory requirements concerning safety and efficacy.[26] In 1975 approximately 57 percent of research and development expenditures by PMAC members was categorized as product development.27

The term, advertising, is construed broadly, with respect to prescription drugs,[28] to refer to,

> ... all the expenses for product promotion including journal advertising, direct mail, samples, product promotion literature, exhibit display expenses plus the costs of the sales force, including salaries, cars and miscellaneous manpower expenses (PMAC, 1978b, p. 34).

Such advertising is directed exclusively at physicians and pharmacists, since, as mentioned in Chapter 1, advertising to the public is prohibited by law. For 30 members of the PMAC advertising, as a percentage of sales, [29] is as follows:[30]

Year	Advertising as a Percentage of Sales
1964	26.3
1965	24.3
1966	23.7
1967	22.9
1968	21.3
1969	19.3
1970	18.6
1971	17.8
1972	16.0
1973	15.7
1974	15.8
1975	15.2

Two points should be noted concerning these percentages. First, by comparison with other industries prescription drugs ranks among the most advertising intensive.[31] Second, advertising, although always a significant percentage of sales, has declined over the period 1964 to 1975 from 26.3 percent to 15.2 percent. This may be the result of the criticism of drug advertising as "wasteful" and "excessive" by both the Hall Commission (1964, p. 666) and Harley Committee (1967, p. 21). However, it may also be a reflection of the introduction of price competition because of compulsory licensing. The Harley Committee (1967, p. 23) commented as follows,

> The answer [to "high" advertising expenses] appears to lie in increased competition.... The greater the competition, the greater the pressure against high prices. As prices drop, inefficiency is bound to decline, and a cut-back in promotion and marketing costs is almost bound to ensue.

TABLE 5-3

NET PROFIT AFTER TAX AS A PERCENTAGE OF SHAREHOLDERS EQUITY FOR MANUFACTURERS OF PHARMACUETICALS AND MEDICINES AND THE MANUFACTURING SECTOR: 1968-1977

Year	Rate of Return on Shareholders Equity[a]	
	Pharmaceuticals and Medicines[b]	All Manufacturing[b]
1968	13.8	9.4
1969	13.0	9.8
1970	14.6	7.2
1971	15.1	8.8
1972	n.a.	10.0
1973	14.0	14.6
1974	15.7	16.2
1975	14.5	12.6
1976	12.9	11.6
1977	12.7	10.6

a. Rate of return refers to firms classified as Pharmaceuticals and Medicines. In other words, the largest percentage of a firm's sales are accounted for by this industry rather than (say) the fertilizer or chemical industry. Rates of return refer to the whole of a firm's operations. These statements apply equally to All Manufacturing.

b. The data source uses the term "Pharmaceuticals". Reference to index of industrial classification of the corporations in the source publication reveals that SIC industry 374, Manufacturers of Pharmaceuticals and Medicines, and "Pharmaceuticals", are identical.

n.a. = not available.

Source: Canada, Statistics Canada, Corporation Financial Statistics, Cat. No. 61-207 (various issues).

This is only a partial explanation since it was only in the early 1970's that licensees entered patentee markets on a large scale, and the decline in advertising was continuous from 1964 onwards. More research is needed before a definitive answer can be given.

Profitability data is available for industry 374 (Pharmaceuticals and Medicines) as well as individual patentees, which are required to file financial statements with the Bureau of Corporate Affairs, Department of Consumer and Corporate Affairs. Several difficulties are encountered in interpreting such data. First, the patentees may engage in transfer pricing, thus obscuring (i.e., reducing) their profits in Canada. Recently, the Department of National Revenue has launched an inquiry to assess the extent of this practice following a number of complaints (Westell, 1980). Second, the reported equity and profit figures refer to the whole of the patentee's operations, not just prescription drugs or activities within industry 374. For the sample of 20 patentees amongst the world's leading 80 drug firms, mentioned above, sales of pharmaceuticals (broadly speaking industry 374) constituted, on average, only 47 percent of their world-wide sales, (see Canada, Department of Industry, Trade and Commerce, 1979c, Appendix A, pp. 39-40). Details for their Canadian operations were not available. Third, although the patentees' dominate industry 374, the industry rates of return will be affected, perhaps marginally, by non-patentee firms including the licensees. Fourth, no adjustment was made for either advertising or R & D expenditures, which are treated as current expenses and, it is argued, should be treated as capital goods. This ommission tends to bias reported profit rates upwards and would appear to be of considerable significance. (See, especially, Brownlee, 1979 and Schwartzman, 1976, pp. 136-161). These caveats should be remembered when considering the inferences drawn below.

The rate of return after tax on shareholders equity for firms in the Pharmaceutical and Medicine Industry and, for comparative purposes, All Manufacturing, is shown in Table 5-3. For all the years over the period 1968-1977, Manufacturers of Pharmaceuticals and Medicines were more profitable, often by a considerable margin, than All Manufacturing, except 1973 and 1974, when the difference was, however, only, 0.6 percent or less. This "high" level of profitability is consistent with previous findings for Canada.[32] The industry did not, however, seem to suffer a significant decline in profitability after 1969. No such uniform picture emerges for the individual patentees, some exhibiting high, others low, rates of return compared with the industry's average shown in Table 5.3. This may reflect the fact that for an individual firm, profitability is often attributable to the disproportionate contribution of a small number of drugs, which are frequently subject to compulsory licence applications.[33] Some idea of the variation in patentee returns may be gained from the following sample of net profits after tax as a percentage of shareholders equity:

	FIRM				
Year	Roche	Merck	Hoechst	Ciba-Geigy	Smith Kline
1970	12.6	8.3	29.6	n.a.	8.0
1971	4.9	14.3	24.0	0.7	12.5
1972	3.0	18.4	42.2	-110.0	11.0
1973	-4.0	24.9	34.5	-15.3	0.8
1974	2.6	23.9	21.0	9.9	9.1
1975	0.7	34.6	16.1	2.0	12.5
1976	1.7	33.0	7.6	-16.2	8.4
1977	0.8	23.9	4.0	1.7	3.5

Source: Financial statements as filed with Bureau of Corporate Affairs, Department of Consumer and Corporate Affairs. See Table 5-1 for full title of firm.

These data show patentees such as Hoffman-La Roche Ltd., and Ciba-Geigy, barely making a return on equity in most years, while others, such as Merck and Co., earn, by industry standards, a very high return. In sum, while industry profitability has remained high by comparison with all manufacturing, individual patentees returns vary considerably.

Trade Association. The trade association which represents the views of the patentees is the Pharmaceutical Manufacturers Association of Canada (PMAC). The association had a membership of 61 in 1978 of which patentees and their subsidiaries constituted slightly under half (45.9 percent).[34] All the patentees among the world's leading 80 drug firms in Table 5-1 were members of the PMAC in 1978, with three exceptions. In two instances, Boots and Bayer, the patentee did not market in Canada the licensed drugs for which it owned the patent or appear in provincial formulary listings. Hence, their non-membership of the PMAC is not surprising. However, such is not the case with the third patentee, Hoffman-La Roche Ltd., which, as reported in Chapter III, owns the patents relating to two of the three drugs which have had 11 or more compulsory licences issued against them by the Commissioner of Patents. The reason why Hoffman-La Roche Ltd. was not a member in 1978 dates back to the late 1960's when both Hoffman-La Roche Ltd. and Frank W. Horner Ltd. were members of the PMAC. Horner subsequently took out compulsory licences on some of Roche's drug products, with the result that the latter firm withdrew its membership and did not rejoin, even after Frank W. Horner Ltd. ceased to be a PMAC member. However, in 1979, Hoffman-La Roche Ltd. reversed this position and rejoined the PMAC.

The PMAC has a full time professional staff of about half a dozen and a full time president, currently Major General W.M. Garton. The PMAC presents briefs to various provincial and federal inquiries, departments, regulatory agencies and commissions on behalf of its members.[35] This contrasts sharply with the resources and range of membership, of the

CDMA, which represents only a few of the licensees and has no full time staff.

Summary The ownership of patents relating to the 47 drugs, for which compulsory licences have been issued by the Commissioner of Patents over the period 1970 to 1978, is distributed amongst 37 patentees. The leading four patentholders account for 47.1 percent of all licensed drugs for which there was a single patentholder. In contrast, the two leading licensees accounted for 52.8 percent of all licences worked as of August 1979. Almost without exception, the patentees are foreign-owned, with many being amongst the world's leading drug firms. The patentees' operations in Canada are much larger than the licensees. For example, 14 of the 20 or 70.0 percent of the patentee subsidiaries (among the world's leading 80 drug firms) had Canadian sales in excess of $15 million while the corresponding figures for the licensees were 2 out of 16 or 12.5 per cent. Not surprisingly, given these inequalities in size patentees, as a group, accounted for approximately 70 per cent of the prescription drugs sold in Canada. The patentees conducted extensive research and development as well as advertising (measured by the ratio of advertising and research and development, respectively, to sales). Patentee profitability, as a group, was high by manufacturing standards, although there was some variation among the patentees. Finally, the patentees were represented through a trade association, the Pharmaceutical Manufacturers Association of Canada.

5.3 The Response Of the Patentees

5.3.1 Introduction

The response of the patentees to the advent of compulsory licensing can be divided into two categories: economic and non-economic. In both instances the intent of the response has been, not surprisingly, to neutralize, if not eliminate, the influence of the licensees in the prescription drug market. The difference between the two categories is that the economic response refers to the marketplace while the non-economic response refers to attempts by the PMAC, as well as patentees individually, to change the rules of the competitive game by influencing public servants and legislators. Section 5.3.2 discusses the economic response while 5.3.3, the non-economic. An evaluation of the overall success is presented in section 5.3.4.

5.3.2 The Economic Response

The economic problem that faces the patentee can be characterized as follows: one or more potential licensees are seriously considering (i.e., have applied to the Commissioner of Patents for a compulsory licence) entering the market for which the patentee, through ownership of the relevant set of drug patents, has had a virtual monopoly. The licensee will

almost certainly compete on the basis of a much lower price than that of the patentee. The licensee is usually relatively small with limited financial resources although, in one or two instances, the parent firm is of substantial size in its own right. However, usually the licensee will already sell prescription drugs for which the patent has expired and, possibly, non-prescription ethical drugs and proprietory medicines. The object of the patentee is to limit the impact of the licensee on profits and prices.

Beset with such a problem and objective the patentees have a wide variety of competitive instruments from which to select. These can be divided into two groups: entry-forestalling devices such as patent litigation, satisfying the demand for the product immediately prior to entrant's appearance for a considerable period of time (referred to as "filling the pipes") and prolonging the period for which the drug is classified as a "New Drug" by the federal regulatory authorities; competing with the entrant once entry takes place by price cutting, "moral suasion" or non-price competition, acquisition of licensees, and the use of the drug safety and efficacy laws to force withdrawal of the licensee's product. This is a list of potential instruments which the patentee could use to neutralize or reduce the impact of the licensees. Evidence exists that some, or all, of the patentees used a number of these instruments. However, it is quite probable that in a number of instances an instrument has been used but concrete evidence cannot be obtained, beyond the hearsay of a licensee or public servant. In the discussion and presentation below, attention is mainly confined to those instruments for which concrete evidence is available. For the remaining instruments a small amount of elaboration on how they can be used by the patentee is presented.

In the discussion of certain instruments, particularly price cutting and moral suasion, extensive reference will be made to the response of one of the patentees, Hoffman-La Roche Ltd., with respect to two drugs diazepam and chlordiazepoxide. These two drugs accounted for slightly in excess of 50 percent of all licensee royalties payable under compulsory patent licensees in 1974,[36] constitute two of the three drugs for which 11 or more compulsory licences have been issued, and, finally, were two of the first drugs for which licensees produced competitive substitute products. Hence, the reaction of Hoffman-La Roche Ltd. is likely to serve as a useful lesson to other patentees. In any event, there is a paucity of data available for the other patentees. Hoffman-La Roche Ltd. documentation is from the trial record of legal proceedings by the Crown under the Combines Investigation Act for predatory pricing for which Hoffman-La Roche Ltd. were convicted and fined in 1980.[37]

Patent Litigation has several advantages from the viewpoint of the patentee as an entry-forestalling device.

First, the licensee may be delayed from marketing a competitive product until the litigation is complete. Since the delay is likely to be difficult to determine with precision, the result is uncertainty in the planning process for the licensee. Second, compared with other competitive instruments, such as price cutting or acquisition, patent litigation may well be the instrument with the highest return to the patentee. Hence, one would expect patent litigation to be extensively used.

In the context of compulsory licensing the opportunity for patent litigation is summarized in Chapter II, section 2.5.2. From that discussion the patentee would seem to have several avenues: attempt to force the Commissioner of Patents to hold a hearing prior to issuing a compulsory patent licence;[38] appeal the Commissioner's decision, whether or not a hearing has been held, to the Federal Court and, ultimately, the Supreme Court of Canada. This process has the potential to delay considerably the licensee's ability to market a competitive product. For example, when Frank W. Horner Ltd. applied for a compulsory patent licence for diazepam, the sequence of events was as follows.[39]

Application to Commissioner of Patents	July 1969
Commissioner's decision after a hearing	Jan. 1970
Exchequer Court [now the Federal Court] decision after patentee appealed Commissioner's decision.	Nov. 1970
Supreme Court of Canada refused to hear patentee's appeal from Exchequer Court decision	March 1972

Although it is difficult to evaluate how much shorter the procedure would have been had a hearing not be held, if the modest period of one month is used, then instead of the licence application being decided by Dec. 1970, it required an extra 2¼ years.[40] Hence, litigation has the potential to considerably delay a final decision on the awarding of a licence by the Commissioner of Patents.

An examination of the record over the period 1969 to 1978 shows that, in several instances, the Commissioner held a hearing and his decision, whether arrived at with or without the benefit of a hearing, was appealed by the patentee to the Federal Court and eventually the Supreme Court of Canada. In a number of instances the Commissioner clearly held a hearing because of a particularly novel or important aspect with respect to the licence application, not at the behest of the patentee. Equally, the patentee appealed certain decisions in order to clarify the law (i.e., on the merits). The question then arises as to the extent, if any, of litigation with the sole

aim of preventing or delaying the licensee from entering the market.

It is beyond the scope of this study to determine or judge whether the actions taken by the patentees are indeed primarily entry-forestalling. However, in several judgments remarks have been made which suggest that the judges, at least, feel that appeals of no merit have been made. For example, Jackett, C.J., remarked in 1973, that, "...there is...some ground for thinking that many appeals under s.41 of the Patent Act are brought regardless of any considered opinion that there is, under the authorities, any valid ground for attacking the Commissioner's decision".[41] Four years later in awarding costs, Jackett, C.J., gave serious consideration to using,

> RULE 1108. Where, in the opinion of the Court, a proceeding in the Court is frivolous, unwarranted or otherwise not brought in good faith, the Court may, by its judgment disposing of the matter, order the party by whom the proceeding was instituted [i.e., the patentee] or carried on to pay to the Registry an amount in respect of the work done and expenses incurred by the Registry in connection with the matter under Rule 1206, Rule 1306 or Rule 1402 or otherwise, which amount shall be fixed by the judgment.[42]

Hence, it would appear that the patentees have used the process of appeal to forestall entry by the licensee.

Although the patentees have used litigation as a method of entry-forestalling, it seems to have been relatively ineffective. The Commissioner decides whether to hold a hearing and attempts by the patentees to undermine the authority of the Commissioner have been firmly rejected by the courts. In appealing to Federal Court, although this may delay the licensee marketing the drug, the patentee has been virtually unsuccessful in every case. Increasingly, the judges have taken a dim view of patentee litigation, thus ensuring this device is rarely used.[43]

Competing with the Licensees: Price vs. Non-Price Competition. The discussion of price vs. non-price competition centres on the experience of Hoffman-La Roche Ltd., particularly with price competition in respect to the hospital market. Reference is made, however, briefly, to a number of other patentees.

One of the initial reactions of Hoffman-La Roche Ltd. to the entry of the licensees was to suggest that their (i.e., Roche's) product was superior to that of the licensee on several broad counts - quality, the originator, new drugs

introduction slowed, research reduced, the licensee does not have the experience and knowledge of the drug in giving advice and information. In one memorandum to all field staff of Hoffman-La Roche Ltd., dated April 2, 1968, the following passage appeared,

> 2. Point out that when a hospital buys Librium - they buy part of 'Roche'.
>
> - part of our knowledge
> - part of our experience
> - part of our guidance regarding over-dosage
> - part of our guarantee
> - part of our department that disseminates information to doctors
> - part of our dedication to the profession
>
> 3. Point out that when they buy an imitation, they get what they see and that is all - there is nothing else!!
>
> (Memo to entire Roche Field staff from K. Bradshaw, titled "Imitation Formulations of Chlordiazepoxide," April 2, 1968, p. 2)

In a letter to doctors signed by the President of Hoffman-La Roche Ltd., J.S. Fralich, and dated February 1968, the following passage appeared,

> The imitation philosophy was recently underlined by Dr. Alfred Gilman, Professor of Pharmacology, Albert Einstein College of Medicine and Co-Editor with Dr. L.S. Goodman of "The Pharmacological Basis of Therapeutics" when he wrote to U.S. Senator Nelson: "... I consider the small generic drug company a completely parasite industry...." Apart from the occasional counterfeiter the current duplications containing chlordiazepoxide are marketed under Compulsory license by tradename. To our knowledge none of these imitators had to duplicate the enormous amount of work which is necessary in the compilation of a new drug application. Likewise, no clinical investigation activities of any consequence by these companies have come to our attention.

This campaign against the licensees was conducted by Hoffman-La Roche Ltd. in the mid and late 1960's as a number of licensees marketed chlordiazepoxide and then diazepam by the use of

section 41(3) of the Patent Act, which is discussed in section 2.4 above.

Hoffman-La Roche Ltd. realized that attempts to persuade doctors and hospital pharmacists not to use licensee products for the type of reasons outlined above were unsuccessful in preventing the licensee from getting a foothold in the market. In one memorandum from the President of Hoffman-La Roche Ltd. dated June 14, 1967 the following passage appears,

> Marketing Department feels that there is no alternative methods of competing for Government business except on a price basis. In other words, the following arguments will not be effective:
>
> i) Roche the originator
>
> ii) Quality - "known predictable results every time"
>
> iii) Support research or you risk having no new drugs
>
> (Memo to the Executive Group from J.S. Fralich, titled "Librium Price Situation", p. 2).

The lack of success was attributed to two factors: the price sensitivity of hospitals, particularly with the formation of buying groups; a change in attitude by the physicians under "continuous pressure from government and criticism of his earnings."[44] In other words, the series of government inquiries in the 1960's was affecting the prescribing habits of doctors.

Somewhat reluctantly, it became apparent that price competition, particularly in the hospital market, was the only method by which Roche could compete with the licensees. In the minutes of the Sales Promotion Planning Group held on the 21st of February 1969 under "Pricing Policy" the following comment appeared,

> The Group reaffirms that the only basis which will maintain hospital unit sales will be related to prices competitive in the market place, regardless of any promotional or prestige activities. This could be handled either by price adjustment or by deals (one free with one). A certain "price guarantee" should be offered to hospital pharmacists who have bought large quantities shortly before a price decrease or deal may come into effect.

> A price for quantities of 250,000 and 500,000 tablets should be established. (Minutes of Hoffman-La Roche Ltd. Sales Promotion Planning Group held on Feb. 21, 1969, p. 1).

The pricing of Librium and Valium to the hospital market over the period Jan. 1970 to Jan. 1974 can be summarized as follows:[45]

BRAND NAME	Time Period: Jan70-June70	July70-June71	July71-Dec71	Jan72-June72	July72-Jan74
	Discount Policy				
LIBRIUM	Buy 1 Get 1 free	Buy 1 Get 1 free	Buy 1 Get 2 free	Buy 1 Get 2 free	Buy 1 Get 3 free
VALIUM	Buy 2 Get 1 free	F R E E	Buy 1 Get 2 free	Buy 1 Get 3 free	Buy 1 Get 4 free

In general, Roche met the price competition except for the period July 1970 to June 1971 when it gave away Valium to hospitals. Although this policy resulted in one licensee withdrawing from the hospital market for the period July 1970 to June 1971, the patentee seems to have gained no longer-term advantage. Prices gradually fell over the next three years. The licensee concerned, Frank Horner Ltd., had other lines besides diazepam so was not going to go bankrupt. Hence, the policy of more than meeting the competition was a failure. Not only was this policy a failure, but it succeeded in Hoffman-La Roche Ltd., being taken to court by the Crown under the Combines Investigation Act for predatory pricing and subsequently convicted and fined, albeit only $50,000.

Attention with respect to price competition has centred on the reaction of one patentee, Hoffman-La Roche Ltd. in the hospital market. The evidence presented demonstrates that Hoffman-La Roche Ltd., has met and in some instances undercut the price of licensees. Vigorous price competition in the hospital market reflects the operation of a tendering system and expert buyers who select primarily on the basis of price amongst a group of interchangeable brands of the same drug. Table 5-4 summarizes Roche's view of price competition not only in the hospital but also retail market, between licensee and patentee, for five licensed drugs. None of the patents relating to these drugs were owned, in whole or in part, by Roche. The table shows (column headed "Prices to Hospitals") that other patentees have tended to follow the same policy as Roche in that prices to hospital are lowered in response to licensees competition, though not to the extent of incurring a charge of predatory pricing under the Combines Investigation Act. However, with respect to the retail market (i.e., column headed "Competitive Activity", especially for amitriptyline and trifluoperazine) the patentees seem to be

able to command a section of the market largely independent of price. This reflects the influence of advertising and the resultant use of "no substitution" prescriptions by physicians. Under such circumstances, it is likely to be unprofitable for the patentee to reduce prices drastically to meet the licensee competition. These inferences are consistent with the discussion in Chapter IV, section 4.5 above, particularly as it applies to Saskatchewan.

Use Of Other Competitive Instruments. As outlined in Chapter III a drug is classified by the Health Protection Branch of the Department of National Health and Welfare as either "New Drug Status" or "Old Drug Status." Classification of a drug in the former category results in the licensee having to perform certain clinical tests prior to marketing the drug. No such tests have be performed if the drug is accorded "Old Drug Status." The dividing line between the two different types of status is at the discretion of the Health Protection Branch. When adverse drug reactions are reported or raised by the patentee then the regulatory authorities will hesitate to transfer a drug from New to Old Drug Status especially if, as seems likely, the authorities are risk-averse. Hence, the patentee, by the presentation of "evidence" that suggests the question of safety and efficacy is not an entirely settled question, may be able to postpone the change in the status of the drug. It is not known, however, to what extent, if any, this has or is the case.

The final entry-forestalling device referred to here is one practiced by Hoffman-La Roche in the late 1960's and early 1970's[46] (whether other patentees have used the device is not known). Just prior to the entry of the licensee the patentee "floods the market," usually on the basis of a price special, so that the licensee cannot establish a foothold for some time. This is described somewhat colloquially as "filling the pipes."

Two other competitive instruments can be considered briefly, since each would appear to be rarely used. The obvious alternative for a patentee which has to meet licensee competition, is to acquire the competitor. A list of licensees in Table 4-2 shows only one, Mowatt and Moore Ltd., has been acquired by a patentee, Beecham. It appears that the acquisition was primarily as a vehicle for Beecham to enter the Canadian market for prescription drugs, not as an attempt to silence the competition of Mowatt and Moore Ltd.[47] The apparent lack of merger activity can be explained on several grounds. Since all of the patentees are foreign-owned enterprises, acquisition of a licensee requires the approval of the federal government under the Foreign Investment Review Act, since 1974.[48] In deciding whether to allow an acquisition (i.e., in assessing "significant benefit") the provincial governments are consulted. Given the commitment of federal and provincial governments to low priced drugs, it seems difficult to envisage the allowing of aquisitions of licensees by patentees, especially of the leading three. The patentee, even in the absence of such control, may have misgivings about acquiring the licensees, since it may create the

TABLE 5-4

COMPETITIVE REACTION OF SELECTED PATENTEES TO ENTRY OF LICENSEES AS VIEWED BY HOFFMAN-LA ROCHE LTD: 1974

Drug (Patentee)	Number of Licences Issued[a]	Competitive Activity	Prices to Hospitals
Amitriptyline (Merck & Co.)	4	M.S. & D. [i.e., Merck] feels that the competitors are competing among themselves at the retail level and have little effect on Elavil. Heavy dealing is suspected, particularly in the case of Novopharm.	Elavil stopped seeking hospital business when its offer of five free units with every 1 unit purchased was insufficient. Therefore it can be surmised that price competition at the hospital level is extremely severe. M.S. & D. has benefited from the severe price erosion at this level as hospitals purchase Elavil at its regular price after the imitators failed to produce amitriptyline at the quoted tender prices.
Ampicillin (various including American Home Products via Ayerst, and Bristol)	8	Until 1970, Penbritin [i.e., Ayerst's brand] price decreases were due to the competitive activity of Bristol. In 1970, with several new entries onto the market, together with the advance knowledge that Novopharm was to introduce its brand of ampicillin, Penbritin's prices were again reduced.	Prices offered to hospitals are not available as these price structures have not been rigid, but as a rule they have been considerably lower than those offered to the drug trade. Ayerst currently are using hospital contracts in which it is mandatory that 50% of the dollar value of the contract must be for Penbritin or Fluothane purchases. Hospitals who have signed such contracts get an additional 5-15% discount, depending on the volume purchased. Novopharm seems to have the lowest hospital price - about $4.00 for 250 mg x 100. However, it is important to note that Novopharm does not have an injectable form of ampicillin.
Chlorpromazine (Rhône-Poulenc)	2	The chlorpromzine market is an old and declining market. Poulenc has fought to maintain its share of this market, increasing its share from 70% in 1963 to 82.6% in late 1973, by offering favourable discounts to the drug trade and lowering prices dramatically to hospitals.	Largactil's [i.e., patentee's brand] price to hospitals has recently been dropped from about $8.00/M for the 25mg strength to $2.99/M. Poulenc believes that they presently offer the lowest price to hospitals.
Thioridazine (Sandoz-Wander)	6	-----	Mellaril [i.e. patentee's brand] is offered to hospitals at the wholesale price. In addition, lower prices are made available on hospital tenders. No information is available on the activity of Empire [i.e., ICN] and Novopharm at the hospital level but it can be assumed that heavy dealing is carried on at this level.
Trifluoperazine (Smith, Kline)	5	Little information is available on this market. Clinazine [i.e., licensee brand] is dealing heavily at the retail level, offering 1 x 5,000 free with every 1 x 5,000 purchased. S.K. & F. believes that due to the nature of Stelazine, it maintains a portion of the market, regardless of price, and that most competition is among the imitators attempting to capture the remainder of the market.	No data is currently available.

a. Between 1970-1974, under section 41(4) of the Patent Act.

Source: Hoffman-La Roche Ltd. (1974) Restrictive Government Practices Affecting Research Based Drug Industry (Montreal: mimeo, Attachement III, various pages.)

incentive for new entrants, secure in the knowledge that patentees will buy them.

The final competitive instrument is one which has only recently arisen but, potentially at least, could have significant implications for the success of the patentees in eliminating the licensees. A patentee's drug is certified by the Health Protection Branch, Department of National Health and Welfare for safety and efficacy for a certain set of indications. The licensee's substitute drug, whether the drug is on Old or New Drug Status, is sold for the same set of indications. Suppose, however, that the patentee subsequently "discovers" a new indication and this is approved by the Health Protection Branch. The issue then arises of the status of the licensee drug - should it be withdrawn until tests for the new indication are complete, should provincial formularies and physicians be informed that the licensee's brand of the drug is only to be used for certain purposes. As yet the issue has not been settled; the regulatory authorities are currently considering an appropriate set of rules, although, it must be added in relation to a drug for which the patent has expired and was not subject to compulsory licensing.[49] Nevertheless, the room for abuse is obvious - a patentee, at the time of introduction, will only ask for certification of the most important indications (in terms of sales), leaving the lesser ones alone. The licensee produces a substitute product. The patentee then files for certification for the new indication, causing the licensee to withdraw[50] its product until various tests are completed. In designing its new regulations, the Health Protection Branch should be careful to weigh the economic implications, especially as viewed from the licensee/patentee competitive struggle.

5.3.3 The Non-Economic Response

Federal and provincial governments pass Acts, proclaim regulations pursuant to these Acts, as well as manage drug reimbursement programs and health insurance schemes that can significantly influence the success of the licensees in competing with the patentees. In Chapter I and, to a lesser extent, Chapter IV these activities of government were discussed. There is no need to repeat the discussion here. The non-economic response refers to attempts by the patentees to influence the above government activities with a view to limiting the effectiveness of the licensees: preventing product selection legislation or the use of formularies or standing offer contracts; repealing of section 41(4) of the Patent Act. The patentees have pursued these aims through a variety of means - representation by individual patentees, through the trade association of the PMAC and via MP's who represent the constituency in which the patentee's manufacturing facilities are located. Time and space preclude a full account of these activities. However, it would appear that, by and large, the patentees have been unsuccessful in

preventing government activities designed to lower drug costs and, hence, usually benefit the licensees and consumers.[51]

Some attention will be paid, however, to the patentee's view, as expressed through the PMAC, on the impact of compulsory licensing. The federal government has been considering reforming the patent system ever since the Ilsley Commission on patents, which reported in 1960. The most recent contribution to the debate was a discussion paper of the Department of Consumer and Corporate Affairs released in 1976. As part of that debate the PMAC has put forward various proposals and suggestions which related to, not only the price effects of compulsory licensing, but also the impact on R & D and the balance of trade. The issues raised by these briefs, which are of concern not only to the PMAC but policy makers, at both the federal and provincial levels of government, are discussed in Chapter VII below.

5.3.4 The Patentee's Response: An Evaluation

The above account of the economic and non-economic response of the patentees suggests they were unsuccessful in preventing and neutralising the development of price competition from firms that had acquired compulsory patent licensees under section 41(4) of the Patent Act, particularly in the hospital market. Several reasons account for this success. On the demand side, numerous hospital buying groups, which were formed in the 1960's and early 1970's, purchased lower priced licensee products. Indeed, one of the main rationales for such buying groups was to obtain lower prices for a whole range of hospital inputs, including prescription drugs. In the retail market provincial product selection legislation and drug reimbursement programmes, in varying degrees, have facilitated market penetration by the licensee brands. This applies particularly to provinces such as Ontario and Saskatchewan.

Against such a set of policies the patentees were able to do little. Patent litigation as a method of entry forestalling proved of little effect, as the higher courts upheld the decisions and jurisdiction of the Commissioner of Patents. The use of non-price methods of competition, particularly the stressing of quality, by the patentees seems to have been unsuccessful in preventing licensee price competition. Attempts to more than meet the competition by price cutting, besides having little effect on the licensees which usually have other drugs to sell, has resulted in the only known instance of a conviction for the practice of predatory pricing under the Combines Investigation Act.

Hence, unless governments change their viewpoint on the price of drugs, licensees and patentees will continue to compete,

in varying degrees, on the basis of price. It seems unlikely, for a variety of reasons, that governments will repeal section 41(4), eliminate product selection legislation and alter the pricing rules of drug reimbursement programmes designed to minimize expenditure for a given drug: increasing provision of prescription drugs funded by government programmes; a period of fiscal restraint; the change in the age distribution of the population, such that the demand for drugs is likely to increase.

5.4 Summary and Overview

The typical patentee is a subsidiary of a large multinational drug firm. Patentees, as a group, dominate the prescription drug industry in Canada, accounting for approximately 70 percent of the sales of prescription drugs, and represented through a trade association, with full-time staff. Prior to the introduction of section 41(4), the discovery of new products via research and development was the dominant form of competition. The R & D usually took place abroad, with new patented drugs advertised extensively to the medical profession in Canada. Little price competition occurred for drugs for which the patent was extant.

Confronted with licensees, which were competing solely on the basis of price, the patentees have had little alternative but to respond in kind in the hospital market and, to a very much lesser extent, in the retail market. Other competitive instruments, such as patent litigation and attempts to pursuade physicians to prescribe and pharmacists to dispense the patentee product because it is of "better" quality, have been used by the patentees, but have not prevented significant price competition from breaking out. The primary reason for the lack of success of the patentees would appear to be, on the one hand, the ease of obtaining a compulsory licence and importing the raw material and, on the other, the various provincial and federal programs designed to encourage price competition and licensee entry. Under such a set of conditions it is difficult to see how the patentees could have prevented the licensees from exerting a significant influence over the price of licensed drugs.[52]

CHAPTER VI

COMPULSORY LICENSING: THE IMPACT ON DRUG PRICES AND BILLS

6.1 Introduction

The major purpose of the 1969 amendment to the Patent Act, section 41(4), and the concomitant provincial measures was to lower the price of prescription drugs. Section 41(4) aimed at the manufacturing level while provincial measures were primarily concerned with the retail level. The material presented in Chapters I through V suggests that the impact of compulsory patent licensing on the price of prescription drugs has been and is likely to be substantial. A few of the more important findings will serve to substantiate this inference. A large number of licences have been issued (142) on a substantial number of drugs (47) over the period 1970-1978. These licences have been issued promptly by the Commissioner of Patents who has set a 4 percent royalty on the licensees' selling price, not the patentees. The courts have taken a dim view of attempts by the patentees to appeal the decision of the Commissioner, when used solely as an entry-forestalling device (i.e., the appeal is not on the merits). Regression analysis confirmed the view of many observers of compulsory licensing - drugs with large volume sales have more licences issued against them by the Commissioner of Patents than do lower volume selling drugs. In competing with the patentee the licensee has used lower prices as the main competitive instrument. Although the patentee has tried a variety of instruments to neutralize the influence of the licensees, the evidence suggests, to date at least, the patentees have had to respond to the licensee's presence by lower prices. As pointed out in Chapter I, government programs such as provincial product selection laws have facilitated the ability of the licensee to compete successfully on the basis of price. In the most price competitive markets such as the hospital and certain provincial retail markets the licensees have been very successful in gaining substantial market shares at the expense of the patentees.

The purpose of this chapter is two-fold. First, to estimate the extent to which compulsory patent licensing and associated provincial policy measures have reduced drug prices. Second, to estimate the impact of these policies on the total prescription drug bill. These two issues are addressed in sections 6.3. and 6.4 respectively. On the second issue particular attention will be paid to the hospital market and the retail market in the provinces of British Columbia, Ontario, Quebec and Saskatchewan. However, prior to this discussion the scope and coverage of compulsory licensing in relation to the prescription drug market will be presented in section 6.2. In other words, what percentage of the total prescription drug market is accounted for by drugs for which compulsory licences have been issued by the Commissioner of Patents. The final section 6.5, presents a brief summary and some conclusions.

6.2 Scope and Coverage of Compulsory Licensing

Several indices of the actual or potential scope and coverage of compulsory patent licensing can be suggested. First, in terms of potential scope and coverage, the relevant measure is the percentage of the total prescription drug bill that is accounted for by drugs having patents extant. Second, in terms of the actual coverage, an appropriate index would be the percentage of the total prescription drug bill that is accounted for by licensed prescription drugs. A variant might be to refer to only licensed drugs for which the licence is currently being worked (i.e., the licensed drug is being marketed by the licensee). Unfortunately, data and information constraints have resulted in this study confining its attention to only measures of the second type, actual coverage and scope of licensing.

The data used to estimate the total sales of compulsorily licensed drugs pose several problems of interpretation, that should be remembered when considering the numbers presented below. First, actual prices are used and these obviously reflect the influence of compulsory licensing. Compulsory licensing is likely to lower prices to below what they would have been in the absence of section 41(4). Hence, the percentage of the total prescription drug bill accounted for by compulsorily licensed drugs is less using actual prices than patentee prices unaffected by section 41(4)[1]. An example will serve to illustrate the point. Suppose, the following set of figures accurately represented the effect of compulsory licensing:

Drug Classes	Sales ($,Million)
non-licensed drugs	400
licensed drugs (actual prices)	200
licensed drugs (patentee prices unaffected by 41(4))	240

The scope and coverage of compulsory patent licensing using actual prices is 33.3 per cent (200/600), but using prices unaffected by section 41(4), 37.5 per cent (240/640).

The second difficulty in interpretation refers to the fact that no account is taken of the cross-elasticity of demand between different drugs. For example, suppose that licensed drug x is a substitute for non-licensed drug y, for which the patent is still extant. If physicians and hospital purchasing committees are sensitive to differences in price then the licensed drug x will be prescribed more frequently than non-licensed y, due to a fall in the relative price of x vis-a-vis y. In order to take into account such cross-elasticity non-licensed substitutes should be included, at least for comparative pur-

poses. However, no convenient method of incorporating this factor into the measures presented is available. Both of these factors result in the indexes of the scope and coverage of compulsory licensing being biased downward.

Table 6-1 presents details of the scope and coverage of compulsory patent licensing. Several indices or measures are presented using two major data sources: Intercontinental Medical Statistics (IMS) and an Ontario government survey. The IMS source is a Canada-wide survey which records the actual acquisition costs of the drug to the pharmacist.[2] Hence the price is equivalent to manufacturer's price plus a wholesale mark-up.[3] The survey covers, on a monthly basis, the retail and hospital market. The sample of pharmacists consists of 200 independent, discount and chain drug stores while the hospital sample is measured in terms of bed size (20,000-25,000 general and allied special beds and 5,000-10,000 mental beds). IMS is a commonly used source for both government and private industry. Similar surveys are conducted by the firm in the U.K. and U.S. The Ontario government survey is a randomly selected (by store type and region) sample of 10 per cent of retail pharmacists in Ontario. The survey records the prescription price of the drug as paid by the customer (i.e., a dispensing fee[4] plus the wholesale price or ingredient cost). The retail market accounts for approximately 80 to 90 per cent of the total Canadian market.[5] In sum, IMS is a Canada-wide survey that refers to both the hospital and retail markets and measures price at the wholesale level, while the Ontario government survey reflects only the retail market, but also refers to the wholesale price.[6]

In Table 6-1 a variety of indices are presented of the scope and coverage of compulsory patent licensing. In all instances the indices refer to the set or subsets of drugs for which compulsory licenses have been issued over the period 1970 to 1978. On the other hand the scope and coverage indices refer to four years wholly contained within this time period: 1969, 1972, 1975 and 1977. Data for 1978 and 1979 were not readily available.[7] However, given the stability of the indices over time and across data sources it seems reasonable to assume that had the indices been measured using 1978 or 1979 information the percentages would have been very similar.

The three indices in Table 6-1 each refer to a different facet of compulsory licensing. Index 1 shows that the maximum actual impact of compulsory licensing by measuring the percentage of the total prescription drug bill accounted for by licensed drugs. As can be readily observed from the table this percentage is approximately 30 percent, which suggests section 41(4) of the Patent Act is likely to have had a considerable impact on drug prices and expenditures. However, one must not run ahead of the story or draw unwarranted conclusions.

While index 1 refers to the maximum actual scope and coverage of compulsory patent licensing, the remaining two

Table 6-1

THE SCOPE AND COVERAGE OF COMPULSORY LICENSING: SELECTED YEARS

Index \ Year	1969	1972	1975	1977
	Wholesale Price, Canada[c]			Wholesale Price, Ontario[d]
1. The percentage of the total prescription drug bill accounted for by licensed drugs[a]	27.4	32.8	29.7	33.6
2. The percentage of the total prescription drug bill accounted for by licensed drugs for which the patent is extant in 1979	19.8	23.2	20.3	26.4
3. The percentage of the total prescription drug bill accounted for by licensed drugs for which at least one licensee has marketed the drug[b]	24.4	26.8	22.4	19.6

a. Refers to all drugs for which a compulsory license has been issued over the period 1970 to 1978 under section 41(4) of the Patent Act. Licensed drug sales refer to both licensee and patentee.

b. Over the period 1970 to August 1979.

c. The individual dollar sales of each licensed drug were estimated by IMS. The total prescription drug market, the denominator of each index, was estimated as follows. Data are available for the size of the ethical pharmaceutical industry (actual for 1975 taken from PMAC, 1979, Appendix 7, p. 1 which is taken from IMS, while for 1969 and 1972 the market size is interpolated from Scrip, 1979, p. 3 which is believed to be based upon or at least very similar to IMS). Ethical pharmaceuticals consist of prescription and non-prescription drugs. Prescription drugs form 60 percent of the total ethical pharmaceutical market, as estimated by IMS. (John McAdam of the Department of Industry, Trade and Commerce together with the PMAC, for the year 1976, went through the IMS estimate of the total ethical pharmaceutical market in deriving the 60:40 split). The 60 percent was then applied to the total ethical pharmaceutical market for 1969, 1972 and 1975 in order to derive the denominator for each index.

d. The print-out of drugs for Ontario uses sales to rank each drug by brand name, dosage form and strength. For example, Valium 5 mg. tablets and Valium 10 mg. tablets each have a separate entry. Attention was paid only to those brand name dosage forms and strengths which accounted for 80 percent of the sales of prescription drugs in Ontario. (Resources did not permit an examination of the remaining 20 percent). The 80 percent included only 34 of the 47 drugs for which licences have been issued. The Ontario retail survey records the number of prescriptions and their value for each drug, by brand name, dosage form and strength. In order to derive the drug cost (i.e., exclude the dispensing fee in the prescription price) a $2.85 dispensing fee was deducted from each prescription. See footnote 4 for further details.

Source: IMS data provided by the Bureau of Intellectual Property, Department of Consumer and Corporate Affairs; PMAC (1979, Appendix 7); Ontario retail drug survey; and Scrip (1979, p. 3).

indices refer to other factors that are relevant to scope and coverage: the date of patent expiration and the incidence of licensees working the patent. The pattern of patent expiration for the 47 drugs for which compulsory licenses have been issued is as follows.[8]

Expiration Date	Frequency	
	No	%
1969-1978	22	46.8
1979-1989	19	40.4
1990 +	6	12.8
Total	47	100.0

The distribution of expiry dates of the patents shows that of the 47 drugs for which compulsory licenses were issued over the period 1970 to 1978, 22 or 46.8 percent had expired in or by 1978. Index 2 in Table 6-1 measures scope and coverage by considering only those licensed drugs for which the patent was extant in 1979. Even with this limitation licensed drugs accounted for betweeen 20-26 per cent of the total prescription drug bill. Nevertheless, exclusion of licensed drugs for which the patent has expired does mark a reduction in scope and coverage varying from 7 to 10 percentage points. Hence 46.8 percent of the number of licensed drugs accounts for a third or less of the total sales of licensed drugs. In other words the drugs for which patents had expired were, on average, the smaller volume drugs, measured by dollar sales. This is not an altogether surprising result. In the 17 years or more[9] for which the licensed drug is "protected" by patent, new drugs will probably be discovered and marketed that may be safer and/or more effective than the existing licensed drug. Hence the sales of the licensed drug will, to some extent, decline as new drugs are introduced.

A second factor pertinent to scope and coverage is whether or not the licensed drug is in fact being worked by the licensee(s). Of the 47 drugs for which licences have been issued over the period 1970 to 1978 in 32 instances, accounting for 68.1 percent of the number of licensed drugs, at least one licensee had marketed the drug on or by August, 1979.[10] Index 3 in Table 6-1 measures scope and coverage by considering only those 32 drugs, which accounted for between 19.6 percent and 26.8 per cents of the total drug prescription bill depending upon the year and data source. The shortfall between index 1 and index 3 varies between 3 and 14 percentage points. In other words, the 15 drugs for which licenses were not worked (32.0 percent of the 47) accounted for between 10.9 and 24.6 percent of the sales of licensed drugs using Canada-wide data but 41.7 percent using Ontario data. Hence, at least for the Canada-wide sales figures the 15 drugs were, on average, the lower volume compulsorily licensed drugs. This is consistent with the findings in Chapter III which showed that the larger the market size of a drug the more licences were worked.[11] In the period subsequent to

August, 1979, two licensed drugs have been marketed for the first time by a licensee, flurazepam and propranolol,[12] both of which are high selling drugs. The disparity between index 1 and 3 would therefore be smaller if index 3 referred to licensed drugs marketed by August, 1980, rather than August, 1979.

All three of the indices in Table 6-1 show that the scope and coverage of compulsory licensing is extensive. Use of index 1 suggests that nearly one-third of total prescription drug sales are accounted for by licensed drugs, while use of either index 2 or 3 yields scope and coverage measures in the one-fifth to one-quarter range. The argument over the most appropriate index, given the uniformity of the overall results, is, to a large extent, therefore academic. Index 1 provides the maximum actual scope and coverage, especially in view of the fact that the licence may not be worked at all.[13] Index 2 ignores licensed drugs for which the patent expired before 1978. To the extent that the advent of compulsory licensing allowed licensee products on the market sooner than would be the case then the influence of section 41(4) is still apparent on the licensed drugs excluded from index 2. Hence this is likely to be biased downwards in terms of the actual scope and coverage of section 41(4). Finally, index 3 excludes those licensed drugs which the licensee has not marketed the licensee product. If the licensees have not entered into competition with the patentee then, unless the patentee has reduced the price in anticipation of or to forestall entry, it seems reasonable to suggest that in such instances the impact of compulsory licensing is negligible.

In sum, index 1 provides the measure of the maximum actual scope and coverage of compulsory licensing, while index 3 records a reasonable approximation of scope and coverage of prescription drugs for which compulsorily licensing is likely to have had some impact on price. Index 2 is in somewhat of an intermediate position.[14] The maximum potential scope and coverage, which is defined to include all prescription drugs for which the patent is extant, will exceed index 1 by some indeterminate amount.

6.3 The Price Effects of Compulsory Licensing

Estimating the price effects of compulsory licensing is, conceptually at least, a relatively straightforward exercise. What is required is a method of predicting what the price of the drug would have been in the absence of section 41(4) induced competitors. This price must be compared to the actual price. The problem, not surprisingly, is to estimate the predicted price. Several methods could be utilized.

The first method is to select a country in which the pharmaceutical industry is, in all its essential features or attributes the same as Canada, except that full patent protection is afforded drugs in that jurisdiction. The prices in that

jurisdiction can be taken as representative of the predicted price. The usual control country is the United States. Several reasons may be cited for this choice. The U.S. accords full patent protection to drugs. Canadian prices prior to the introduction of section 41(4) appeared to be much closer to U.S. prices than those of other industrialized countries.[15] Approximately 70-75 per cent of the drug industry in Canada is controlled by U.S. corporations,[16] which are likely to regard Canada as a submarket within the North American continent. It is significant that a Swiss based firm, Hoffman-La Roche Ltd treated North America as a single market[17] until the advent of compulsory licensing. For example, in early 1971 in assessing the market position of Valium and Librium, for which 22 licenses were issued by the Commissioner over the period 1970-1978, Hoffman-La Roche Ltd. concluded,

> In the past, our pricing policies were closely related to those of Nutley [i.e., the U.S. headquarters] because of the proximity of our markets and the close medical and scientific cooperation. Inasmuch as Canada no longer enjoys meaningful patent protection for drugs, contrary to the U.S., where full patent protection is maintained, our pricing policy therefore can no longer be related to the U.S. and, instead, ought to reflect [lower] European price levels. (Hoffman-La Roche Ltd., Corporate Marketing Group, 1971, Market Position of Librium and Valium, Montreal, mimeo, p. 19).

Although European countries often accord full patent protection to drugs, their quite different institutional arrangements[18] and income levels to North America do not make them convenient control groups with which to generate the "predicted" price.

A second method examining the price effects of compulsory licensing is to examine the patentee's price both before and after the entry of licensee competition. The decline[19] in price of the patentee would be considered the effect of licensee competition on patentee's price. A model could be estimated which related patentee's price to such factors as licensee price, market share of the licensee, whether the licensees were successful in being listed in provincial formularies and factors related to the patentee such as market share, length of time the drug had been on the market, the number of "me-too" products, together with their price. Such a model might be useful not only to estimate the effects of compulsory licensing on the price charged by the patentee but also in discovering whether there is a critical number of competitors, price differential or market share required in order for the patentee to meet the price competition of the licensee.

A number of studies have been undertaken using the first approach to estimating the price effects of compulsory licensing. Each of these is reported here. The second approach, either as a simple comparison of patentee's price pre and post the introduction of licensee competition or as a more complicated modelling process, has not been used in previous work. Unfortunately Statistics Canada price indices cannot be used for this purpose.[20]

Of the three studies on the price effects of compulsory licensing the most thorough was that of Fulda and Dickens.[21] The authors used a sample of 16 of the 42 drugs for which compulsory licences had been issued in the period 1970 to June 1975. These 16 were selected because "...they account for two thirds of all licenses issued during this period [i.e., 1970 - June 1975] and because, among those licensed, they had the largest sales volumes." (Fulda and Dickens, 1979, p. 59) In fact, the 16 accounted for 35.8 per cent of the sales of all licensed drugs in 1975.[22] The authors selected one dosage form and strength for each of the 16 drugs, the most frequently prescribed or highest selling. Only patentee prices were used. The price used was that to the pharmacist (i.e., the wholesale price). The data source was IMS, which is described in section 6.2 above.

Fulda and Dickens investigated a variety of issues relating to the price effects of compulsory licensing. Table 6-2 presents, somewhat reformulated, the particular strand that is of interest here. The 16 drugs are divided into two categories, depending upon whether or not licensee competition existed in 1974. On average for those 11 drugs experiencing licensee competition, the percentage decline in patentee prices was 10.4 between 1970 and 1974 for Canada, but a 2.1 percent increase in the United States. The difference in the average just failed to be statistically significant at the 0.10 level (t-value = 1.30 compared with the critical value of 1.33). In contrast the average price change for those five drugs not experiencing licensee competition was very similar for both countries. The small difference was not statistically significant at the 0.10 level (t-value =0.21), not surprising in view of the small sample. Hence, on the basis of an admittedly small overall sample, it would appear that where licensees compete with the patentee, the latter reduces its price.

A second attempt to measure the price effects of compulsory licensing was conducted by S. Jackson of the Department of National Health and Welfare in 1975. As with Fulda and Dickens, IMS data was used and the sample of licensed drugs was the 42 for which compulsory licences had been issued between 1970 and 1975. Jackson divided the 42 drugs into two samples, those for which the licensees had and had not made significant gains in market share over the period 1970 to 1974. In the former sample were 11 drugs, for which the licensees held market shares varying from 8 to 67 per cent in 1974.[23] Jackson estimated variety of price

TABLE 6-2

THE TREND IN PATENTEE[a] PRICES FOR SIXTEEN LICENSED DRUGS FOR CANADA AND THE UNITED STATES: 1970-1974

Drug and Dosage Strength[b]	Percentage Change in Wholesale Price	
	Canada	United States
Drugs experiencing licensee competition in 1974[c]		
amitriptyline 25 mg.	33.3	1.4
ampicillin 250 mg.	-44.6	-28.7
chlordiazepoxide 10 mg.	-30.4	1.7
chlorthalidone 100 mg.	31.3	11.6
diazepam 5 mg.	-34.6	2.8
erythromycin estolate 250 mg.	-37.2	-11.0
imipramine 25 mg.	-1.6	32.4
metronidazole 250 mg.	-32.7	4.4
thioridazine 25 mg.	19.2	5.3
triamcinolone 4 mg.	-9.9	1.9
trifluoperazine 5 mg.	-6.8	1.0
Average:	-10.4	2.1
Drugs not experiencing licensee competition in 1974[c]		
chlorothiazide 500 mg.	8.8	0
chlorpromazine 50 mg.	17.8	-12.5
glutethimide 500 mg.	9.3	27.3
methylphenidate 10 mg.	7.1	17.7
oxytetracycline 250 mg.	-7.5	1.7
Average:	7.1	6.8

a. Referred to as "major manufacturer" in the source tables.
b. Source did not indicate whether tabs., caps., etc.
c. Drugs experiencing licensee competition were determined on the basis of market share of licensees. When this varied between 0-3 percent, no licensee competition was considered to have been experienced, while the converse applied when the licensee market share was 10 percent or greater.

Source: Fulda and Dickens (1979, Table 1, p. 60, Table 2, p. 60 and Table 3, p. 62).

TABLE 6-3

WHOLESALE PRICE INDICES FOR LICENSED DRUGS, CANADA AND THE UNITED STATES: 1971-1974

Price Index[a] \ Year	1971	1972	1973	1974
All licensed drugs, Canada[b]	100	86.1	80.0	78.7
Eleven licensed drugs, significant licensee competition[c]				
Canada	100	80.7	70.7	69.3
U.S.	100	96.2	95.6	96.3
Thirty-one licensed drugs, not significant licensee competition	100	95.6	92.7	92.3

a. The price index is a Fisher Ideal Index which is the geometric mean of the Paasche and Laspeyres index. The weight used for each drug is Canadian sales.
b. There were 42 licensed drugs between 1970 and 1975.
c. Measured by market penetration.

Source: Indices estimated by S. Jackson, Department of National Health and Welfare, using IMS data.

indices which are presented in Table 6-3. The results like those of Fulda and Dickens, accord with a priori expectation: the price index for the licensed drugs which experienced significant licensee competition declined to a larger extent (-30.7 per cent) than either the price index for the same 11 drugs in the U.S. (-3.7 per cent) or for the 31 licensed drugs which did not experience significant licensee competition (-7.7 per cent).

The third attempt to evaluate the impact of compulsory licensing on the price of drugs was conducted by G. Plet of the Consumer Research Branch of the federal Department of Consumer and Corporate Affairs. Plet's sample of licensed drugs were those for licenses which had been issued between 1969 and May 1976. Of these 43 drugs, Plet identified 19 for which the licensees had marketed a competitive product in 1975[24] and 22 for which such competition did not exist.[25] The price data was again at the wholesale level (i.e., the price to the pharmacist). However, there were some differences between Plet's data source and those used by the previous two studies cited above. Plet relied upon published list prices[26] whereas the IMS data price used actual acquisition costs of the pharmacist. Plet compared, for the most popular strengths and dosage forms, the trend in price of the drug in Canada with that for the U.S. For both countries the patentee's brand was selected.

The results of Plet's exercise are summarized in Table 6-4. For the 19 licensed drugs which the licensee marketed a competitive product in 1975 the patentee's price, on average, declined by 4 per cent in Canada but increased by 18.6 per cent in the United States. This difference was statistically significant at the .01 level (t-value = 2.8). On the other hand, the sample of 22 licensed drugs for which licensee(s) did not market a competitive product in 1975, showed similar price trends in both Canada and the United States, an increase of approximately 20 per cent between 1969 and 1975. Not surprisingly the small observed difference was not statistically significant at the 0.10 level (t-value = 0.36). These results are in accord with a priori expectations: the price of the patentee's brand declines when competition from licensees is experienced; the price experience of licensed drugs in the U.S. is much the same whether or not the patentee is encountering competition from licensees in Canada.

All of the above attempts to measure the effects of compulsory licensing on the price of drugs used as their basic methodology a comparison of U.S. and Canadian price trends. The rationale for this approach was outlined at the beginning of this section. A second approach, also mentioned above, is to examine the price of the patentee's drug as the licensee product came upon the market. The disadvantage of this approach is that no control sample is available to predict what would have happened had the licensee competition not taken place. Hence, precise quantification is not possible.

TABLE 6-4

THE TREND IN PATENTEE'S WHOLESALE PRICES[a] FOR LICENSED[b] DRUGS IN CANADA AND THE UNITED STATES: 1969-1975

Drug and Dosage Form			Percentage Change In Listed Price 1969-1975	
Brand-Name	Generic-Name	Dosage Form	Canada	United States
Drugs Marketed By Compulsory Licensees in 1975				
Penbritin	ampicillin	250 mg caps.	-58.2	-33.4
Valium	diazepam	5 mg tabs.	-28.4	9.1
Elavil	amitriptyline	25 mg tabs.	0.0	18.9
Librium	chlordiazepoxide	10 mg caps.	-28.4	-0.2
Mellaril	thioridazine	25 mg tabs.	3.1	22.9
Lasix	furosemide	40 mg oral tabs.	0.0	10.1
Stelazine	trifluoperazine	2 mg tabs.	10.0	16.2
Ilosone	erythromycin estolate	250 mg caps.	-17.1	-5.5
Hygroton	chlorthalidone	100 mg tabs.	29.0	60.4
Diabinese	chlorpropamide	250 mg tabs.	3.5	43.6
Orbenin	cloxacillin	250 mg tabs.	-18.5	n/a
Flagyl	metronidazole	250 mg oral tabs.	3.0	34.7
Dulcolax	bisacodyl	5 mg tabs.	5.7	27.8
Mysoline	primidone	250 mg tabs.	9.6	16.2
Myambutol	ethambutol	100 mg tabs.	-17.7	63.7
Ritalin	methylphenidate	10 mg tabs.	23.5	29.0
Trilafon	perphenazine	4 mg tabs.	-10.1	-2.7
Largactil	chlorpromazine	25 mg tabs.	0.0	n/a
Aldomet	methydopa	250 mg tabs.	15.4	5.9
Average change in price			-4.0[c]	18.6
Drugs Not Marketed By Compulsory Licensees in 1975				
Zyloprim	allopurinol	100 mg tabs.	31.6	15.8
Diuril	chlorothiazide	500 mg tabs.	26.8	0.0
Duapen	penicillin G benzathine	500 min/60 c.c. btl.	0.0	n/a
Atromid-S	clofibrate	500 mg caps.	26.3	9.2
Periactin	cyproheptadine	4 mg tabs.	46.0	18.8
Tenuate	diethylpropion	25 mg tabs.	42.6	40.6
Furoxone	furazolidone	100 mg tabs.	0.0	20.0
Doriden	glutethimide	500 mg tabs.	41.1	55.6
Somnothane	halothane	250 ml/btl.	24.9	n/a
Solu-Cortef	hydrocortisone	100 mg vl.	22.9	0.0
Atarax	hydroxyzine	25 mg caps.	28.6	36.0
Tofranil	imipramine	25 mg tabs.	6.2	29.6
Indocid	indomethacin	25 mg caps.	28.4	21.7
Xylocaine	lidocaine	100 mg vl.	3.5	0.0
Nozinan	methotrimeprazine	25 mg tabs.	12.5	n/a
Arlidin	nylidrin	6 mg tabs.	15.5	31.8
Tandearil	oxyphenbutazone	100 mg tabs.	11.6	38.8
Terramycin	oxytetracycline	250 mg caps.	8.0	6.7
DBT	phenformin	25 mg tabs.	12.1	20.3
Inderal	propranolol	100 mg tabs.	30.1	12.6
Rimactane	rifampin	150 mg caps.	4.3	n/a
Aristocort	triamcinolone	15 gm tube	13.0	4.9
Average change in price			19.8[d]	20.1

a. Two points should be noted. First, the wholesale prices are list, not actual prices, with the exception of Librium and Valium. (See footnote 26 of the text for details). Second, the prices are based upon package sizes of 100's for all of the drugs, with 11 exceptions, where smaller package sizes were usually used.

b. Under section 41(4) of the Patent Act.

c. If Orbenin and Largactil are excluded, the average percentage changes from -4.0 per cent to -3.4 per cent.

d. If Duapen, Somnothane, Nozinan and Rimactane are excluded, the average percentage changes from 19.8 per cent to 21.9 per cent.

Source: Estimated by G. Plet, Bureau of Consumer Affairs, Department of Consumer and Corporate Affairs, using Drug Topics Red Book (1975) and information collected for the QUAD reviews.

This section has reviewed a number of studies that have attempted to examine the price effects of compulsory licensing. The studies relate to the period 1969 to 1975. Although there are differences in the sample of licensed drugs selected, whether listed or actual wholesale price is used, all dosage forms or the most popular selling, prices of the patentees or patentees and licensees, the result is the same: prices have declined in Canada for compulsorily licensed drugs where the licensee has marketed a competitive product to a much greater extent than licensed drugs for which a competitive product is not sold or for the same sample of competitively licensed drugs in the United States. In other words for those compulsorily licensed drugs which are worked the object of section 41(4) has been achieved: prices have fallen, in some instances dramatically.[27]

6.4 The Impact of Compulsory Licensing on the Prescription Drug Bill

6.4.1 Introduction

A suggested approach for evaluating the impact of compulsory licensing on the prescription drug bill is presented in section 6.4.2. This approach is then applied to the hospital market and a series of four provincial retail markets in sections 6.4.3 to 6.4.7. The Ontario and Quebec retail markets were selected because of their overwhelming economic significance, accounting for, respectively, 37.6 percent and 28.5 percent of retail sales of prescription drugs in Canada in 1973. In contrast British Columbia and Saskatchewan were selected because of unique aspects of the provincial product selection legislation and/or provincial drug reimbursement programmes: Saskatchewan's system of tendering for high volume drugs and the combination in B.C. of permissive production selection legislation and reimbursement based on actual pharmacist's costs. A final section, 6.4.8, makes a number of policy suggestions.

6.4.2 A Suggested Approach

The approach used here to measure the impact of compulsory licensing on the prescription drug bill is to estimate the bill in the absence of section 41(4). This provides an upper limit. This total can then be compared to the actual or observed drug bill in order to gain an indication of the actual or realized savings occasioned by compulsory licensing. Further potential gains may be obtained if typically lower priced licensee brands were to set the market price for all brands. Actual expenditure can therefore also be compared with an estimate of the minimum level of drug expenditures based upon licensee prices. From this brief account of the approach employed it is evident that a number of totals have to be derived. Each is considered in turn.

The first total, X, to be estimated is the total prescription drug bill in the absence of compulsory patent licensing. In such a world the relevant prices are those of the patentee, since the licensees would not be in a position to market competitive products. The problem then becomes to predict the patentee's price. In the previous section the trends for prices in Canada and the U.S. were estimated, with the U.S. trend indicating what prices would have been in the absence of section 41(4). For groups of the licensed drugs where licensee competition existed the price changes for the patentees were as follows:

Study	Canada	U.S.	Difference
Fulda & Dickens	-10.4	+2.1	12.5
Plet	-3.4	+18.6	22.0
Average	---	---	17.8

Fulda and Dickens refer to the period 1970-1974, Plet to 1969-75. Both indicate that the patentee's price in Canada for 1974 or 1975 would have been substantially higher, in the absence of compulsory patent licensing. In estimating the effect of compulsory licensing on the drug bill price and quantity data for the late 1970's will be used, not 1974 or 1975. Hence a problem arises over how much to adjust the patentees' price to reflect the influence of compulsory licensing. It seems reasonable to assume that in the period subsequent to 1975 licensee competition will have prevented patentees from raising prices, in fact, the contrary may have occurred.[28] In view of these factors it has been decided to adjust patentee prices, where a competitive licensee product is on the market, upward by 20 percent. Where no licensee product is competing with the patentee, no price adjustments have been made. It is felt that 20 percent is, if anything, an underestimate of the influence of section 41(4).

The second total, Y, measures the potential impact on the total drug prescription bill if the lowest priced licensee brand for each dosage form and strength were, in effect, to set the price at which all other suppliers, be they patentee or another licensee, could charge at the wholesale level to the pharmacist. Simply stated total Y demonstrates the effect of a mandatory selection law which requires the pharmacist to dispense the lowest price drug, with no allowance for physicians to write "no substitution" across a prescription. It is unlikely that the maximum potential reduction in the prescription drug bill will have been realized since no province has mandatory price selection for all prescriptions; all provinces permit physicians the right to write "no substitution" across the prescription.

The third total, Z, is simply the actual total prescription drug bill, which will lie between total X, the upper limit, and total Y, the lower limit. The more successful compulsory licensing is in lowering the prescription drug bill,

the closer will total Y approximate total Z. The three totals can be used to define two indices. Index A is defined as total Z/total X, and measures the reduction in the total drug prescription bill due to compulsory licensing; index B, total Y/total X, indicates the maximum reduction in the prescription drug bill due to compulsory licensing.

An example may clarify the estimation procedure employed and aid in the interpretation of the results presented in the next few sections. For this purpose the total prescription drug bill can be split into three categories: non-licensed drugs; licensed drugs for which no licensee competition exists; licensed drugs for which licensee competition exists. In all of the calculations presented below expenditures on drugs falling in the first two categories remain unchanged, since the evidence in section 6.3 above and Chapter VII, section 7.4.4 below suggests such categories of drugs are unaffected by compulsory licensing. The last category of drugs are those affected by compulsory licensing and for which adjustments are made. The following is an illustrative example of the procedure.

Drug Category	Expenditure ($ million)
Non-licensed drugs	
actual expenditure	70
Licensed drugs, no licensee competition	
actual expenditure	10
Licensed drugs, licensee competition	
o actual expenditure	20
o actual quantities X patentee prices adjusted upward by 20 percent	40
o actual quantities X lowest priced licensee	16

Given these numbers index A = 83.3 percent[29] while index B = 80.0 percent.[30] If instead of defining A and B over the entire drug prescription bill, attention is concentrated only on licensed drugs for which licensee competition existed, then index A = 50 percent and B = 40 percent. In the tabulations presented below, indices A and B are sometimes defined over the entire drug bill, single drugs and/or those for which licensee competition exists. The use of different categories of drugs permits a fuller picture to be gained of the effects of compulsory licensing.

A critical factor in the estimation of indices A and B is the adjustment upward by 20 percent of patentee prices. In order to test the sensitivity of the results to the choice of the adjustment factor indices A and B were estimated for 15 and 25 percent adjustment factors. These estimates of indices A and B are shown in brackets, in the tabular results presented below for each market. A second consideration concerning the 20 percent

adjustment factor is that it was derived from manufacturer's or wholesaler's prices, whereas the intent of section 41(4) was to leave the price to the patient or consumer. This issue is best addressed in each of the sections below concerning the individual markets, because of particular institutional or economic factors unique to each market.

6.4.3 Hospital Market: Hospital Purchasing Incorporated

As pointed out in Chapter 1, section 1.2.7 above, most hospitals belong to buying groups which operate tendering systems for the purchase of drugs. For the purposes at hand Hospital Purchasing Incorporated (HPI) was selected as being representative of such groups. HPI was established in 1969 as a buying group in the Toronto area.[31] In 1979 there were nearly 40 member institutions and 10 associated or affiliate members. In 1975 HPI let contracts that, in total, were worth $24 million. This included not only drugs but the full range of hospital supplies.

In purchasing drugs HPI requests quotations from the drug firms, usually for a full year, for a variety of package sizes (e.g., 100's 1000's, 5000's, etc.) and for a variety of dosage forms, and strengths (e.g., 25 mg. tabs., 50 mg. tabs. etc.). Final selection is made by the Pharmacy Standardization Committee. The sample of drug firms from which HPI solicits quotations is drawn from the Ontario formulary. It should be noted that other factors, besides price, are taken into consideration when awarding a contract.[32] These considerations result in, for example, all solid dosage forms and strengths usually being awarded to a single firm although for a particular strength and package size, another firm may have a marginally lower bid. This should be borne in mind when interpreting the data presented below.

Table 6-5 presents indices A and B for a sample of 27 licensed drugs for which contracts were awarded by HPI for 1980/81. Licensee competition, defined in this context as a bid submitted by a licensee, was present in all but five instances (i.e., those drugs for which index A and B are equal to 100)[33]. The 27 drugs refer to 57.4 percent of all licensed drugs, contains 64.7 percent of those licensed drugs for which licensee competition was experienced,[34] includes virtually all of those drugs in the PMAC set in Table 4-4 above and all of the leading five licensed drugs, ranked by number of licences issued per drug. The omitted licensed drugs refer to those for which HPI did not let a tender (i.e., the individual hospitals purchased the drug separately), or for which data could not be extracted readily from HPI files within the time and resource contraints.

Overall, Table 6-5 shows that the bill for the 27 drugs in 1980/81 was 45.2 percentage points lower than would have been due to the impact compulsory licensing (index A). If attention

TABLE 6-5

THE IMPACT OF COMPULSORY LICENSING ON SELECTED LICENSED DRUGS[a] FOR HOSPITAL PURCHASING INCORPORATED: 1980/1981[b]

Drug, dosage form and strength	INDEX[c]	
	A. Actual drug prescription bill as a percentage of that which would obtain without section 41(4)	B. The drug prescription bill with mandatory selection of the lowest priced licensee brand as a percentage of that which would obtain without section 41(4)
amitriptyline 25 mg. tabs.	7.8 (8.2; 7.5)	7.8 (8.2; 7.5)
diazepam 5 mg. tabs.	4.9 (5.2; 4.7)	4.9 (5.2; 4.7)
furosemide 40 mg. tabs.	13.3 (13.9; 12.8)	13.3 (13.9; 12.8)
methyldopa 250 mg. tabs.	45.3 (47.3; 43.5)	45.3 (47.3; 43.5)
chloropropamide 250 mg. tabs.	83.4 (87.0; 80.0)	40.1 (41.8; 38.5)
haloperidol 5 mg. tabs.	100.0	100.0
hydroxyzine 25 mg. caps.	100.0	100.0
propranolol 40 mg. tabs.	83.4 (87.0; 80.0)	49.3 (51.4; 47.3)
indomethacin 25 mg. caps.	51.6 (53.9; 49.5)	51.6 (53.9; 49.5)
imipramine 25 mg. caps.	17.4 (18.1; 16.7)	17.4 (18.1; 16.7)
trifluoperazine 5 mg. tabs.	27.4 (28.6; 26.3)	27.4 (28.6; 26.3)
chlorthalidone 50 mg. tabs.	32.9 (34.4; 31.7)	32.9 (34.4; 31.7)
hydrochlorothiazine 50 mg. tabs.	9.7 (10.1; 9.3)	9.7 (10.1; 9.3)
spironolactone 25 mg. tabs.	100.0	100.0
ibuprofen 300 mg. tabs.	83.3 (87.0; 80.0)	81.7 (85.3; 78.5)
perphenazine 8 mg. tabs.	55.5 (57.9; 53.1)	55.5 (57.9; 53.1)
hydrocortisone sodium succinate 100 mg. vial	100.0	100.0
flurazepam 30 mg. tabs.	58.4 (60.9; 56.0)	58.4 (60.9; 56.0)
allupurinol 100 mg. tabs.	58.1 (60.5; 55.8)	58.1 (60.5; 55.8)
chlordiazepoxide 25 mg. tabs.	10.2 (10.6; 9.8)	10.2 (10.6; 9.8)
thioridazine 25 mg. tabs.	83.2 (86.8; 79.9)	83.2 (86.8; 79.9)
chlorpromazine 25 mg. tabs.	83.3 (87.2; 80.2)	48.2 (50.5; 46.4)
ampicillin 250 mg. caps.	133.0 (138.7; 127.8)	133.0 (138.7; 127.8)
amoxicillin 250 mg. caps.	69.7 (72.6; 66.8)	69.7 (72.6; 66.8)
cloxacillin 250 mg. caps.	83.4 (87.0; 80.1)	86.2 (90.0; 82.8)
erthromycin estolate 125 mg/5ml.	100.0	100.0
trimethoprim and sulfa-methoxazole 800 mg./ 160 mg. tabs.	47.3 (49.4; 45.4)	47.3 (49.4; 45.4)
All Drugs	54.8 (56.8; 53.0)	50.1 (51.9; 48.4)
Licensee Competition	45.8 (47.8; 44.0)	40.2 (41.9; 38.5)

a. The drugs were selected from the files of HPI. The omitted licensed drugs referred to those for which HPI did not contract (i.e., the individual hospitals, which compose HPI, each purchased the drug separately) or for which data could not be extracted readily from HPI files within the time and resource contraints of the study.

b. Should be read as year ending June 1981, although this did vary somewhat by drug.

c. There are usually a number of different prices which can be taken in comparing patentee and licensee prices, depending upon the package size (e.g., 100's 250's, 1,000's) selected and which licensee's price is chosen. In general for both indices A and B, the price of the licensee awarded the contract is selected and where the licensee did not succeed, the licensee price closest to the patentee. The package size was selected which minimized the difference between patentee and licensee price per unit (e.g., tab., or cap.). The effect of this procedure is to systematically bias upward indices A and B, for those drugs experiencing licensee competition. In estimating the denominator of indices A and B, patentee prices are adjusted upward 20 percent where licensee competition is present. The effect of using 15 or 25 percent adjustments instead are shown in parenthesis. The presence of a bid from a licensee is the indicator of licensee competition.

Source: Information provided by Hospital Purchasing Inc.

is confined only to those drugs experiencing licensing competition the percentage increases to 54.2. Mandatory price selection would reduce the bill by several more percentage points (index B). Because of the estimation procedures involved these percentage reductions are probably underestimates.[35] There is a considerable variation in the values of indices A and B by drug, with very large savings for drugs such as diazepam, furosemide, imipramine and trifluoperazine and more moderate reductions for drugs such as indomethacin, flurazepam and trimethoprim. Where index A is the same as B, the licensee was awarded the contract. In the case of ampicillin, the patentee price was lower than the licensee price, but nevertheless the licensee was awarded the contract, hence indices A and B are both greater than 100. This was the only example of an exception to the rule that both indices would not exceed 100.

In sum, compulsory patent licensing has led to a substantial reduction in the drug bill for HPI with respect to the sample of licensed drugs in Table 6-5. For particular drugs, such as propranolol[36] further reductions in expenditure are possible. Since most other hospitals either individually or collectively, via purchasing groups, purchase drugs by a tendering system it is likely that similar savings to HPI would be recorded throughout the hospital sector.

6.4.4 Retail Market: British Columbia

British Columbia accounts for approximately 7 percent of Canada's retail market for prescription drugs.[37] As pointed out in Chapter 1, section 1.4 above, B.C. operates a universal drug reimbursement programme which contains a co-payment element for some classes of population covered by the programme. Unlike the other three provinces examined in this chapter, B.C. does not publish a formulary to guide government in determining reimbursement or as an aid to pharmacists in product selection and pricing. Instead, with respect to pricing, the provincial drug plan closely monitors the prices charged as between the wholesaler and the retail pharmacist. As a result the amount reimbursed by the provincial government is claimed to be the actual acquisition cost of the pharmacist. Product selection is permissive. The consumer is, however, made aware of the ingredient cost and dispensing fee, which are marked on the prescription receipt. This may stimulate some price competition and search for lower priced brands.

Table 6-6 presents indices A and B for a small sample of high selling drugs for B.C. for 1977 and 1979. The smallness of the sample - only five - is a reflection of the limited amount of information available with reference to expenditures made under the B.C. drug reimbursement programme.[38] Nevertheless the sample included the four leading licensed drugs, ranked by number of licences issued per drug. Overall, Table 6-6 shows that the bill for the five drugs in 1977 was 39.7 percentage points lower than it would have been, due to compulsory licensing and associated provincial policy measures. In 1979 the corresponding percentage was 42.8 percent. Indices A and B were lower where

licensee competition was least successful in penetrating the market formerly held exclusively by the patentee (i.e., for diazepam 5 mg. tabs. and hydrochlorothiazide 50 mg. tabs. the licensee market share, measured by the number of prescriptions, was 55 percent or less; for the remaining three drugs the licensee market share was 63 percent or greater). These results show little sensitivity as to whether a 15, 20, or 25 percent adjustment factor is applied to patentee prices to take into account the effect of compulsory licensing. For both years, but especially 1979, substantial reductions in the drug prescription bill could be made - by another 40.8 percentage points in 1979 - if mandatory price selection were introduced. The declines are particular noticeable for diazepam, furosemide and hydrochlorothiazide, where 40 percentage points or greater reduction could be realized.

Hence, on the basis of an admittedly small sample of licensed drugs, accounting for only 15.6 percent of those licensed drugs experiencing licensee competition by 1979, it would appear that the B.C. drug programme has realized substantial declines in its drug bill because of compulsory licensing. However, further substantial declines can be realized through more extensive use of lower priced brands.

6.4.5 Retail Market: Ontario

Ontario accounts for approximately 38 percent of the retail drug market in Canada.[39] The Ontario government has been the leading province in the 1970's in encouraging the use of lower priced drugs. As noted in Chapter 1, the PARCOST Comparative Drug Index, which listed drugs and brands of acceptable quality as well as their prices was introduced in 1970 followed by product selection legislation in 1972. The government reimbursement scheme, Ontario Drug Benefit (ODB), was introduced in 1974 with the present coverage beginning in 1976. ODB covers 14 percent of Ontario's population, which accounted for 28-30 percent of all prescriptions dispensed in Ontario in the period.

The estimation of indices A and B presented in Table 6-7 refers to the total drug bill for Ontario and various samples of licensed drugs for 1977. The quantity data is drawn from the Ontario retail drug survey, described in section 6.2, above. The quantity refers to those high volume drugs, by brand name, dosage form and strength, ranked by sales, which accounted for 80 percent of the sales of prescription drugs in Ontario.[40] The 80 percent cut-off included dosage forms and strengths relating to 34 of of the 47 licensed drugs, 14 of which were experiencing licensee competition in 1977. The price data is drawn from the Ontario formulary for the first half of 1977.[41]

The results in Table 6.7 indicate that for Ontario in 1977 compulsory patent licensing and associated provincial policy measures led to a reduction of 11 percent (index A), in the total drug prescription bill of the province, compared with what would have been the case had full patent protection been accorded the

TABLE 6-6

THE IMPACT OF COMPULSORY LICENSING ON SELECTED LICENSED DRUGS FOR BRITISH COLUMBIA:[a] 1977 AND 1979

Drug, dosage form and strength	INDEX[b] A. Actual drug prescription bill as a percentage of that which would obtain without section 41(4)		B. The drug prescription bill with mandatory selection of the lowest priced licensee brand as a percentage of that which would obtain without section 41(4)	
	1977	1979	1977	1979
diazepam 5 mg. tabs.	52.0 (54.2; 49.9)	48.9 (51.0; 46.9)	17.7 (18.5; 17.0)	7.2 (7.5; 6.9)
chlordiazepoxide 10 mg. tabs.	63.3 (66.1; 60.8)	63.9 (66.7; 61.4)	28.3 (29.5; 27.1)	30.0 (31.3; 28.8)
ampicillin 250 mg. caps.	76.8 (80.1; 73.7)	78.5 (81.9; 75.4)	65.3 (68.1; 62.7)	70.0 (73.1; 67.2)
furosemide 40 mg. tabs.	79.1 (82.6; 75.9)	70.2 (73.2;67.4)	61.6 (64.3; 59.1)	14.9 (15.5; 14.3)
hydrochlorothiazide 50 mg. tabs.	54.3 (56.6; 52.0)	52.2 (54.4; 50.0)	16.3 (16.9; 15.6)	10.7 (11.1; 10.3)
All Drugs[c]	60.3 (62.9; 57.9)	57.2 (59.7; 54.9)	29.4 (30.6; 28.2)	16.4 (17.1; 15.8

a. Refers to drugs dispensed under the provincial drug reimbursement programme, Pharmacare. See Chapter 1, Table 1-2 above for details of population coverage.

b. The data upon which the indices are based can be described as follows: for the 95 highest selling drugs, by brand name, dosage form and strength, ranked by number of prescriptions for 1978, prices for units of 100 were provided for 1977 and 1979. (Valium 5 mg. tabs. and Vivol 5 mg. tabs., two brands of diazepam 5 mg. tabs. are both counted separately, as would be Valium 10 mg. tabs. and Valium 5 mg. tabs., in the ranking procedure). The prices referred to the wholesale cost to the pharmacist as reimbursed by the government programme. Hence, the indices used 1978 quantities and 1977 and 1979 prices. It was assumed that all prescriptions were for 100 units. In other words, across any drug dosage form and strength, the assumption was that all the prescriptions were for the same number of caps. or tabs. In estimating the denominator of indices A and B of patentee prices are adjusted upward by 20 percent where licensee competition is experienced. The effect of using 15 and 25 percent adjustments instead are shown in parenthesis. The presence of a licensee brand in the 95 highest selling drugs, by brand name, dosage form and strength is taken as evidence of licensee competition.

c. In estimating All Drugs, the weighted average is taken of indices A and B for the five drugs, where the weights are the number of prescriptions.

Source: Information provided by the British Columbia Pharmacare prescription drug benefit programme.

TABLE 6-7

THE IMPACT OF COMPULSORY LICENSING ON THE DRUG PRESCRIPTION BILL: THE CASE OF ONTARIO, 1977

Index[a]	Total Drug Bill	All Licensed Drugs[b]	Where Licensee Competition Exists[c]
A.Actual prescription drug bill as a percentage of that which would obtain without section 41(4)[d]	89.0 (89.8; 88.2)	73.1 (74.8; 71.5)	49.8 (52.0; 47.8)
B.The drug prescription Bill with mandatory selection of the lowest priced licensee brand as a percentage of that which would obtain without section 41(4)[e]	86.5 (87.2; 85.7)	66.8 (68.3; 65.3)	38.1 (39.7; 36.5)

a. The print-out of drugs for Ontario uses sales to rank each drug, by brand name, dosage form and strength. For example, Valium 5 mg. tablets and Valium 10 mg. tablets each have a separate entry. Attention was paid only to those brand name dosage forms and strengths which accounted for 80 per cent of the sales of prescription drugs in Ontario. (Resources did not permit an examination of the remaining 20 per cent). The 80 per cent included only 34 of the 47 drugs for which licences have been issued. The Ontario retail survey records the number of prescriptions and their value for each drug, by brand name, dosage form and strength. In order to derive the drug cost (i.e., exclude the dispensing fee in the prescription price) a $2.85 dispensing fee was deducted from each prescription. See footnote 4 for further details.

b. The 34 licensed drugs mentioned in the previous footnote had one or more compulsory licences issued against them by the Commissioner of Patents in the period 1970-1977.

c. If a licensee brand is listed in the Ontario formulary then this is taken as prima facie evidence of licensee competition. Of the 34 licensed drugs licensee competition was recorded in 14 instances for 1977 on at least one dosage form and strength.

d. The estimation of the numerator of the index (i.e., actual drug prescription bill) is detailed in footnote a, above. The denominator is estimated by taking the patentee's prices, which are then adjusted upward to take into account the effect of compulsory licensing, and multiplied by the quantity purchased. The adjustment factor was 20 per cent. However, to test for the sensitivity of the results, 15 and 25 per cent were also used. These results are in parenthesis. In those cases of more than one patentee per drug, the patentee price was the weighted average of their prices, using their sales of that particular drug, by dosage form and strength, as the weights.

e. The denominator of this index is detailed in the previous footnote, d. The numerator is the lowest licensee price for a given drug, by dosage form and strength, multiplied by the quantity sold of that particular dosage form and strength.

Source: Ontario retail drug survey and Ontario, Minister of Health (1977a).

patentees (i.e., in the absence of section 41(4)). If only licensed drugs, for which licensee competition with the patentees is in evidence, are considered then the fall is much more marked - 50.2 percent. Not surprisingly index A for all licensed drugs is in an intermediate position. Table 6.7 also shows that the full potential of compulsory licensing has, as yet, not been realized (index B). For example, the current (i.e., 1977) bill for patentee drugs experiencing licensee competition could be reduced a further 25 percent if mandatory selection for the lowest priced licensee brand was introduced.

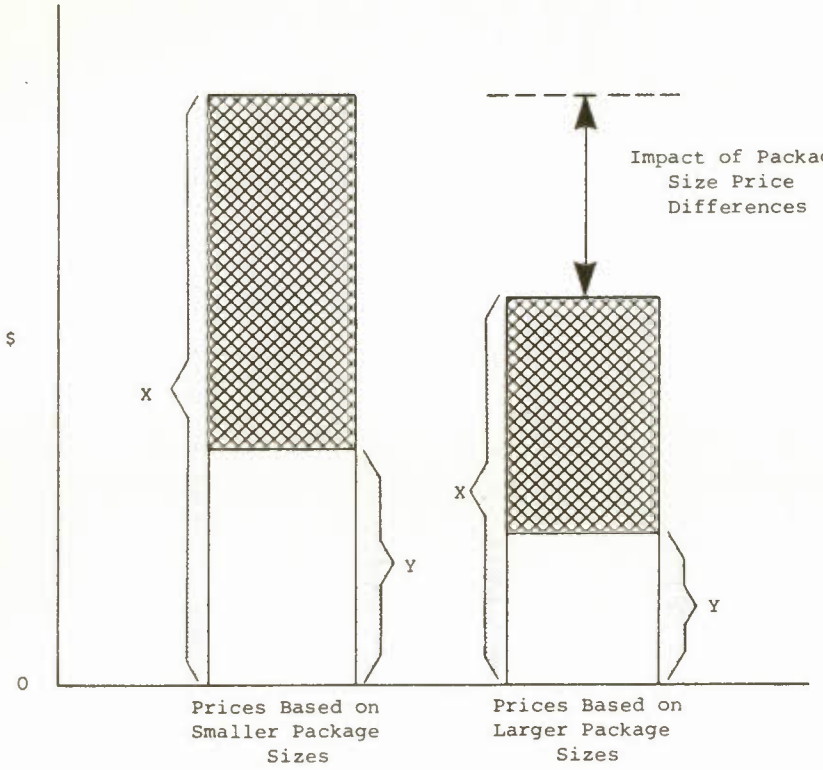
The values of the two indices in Table 6.7 presented assume, as mentioned above, that patentee prices, in the absence of compulsory licensing would have been 20 per cent higher than those listed for 1977. This assumption applied only to those instances where there was licensee competition. In order to test the sensitivity of the results to the 20 per cent assumption indices A and B were re-estimated for two alternative views of the effects of compulsory licensing 15 and 25 percent. These resulting values of index A and B are shown, in parenthesis, in Table 6-7. The major findings remain substantially unaltered: the impact of compulsory licensing has reduced the total drug prescription bill of Ontario markedly with very substantial declines for licensed drugs where the licensee markets a competitive product.

The prices used to estimate indices A and B for Ontario are based upon smaller package sizes, typically 100's. Pharmacists usually purchase the large volume drugs in much larger package sizes, usually at a significantly lower per unit price.[42] Under the present system the difference between the two sets of prices accrues to the pharmacist (or pharmacy owner). This intra- marginal rent or hidden mark-up means that not all of the benefits of compulsory licensing are passed on to the consumer. Indeed, much of the competitive effort of manufacturers in Ontario is devoted to maximizing this spread so as to attract business.[43] Hence, it could be argued that the estimates in Table 6-7 seriously overstate the benefits of compulsory licensing in Ontario to the consumer. This discussion raises two issues. First, if larger package sizes were used, would indices A and B yield remain much the same? Second, what is the magnitude of the intra-marginal rent or hidden mark-up?

On the first point the limited evidence available suggests somewhat tentatively that the indices remain much the same if larger package sizes are used.[44] This is illustrated by Chart 6-1, which also shows how differences in package sizes have substantially affected expenditure. On the second issue, the Ontario government has been aware of the difference between the price quoted in the formulary and the cost of the drug to the pharmacist because of purchasing in larger quantities. Internally prepared statistics by the Ontario Ministry of Health, for example, for multisource licensed drugs among 36 high volume drugs,[45] showed the following:

Chart 6-1

Index B for Licensed Drugs where Licensee Competition Exists, Based upon Different Package Sizes, Ontario, 1977



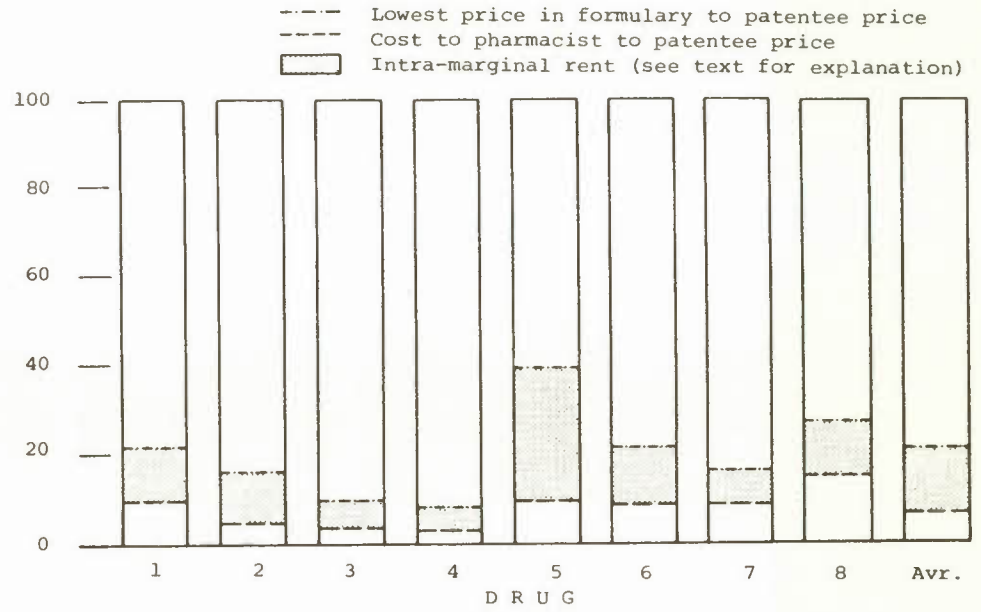
X = Total expenditure in absence of compulsory licensing and associated Ontario policy measures.

Y = Total expenditure with compulsory licensing and a rule specifying that all drugs be priced on the basis of the lowest licensee brand for each drug, by dosage form and strength.

Source: Table 6-7 above and footnote 44.

Chart 6-2

Patentee's Price,[a] Licensee's Price,[b] Cost to the Pharmacist,[c] for Eight High Volume Multisource Drugs, by Dosage Form and Strength,[d] Ontario, Jan.-July 1980



a. As per the formulary.
b. Lowest priced licensee brand as per the formulary.
c. As supplied by a successful licensee in the Ontario market.
d. Amitriptyline 25mg. tabs.; diazepam 10mg. tabs.; diazepam 5mg. tabs.; diazepam 2mg. tabs.; furosemide 40mg. tabs.; hydrochlorothiazide 25mg. tabs.; hydrochlorothiazide 50mg. tabs.; and chlorpropamide 250mg. tabs.

Source: Ontario, Minister of Health (1980a) and data made available by a licensee.

Year	Average percentage mark-up over cost to pharmacist[46] for 10 multisource licensed drugs[47]
1976	71.2
1977	109.8
1978	158.2

Source: Information provided by Ontario, Ministry of Health, based upon IMS, various editions of the Ontario formulary and Ontario Drug Benefit records.

As can be readily observed the mark-up problem would appear to be worsening rather than declining over this three year period. In 1977 the Ontario Drug Benefit Formulary Pricing Committee was formed to look into the mark-up problem. In its report, one of the main findings was that,

> It has been established that although the Formulary prices are almost invariably based on relatively small package sizes such as 100's, the vast majority of the high volume products are normally purchased in substantially larger packages. (Bailey Committee, 1978, p. 12).

As shown in Chapter III above, licensed drugs tend to be in the higher volume category so that this comment is particularly relevant to the discussion at hand. In the Jan. 1979 formulary, the Ontario government based prices upon larger package sizes for 36 drugs, by dosage form and strength. Indeed, 17 of the 36 were licensed drugs.[48]

Hence, it would appear that while the margin problem is an important qualification to the estimates in Table 6-7, referring to 1977, by 1979 and 1980 this had largely disappeared because of the implementation of the Baily Committee recommendations. In order to see whether this was in fact the case, the pharmacist's mark-up was estimated for those eight multisource licensed drugs amongst the 36 high selling drugs, by dosage form and strength, for which data was available. The results are as follows:

Year	Average percentange mark-up over cost[49] to pharmacist for eight[50] multisource licensed and strength
1980	192.5

Source: Ontario, Minister of Health (1980a) price and data made available by a licensee.

The corresponding percentage for these eight drugs in 1978 was 183.8.[51] Hence it would appear that the intra-marginal rent has been stabilized rather than eliminated by the 1979 change in pricing in the formulary.[52]

Chart 6-2 is an attempt to put the intra-marginal rent or mark-up problem into some sort of perspective, by comparing the patentee price charged to the pharmacist with the minimum price in the formulary and the actual price charged to the pharmacist by a successful licensee in the Ontario market. The results indicate that for the eight licensed drugs, by dosage form and strength, among the sample of 36 mentioned above, that while the intra-marginal rent is clearly of significance, the reduction in expenditure because of the use of the licensee brand rather than patentee is clearly much more substantial. Chart 6-2 applies particularly to the ODB sector of the market where the province will only reimburse the pharmacist for the lowest priced brand in the formulary for the given drug, by dosage form and strength, no matter which brand is dispensed. For other sectors prices would appear to be slightly above this minimum, since the product selection rule for the non-ODB market is "... the lowest priced interchangeable pharmaceutical product in his inventory...." not in the formulary. This increases the magnitude of the intra-marginal rent for this sector, a factor confirmed by comparing indices A and B in Table 6-7 which both refer to the whole of the Ontario market, not just ODB.

In sum, Ontario has realized substantial declines in the price of drugs at the level of the manufacturer, which in large part have been passed onto the consumer. However, relative to licensee's actual prices, further substantial declines can be realized with appropriate changes in the retail system, a factor discussed in section 6.4.8 and Chapter VIII below.

6.4.6 Retail Market: Quebec

Quebec accounts for approximately 29 percent of the retail drug market in Canada.[53] The province has permissive product selection legislation which was introduced in 1974. The publication of a formulary which lists drugs of acceptable quality as well their prices, started in 1972. The provincial government drug reimbursement programme covers those on welfare and over 65 years of age. This corresponds fairly closely with Ontario although the Quebec programme only accounts for 25 percent of the consumption of drugs in the province.

Extensive data was provided by the Régie de l'assurance-maladie du Québec for drugs dispensed to that section of the population covered by the government reimbursement scheme.[54] (However, since the same rules concerning product selection apply to both the government and non-government sector, the results presented below for the former might also be applicable to the latter). The sample of 40 of the 47 licensed drugs included all of these in the PMAC list in Table 4-4 except one,[55] the leading five drugs ranked by number of licenses issued per drug[56], the sample of 15 high selling drugs which are presented in the next section for Saskatchewan and all of the 34

drugs used to estimate indices A and B for Ontario except three.[57] The Quebec sample is, therefore, by far the most all embracing set of licensed drugs presented at the retail level in this chapter.

Table 6-8 presents indices A and B for the most popular selling (measured by the number of prescriptions) dosage form and strength, for each of 40 licensed drugs for 1976 and 1978. The results indicate that the overall prescription drug bill for these 40 drugs was, due to compulsory licensing, 10.7 percentage points in 1976 and 12.7 in 1978 lower than it would have been (index A). For the 20 licensed drugs subject to licensee competition in 1976 and the 24 in 1978, the savings were, not surprisingly, somewhat greater. Index B suggests that substantial gains remain to be achieved. For example, the bill for those licensed drugs subject to licensee competition in 1978 could be reduced a further 22.1 percentage points. Particularly large (i.e., 25 percentage points or more) reductions seem possible for amitiptyline, furosemide, chlorpropamide, chlordiazepoxide, chlorpromazine, hydrochlorothiazide, imipramine, and trifluoperazine. The permissive product selection legislation and the relatively small inroads in the Quebec market by the licenses shown in Chapter IV, Table 4-5 above probably account for these potential further savings. Also several of the drugs in Table 6-8 which did not experience competition in 1978 in Quebec (i.e., index A = index B = 100) did in subsequent years. Hence, the reductions in the drug bill for the 40 licensed drugs in 1980 and 1981 may be greater than indicated in the table.

The prices in the Quebec formulary which form the basis of the reimbursement by the provincial government are selected as follows:

> CALCULATING THE UNIT COST OF CERTAIN MEDICINES
>
> The price for all large volume medicines is determined from a reference size other than the smallest size generally available on the market [the rule for all other drugs]. The calculation method is:
>
> 1. all pharmacies that claimed payment for this type of medicine in the second last edition are listed in increasing order of quantity claimed;
>
> 2. the pharmacy falling in the middle of this distribution is identified and the monthly quantity claimed by this pharmacy is used as the basis for determining the size;
>
> 3. consumption of medicine by program recipients represents about 25 per cent of consumption for the total population, so the base quantity is multiplied by four and the reference size is chosen in the neighbourhood of this median monthly quantity dispensed.

TABLE 6-8

THE IMPACT OF COMPULSORY LICENSING ON SELECTED LICENSED DRUGS FOR QUEBEC:[a] 1976 AND 1978

Drug, dosage form and strength	INDEX			
	A. Actual drug prescription bill as a percentage of that which would obtain without section 41(4)[b]		B. The drug prescription bill with mandatory selection of the lowest priced licensee brand as a percentage of that which would obtain without section 41(4)[c]	
	1976	1978	1976	1978
amitriptyline 25 mg. tabs.	80.0 (83.4; 76.8)	78.4 (81.8; 75.3)	39.8 (41.5; 38.2)	39.9 (41.6; 38.3)
diazepam 5 mg. tabs.	86.8 (90.5; 83.3)	79.8 (83.2; 76.5)	60.0 (62.6; 57.6)	57.0 (59.5; 54.7)
ibuprofen 300 mg. tabs.	100.0	100.0	100.0	100.0
clofibrate 500 mg. caps.	100.0	100.0	100.0	100.0
furosemide 40 mg. tabs.	82.7 (86.3; 79.4)	80.2 (83.6; 76.9)	71.9 (75.1; 69.0)	52.6 (54.9; 50.5)
methyldopa 250 mg. tabs.	82.8 (86.4; 79.5)	82.1 (85.7; 78.8)	68.6 (71.6; 65.8)	65.9 (68.8; 63.3)
propranolol 40 mg. tabs.	100.0	100.0	100.0	100.0
ampicillin 250 mg. caps.	83.4 (87.0; 80.0)	82.8 (86.3; 79.5)	75.5 (78.8; 72.5	79.9 (83.4; 76.7)
amoxicillin 250 mg. caps.	100.0	84.0 (87.6; 80.6)	100.0	85.9 (89.6; 82.5)
cloxacillin 250 mg. caps.	83.3 (86.9; 80.0)	81.8 (85.3; 78.5)	65.3 (68.2; 62.7)	64.7 (67.5; 62.1)
erythromycin estolate 250 mg. caps.	75.4 (78.7; 72.4)	78.2 (81.6; 75.1)	42.0 (43.9; 40.3)	53.2 (55.5; 51.1)
cephalexin monohydrate 250 mg. tabs.	100.0	100.0	100.0	100.0
chlorpropamide 250 mg. tabs.	81.5 (85.0; 78.2)	80.8 (84.3; 77.5)	49.3 (51.4; 47.3)	38.1 (39.7; 36.6)
allopurinol 100 mg. tabs.	100.0	83.1 (86.7; 79.8)	100.0	90.3 (94.3; 86.7)
triamcinolone acetonide 0.1% top. cr.	100.0	82.5 (86.1; 79.2)	100.0	66.3 (69.2; 63.7)
betamethasone valerate 0.1% top. cr.	100.0	100.0	100.0	100.0
chlordiazepoxide 10 mg. caps.	82.3 (85.8; 78.9)	82.6 (86.2; 79.3)	53.7 (56.1; 51.5)	55.0 (57.4; 52.8)
chlorothiazide 500 mg. tabs.	82.4 (85.9; 79.1)	100.0	130.3 (135.9; 125.0)	100.0
chlorpromazine 50 mg. tabs.	79.1 (82.5; 75.8)	79.8 (83.3; 76.7)	48.5 (50.6; 46.5)	45.6 (47.6; 43.8)
chlorthalidone 50 mg. tabs.	82.8 (86.3; 79.5)	82.1 (85.6; 78.8)	73.1 (76.2; 70.1)	65.8 (68.6; 63.2)
ethambutol 400 mg. tabs.	80.5 (84.0; 77.3)	82.9 (86.5; 79.6)	67.8 (70.7; 65.1)	78.3 (81.6; 75.1)
fluocinolone acetonide 0.025% top. cr.	100.0	81.4 (84.9; 78.1)	100.0	73.1 (76.3; 70.2)
flurazepam 30 mg. caps.	100.0	100.0	100.0	100.0
glutethimide 500 mg. tabs.	84.1 (87.7; 80.7)	82.7 (86.3; 79.4)	59.6 (62.1; 57.2)	59.7 (62.3; 57.3)
haloperidol 5 mg. tabs.	100.0	100.0	100.0	100.0
hydrochlorothiazide 50 mg. tabs.	83.2 (86.8; 79.8)	80.7 (84.3; 77.5)	59.4 (61.9; 57.0)	58.6 (61.2; 56.3)
hydrocortisone sodium succinate 250 mg. inj. pd.	100.0	100.0	100.0	100.0
hydroxyzine 25 mg. caps.	100.0	100.0	100.0	100.0
imipramine 25 mg. tabs.	79.5 (83.5; 76.8)	77.8 (81.2; 74.7)	34.7 (36.5; 33.6)	37.3 (38.9; 35.8)
indomethacin 25 mg. caps.	100.0	100.0	100.0	100.0
methotrimeprazine 25 mg. tabs.	100.0	100.0	100.0	100.0
metronidazole 250 mg. tabs.	81.4 (85.0; 78.2)	81.4 (84.9; 78.1)	61.6 (64.3; 59.1)	71.3 (74.4; 68.4)
oxphenbutazone 100 mg. tabs.	100.0	100.0	100.0	100.0
oxytetracycline 250 mg. caps.	100.0	100.0	100.0	100.0
perphenazine 2 mg. tabs.	83.2 (86.8; 79.8)	83.2 (86.8; 79.8)	65.1 (67.9; 62.5)	71.6 (74.6; 68.7)
primidone 250 mg. tabs.	100.0	83.5 (87.2; 80.2)	100.0	66.8 (69.7; 64.1)
spironolactone 25 mg. tabs.	100.0	100.0	100.0	100.0
thioridazine 25 mg. tabs.	81.0 (84.7; 77.8)	80.7 (84.3; 77.5)	46.1 (48.0; 44.2)	56.2 (58.6; 53.9)
trifluoperazine 2 mg. tabs.	79.1 (82.5; 75.9)	78.3 (81.6; 75.2)	34.2 (35.7; 32.9)	40.4 (42.2; 38.8)
trimethoprim sulfamethoxazole 80/400 mg. tabs.	100.0	100.0	100.0	100.0
All Drugs[d]	89.3 (91.8; 87.0)	87.3 (89.8; 85.0)	74.6 (76.7; 72.6)	72.7 (74.8; 70.8)
Licensee Competition 1976[e]	83.6 (87.2; 80.2)	80.7 (84.6; 77.5)	60.8 (63.5; 58.4)	57.2 (59.7; 54.9)
Licensee Competition 1978[e]	84.6 (88.0; 81.4)	80.9 (84.4; 77.6)	63.1 (65.6; 60.7)	58.8 (61.4; 56.5)

a. Refers to drugs dispensed under the provincial drug reimbursement programme. See Chapter 1, Table 1-2 above for details of population coverage.

b. The estimation of the numerator of the index (i.e., actual drug prescription bill either for a given drug, by dosage form and strength, or for one of the three totals - All Drugs, Licensee Competition 1976, Licensee Competition 1978) is taken directly from the raw data supplied by the Régie de l'assurance-maladie de Québec. The denominator is estimated by taking the actual patentee's price used for reimbursement purposes (based on the data supplied by the Régie de l'assurance-maladie du Québec, which is the same as in the formulary) which is then adjusted upward to take into account the effect of compulsory licensing, and multiplied by the quantity purchased. The adjustment factor was 20 per cent. However, to test for the sensitivity of the results, 15 and 25 per cent were also used. These results are in parenthesis. In those cases of more than one patentee per drug, the patentee price was the weighted average of their prices, using the number of prescriptions for each patentee's brand of that particular dosage form and strength as the weights.

c. The denominator of this index is detailed in the previous footnote, b. The numerator is the lowest price used for reimbursement purposes for a given drug, by dosage form and strength, multiplied by the quantity sold of that particular dosage form and strength. The lowest price is taken from the raw data as supplied by the Régie de l'assurance-maladie du Québec, which is the same as that in the formulary. Note that there exists in Quebec a number of smaller licensees which sell exclusively in the province of Quebec. Generally the prices of these firms were not considered in estimating index B. Instead attention was paid to licensee brands which were generally available across Canada. This should ensure comparability with the other material presented for B.C., Ontario and Saskatchewan. In any event the price of the smaller Quebec licensees was not necessarily the lowest.

d. This refers to the 40 drugs, by dosage form and strength, in the table, not all drugs sold in Quebec.

e. Licensee competition is taken to exist in either 1976 or 1978 when a licensee is reported as selling a drug in Quebec. This corresponds exactly to those instances where licensees are listed in the Quebec formulary, except in one or two instances where, although a licensee was listed, recorded sales were zero or practically non-existent.

Source: Information provided by Régie de l'assurance-maladie du Québec and various issues of the Quebec formulary.

Example:

> 1205 pharmacies claimed payment from the RAMQ [Régie de l'assurance-maladie du Québec] for methyldopa, 125 mg tabs., in the thirteenth edition. The 603rd or median pharmacy alone claimed 283 tablets a month. Multiplying by four, we obtain the quantity this pharmacy dispensed to all its customers in one month, 1132 tablets. The reference size therefore is 1000, the closest available size to 1132. (Québec, Régie de l'assurance-maladie du Québec, 1980, p.i. translated from original, emphasis supplied).

All package sizes are increased by nine percent to take into account the wholesale margin. In the July 1980 edition of the formulary, 73 drugs covering 118 dosage forms and strengths are classified as "large volume".[58] Licensed drugs accounted for 28.8 percent or 21 of the 73 drugs and 33.9 percent or 40 of the 118 dosage forms and strengths. For licensed, chlordiazepoxide, diazepam, ibuprofen, and methyldopa each had three dosage forms and strengths listed. Hence, the rules for a pricing of large volume drugs has special relevance to licensed drugs.

The pricing rules outlined above for high volume drugs suggest that advantage of the lower unit prices associated with the purchase of large package sizes has been taken advantage of by the Quebec drug programme. The number of high volume drugs, by dosage form and strength is much higher than Ontario (118 vs 36) with 33 priced on the basis of package sizes of 1,000, 3, 5,000, one 6,000 and all the rest on package sizes less than 1,000. However, the evidence nevertheless suggests that some, if not all, pharmacists earn intra-marginal rent or reap hidden mark-ups. Although it may be tempting to make comparisons with Ontario, this is a difficult and hazardous undertaking, as will be seen below.

The pricing rules combined with a number of other factors, outlined below, permit intra-marginal rents to exist. First, the size distribution of pharmacists is heavily skewed towards those pharmacies with smaller claims against the Quebec government drug plan. For example, in 1977, the details were as follows:

CLASS OF PAYMENTS ($)	NUMBER OF PHARMACIES	CUMULATIVE PHARMACIES	PERCENTAGE PAYMENTS
Less than 10,000	247	18.5	1.8
10,000 - 19,999	186	32.4	6.4
20,000 - 39,999	310	55.6	21.4
40,000 - 59,999	241	73.6	41.0
60,000 - 79,999	134	83.6	56.3
80,000 - 99,999	85	90.0	68.7
100,000 - 119,999	51	93.8	77.9
120,000 - 139,999	27	95.8	83.6
140,000 - 159,999	21	97.4	88.8
160,000 - 179,999	19	98.8	94.0
180,000 - 199,999	6	99.3	95.9
200,000 and above	10	100.0	100.0

Source: Quebec, Régie de l'assurance-maladie du Québec (1978, Table 95, p. 194).

As can readily be observed the median pharmacist falls in the range of $20,000 - $39,999 although pharmacies of $39,999 or less only account for 21.4 percent of all claims. In other words, the vast majority (i.e., approximately 80 percent) of drugs will be purchased in quantities greater than the median pharmacist with consequent per unit cost reductions accruing to the pharmacist. Second, the procedure adopted refers to the individual pharmacy claim. Since buying groups are common, this process will considerably understate the actual package size purchased. Third, pharmacists may purchase quantities for periods longer than a month, consequently enjoying the lower per unit cost consequent upon ordering larger package sizes. Fourth, the prices are list price, not actual, and many pharmacists buy direct from the manufacturers who may not charge the nine percent wholesale mark-up. These four factors will result in some, indeed probably the majority, of pharmacies earning intra-marginal rents on substantially over 50 percent of the drugs sold in Quebec under the government reimbursement programme.

It is not easy to estimate the intra-marginal rent in Quebec, as compared with Ontario, because there is no mandatory price selection which can serve as a benchmark against which actual prices can be compared. Nevertheless, an attempt is made in Chart 6-3 to estimate the magnitudes of the intra-marginal rent for the same eight drugs, by dosage form and strength, as used in Ontario as well as a further four drugs, by dosage form and strength.[59] All twelve were on the list of 118 high setting dosage forms and strengths mentioned above. The procedure employed is estimating Chart 6-3 is exactly the same as Chart 6-2 except in one respect. Instead of the lowest priced licensee brand in formulary, the formulary price of the brand of the successful licensee, whose actual prices provide a guide to

the cost to the pharmacist, is used. This difference reflects the mandatory price selection of Ontario and the permissive product selection in Quebec. The successful licensee had a number of different drugs listed in the Quebec formulary, sold well in the Quebec market as far as can be judged from the raw data underlying Table 6-8 and, based on other evidence, its actual prices to pharmacists were matched by another successful licensee.[60] Hence, the chart should provide at least an indication of the order of magnitude of the intra-marginal rent.

Chart 6-3 shows that substantial intra-marginal rents are being reaped, with the pharmacist realising markups in the order of several hundred percent over cost.[61] As pointed out above, these estimates are based on the actual selling price to the pharmacist of a single, though competively significant, licensee and may not be applicable to all of the suppliers of the twelve drugs in Chart 6-3. Nevertheless, it would seem likely that other supplies of a drug would have to offer terms competitive with those shown in Chart 6-3 or else the licensee concerned would gain substantial business.

In sum, Quebec has realised relatively minor gains from the introduction of compulsory licensing compared with either Ontario or Saskatchewan, in part reflecting the permissive product selection law and the willingness of the provincial drug reimbursement plan to pay the suppliers' price for the brand selected. Nevertheless, further substantial gains can be made by the introduction of stronger product selection laws and perhaps mandatory price selection. Overall substantial intra-marginal rents are being made by pharmacists and measures should be considered to reduce them. Such measures are considered in section 6.4.8 and Chapter VIII below.

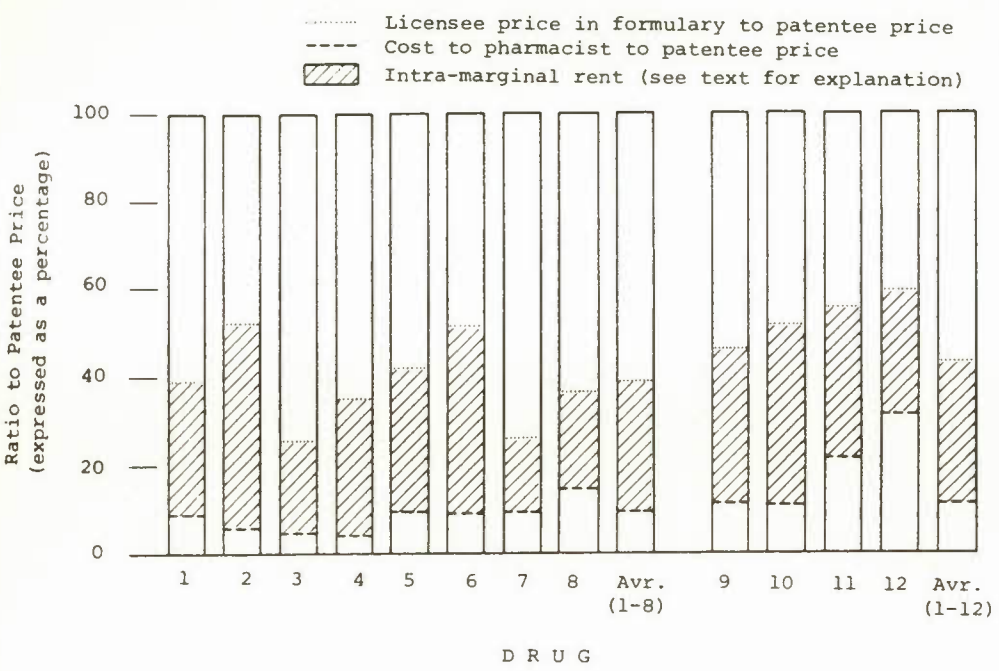
6.4.7 Retail Market: Saskatchewan

Saskatchewan accounts for appoximately 3 percent of the Canadian retail drug market.[62] The provincial drug reimbursement programme is universal with a co-payment of up to a maximimum of $2.80 per prescription for all except certain welfare recipients and special beneficiaries who receive drugs free of charge. The unique feature of the Saskatchewan drug plan, resulting in this province having one of the most price competitive market after the hospital market, is the use of a tendering system, referred to as Standing Offer Contracts (SOC). An SOC is defined as,

> ... a contract between a manufacturer and the Drug Plan to supply certain drug products to approved wholesalers ... at a contracted price. These distributors will purchase the drugs from the manufacturer and will distribute them to pharmacies at the Formulary price (Saskatchewan, Department of Health, 1978, p. 10).

Chart 6-3

Patentee's Price,[a] Licensee's Price,[b] Cost to the Pharmacist,[c] for Twelve High Volume Multisource Drugs, by Dosage Form and Strength,[d] Quebec, July-Dec. 1980

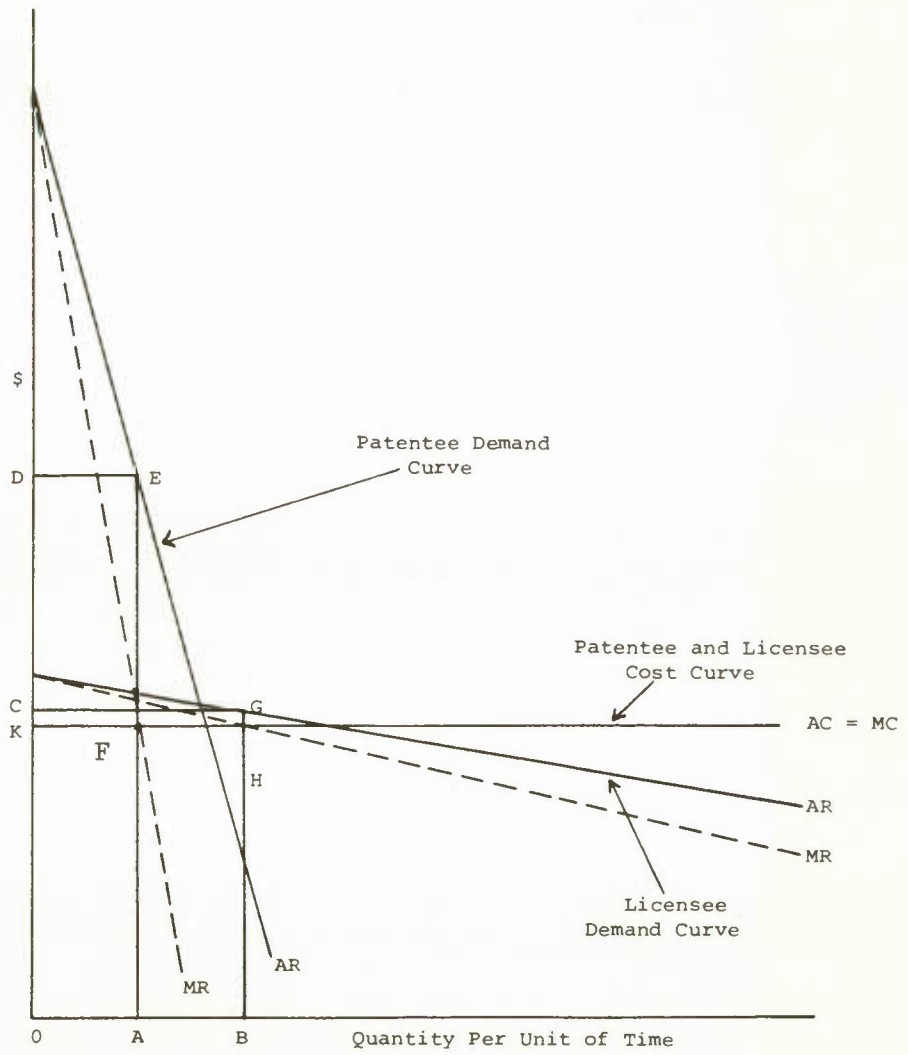


a. As per the formulary.
b. The formulary price of the licensee referred to in footnote (c).
c. As supplied by a successful licensee in the Quebec market.
d. Amitriptyline 25 mg. tabs.; diazepam 10 mg. tabs.; diazepam 5 mg. tabs.; diazepam 2 mg. tabs.; furosemide 40 mg. tabs.; hydrochlorothiazide 25 mg. tabs.; hydrochlorothiazide 50 mg. tabs.; chlorpropamide 250 mg. tabs.; amitriptyline 10 mg. tabs.; furosemide 20 mg. tabs.; thioridazine 10 mg. tabs.; and thioridazine 25 mg. tabs.

Source: Quebec, Regie de l'assurance du Quebec (1980) and data made available by a licensee.

Chart 6-4

PATENTEE AND LICENSEE DEMAND AND COST CURVES FOR DIFFERENT BRANDS OF THE SAME DRUG: THE CASE OF SASKATCHEWAN



AR = Average Revenue
MR = Marginal Revenue
AC = Average Cost
MC = Marginal Cost

For high volume drugs, especially multisource, the province's Formulary Committee identifies approved suppliers of a drug, which are then invited to bid for the period convered by the province's formulary (i.e., six months, January-June and July--December). In the first quarter of 1979 the ingredient cost of approximately 40 per cent of the province's prescriptions were provided for this way, compared to 30 per cent in 1976. It is usual that the supplier with the lowest prices will be selected for a given tender. (In some instances, particularly for the larger contracts, the two lowest bids are both successful in gaining a contract.) Not surprisingly, this system results in "low prices". Although comparisons are difficult across provinces, for the eight drugs by dosage form and strength, used in Chart 6-2 the lowest price of licensee brand in Saskatchewan is approximately, on average, half that of the lowest priced licensee in Ontario, the most suitable province in the sample studied here for comparative purposes.[63] Under the rules of the Saskatchewan plan unless the physician writes "no substitution" on the prescription then the pharmacist must dispense the brand of the supplier(s) awarded the contract. Hence, except for the presence of "no substitution" prescriptions, Saskatchewan SOC are the same as the tendering system outlined above for Hospital Purchasing Incorporated.

Table 6-9 presents indices A and B for Saskatchewan for a sample of 15 high volume licensed drugs, by dosage form and strength, covering a variety of therapeutic classifications for the January-March quarter of 1976 and 1979.[64] These 15 drugs accounted for 18.1 percent of the total Saskatchewan drug bill in January-March 1976 and 11.8 percent in the corresponding quarter in 1979.[65] Of the 15, eight were subject to an SOC in 1976 (amitriptyline, cephalexin monohydrate, diazepam, furosemide, ampicillin, methyldopa, erythromycin estolate, and chlorpropamide) while in 1979 a further two were added (amoxicillin and cloxacillin). Where index A = index B = 100 then no licensee competition is experienced. Hence, by reference to Table 6-9 it can be observed that in a small number of instances an SOC involves a drug which is experiencing no licensee competition, such as furosemide in 1976, but not 1979.

Table 6-9 shows that overall (i.e., All Drugs) for the 15 licensed drugs the actual prescription drug bill, as a percentage of that which would obtain without section 41(4) and accompanying provincial policy measures, dropped from 74.0 percent in 1976 to 64.6 percent in 1979. However, should mandatory price selection be introduced for the lowest priced licensee brand, then the drug bill in 1979 could be reduced by a further 12.2 percentage points, compared with what it would be in the absence of section 41(4). Not surprisingly, indices A and B for licensed drugs experiencing competition in 1976 or 1979 are lower than for all 15 licensed drugs. Equally, it is not altogether unexpected that for the five drugs which experienced licensee competition in 1976 and 1979 (i.e., Licensee Competition 1976) indices A and B were lower and showed a smaller percentage point decline between 1976

TABLE 6-9

THE IMPACT OF COMPULSORY LICENSING ON SELECTED LICENSED DRUGS FOR THE PROVINCE OF SASKATCHEWAN: 1976 AND 1979

DRUG AND DOSAGE FORM		INDEX[a] A. Actual drug prescription bill as a percentage of that which would obtain without section 41(4)[b]		B. The drug prescription bill with mandatory selection of the lowest priced licensee brand as a percentage of that which would obtain without section 41(4)[c]	
		1976	1979	1976	1979
amitriptyline	25 mg. tabs.	31.2 (32.5; 29.9)	32.7 (34.1; 31.4)	21.4 (22.3; 20.5)	9.2 (9.6; 8.8)
diazepam	5 mg. tabs.	33.0 (34.4; 31.6)	26.6 (27.4; 25.2)	10.7 (11.1; 10.2)	4.4 (4.6; 4.2)
ibuprofen	300 mg. tabs.	100	100	100	100
clofibrate	500 mg. caps.	100	82.4 (84.9; 79.1)	100	76.7 (80.0; 73.6)
furosemide	40 mg. tabs.	100	33.4 (34.8; 32.1)	100	11.8 (12.3; 11.3)
methyldopa	250 mg. tabs.	83.2 (86.8; 79.9)	60.4 (63.1; 58.0)	79.2 (82.6; 76.0)	46.3 (48.4; 44.5)
propranolol	40 mg. tabs.	100	100	100	100
ampicillin	250 mg. caps.	70.9 (74.0; 68.0)	74.6 (77.8; 71.6)	61.0 (63.6; 58.5)	70.1 (73.1; 67.2)
amoxicillin	250 mg. caps.	100	68.0 (70.9; 65.2)	100	49.2 (51.4; 47.2)
cloxacillin	250 mg. caps.	100	63.1 (65.9; 60.6)	100	58.4 (61.0; 56.1)
erythromycin estolate	25 mg. susp.	100	65.4 (68.3; 62.8)	100	56.9 (59.4; 54.6)
cephalexin monohydrate	250 mg. caps.	100	100	100	100
chlorpropamide	250 mg. tabs.	62.2 (64.9; 59.7)	40.6 (42.3; 39.0)	41.4 (43.2; 39.8)	16.3 (17.0; 15.6)
allopurinol	100 mg. tabs.	100	82.8 (86.4; 79.5)	100	80.7 (84.2; 77.5)
triamcinolone acetonide	0.1% cream	100	100	100	100
All Drugs[d]		74.0 (75.2; 72.4)	64.6 (66.5; 62.5)	66.2 (67.2; 64.7)	52.4 (54.0; 50.7)
Licensee Competition[e] 1976		49.9 (52.0; 47.9)	43.8 (45.5; 41.8)	34.8 (36.3; 33.4)	26.0 (27.0; 24.8)
Licensee Competition[e] 1979		69.5 (70.8; 67.8)	52.1 (54.2; 49.9)	60.3 (61.4; 58.8)	35.6 (37.1; 34.1)

a. The indices are based upon all sales of each brand of a given drug, by dosage form and strength, for the first 3 months of 1976 and 1979.
b. The estimation of the numerator of the index (i.e., actual drug prescription bill either for a given drug, by dosage form and strength, or for one of the three totals - All Drugs, Licensee Competition 1976, Licensee Competition 1979) is detailed in footnote a above. The denominator is estimated by taking the actual patentee's price which is then adjusted upward to take into account the effect of compulsory licensing, and multiplied by the quantity purchased. The adjustment factor was 20 per cent. However, to test for the sensitivity of the results, 15 and 25 per cent were also used. These results are in parenthesis. In those cases of more than one patentee per drug, the patentee price was the weighted average of their prices, using their sales of that particular dosage form as the weights.
c. The denominator of this index is detailed in the previous footnote, b. The numerator is the lowest price for a given drug, by dosage form and strength, multiplied by the quantity sold of that particular dosage form and strength.
d. This refers to the above fifteen drugs, not all drugs sold in Saskatchewan.
e. Licensee competition is taken to exist in either 1976 or 1979 when a licensee is reported as selling a drug in Saskatchewan. This corresponds exactly to those instances where licensees are listed in the Saskatchewan formulary, except in one instance, where, despite the fact a licensee is listed in the formulary for the period January-June 1979, no sales are recorded. Confidentiality requires the name of the drug not be released.

Source: Saskatchewan, Department of Health (1977 and 1979a) and information provided by the Saskatchewan Drug Prescription Plan, Ministry of Health.

and 1979, than for the 11 drugs which experienced licensee competition in 1979 (i.e., Licensee Competition 1979), only five of which, however, also experienced such competition in 1976.

In terms of individual drugs in four instances, amitriptyline, diazepam, furosemide and chlorpropamide, the introduction of section 41(4) has led to a reduction in the drug bill of 59 percentage points or more (i.e., 100-index A) for 1979.[66] In all four instances SOC's were in place in both 1976 and 1979. Perhaps the most dramatic reduction was for furosemide 40 mg. tabs. However, in all four instances there are still substantial gains in terms of reducing the drug bill by the introduction of mandatory price selection of the lowest price licensee brand (i.e., the SOC contract price applied to all prescriptions including "no substitution".) This reflects the continued success of the patentee in charging a price far in excess of that of the licensees' and retaining a small but, significant, market share when measured in terms of volume of the dosage form. (This is consistent with the results of Table 4-5 above for 1979.) For example, for one of the four drugs[67] the situation is as follows:

Units dispensed	No.	Value
	(percentage)	
patentee		
1976	23.1	48.5
1979	19.4	61.6
licensees		
1976	76.9	51.5
1979	80.6	38.4

For this drug the patentee's market share, measured in terms of the number of units sold actually declined between 1976 and 1979 (i.e., 23.1 percent to 19.4 percent) but its market share, measured as a percentage of the total value of all brands of that particular dosage form actually increased (i.e., 48.5 percent to 61.6 percent). In the remaining instances the difference between the value of index A and B, in terms of the number percentage points, is much less, reflecting, in part, a smaller number of licensee competitors.

The issue which the above facts raise is as follows: what set of demand and cost curves explain the observed facts. An answer is provided in Chart 6-4. The patentee's demand curve is inelastic, reflecting the brand loyalty induced by considerable sales promotion and advertising, as reported in Chapter V above. In other words, physicians, prescribe the patentee's product on a "no substitution" basis. It should be noted that the effect of government programs described in Chapter 1 is to shift the patentee's demand curve to the left over time and possibly make it more elastic. An individual licensee's demand curve, on the other hand, is very elastic. The elasticity will likely increase with the number of competitors. It is assumed for convenience patentee and licensee costs are the same. The net result is that the profit maximizing patentee charges OD with profits equal to DEFK while the licensee (assume it is

awarded the SOC) charges a lower price, OC, with profits equal to CKGH. However, note that the market share, measured in quantity terms, is greater for the licensee, OB, than the patentee, OD, while the converse applies to market share measured in dollar terms. Under such a set of conditions it is clearly "irrational" for the patentee to lower prices, since quantity increases only marginally but profit falls drastically.

The above discussion of Table 6-9 has concentrated upon those values of index A and B which assumed, based on the evidence in section 6.3 and 6.4.2 above, that the patentee's price would, but for licensee competition, be 20 percent higher. The numbers in parentheses are indices A and B estimated assuming a 15 and 25 percent mark-up. The results and inferences remain essentially unchanged. Even if the assumption was made that section 41(4) had no effect on the patentee's price, despite licensee competition, then the results remain much the same.[68]

In sum, Saskatchewan has realised substantial declines in expenditure on licensed drugs, primarily because of the SOC tendering system. Nevertheless, the physicians use of "no substitution" prescriptions mean further gains can be realized.

6.4.8 Future Policy Directions

The effect of the passage of section 41(4) combined with provincial product selection legislation and drug reimbursement programmes has been to substantially reduce the prescription bill in the hospital market (i.e., Hospital Purchasing Incorporated) and the retail markets of British Columbia, Ontario and Saskatchewan. In contrast, the effect in Quebec has been much less pronounced. In all markets, in varying degrees, there exists considerable scope for further reductions of drug bills. Specific suggestions for realizing these gains will be made on a province by province basis because of difficulty of generalising across all markets.

In Ontario and Quebec the prices currently listed in the provincial formularies allow substantial intra-marginal rents to be captured by pharmacists instead of being passed on to the consumer or the government as the provider of drugs at reduced cost to various classes of consumers. (In Quebec only pharmacists can own a pharmacy, but in Ontario some non-pharmacists will reap the intra-marginal rents because non-pharmacists can own pharmacies). In both provinces use of more appropriate (i.e., lower) prices should be made in the formulary. Numerous sources of price information exist with which to monitor the presence and magnitude of intra-marginal rents: IMS; hospital market prices; Saskatchewan SOC prices; and, possibly, requesting information, on a confidential basis, from pharmacies.[69]

In Ontario, in the ODB sector of the market, the drug cost of a prescription is derived by mandatory price selection

of the lowest priced interchangeable pharmaceuitcal product in the formulary. In the non-ODB section of the market the relevant rule is set out in section 158(3) of the Health Disciplines Act, which reads,

> No person shall knowingly supply an interchangeable product ... at a price in excess of the cost of the lowest priced interchangeable pharmaceutical product in his inventory....[emphasis supplied]

These differences between the two markets lead to the following practice: the pharmacist will stock brands of a particular drug which have medium to high formulary prices and low real prices so he can profit from the spread, especially to non-ODB consumers.[70] Hence, serious consideration should be given to changing section 158(3) such that the words "his inventory" are replaced by "as set out in the PARCOST C.D.I." Other provinces with formularies and reimbursement programmes which cover less than the whole population experiencing analogous problems, should consider whether it is appropriate to make similar changes.[71]

Product selection legislation could be strengthened in British Columbia and Quebec, particularly in the latter province where the law requires the pharmacist to notify the patient that product selection is taking place, in order to get the patient's permission. However, since such exercises are likely to be time consuming and may work to the economic disadvantage of the pharmacist, there is little, if any, incentive to product select. Serious consideration should be given to removing this disincentive. Provincial drug reimbursement programmes in British Columbia and Quebec could introduce mandatory price selection, as in Ontario, in order to further reduce drug costs.

Finally, some criticism has been levelled against Saskatchewan for its use of wholesalers to distribute SOC drugs with "... consequent high handling costs" (Bailey Committee, 1978, p. 9). In addition, the significant market share held by the patentee in Saskatchewan because of "no substitution" prescriptions could perhaps be reduced by an education programme aimed at physicians, so that they become more price sensitive. Finally, the considerably longer period of time taken by Saskatchewan to list licensed brands, as noted in Chapter IV, section 4.4 above, may delay the realization of cost savings.

6.5 Summary and Overview

The main findings of this chapter can be summarized as follows: the 47 drugs for which compulsory licenses have been issued by the Commissioner of Patents between 1970 and 1978 accounted for approximately one-third of the total drug prescription bill throughout the period 1969-1977, while if attention is confined to those drugs for which the licensee marketed a

brand to compete with the patentee, the percentage varied between 20 and 26, depending upon the year; patentee prices, where licensee competition was experienced, would have been on average, at least 20 per cent higher, had section 41(4) not been introduced.

A detailed evaluation of compulsory patent licensing, provincial drug reimbursement programmes and product selection legislation in the hospital market, using Hospital Purchasing Incorporated of Toronto as a case example, and the retail markets of British Columbia, Ontario, Quebec and Saskatchewan suggested that drug prices and bills had been reduced substantially to the consumer with the possible exception of Quebec. Nevertheless, in virtually all markets further reductions in drug expenditure can be realised by for example, changing the structure of the reimbursement system or introducing stronger product selection legislation. In Chapter VIII these and other measures are discussed in more detail. Two points should be made concerning the applicability of these general findings. First, the problems and possibilities identified for reduced drug bills are likely to apply to all multisource drugs in each of the markets considered. Second, similar problems and difficulties may be encountered in provinces not included in the discussion here, since, as shown in Chapter 1, sections 1.3 and 1.4 above, there would appear to be some common elements across the various provinces.

No attempt has been made to estimate the Canada-wide actual or potential savings in terms of reduced drug bills. Instead, the approach taken has been to concentrate on particular hospital and retail markets, which differ quite significantly in their institutional framework for the delivery of drugs, so that a fuller understanding of the way in which different rules affect prices and competition can be gained. Nevertheless, some estimates of the overall Canada-wide savings in drug bills resulting from government policy have been made.[72] In recognition of provincial differences these estimates have been at the manufacturing level only. Unfortunately no supporting documentation or the underlying rationale for the estimates is presented thus precluding any assessment of their significance.

CHAPTER VII

COMPULSORY LICENSING: THE IMPACT ON THE DRUG INDUSTRY

7.1 Introduction

An evaluation of compulsory licensing would be incomplete and seriously remiss if no attention was paid to its effect on such indicators of industry performance as research and development, balance of trade and advertising. Not only was the Harley Committee concerned about some of these impacts, but the patentees, through their trade association, the PMAC, have made presentations to government alleging that section 41(4) and concomitant policies described in Chapter I above, have had adverse affects on industry performance.[1] An assessment of these effects is thus necessary in order to make any judgement as to the overall cost vs. benefits of compulsory patent licensing.

This chapter is organized as follows. The first two sections, 7.2 and 7.3, discuss the impact of compulsory licensing upon the balance of trade and the level of research and development, respectively. In section 7.4, a series of other possible effects or impacts of compulsory licensing are considered, including those on advertising, rate of introduction of new drugs and the pricing policy of patentees with respect to non-licensed drugs. Also considered is the public cost of implementing programmes and policies designed to lower drug prices which were described in Chapter I. Although such costs are clearly not an aspect of industry performance, they nevertheless deserve attention in evaluating the costs and benefits of section 41(4). Finally, a summary and overview is presented in section 7.5.

7.2 Balance of Trade

In considering the impact of compulsory licensing on the balance of trade, attention must be paid not only to the policy itself, but also to more general factors that are likely to influence exports and imports, independently of section 41(4). It is only against the background of broader developments and trends that section 41(4) can be evaluated.

The world drug industry is dominated by a group of large multinational firms, as discussed in Chapter V, section 5.2 above, none of which are of Canadian origin. These firms, as discussed in Chapter I, section 1.2.2 above, typically manufacture the raw material (i.e., bulk active ingredient) in a limited number of geographical locations to supply their worldwide oper-

ations, where final dosage preparation takes place. Canada has typically attracted little investment in the manufacture of the raw material because of the smallness of the domestic market. These multinational firms optimize their pattern of production on the basis of a global opportunity set of investments. In doing so their decisions are likely to alter the trade flows of particular countries. Within such a context the role for independent initiative by a subsidiary in Canada with respect to imports and exports is likely to be limited. As a recent Department of Industry, Trade and Commerce study, based upon extensive industry interviews, put it,

> ... optimization of overall international performance usually takes precedence over optimization of the Canadian operation. Canadian subsidiaries are often not encouraged or permitted by the head office to assume responsibility for exports of their products and are limited to marketing in Canada. (Canada, Department of Industry, Trade and Commerce, 1980, p. 5).

Hence, the issue arises as to the major influences with respect to the location of new production plants by these multinational firms.

The drug industry is, in many ways, able to respond to investment incentives to encourage location of production facilities very well. It is, to use the jargon, an example par excellence of the "footloose" industry, since it uses readily available inputs, while on the other hand having outputs that are easily transportable with high value/weight ratios. It is for these reasons that the industry has responded to the tax incentives of the governments of Puerto Rico and Ireland in the 1970's,[2] with Ireland granting access to the markets of the European Economic Community and Puerto Rico to that of the U.S.A. Such investment incentives are likely to have resulted in less new investment in Canada and more in the two aforementioned "tax havens". This is therefore likely to lead, for Canada, other things being equal, to higher imports and lower exports, i.e., the import/export ratio will increase. Before examining the pattern of the balance of trade it should be noted that Puerto Rico has increased substantially its share of Canada's imports of prescription drugs from 0.05 percent in 1970, to 7.2 percent in 1977.[3] This is consistent with the above discussion.

Attention is now focussed on the specific influence of compulsory licensing. Section 41(4) was passed in 1969 with the objective of encouraging licensees to import drugs. However, this does not necessarily imply that total imports will rise, since the licensee will, presumably, displace imports that the patentee had formerly imported. (Remember the generally accepted view that total demand for drugs is relatively price inelastic). However, the net effect on the value of imports is not likely to

be zero for two reasons. First, the patentee when importing the raw material into Canada from the multinational parent may pay artificially high prices (i.e., transfer pricing as discussed in Chapter V, section 5.2 above) while the licensee, buying on a much more competitive world market, at arms length, will probably pay a lower price. Hence the import/export ratio will fall, other things equal. Second, the patentees conduct, albeit on a small scale, some production of the raw material in Canada, thus imports by licensees would be substituted for domestic production. Hence, the import/export ratio will increase. No evidence is available on the relative importance of the two factors, but given that the vast majority of the drug raw material is imported the first effect will likely be more significant. On the question of exports it is known that some of the licensees do export, such as Apotex Inc., Jerram Pharmaceuticals Ltd., and Novopharm Ltd. However, the scale is not known. Nevertheless, unlike imports, the exports of the licensee are unlikely to displace those of the patentee since the latter form part of the worldwide product trade distribution pattern of the parent in Switzerland, the United Kingdom or the United States.

In considering the impact of the general factors, outlined above, influencing imports and exports of all prescription drugs as well as those relating to only licensed drugs, the probable overall impact is not clear. The general factors are likely to result in an increase in the import/export ratio (although the appreciation of the Canadian dollar in the early and mid-1970's compared with the 1960's may have offset this somewhat) while compulsory licensing, considered by itself, will have the opposite effect. However, since the general factors refer to all prescription drugs, this impact may well prevail.

Data on imports and exports of prescription drugs, as such, are not presented in Statistics Canada publications. Instead, there are a series of quite fine categories which come under the general heading of Pharmaceuticals and Medicines, industry 374. Table 7-1 presents what would appear to be the closest, albeit rough, approximation to the balance of trade for prescription drugs, comparable data being unavailable for those drugs subject to compulsory licensing. The table excludes such classifications as "veterinary biological products" and "veterinary medicines and feed supplements" which, as pointed out in Chapter III, section 3.2.2 above, are not the concern of this study. Also excluded are categories such as "blood and blood fractions" for similar reasons. In an effort to keep comparisons between years consistent, imports for 1963 were not included, as the classifications for that year were different from subsequent years. Also, the classification system for both imports and exports changed for 1978 and subsequent years, and hence these years are not included.

Table 7-1 shows that Canada has traditionally incurred a balance of trade deficit on prescription drugs, which, in nominal dollars has increased from $21.4 million in 1964 to $123.3 million in 1977, reflecting, in part, the effects of

Table 7-1

Value of Imports and Exports, Prescription Drugs,[a] 1963-1977

Year	Imports ($'000)	% Increase Over Previous Year	Exports ($'000)	% Increase Over Previous Year	Trade Deficit ($'000)	% Increase Over Previous Year	Import/Export
1963	—	—	4,204	—	—	—	—
1964	26,058	—	4,673	11.2	21,385	—	5.58:1
1965	27,611	6.0	6,323	35.3	21,288	-0.5	4.37:1
1966	31,422	13.8	7,206	14.0	24,216	13.8	4.36:1
1967	36,013	14.6	6,908	-4.1	29,105	20.2	5.21:1
1968	36,889	2.4	7,792	15.4	28,917	-0.6	4.63:1
1964-68 Average Annual Growth Rate		9.2[b]	—	14.4	—	8.2	Average 4.83:1
1969	45,098	22.3	9,260	16.2	35,838	23.9	4.87:1
1970	54,011	19.8	10,538	13.8	43,473	21.3	5.13:1
1971	53,387	-1.2	11,085	5.2	42,302	-2.7	4.82:1
1972	67,465	26.4	14,040	26.7	53,425	26.3	4.81:1
1973	76,179	12.9	22,473	60.1	53,706	0.5	3.39:1
1974	98,388	29.2	20,880	-7.2	77,538	44.4	4.72:1
1975	122,081	24.1	23,459	12.5	98,622	27.2	5.20:1
1976	124,983	2.4	25,958	10.7	99,025	0.4	4.81:1
1977	154,395	23.5	31,124	19.9	123,271	24.5	4.96:1
1969-77 Average Annual Growth Rate		17.2	—	19.0	—	18.1	Average 4.75:1

a. Value of imports was calculated from the following classifications: Cortical hormones; sex hormones; bacteriological products for human use; penicillin; streptomycin and dihydrostreptomycin; antibiotics n.e.s. (not elsewhere specified); narcotics; sulphonamides and their salts; barbiturates and amphetamines; papain; medicinal and pharmaceutical products, n.e.s. The export classifications were: penicillin; antibiotics, n.e.s.; narcotics; medicinal and pharmaceutical products, n.e.s.

b. 1965-68.

Source: Canada, Statistics Canada Imports by Commodities December issues (Ottawa: Statistics Canada) Cat. no. 65-007; Imports. Merchandise Trade (Ottawa: Statistics Canada) Cat. no. 65-203; Exports by Commodities (Ottawa: Statistics Canada) Cat. no 65-004; Exports. Merchandise Trade (Ottawa: Statistics Canada) Cat. no. 65-202; Canada, Department of Industry, Trade and Commerce (1972, 1973, 1974, 1975, 1976, 1977, 1978) Chemicals Branch Statistical Review (Ottawa: Department of Industry, Trade and Commerce).

inflation. In accordance with the above discussion, the balance of trade issue will be addressed in terms of the import/export ratio (see extreme right hand column of Table 7-1). Over the period 1964 to 1968 the average ratio of imports to exports was 4.83:1 while for the period immediately following the introduction of compulsory licensing 1969-1977, the ratio declined, somewhat marginally, to 4.75:1. No trend for the ratio is apparent in either sub-period. The difference in the average import/export ratio for the two periods was not statistically significant, the t-value not exceeding 0.50. Hence, it would appear, that the impact of the various factors, both general and specific, has had a broadly neutral effect on the balance of trade for prescription drugs.[4] As such it is difficult to isolate the impact of compulsory licensing without further information. However, it would appear to be of minimal magnitude, based on the available, albeit imperfect, information.[5]

7.3 Research and Development

A lively debate has been and is continuing in Canada over the subject of research and development.[6] A number of issues such as the influence of foreign ownership, the "low" level of R & D, appropriate government policy, and reliance on imported or domestic technology, have been raised and, in some instances, still require fully satisfactory answers. The drug industry is generally recognised as one of the most research-intensive of all manufacturing industries.[7] Hence, if compulsory licensing has had a seriously adverse impact on the level of research and development, as has been claimed, then this is likely to be of particular interest in the present policy environment.

As discussed in Chapter V, section 5.2 above, the drug industry in Canada is dominated by large multinational firms, particularly those of U.S. origin which accounted for 70 to 75 percent of industry sales in 1970. Hence, considering, within a broader context, the factors influencing research and development in Canada, attention must necessarily focus, initially at least, on the determinants of both the level and location of R & D conducted by the parent, particularly those of U.S. origin.

The typical multinational drug firm, whether of Swiss, U.K. or U.S. origin, in designing its strategy for the level and location of its worldwide R & D operations is limited by a number of technological and economic constraints. The available evidence indicates that in conducting R & D there exists a threshold level of expenditures, "...below which a company would have to concentrate on minor improvements rather than genuine innovations" (OECD, 1979, p.48). In terms of actual size and number of projects imposed by such a threshold the evidence is as follows:

> It has been suggested that the minimum usable unit would be one large enough to work on three projects at the same time. In 1973, this would probably have cost about $3 million per year in a relatively cheap country such as the United Kingdom or about $6-7 million in the United States. (OECD, 1977, p. 48.)

In relation to the size of a firm's R & D budget the implications are as follows:

> A large company would expect to work on 8 to 10 projects and spend $12-14 million in the United Kingdom or $25-30 million in the United States....It is not surprising to find that research-oriented pharmaceutical companies are generally large and limited in number. (OECD, 1977, p.48.)

Given these constraints, the multinational drug firm has one or perhaps two major R & D centres, since it appears that diseconomies of scale exist in the range of 1,000 to 5,000 employees. (The corresponding threshold level to the dollar figures cited above is between 200 to 300 personnel.)[8] The location of the first and usually largest R & D centre is, naturally enough, in the firm's country of origin. Indeed, of the world's leading 25 pharmaceutical firms, in only three instances are there approximately equal or larger research centres outside the parent country.[9] The criteria for the selection of the site for the second main research centre have been detailed as follows:

> ...the chosen nation should be politically stable, have a large and flourishing scientific community, and have a proven record of successful innovation. Less critically, it should offer the full range of ancillary services necessary for successful research and should be culturally compatible with the parent country. If possible, it should also be cheap. These desiderata limit the choice to large developed countries and in particular to the United States, Germany and, especially, the United Kingdom. (OECD, 1977, p.81.)

Although Canada may meet some of the criteria, such as the first, it has not been selected as a major centre for multinational drug firms' R & D expenditures.

The multinational enterprise does, however, conduct R & D activities outside the one or two major centres discussed above. For most subsidiaries in developed countries there is

usually an R & D capability which is devoted to applied research and development since this is the most easily decentralised function.[10] This applied R & D consists of, at a minimum, "...a small product development section to assist in the adaption of standard preparations to local conditions"(OECD, 1977, p.82). Under this general heading is clinical testing which seems to be particularly mobile across countries. In the words of the OECD study into the influence of multinational firms on the drug industry, the following comments are made with respect to clinical testing,

> Here company priorities are to have the studies conducted competently and cheaply in centres with high standards of medical practice. Developed countries are favoured for detailed trials as they are most likely markets; similarities of medical practice are also of importance. Small nations may provide facilities equal to those of large ones. These preconditions lead, for example, to the Anglo-Saxon countries favouring the United Kingdom, Scandinavia and South Africa as centres for clinical testing. (OECD, 1977, p.82.)

R & D conducted in Canada does not fall into the category of major research centres, but the supplementary type, with some clinical testing.

As mentioned above, U.S. multinational drug firms dominate the Canadian drug industry. There is a large literature on the determinants of the level and location of research and development of U.S. multinationals for the 1960's and 1970's. The major findings of this research can be summarised as follows: the returns to research and development investment in the U.S. fell dramatically in the mid- and late-1960's and 1970's compared to alternative investments and the rates of return experienced in the early 1960's[11]; this fall in the rate of return was caused by two major separate sets of factors, the stringent regulatory requirements imposed on new drugs because of the 1962 amendments to the Food, Drug and Cosmetic Act and the depletion of research opportunities, a worldwide phenomenon[12]; U.S. multinational firms, in response to the above factors, have substantially increased R & D expenditures abroad since the early 1970's.[13] One would not expect Canada to capture a significant share of this R & D investment for two reasons. First, one of the major factors causing the change in location of U.S. investment was the 1962 amendments regarding drug safety and efficacy. Canada, it would appear, has a system very similar to that in the U.S.[14] Second, it seems that much of the R & D investment abroad by U.S. firms is in setting up a second major research centre. As discussed above, these have not been sited in Canada but in countries such as the United Kingdom, which also

TABLE 7-2

MEASURES OF R&D EXPENDITURES FOR MANUFACTURERS OF PHARMACEUTICALS AND MEDICINES: 1963-1976

Year	Current R&D Expenditures[a]			Scientists and Engineers Engaged In R&D		Capital Expenditures on R&D			Constant[b] Dollar Current R&D as a % of Constant Industry Sales[c]	Constant[b] Dollar Capital R&D Expenditures as a % of Constant Industry Sales[c]
	Actual	Constant[b]	% of Industry Sales	Number	% of Industry Employment	Actual	Constant[b]	% of Industry Sales		
	($ Millions)					($ Millions)				
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
1963	6.2	6.2	3.2	n.a.	n.a.	1.4	1.4	0.7	3.2	0.7
1964	7.4	7.2	3.6	n.a.	n.a.	3.2	3.1	1.5	3.5	1.5
1965	8.9	8.4	3.7	n.a.	n.a.	3.2	3.0	1.3	3.5	1.3
1966	11.4	10.3	4.2	n.a.	n.a.	1.3	1.2	0.5	3.8	4.5
1967	13.6	11.8	4.6	362	3.0	0.9	0.8	0.3	4.1	0.3
1968	15.4	13.0	4.7	n.a.	n.a.	0.7	0.6	0.2	4.2	0.2
1969	17.3	14.0	4.9	378	3.0	2.9	2.3	0.8	4.2	0.7
1970	18.2	14.1	4.7	n.a.	n.a.	0.6	0.5	0.2	3.9	0.1
1971	21.5	16.1	5.0	411	3.0	0.4	0.3	0.1	4.0	0.1
1972	21.5	15.3	4.6	n.a.	n.a.	1.2	0.9	0.3	3.6	0.2
1973	24.1	15.7	4.6	455	3.1	0.7	0.5	0.1	3.4	0.1
1974	26.4	14.9	4.6	460	3.1	1.0	0.6	0.2	3.0	0.1
1975	29.8	15.2	4.6	n.a.	--	1.4	0.7	0.2	3.0	0.1
1976	n.a.	--	--	n.a.	--	1.1	0.5	0.2	-	0.1

a. Includes both intramural and extramural R&D expenditures.
b. In order to derive constant dollar R&D expenditures, whether current or capital, the GNE deflator was used.
c. In order to derive constant industry sales, the industry selling price deflator for Industry 374, Manufacturers of Pharmaceuticals and Medicines was used. Similar results to columns 9 and 10 were recorded if the industry selling price index for Ethical Preparations for Human Use was used instead.
n.a. not available.

Source: Canada, Statistics Canada, Industrial Research and Development Expenditures in Canada (Ottawa: Statistics Canada) Cat. No. 13-203, various issues; Industry Price Indexes (Ottawa: Statistics Canada) Cat. No. 62-011, various issues; Manufacturers of Pharmaceuticals and Medicines (Ottawa: Statistics Canada) Cat. No. 46-209, various issues; National Income and Expenditures Accounts (Ottawa: Statistics Canada) Cat. No. 13-201 various issues, and PMAC (1976b, p. 12).

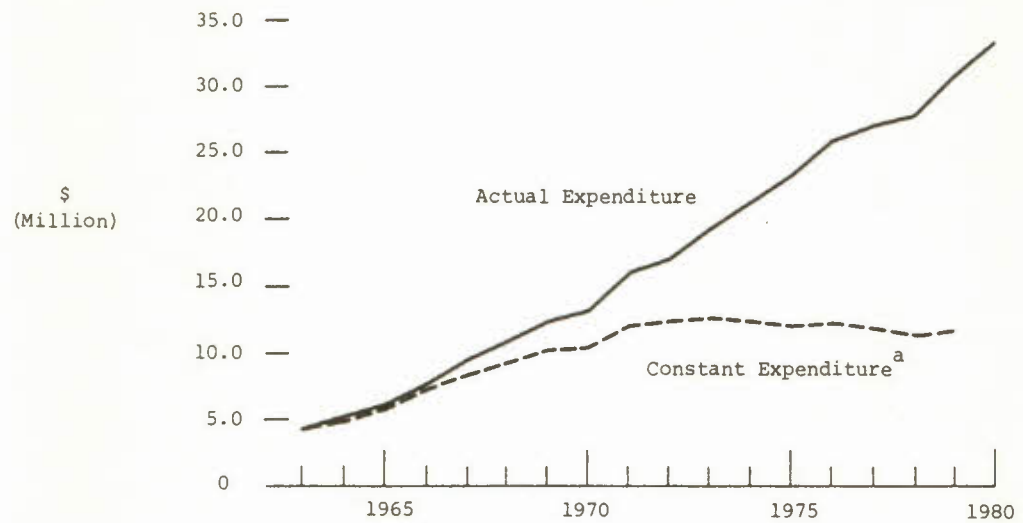
have less stringent, though not necessarily less adequate, regulatory systems for screening new drugs prior to sale on the market.

Attention is now confined specifically to the influence of compulsory licensing on R & D activity in Canada. Clearly, compulsory licensing is not an incentive to conduct R & D. Indeed, studies for countries with major R & D programmes suggest that if patent protection were seriously eroded, R & D would fall significantly.[15] Several reports suggest that compulsory licensing is a disadvantage when the Canadian subsidiary is seeking and competing for investment funds from the parent firm and has led to reduced R & D in Canada. For example, the OECD (1977, p.218) commented that section 41(4) "...may well be significant...," while a federal Department of Industry, Trade and Commerce (1979b, p.19) study on R & D in the health care products sector commented "...there is some evidence that it [i.e., compulsory licensing] has contributed to the decline in international drug companies' R & D in Canada...." (This latter study also notes that regulatory requirements in Canada "...constitute a substantial impediment to more R & D being carried out in Canada."[16]) In neither case, however, is hard evidence cited to substantiate the view that compulsory licensing has led to a decline in R & D.

The above discussion of the factors, both general and those relating to compulsory licensing, influencing the level of R & D expenditures in Canada leads to the inference that such expenditures may well have declined due in part, to compulsory licensing, but also due to the regulatory procedures for establishing the safety and efficacy of new drugs. Table 7-2 attempts to throw some light on these predictions. Most of the indices in the table are self-explanatory and require little or no elaboration. However, columns 9 and 10 deflate both sales and R & D (whether current or capital) by a price index. The results are different from columns 3 and 8 because different price indices are used for numerator and denominator. R & D is deflated by the GNE deflator while industry sales by the industry selling price index for industry 374, Manufacturers of Pharmaceuticals and Medicines. The use of these two indices reflects the different rates of inflation which each has experienced.[17] Also in the table, both absolute magnitudes such as nominal and current (i.e., inflation deflated) dollar levels of R & D expenditure as well as a number of commonly used indicators of R & D intensity, such as the number of qualified scientists and engineers engaged in R & D as a percentage of total employment, are presented. The table refers to industry 374, Manufacturers of Pharmaceuticals and Medicines, which, as mentioned in section 7-2 above, refers to other drug products besides prescription drugs. However, most R & D conducted by drug firms result in products that are categorized by the appropriate regulatory authorities as "prescription". In addition patentees, as shown in Chapter 1, section 1.2.2 above dominate the drug industry. Hence, the data presented is relevant to the issues discussed previously.

CHART 7-1

CURRENT INTRAMURAL R&D EXPENDITURES FOR MANUFACTURERS OF PHARMACEUTICALS AND MEDICINES: 1963-1980

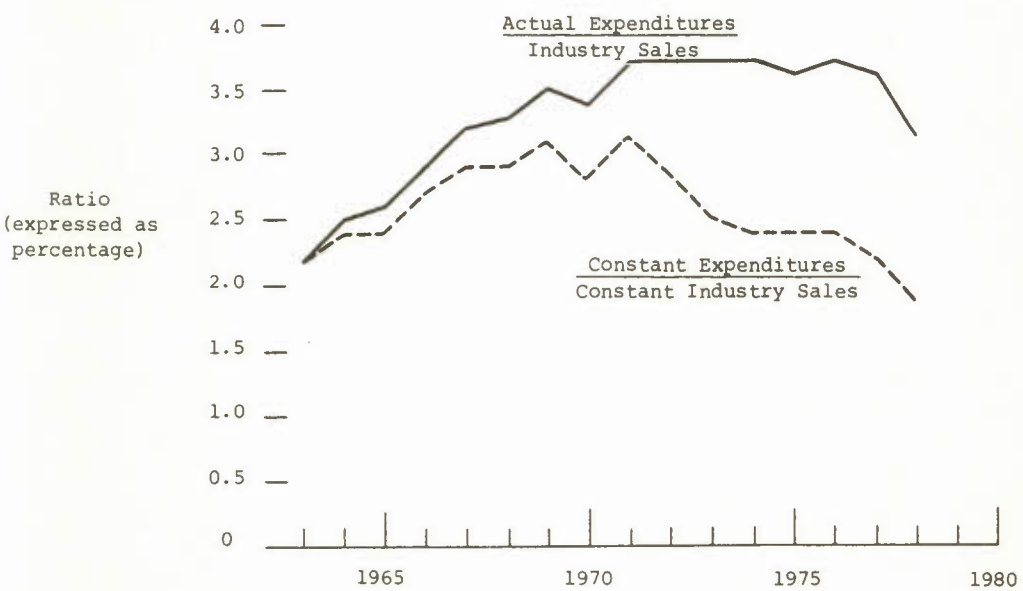


a. For 1980 only an estimate of the GNE deflator was available. This resulted in a constant expenditure of $8.8 million.

Source: See Table 7-2 above and Canada, Statistics Canada (1980) Science Statistics (Ottawa: Statistics Canada) Cat. No. 13-003, Vol. 4, No. 9, Nov., various tables.

CHART 7-2

CURRENT INTRAMURAL R&D EXPENDITURES DEFLATED BY INDUSTRY SIZE FOR MANUFACTURERS OF PHARMACEUTICALS AND MEDICINES: 1963-1978



Source: See Chart 7-1 above.

Table 7.2 shows that there has not been a massive reduction in R & D activity in Canada as multinational drug firms switched all their research away from Canada to other subsidiaries measured either in actual or constant dollars (columns 1, 2, 4, 6, and 7). Hence, the view of the Canada Task Force on Biotechnology (1981, p 33) that compulsory licensing has "... had a devastating effect upon investment in pharmaceutical research and development in Canada," is not consistent with the available data. Indeed, the weaker inference that R & D has declined is not supported. For current constant R & D expenditures (column 2) there is a steady increase until 1971 a slight drop to above the 1969 level and little change thereafter. The drop in capital expenditures and subsequent stabilization (with considerable fluctuation) took place in 1966, not 1969 or 1970. In contrast, when industry size is taken into account, R & D (measured by current or capital expenditures as well as employment) has been virtually unchanged since 1967 (columns 3, 5 and 8). For example, current R & D as a percentage of industry sales varied between 4.6 and 5.0 over the period 1967 to 1975. However, when both industry sales and R & D (either capital or current expenditures) are deflated by appropriate price indices, current R & D does decline in the period 1972-1975, compared with 1966-1971, by approximately 1 percentage point, while capital expenditures on R & D behaves in much the same way as column (8).

In the late 1970's data on R & D expenditure is much more limited than that shown in Table 7-2 for 1963-1976. Current intramural R & D expenditure is published for 1963 through to 1980. Intramural expenditures refer to those conducted within the firm, in contrast to extramural, which refer to payments made for R & D undertaken outside the firm. In the period 1972 to 1975, the most recent period when both sets of figures were available, of total current R & D expenditures by firms classified to industry 374, 79 to 81 percent were classified as intramural. Hence the discussion of R & D activity subsequent to 1976 is likely to be most closely related with the current R & D presentation above.

Chart 7-1 displays actual and constant current intramural R & D expenditures for industry 374, Manufacturers of Pharmaceuticals and Medicines, for the period 1963 to the late 1970's. Actual expenditures show an increase every year between 1963 and 1980 while, in contrast, such expenditures expressed in constant dollar terms increase annually until 1973, drop slightly subsequently level off, before declining somewhat in the late 1970's. Nevertheless the level of R & D in 1979 in real terms was above that in the late 1960's. When actual R & D is deflated by industry sales (Chart 7-2), a steady annual rise is recorded until a plateau (3.6-3.7 percent) is reached between 1971 and 1977, when a decline is observed in 1978 to below the 1969 level. In contrast, constant R & D deflated by constant industry sales, exhibits a levelling off in the period 1967 to 1972 (2.8 to 3.1 percent) then declines gradually from 2.5 percent in 1973 to 1.9 percent in 1978. In sum, by whatever measure of R & D activity

using current intramural expenditures, apart from actual dollar expenditures, a period of levelling off is observed, then a subsequent decline in the late 1970's. In some instances the beginning levelling off pre-dates 1969, in others it post-dates. The decline, in percentage point terms (Chart 7-2) is, like that for Table 7-2, approximately 1 percentage point.

In sum, it would appear that a decline in the absolute level of R & D has not taken place except perhaps for current intramural expenditure. However, when related to industry sales, again contrary to either a priori expectations and the general trend in the economy, which saw R & D expenditures as a percentage of GNP decline from 1.28 in 1967 to 0.92 in 1977,[18] there is no decline in R & D except for a small decrease in 1978 of 0.5 of a percentage point for current intramural R & D expenditure. It is only when both R & D and industry sales are deflated by appropriate price indices that R & D declines. However, the decline is only 1 percentage point using either constant current R & D expenditures (1966-1971 to 1972-1975) or constant current intramural R & D expenditures (1967-1972 to 1973-1978). Hence, a small decline according to one indicator, occurred in R & D; while some portion may have been due to compulsory licensing, the other factors mentioned above must also be considered.

7.4 Some Other Impacts

7.4.1 Introduction

In the course of conducting the research for this study extensive consultation, with both the private and public sectors, was undertaken in accordance with the terms of reference given to the Economic Council for the Regulation Reference by the Prime Minister.[19] In the process of consultation a number of possible effects or impacts of compulsory licensing, in addition to those already discussed above, were raised. Unfortunately, almost without exception, no supporting data was provided and, on further examination, only sketchy data could be obtained, which is not always conclusive or even, in some instances, suggestive. Nevertheless it is important that these alleged impacts of compulsory licensing should be mentioned and the available evidence presented.

7.4.2 Advertising

The prescription drug industry has often been characterized as one in which the major form of competition was via the discovery of new drugs - generated by R & D expenditures - which were then promoted through extensive advertising to physicians and pharmacists. Price competition was, by comparision, of little significance. Compulsory licensing and concomitant measures taken by federal and provincial governments all had the effect of substantially shifting the balance between price and non-price competition, toward the former. In addition, as detailed in Chapter 4, section 4.5 above, the licensee firms

were often able, as a group, to secure a significant share of the market exclusively held by the patentee, although this varied considerably by province, retail or hospital market. Hence, the potential return from the marginal dollar of advertising for a firm whose drugs are or will likely become subject to licensee competition will probably decline: the advertising expenditure is likely to spread over a smaller number of units sold than would otherwise be the case; physicians and pharmacists as well as managers of drug reimbursement programmes are likely to pay more attention to price. The usual indicator of the significance of advertising is the ratio of advertising to sales. The available evidence, presented in Chapter V, section 5.2 above, shows that this ratio has declined substantially over the period 1969 to 1975, from 19.3 percent to 15.2 percent. However, as pointed out in Chapter V, factors other than compulsory licensing were likely to have played as much, if not more important, a role in determining this decline, which started well before 1969.

7.4.3 Date of Introduction of New Drugs

The individual owner of a patent has considerable discretion in deciding when to make the drug available for physicians to prescribe and pharmacists to dispense. Some have suggested that because compulsory licensing lowers the prospective return to patent owners, this will result in new drugs generally becoming available in Canada later than otherwise would be the case. However, it is difficult to see the logic of the argument. Clearly, if, as soon as a new drug is made available in Canada, a firm obtains a compulsory licence and then proceeds, very rapidly, to drop the patent owners' share to zero, then the latter may decide not to sell the drug in Canada at all, or alternatively, to delay its introduction until worldwide experience and familiarity with the drug reduce the safety, efficacy and advertising expenditures required to make physicians aware of the new product. However, this is an inaccurate characterization of the competition between licensee and patentee, as the earlier parts of this study have made abundantly clear. Usually the patentee has a period of several years, in the order of 3 to 5, while the drug is on New Drug Status and the sales of the drug are growing until it becomes profitable for someone to obtain a compulsory licence. Once licensee competition is experienced, the patentee, depending upon the province or even the sub-market within a province, is able in some instances to retain a substantial share of the market. Hence, it seems unlikely that a patent-holder will delay the date of introduction. This is not to deny that compulsory licensing lowers the prospective return to the patentee, but nevertheless the return is probably substantially above the marginal costs of launching the drug in the relatively small Canadian market.

It is difficult to find evidence that will address the issues raised in the previous paragraph. However, the information presented in Table 7-3, should go a considerable way toward meeting the problem. Data is presented as to the date of

introduction of a sample of fourteen therapeutically important drugs for Canada, the U.S. and U.K. The U.S. and Canada have similar regulatory systems, as noted above, for approving the safety and efficacy of a new drug and hence, other things equal,[20] the date of introduction should be roughly the same. This would appear to be the case and in any event, the difference rarely exceeds one year. When it did, Canada was first in three of the five instances. Although only two of the drugs in Table 7-3 have had compulsory licenses taken out against them (i.e, cimetidine and propranolol) the argument about the rate of introduction applies to all new drugs. For these two drugs, cimetidine and propranolol (hypertension), both were introduced in Canada before the U.S., in the latter case by just under two years. In both instances, licensee competition was not experienced for some time after the date of introduction: Apotex Ltd. launched its brand of propranolol in 1980 while, although licences have been taken out against cimetidine, the licensees have not, as yet, marketed their brand.

Table 7-3 also presents the date of availability for the fourteen drugs for the U.K., which has quite a different regulatory system with respect to the introduction of new drugs than Canada or the U.S. Indeed, in the U.S. studies[21] of the "drug lag" problem, the U.K. is always held up as a sensible system under which drugs are introduced much earlier than the U.S. (even for a significant percentage of U.S.-discovered drugs). The figures in Table 7-3 support this view. In every instance except one (i.e., vidarabine) each of the fourteen drugs was introduced earlier in the U.K. than the U.S., while for Canada there were only two (i.e., vidarabine and phospho lipids) exceptions to this rule. Further, the differences in the date of introduction between Canada and the U.S. and the U.K. were frequently in terms of years, not months. In sum, it seems that compulsory patent licensing had little, if any, effect on the date of introduction of new drugs in Canada.

7.4.4 Increase in Price of Drugs

In Chapter VI above, the evidence presented demonstrated that compulsory licensing has had the effect of substantially lowering the price that the patentee charged for those drugs experiencing licensee competition, while Chapter IV, section 4.5 above demonstrated that, depending upon the province, the licensees had often successfully captured a significant segment of the market, formerly the sole domain of the patentee. The combined effects of these two impacts are, other things equal, to lower the profitability of the patentee's operations in Canada. As a result, it has been suggested, that the patentee raise prices for some drugs in order to recoup the losses incurred because of compulsory licensing. This implies that the firm has some target rate of return on its assets and that the demand is inelastic enough for its products that prices can be

TABLE 7-3

THE AVAILABILITY OF FOURTEEN THERAPEUTICALLY IMPORTANT DRUGS: CANADA, U.K. AND U.S.

DRUG	COUNTRY		
	Canada	United States	United Kingdom
	(Month and Year Available)		
beclomethasone dipropionate	June 1976	May 1976	Oct. 1972
sodium valproate	(a)	Feb. 1978	Aug. 1972
cimetidine	May 1977	Aug. 1977	Nov. 1976
protirelin	(a)	Nov. 1976	Jan. 1975
vidarabine	Aug. 1976	Nov. 1976	July 1977
somatotropin	(a)	July 1976	Feb. 1972
sodium iodide I-123	(b)	Mar. 1976	(c)
diazoxide	July 1969	May 1976	(c)
phospho lipids	Oct. 1972	Oct. 1975	Jan. 1975
amino acids	May 1977	Dec. 1975	(c)
danazol	Jan. 1976	June 1976	June 1974
prazosin	Aug. 1976	June 1976	Oct. 1973
disopyramide phosphate	Mar. 1977	Aug. 1977	July 1972
propranolol:			
arrhythmias	July 1968	Nov. 1967	June 1965
angina	June 1969	Nov. 1967	June 1965
hypertension	July 1974	June 1976	Apr. 1969

a. Under review by the Department of National Health and Welfare at the time Table was assembled. This would appear to have been in late 1977 to mid-1978.

b. The New Drug Application was withdrawn.

c. Data not available.

Source: U.S., Comptroller General (1980, Appendix III, p. 68).

raised sufficiently to generate extra revenue and hence restore the rate of return to that desired by the firm. This is in accordance with the conventional view that the demand for drugs is fairly inelastic.[22] However, more recent studies have suggested that prices may not be as inelastic as conventionally was thought to be the case.[23] Teeling-Smith (1975, p. 24) for example, writes that, "A major innovation may be priced high with a good prospect of success, however, a minor innovation at a high price will probably be a failure. A minor innovation must be priced low to be successful." In other words, drug pricing depends upon the significance of the innovation and availability of alternatives. If the Teeling-Smith view of drug pricing is accepted, then the patentee, subject to licensee competiton, may be unable to raise prices on other drugs to meet the target rate of return. No observable changes in prices will take place. The patentee may, however, reduce expenditures such as advertising. With this general discussion in mind attention is now turned to the somewhat sketchy evidence on prices.

Three sets of circumstances in which the patentee may raise the price in response to compulsory licensing are considered. The second and third categories are the two most often cited as cases where patentees raise prices. This list is not, unfortunately, exhaustive, but it is hoped the results will be suggestive. First, are those drugs for which a compulsory licence has been issued but the licensee has not, as yet, marketed a product to compete with the patentee. In view of the probably imminent arrival of a competitor, it might be thought that the patentee would raise its price while the monopoly was still intact. The evidence presented in Chapter VI, Tables 6-2 and 6-4 above, suggests, however, that for such drugs the patentee has not raised the price higher than would otherwise be the case. Indeed, the material presented in Chapter V, section 5.3.4 above suggests that patentees lower, not raise, prices when entry is about to take place. Second, it is argued that when a drug firm introduces a new drug on the market because of the possibility of a compulsory licence being issued, the price is higher than would otherwise be the case. In this instance the argument concerns actual as well as potential patentees. Unfortunately, data on new drug prices and what they would have been had not section 41(4) existed are not available. However, some very limited evidence can be presented. One recently introduced (i.e., 1977) high selling drug is cimetidine, brand name Tagamet (the Economist has suggested that after Valium i.e., diazepam, this is the most profitable prescription drug[24]) - an ideal candidate, following the findings of Chapter III above, for a compulsory licence application. Indeed, in 1980 at least two licences have been issued. The available price information, supplied by the manufacturer in a PMAC brief (1979, Appendix 6, Attachment E), shows that in 1978 the price of Tagamet in Canada is virtually the same as in the U.S., where the drug was introduced in 1977 as well. Indeed, prices in Canada and U.S. were lower than those in a number of European countries. While this evidence is hardly conclusive, in view not only of the problems

of international price comparisons but also the methodological problems involved, it does at least provide a starting point.

Third, a drug will virtually always be sold in a variety of dosage forms and strengths. The compulsory licence is valid for all such actual and potential dosage forms and strengths. However, the licensee will typically market the high selling dosage forms, which are usually solid oral forms. Those dosage forms that are hard to formulate and sell in relatively small quantities tend to be sold only by the patentee. It is argued that on such single source dosage forms the patentee raises prices higher than would be the case had not section 41(4) been introduced. Clearly if the patentee raises the price too much then the licensee is likely to attempt to formulate the dosage form to compete with the patentee and there may be some substitution from the competitively supplied dosage forms.

Price changes were examined for those drugs with single source suppliers (i.e., patentees) on some dosage forms, but licensee competition on others. Using the Ontario formulary the period 1974 to 1980 was selected, since prior to 1974 the formulary was not as extensive. Ontario was selected because, as shown in Chapter IV, section 4.5 above, patentees had lost substantial shares of their market to licensees where competition existed and would therefore have the greatest incentive to raise prices on the single source dosage forms. Of the 47 licensed drugs 19 or 40.4 percent were either not listed in the 1980 formulary or had no licensee competition on <u>any</u> dosage form. (The implications of compulsory licensing for pricing with respect to this second set of drugs were discussed above.) Another 11 or 23.4 percent had licensee competition on <u>all</u> dosage forms listed in the formulary, while 17 or 36.2 percent only had licensee competition on <u>some</u> dosage forms. However, in 5 of the 17 instances there were multiple patentees, which may influence pricing behaviour. Hence attention was paid to those 12 drugs for which there was a single patentee. Unfortunately, in three cases the price of the single dosage form was not listed for both 1974 and 1980 leaving a residual sample of nine drugs. The results were as follows:

Drug	Dosage Form and Strength	Percentage Increase in Unit Price 1974 to 1980	
amitriptyline	2 mg./ml. O/L	112.8	
chlorpromazine	40 mg./ml O/L	33.2	
diazepam	5 mg./5ml. O.L.	50.0	
fluocinolone acetonide	0.025% top. oint.	89.0	59.6
	0.01% top. oint.	25.4	
	0.01% top. sol.	64.3	
metronidazole	10% vag. cr.	20.2	
penicillin G (benzathine)	1,200,000 lU/2ml. inj. sol.	40.1	22.6
	600,000 lU/ml. inj. sol.	5.0	
perphenazine	3.2 mg./ml. O/L	47.4	41.1
	0.4 mg./ml. O/L	47.5	
	5 mg./ml. inj. sol.	28.3	
thioridazine	30 mg./ml. O/L	52.5	
trifluoperazine	4 mg. sup.	20.7	42.8
	20 mg./10 ml. inj. sol.	46.4	
	1 mg./ml. inj. sol.	61.4	
Average		46.5	48.3

Source: Ontario, Minister of Health (1974,1978).

All single source dosage forms increased in price over the period 1974 to 1980, some dramatically, such as amitriptyline 2mg./ml. O/L, which more than doubled. However, on average the rise was 46.5 percent, or slightly higher, 48.3, if only one entry is used for each drug. The question that naturally arises is whether this rate of increase is "high" or "low". In other words, a standard of comparison is needed. For this purpose, the industry selling price index of Ethical Preparations for Human Use as estimated by Statistics Canada was used. This index includes not only prescription drugs, but also drugs normally sold through a pharmacist not requiring a prescription or advertised to the public.[25] While the index is not perhaps ideal, it at least provides a standard of comparison. Over the period 1974 to 1980 this index rose by 51.0 percent.[26] Hence, if this standard of comparison is used, on average, price increases for single source dosage forms of drugs for which licence competition

existed on some dosage forms, would not appear to have been significantly affected by the advent of compulsory licensing.

As noted in Chapter VI above, prices in the Ontario formulary may not be an accurate reflection of industry selling prices. However, this inference applies mainly to multisource dosage forms where there is competition between licensee and patentee. For single source drugs, where such alternative sources of supply do not exist, prices quoted are much more likely to reflect actual selling prices. Nevertheless as a check against the results presented above, a similar exercise was undertaken for contracts issued, based upon a tendering system, by Hospital Purchasing Incorporated. Both the tendering system and Hospital Purchasing Incorporated are described and discussed in Chaper VI, section 6.4.3 above. In cases where the quantities tendered varied considerably over time, and hence price differences may in part reflect this, such dosage forms were excluded. Data was available for the period 1978/79-1980/81 for a sample of six drugs and seven single source dosage forms. In all instances the contracts were won by the licensees in 1980/81 and, with one exception, 1978/79. The results of the exercise are as follows:

Drug	Dosage Form and Strength	Percentage Changes in Unit Price, 1978/79 to 1980/81[a]
furosemide	20 mg. amp.	0.0
	40 mg. amp.	0.0
chlordiazepoxide	100 mg./5ml. amp.	15.0
imipramine	150 mg. tabs.	17.7
indomethacin	100 mg. supp.	60.5
methyldopa	250 mg./5ml. amp.	48.4
perphenazine	2mg./5ml. syrup	6.1
Average	-----	21.1

a. Firms are asked to quote prices for one year's supply. In some instances, different prices are quoted for the first and second halves, in which case the average is taken.

Source: Information provided by Hospital Purchasing Incorporated.

The average value of the industry selling price index for Ethical Preparations for Human Use over the period 1978/79 to 1980/81 increased by 16.6 percent,[27] which is only slightly below that of the six drugs and seven dosage forms, although two drugs did show substantial price rises (i.e., indomethacin and methyldopa). Hence, the evidence is somewhat inconclusive as to

whether compulsory licensing has led to dramatic price increases of single source dosage forms, either for the retail or hospital market.

The results presented here suggest that the view drug firms raise prices in order to compensate for the actual or anticipated effects of compulsory patent licensing is not supported by the evidence. It needs to be noted and repeated that the evidence is by no means definitive and in some instances is of a limited and somewhat tentative nature. At the beginning of this section, two views of drug pricing were briefly outlined and predictions made as to the reaction of drug firms with single source products. From the evidence here it would appear that the view of Teeling-Smith expounded in the Canberra hypotheses is confirmed. However, there is another, somewhat simpler, explanation. Drug products subject to compulsory licensing are large sellers, as shown in Chapter III, and usually account for a very substantial share of the patentees' profits and sales, as noted in Chapter V, section 5.2 above. This perception is shared by the patentees, which, through their trade association the PMAC (1979, p. 11, emphasis in original), commented in discussing compulsory licensing, "For innovative companies with a small product line a copier [i.e., licensee] usually attacks a successful product which account for say 50 percent of the sales of the firm but which contributes say 80 percent of its profits." For those drug firms with broad product lines the impact of compulsory licensing"... of a company's "big sellers" products, have resulted in an accelerated attrition of profit margins..." (p. 11). Under such conditions, it is simply likely to be very difficult to maintain profits by raising prices on non-licensed drugs, since demand is likely to be affected by such large price increases.

7.4.5 Negative Investment Climate

The patentees, through their trade association, the PMAC, argue that compulsory licensing is but one facet of a whole series of government policies that have contributed to a "... considerable negative influence on the growth rate of research and development in plant and equipment.... It also led to a dramatic reversal in previously favourable import-export trends ..." (PMAC, 1979, p. 10). These policies include many of those described in Chapter 1 above, such as product selection legislation, tendering by hospitals and Saskatchewan for high volume drugs, and reimbursement policies of provincial governments which favour lower priced brands. These conditions are, of course, essential for the success of compulsory licensing. However, compulsory licensing is singled out as having "... perhaps the most damaging effect..."(p. 11). In this chapter, although attention has been confined mainly to the impact of compulsory licensing on various indicators of industry performance, it may, nevertheless, also serve as a very useful surrogate for the aforementioned policies. In other words, conclusions and inferences drawn in this chapter with respect to the rate of introduction of new drugs, R & D, import/export ratio, may not only reflect the influence of compulsory licensing but also other

factors which affect the negative investment climate, as seen by the patentees.

Although it must be agreed that policies such as product selection and compulsory patent licensing do indeed result in a negative investment climate in Canada, it should be remembered that other countries pass legislation and institute programmes which also adversely affect the profitability of the multinational drug industry. Indeed, the policies pursued by Canada in the 1960's and 1970's were part of a worldwide concern and questioning of drug industry practices and policies. Other countries reacted differently to Canada. The United Kingdon instituted in 1957 a Voluntary Price Regulation Scheme[28] for setting prices, while the U.S. has a number of drug programmes similar to those in Canada[29] and product selection legislation in over 40 states.[30] On the other hand, some countries, such as Ireland and Puerto Rico, offer very generous tax incentives to the drug industry which lead to a positive investment climate as noted in section 7.2.2 above. Hence, the issue is not so much whether Canada has a positive or negative investment climate, but how conditions in Canada compare to other countries. Unfortunately there is no reliable indicator of "investment climate" on a country by country basis.

7.4.6 The Costs of Provincial Drug Reimbursement Programmes[31]

Although not an indicator of industry performance in the same sense as the various other factors discussed in this chapter, the costs of provincial drug programmes, it has been suggested, should be considered in evaluating the overall impact of compulsory patent licensing. The decision of provincial governments to provide drugs free of charge to certain sections of the population, such as those on welfare and/or over 65 years of age, is clearly based upon a wide political consensus and unrelated to the advent of compulsory licensing. Interest therefore centres here on the extra or marginal costs of these programmes that are due to compulsory licensing. This is not to deny, of course, that the benefits, in the form of lower drug prices, may exceed these increased programme costs. However, this issue of drug prices is addressed in the previous chapter of this study.

The costs to provincial governments of their reimbursement programmes can be divided into prescription (i.e., ingredient or drug cost plus dispensing fee) and administrative categories, with the latter typically only 1.5 to 3.2 percent of the former, although for one province the percentage was 9.8 percent.[32] The increased costs of drug reimbursement programmes due to compulsory licensing are said to arise because of increased administrative, not prescription, costs. Administrative costs can be divided into several categories. First, the processing and payment of claims, post-payment auditoring to verify the claims and the preparation, distribution and monitor-

ing of identifiers for the population eligible for benefits under the drug programme. Second, monitoring drug prices and dispensing fees for the purposes of reimbursement. This would entail, for the dispensing fee, a periodic negotiation in most provinces with the pharmacists' trade association. On the other hand, for the drug prices, the provincial officials are likely to ask drug firms for their prices directly as well as relying on such independent sources as IMS. Third, deciding which new drugs (not brands of existing drugs) merit inclusion as a benefit. Fourth, deciding which brands of drugs, already accepted for reimbursement purposes, should be added to those of the originator or patentee. It should be noted that compulsory licensing accounts for only a small percentage of the number of all multisource drugs. The relevant data for Ontario, Quebec and Saskatchewan, based upon their 1979 formularies, are as follows:

Province	Multisource Drugs[a]	
	Total Number	Percent subject to compulsory licensing
Ontario	163	17.8
Quebec	282	12.4
Saskatchewan	135	20.7

a. Multisource for one or more dosage forms listed in the formulary.

Source: Ontario, Minister of Health (1979b), Quebec, Régie de l'assurance-maladie du Québec (1979b), Saskatchewan, Department of Health (1979a).

However, as pointed out in Chapter VI, section 6.2 above, licensed drugs, although relatively unimportant in terms of the percentage of all drugs on the market, are, by comparison, significant measured in terms of the percentage of total drug sales for which they account. Fifth, for the provinces of Manitoba, New Brunswick, Ontario, Quebec and Saskatchewan, all of which have a provincial drug formulary, the costs incurred in organizing, printing and distributing such formularies.

No estimates of the relative importance of each of these components is available or the incremental costs due to compulsory licensing. However, it is probable that the most significant cost is the first, which like the second, third and fifth are likely to be trivially higher because of compulsory licensing. The major impact of compulsory licensing is likely to be on the fourth category of administrative costs. However, the incidence will vary considerably by province. For Newfoundland, Nova Scotia and Prince Edward Island, all of which have no product selection legislation or formulary, the fourth cost category is zero. (However, Newfoundland expects to introduce a formulary in late 1980 so this will change). Alberta, British Columbia and Quebec, although all having both product selection

legislation, and, in the case of Quebec, a formulary, seem to rely essentially on the safety and efficacious requirements of the federal Food and Drugs Act. Hence the fourth category is also zero for these provinces. Such is not likely to be the case of Ontario, Sasktchewan and, to a much lesser extent, Manitoba and New Brunswick. In particular, the first two provinces carefully consider licensee applications for inclusion in the formulary and, in some instances, conduct plant inspections as well as occasionally requesting tests in addition to those conducted to meet federal regulatory requirements.

In sum, the impact of compulsory licensing on the administrative costs of provincial drug reimbursement programmes is confined to four provinces, Manitoba, New Brunswick, Ontario and Saskatchewan and only those costs associated with deciding which of the licensee brands to list are relevent. Other administrative categories, some of which would appear to be more significant, would appear to be only nominally affected by compulsory licensing. For the four provinces mentioned above the total administrative costs for the recent past are as follows:

Year[a]	Administrative Cost ($ million)
1976/77	4.782
1977/78	5.142
1978/79	5.608

a. Should be read as follows: 1976/77 year ending March 31, 1977. Similarly for other years.

Source: Information provided by provincial and federal officials through the QUAD programme.

Although it involves a somewhat arbitrary judgement, it seems reasonable to suggest that the maximum percentage of these administrative costs due to compulsory licensing is 10 percent, yielding an upper bound of approximately $500,000. One of the four provinces suggested that these costs were considerably less than 10 percent, while another thought any estimate very arbitrary. In any event the added administrative costs because of compulsory patent licensing would not appear to be a large item of expense in provincial drug reimbursement programmes, especially when compared to the resulting lower prices.

7.5 Summary and Overview

In this chapter an attempt has been made to assess the impact of compulsory licensing upon a series of indicators of industry performance, such as research and development, balance of trade, the rate of introduction of new drugs and the pricing policy of patentees, both potential and actual. There are fundamental methodological and data problems in coming to terms with these issues: rarely was it possible to hold other things

equal and hence determine the effect of the policy; data often referred to broader aggregates than desired and far less than the ideal number of years; in some instances the effects of compulsory licensing could only be tested on a limited number of drugs, far less than required for a conclusive result. Nevertheless, despite these shortcomings, the accumulated evidence suggests that compulsory patent licensing for drugs has had very little, if any, impact on the industry performance indicators selected for study.

CHAPTER VIII

SUMMARY AND RECOMMENDATIONS

8.1 Introduction

This, the final chapter, is divided into three major sections. The first, section 8.2 details very briefly the major findings, conclusions and inferences which can be drawn from the previous seven chapters. The next two sections refer to policy analysis and recommendations concerning the issue of the future of compulsory licensing (8.3) and appropriate provincial government policy at the retail level (8.4). The recommendations are summarized in section 8.5.

8.2 Summary of Major Findings

This study has assessed the impact of a variety of policy measures on various indicators of performance of the drug delivery system from the manufacturer to the consumer, including the pharmacist and both levels of government. While particular attention has been paid to the impact of compulsory patent licensing this has been within the context of product selection laws and provincial government reimbursement programmes. Industry performance indicators considered included not only price (on which most emphasis was placed given its overriding importance in motivating the various policy measures) but also R & D, the balance of trade, advertising and the date of introduction of new drugs.

The introduction by the federal government of compulsory patent licensing reflected a concern over the "high" price of drugs. This policy solution was based on several premises of which the most important were as follows. First, patent protection, which granted the owner a monopoly right over the drug for a period of 17 years, allowed the patent holder to raise prices substantially above what otherwise would be the case. Second, reducing the protection afforded patents would result in a drop in prices since the only competitive weapon of the new entrant would be price. The evidence presented here is consistent with both of these premises: entry has taken place; the entrant's prices are usually substantially below those of the patent owner whose prices have fallen, in turn, partly in response to this competition.

Compulsory licensing is concerned with entry and prices at the level of the manufacturer, but the objective of the legislation is to lower prices at the retail level and reduce drug costs to the consumer. In this respect new entrants or as they have been referred to here, licensees, have faced a number of problems including acceptance by physicians and pharmacists of their brands of a given drug as therapeutically equivalent to those of the patent owner and the creation of incentives for physicians to prescribe, pharmacists to dispense and the consumer

to search for lower priced brands. Policy measures in these areas have largely been the responsibility of the provincial governments through the enactment of product selection legislation which allows pharmacists to select, under certain conditions, a different brand, than that prescribed by the physician, and various aspects of provincial drug reimbursement programmes also designed to promote the use of lower priced brands. No uniform approach has been adopted by the provinces for achieving a pass-through of price reductions at the manufacturing level to the consumer. Nevertheless, substantial reductions at the consumer level have taken place in the hospital market as well as the retail markets of British Columbia, Ontario, Saskatchewan and, to a lesser extent, Quebec.[1] However, in all markets, in varying degrees, there exists further scope for reductions in drug prices at the consumer level.

The performance of the drug industry was assessed with a view to examining the impact of compulsory licensing on such key variables as the level of R & D, the date of introduction of new drugs, the price of drugs not subject to compulsory licensing, the investment climate, the balance of trade and advertising. Despite a number of methodological and data problems in coming to terms with these issues the accumulated evidence suggests that compulsory patent licensing has had very little, if any, impact on the industry performance indicators selected for study.

8.3 Reforming the Patent Act: Compulsory Licensing

The federal government at the present time is reviewing the compulsory patent licensing provisions of the Patent Act as part of a general revision of Canada's patent legislation. Amendments are expected to be introduced in Parliament. Prior to this the federal Department of Consumer and Corporate Affairs issued a discussion paper in 1976 entitled Working Paper on Patent Law Revision, which opted for the status quo concerning compulsory licensing, with some very minor modifications.[2] In response to the working paper a number of briefs were submitted to the department with respect to this particular aspect of the Patent Act. The suggestions ranged from increasing the size of the royalty payments under section 41(4) for those drugs which were discovered exclusively or predominantly in Canada,[3] to allowing the issuing of compulsory licences to import 10 years after the drug had first been marketed in Canada.[4] More recently, a task force report on biotechnology recommended the abolition of compulsory licensing.[5]

The previous section suggested that compulsory licensing is working reasonably well and results were in line with the major objective of the legislation, reduced drug prices. On the basis of these findings it is recommended[6] that,

1. Compulsory licensing be retained in its present form.

8.4 Controlling Drug Costs at the Retail Level

8.4.1 Introduction

The various health care and drug inquiries sponsored by the federal government in the 1960s recognized the fact that, although increased price competition at the manufacturing level was a necessary condition, it was not a sufficient condition for lower consumer prices. Of each dollar the patient paid for a prescription in the mid-1960's, the split was approximately 50-50 between the manufacturer and the pharmacist.[7] These inquiries documented that pharmacists by means of decisions taken by their professional bodies effectively discouraged price competition through, for example, price disclosure, at the retail level. In order to reduce prices to the consumer incentives would be needed to induce the pharmacist to pass reductions in the manufacturers' price to the consumer. In recognition of this need, the Harley Committee (1967, p. 37) for example, stated,

> Your Committee expresses the hope that provincial governments and provincial pharmaceutical associations will take whatever steps are necessary, in the light of changing circumstances to ensure that sufficient competition can be engendered in the retail drug business to lower prescription drug prices.

Despite the efforts of provincial governments to take advantage of the price competition at the manufacturing level through product selection legislation and various rules introduced as part of government drug reimbursement programmes, the evidence presented in Chapter IV, section 4.5 and Chapter VI suggests that further price reductions at the consumer level can be obtained. This inference applies not only to licensed drugs but almost certainly to all, but especially multisource, drugs.

The discussion of controlling drug costs at the retail level is divided into three major parts. Section 8.4.2 considers the best way in which to provide pharmacists' services to the public. The next two sections are concerned with specific recommendations regarding dispensing fees (8.4.3) and ingredient or drug cost (8.4.4). A final section, 8.4.5, offers some concluding remarks concerning the relationship between dispensing fees and ingredient costs. In formulating recommendations, an attempt is made to use existing institutions and to avoid radical changes which may result in unforeseen implementation and operating problems.

8.4.2 The Provision of Pharmacist's Services

The pharmacist is a health professional - often considered as important in the provision of health services as the physician.[8] This is formally recognized by the creation, under provincial law, of a professional body responsible for overseeing the conduct and discipline of pharmacists on behalf and in the interests of the public. The professional dimensions of the services that can be supplied by the pharmacist, particularly at the retail level, include monitoring each patient's drug regimen prior to dispensing so as to avoid dangerous drug interactions and overconsumption, giving advice on the administration of the drug, counselling patients to promote rational self-medication and participating in drug utilization and other survey work. In considering appropriate public policy at the retail level an important issue is by what method these services should be provided to the public. Several alternatives have been suggested.[9] The major disagreement concerns the impact and role of regulation, via negotiated fee schedules, compared with the use of the market buttressed by the professional body monitoring the quality of service.

The professional view argues that the pharmacists' services are not always adequately taken into account by the market and drug reimbursement programme managers when negotiating dispensing fees. Also, according to this view, advertising by pharmacists should not be allowed. Not only could the general quality of service decline with advertising but overconsumption might result as patients pressure physicians to prescribe the advertised product. Greater reliance on the market is rejected, therefore, in favour of carefully negotiated fee schedules which take into account all of the professional services provided without separate charge by the pharmacists. In order to fully utilize the expertise of the pharmacist in advising the patient, all over-the-counter and non-prescription ethical drugs should also be sold exclusively by pharmacists rather than through supermarkets, corner stores and department stores.

An alternative method of ensuring that professional services are supplied, referred to as the market view, is for the professional body to mandate and enforce the provision of services (in consultation with the provincial Minister of Health) which the profession should provide to the public. These services could be listed in all pharmacies. This, after all, is the function of the professional body. If the professional body monitors quality, then the market forces can be used to determine the question of dispensing fee and ingredient cost. This approach then has the virtue of assuring quality of service, without precluding the benefits of competition in retailing.

Negotiated Fee System. No comprehensive fee schedule, covering all the services provided by the pharmacist, consistent with the professional view exists in Canada. (In a number of provinces the drug reimbursement programme negotiates with the

pharmacists' trade association to determine compensation for a number of services). In a recent inquiry into health professions in Quebec, however, a system - the modulated fee - consistent with the professional view was outlined. The modulated fee system advocated by the Comité Hould (1980, p. 218, translated from the original) is as follows:

> Each negotiated agreement [between the provincial government and the profession] starts with a base rate or hourly base rate for the profession; it also sets out modulations [i.e., adjustments] of this base rate or coefficients to take into account characteristics of a professional's training or experience and of his professional activities; organizations responsible for teaching and research intervene in negotiations for the modulations applying to these professional activities.

However, this approach has several problems. First, the hourly rate and modulations will have to be negotiated. This is likely to be a lengthy process particularly if there are a lot of modulations, and may lead to confrontations similar to those now occurring for physicians[10] and, in some instances, dispensing fee negotiations for pharmacists.[11] Second, there may be a problem of auditing the hours worked and services performed. Third, the quality of the services will have to be monitored.[12] Fourth, the services provided will depend upon the modulated fee system. In negotiation an important aim of the pharmacists may be to receive higher fees for intangible services which are not easily monitored. Fifth, such fee system does not remove commercial incentives. Rather a different set of monetary incentives, represented by the fee schedule, will now determine the activity of the pharmacist. The modulated fee system is similar to a minimum fee schedule and the available evidence suggests that this is no guarantee of quality of service. In particular, Quebec, Office des Professions (1978, p. 167) concluded, "... it is difficult to make any serious claim that a tariff can directly and systematically influence the quality of services...."

Quality Control and Professional Body. The market view envisages that once the agreed set of professional services have been determined then the professional body, charged with the licensing and control of pharmacists, should monitor the quality of the provision of such services. Quality could, for example, be monitored by surveys such as those outlined in Comité Hould (1980, pp. 146-152), where pharmacists are asked questions or presented with prescriptions for drugs with potential adverse interactions.[13] The results of such surveys should of course be made available to the public. In the province of B.C. a

beginning has been made on assessing the competency of pharmacists with respect to the services and knowledge which must be in evidence under the Pharmacy Act of B.C.[14] In 1977 all the province's pharmacists were sent an assessment questionnaire paper. The results were used as the basis for peer review. In a report on the Competency Assessment Program it would appear that there "... has been surprisingly little resistence to the program" (Fielding, et al., forthcoming 1981, p. 14) and the feedback has indicated "... enthusiastic endorsement by the vast majority of ... pharmacists" (p. 14). Hence, the use of programs such as that started in B.C. combined with continuing education, mandatory in three provinces, should be able to provide an adequate control mechanism to ensure quality standards are met, especially in view of the penalties that a professional body can impose - licence suspension or revocation in extreme cases.

The market view sees a greater role for advertising while the professional view is strongly opposed to this. The limitations placed on pharmacists by their professional bodies regarding price disclosure of either the dispensing fee or the ingredient cost (i.e., drug cost) serve to reduce competition and raise prices.[15] This is consistent with empirical evidence drawn from the U.S.A. concerning optometry,[16] and for both the U.S.A. and Canada with respect to pharmacy.[17] The evidence shows that the introduction of price disclosure did not result in a lower quality of service.[18] Despite the existence of advertising restrictions in Quebec an inquiry concluded, "The available studies therefore reveal serious problems of quality for pharmaceutical services dispensed in the community" (Comité Hould, 1980, p. 151, translated from original).[19] In sum, available empirical research indicates that restrictions on price disclosure raise prices and do not lead to any improvement in the quality of professional service.[20]

The above assessment of the two methods of ensuring quality of service be provided to the public suggests that the market view, on balance, should be adopted. Therefore it is recommended that,

> 2. The standards and quality of professional service supplied by the profession of pharmacy should be set and enforced by the professional body in consultation with the provincial Minister of Health.

It should be noted that this recommendation concerning quality control would apply under both the professional and market approaches. However, if the market view is adopted then the dispensing fee and ingredient cost can be determined to a much greater extent by the market instead of through negotiation.

8.4.3 Dispensing Fees

Four recommendations are made with respect to the dispensing fee. These are designed to encourage greater competition in the provision of this professional service. The first two recommendations should allow a competitive market to develop in the provision of standard service for which there are a large number of buyers and sellers.[21] Responsibility for seeing the market functions correctly is that of the Director of Investigation and Research under the Combines Investigation Act. During the early stages of implemention it may be felt necessary to retain a maximum fee. Therefore it is recommended that,

> 3. The dispensing fee should be defined in such a way that it is a standard service provided and monitored by the pharmacists' professional body in consultation with the provincial Minister of Health.
>
> 4. All restrictions on the disclosure of the price of dispensing fees, either over the phone, in the store, in newspapers, television and radio should be removed from provincial statutes and regulations.

In order to provide greater routine disclosure to the public the practice of B.C. whereby the ingredient or drug cost and the dispensing fee are marked upon the prescription receipt might also be considered.

In some provinces the pharmacist may only dispense a 30 day supply when the physician writes the prescription for 60 or 100 days, as in some provincial drug reimbursement programmes.[22] Such a practice is not based upon health hazards concerning the patient, but appears to be primarily in the economic interest of the pharmacist, who may collect three, instead of one, dispensing fee. The Bailey Committee (1978, p. 16) in Ontario commented on this practice as follows:

> That the common practice of dispensing only 30 days medication to senior citizens should be modified in view of the fact that most of these individuals are on long term therapy and many find it inconvenient to visit the pharmacy monthly. Dispensing of more rational quantities at one time should result in substantial economies to the pharmacy. These savings could be passed on to the taxpayer, and at the same time the hardship of repeated visits to the pharmacy by the ODB recipients could be alleviated.

Hence, it is recommended that,

> 5. The quantity dispensed by a pharmacist on receipt of a prescription should be that authorized by the physician, whether it is 30, 60 or 100 days, for all sectors of the marketplace.

In some instances, clearly, the pharmacist may have good professional (i.e., health care) reasons for questioning the authorized supply, in which case reference should be made to the physician.

In order to bring about a competitive market in dispensing fees a problem arises because some segments of the population in some provinces are included under a provincial drug reimbursement programme and are not required to make any payment for prescriptions. As a result such persons have no incentive to use lower priced pharmacies. This is particularly the case for those over 65 years age who are likely to be very sensitive to prices, since they are heavy consumers of drugs and frequently are on long term therapy. A number of possible alternative schemes could encourage the use of the market in meeting these patient's demand for drugs, while still providing these drugs free of charge to the target population. These alternatives would also have the advantage of extricating the provincial governments from the fee setting process.

One suggestion is that the patient pay for the entire prescription including ingredient cost and then on (say) a monthly or quarterly basis get reimbursement from the provincial government. In other words the patient is reimbursed not the pharmacist. A second suggestion would be confined to those groups receiving regular income supplements from the provincial government. The supplement would be adjusted upward to include an amount which would cover the drug expense of a substantial section of that group. Amounts in excess of this could be reimbursed to the patient directly from the provincial government.[23] Both of these schemes have two disadvantages which make them unattractive from an administrative and equity viewpoint: they may easily result in bureaucratic problems and difficulties; and the burden of paperwork and any administrative problems would fall disproportionately on those two groups most frequently receiving drugs free of charge - those over 65 years of age or on welfare. On a somewhat different level if no change in the present payment system is made with respect to those who currently receive drugs free of charge then consideration could be given to allowing pharmacists to advertise that they will pay $X or give discounts on non-pharmacy items if allowed to dispense such prescriptions. Finally, the government may decide to introduce some sort of co-payment scheme for those hitherto receiving drugs free of charge, perhaps with an exemption for

those over 65 or on welfare. A number now exist and are discussed in Chapter I, section 1.4 above.

In view of the above the next recommendation is as follows:

> 6. Provincial governments should consider, where practical, using the forces of the market for those currently receiving drugs free of charge so that greater utilization of pharmacies offering lower priced dispensing fees is made.

In Saskatchewan,[24] for example, an element of price competition has occurred which suggests that potential exists for such a scheme to succeed, while in British Columbia the fee is set by monitoring the market with an upper limit set at the average dispensing fee plus 15 percent.

This section has advocated much more competition in the setting of dispensing fees. It would appear that the climate in the 1960's and early 1970's was not generally favourable to price disclosure or greater competition among professions, including, of course, pharmacy. That attitude has, it would appear, changed in the mid and late 1970's: at the federal level, the Combines Investigation Act, Canada's competition policy statute, was amended in 1976 so that all professional services, such as lawyers, pharmacists and dentists, became subject to its provisions;[25] and the provinces of Ontario and Quebec held and published inquiries into the professions, which generally supported greater price disclosure.[26] Hence the recommendations made here are consistent with the recent trend of thought at both the federal and provincial level.

8.4.4 Ingredient or Drug Costs

In Chapter VI above, it was shown that in Ontario and Quebec substantial intra-marginal rents (i.e., mark-up over cost) were captured by pharmacists in the sale of multisource prescription drugs while in Chapter IV, section 4.4 and Chapter VI, above, significant further gains in reducing retail drug prices can be obtained in all of the markets studied - British Columbia, Ontario, Quebec and Saskatchewan. The mechanisms to realize lower retail drug prices can be divided into three parts: price disclosure; government rules and regulations; provision of information to physicians.

Extensive price disclosure through a variety of media forms was considered the major policy solution with respect to controlling the dispensing fee component of the price of a prescription. However, there are a number of problems with relying on such techniques as the main device to control drug prices. First, there is a concern among pharmacists and others interested

in the drug delivery system that advertising of any kind will lead to overconsumption. (It should be noted that this view is held not only about advertising the therapeutic attributes of the drug (e.g., "Feel tired, relax with a Valium," "Stomach upset - it could be an ulcer, try Tagamet") but also price disclosure. Attention is concentrated here, however, solely on price disclosure). Such disclosure, it is argued, will result not only in the switching of brands, but also increased consumption. There will be increased patient pressure on physicians to prescribe and perhaps multiple use of physicians by an individual. However, these arguments have not gone unchallenged.[27] A second problem which may inhibit the effectiveness of price disclosure as a method of controlling the costs of retail drugs is that the consumer may have difficulty in understanding, and hence become confused, when interpreting a multi-syllabic generic or proper name such as chlordiazepoxide, perphenazine or amitriptyline combined with several brands of the given drug, dosage form and strength. In view of these problems, which are both genuine and difficult to quantify, plus the presence of alternative policy instruments to control drug costs, it is not recommended that extensive price disclosure of prescription drugs be introduced. Further research is needed.

Some consumers, however, are knowledgeable enough to be able to interpret the multi-syllabic generic drug names and the numerous brand names. Should these consumers wish to obtain price information, then this should be provided by the pharmacist over the phone or in the pharmacy. (A number of provinces permit this explicitly already.[28]) Another source of information about drug prices is the formulary and these should be available in the pharmacy. (Clearly this applies only to those provinces publishing such documents). Finally, some suggestions have been made that the consumer be made aware that the pharmacist will dispense the lowest priced drug in the formulary or generally available. The "dot" proposal and generic choice charts of M. Katz of the Consumers Association of Canada is one such example. The Bailey Committee (1978, p. 15) recommended to the Ontario Minister of Health that "... the government should encourage fair pricing ... by periodically making the public aware of the price paid by the government [under ODB] ... through the news media." A number of factors the public should be made aware of included the "... fact that ... interchangeable products comparable in quality to the more expensive products frequently prescribed [are available]." Such proposals do not mention drug brand or generic names, but inform the consumer of easily understood pricing rules and hence do not suffer from the two problems mentioned above, but hold out the possibility of realizing savings found in the U.S. where price disclosure is allowed in some states.[29] In sum, it is recommended that,

7. Pharmacists should be expressly permitted to provide information on drug prices over the phone or in the store; formularies should be available

> for inspection in the pharmacy (where the province publishes such documents); proposals for dissemination of pricing rules, which do not mention individual brands or generic names, used by pharmacists should be permitted.

Instead of encouraging drug price disclosure provincial governments have, in varying degrees intervened directly in the setting of retail prices. In this study a number of different provincial government rules and regulations have been analyzed with respect to their impact on the retail price of drugs, particularly in Chapters IV and VI. These measures included product selection legislation, mandatory price selection, tendering and formularies. Sometimes these policy instruments are part of the general rules pharmacists are required to comply with while in other instances they refer to aspects of provincial government reimbursement programmes, which, in turn, often interact and affect the non-government sector of the market. Each province has adopted a different approach in using these measures, from Nova Scotia, which made no attempt to lower retail drug prices by any of the above means, to Saskatchewan, which employs mandatory product selection, and the SOC tendering system for high volume drugs. Detailed attention was confined in this study to four provincial retail drug markets - British Columbia, Ontario, Quebec and Saskatchewan. In general the measures introduced have been successful, in varying degrees, in reducing drug prices. However, improvements, often substantial, are still possible. A number of suggestions were made in Chapter VI, section 6.4.8, above for improving the mix of policy instruments in each of these four provinces such that lower prices could be realized at the retail level. These were usually fairly specific For example, the suggestion that section 158(3) of the Health Disciplines Act of Ontario which now reads,

> No person shall knowingly supply an interchangeable product ... at price in excess of the cost of the lowest priced interchangeable pharmaceutical product in his inventory....

should be changed such that the words "his inventory" are replaced by "as set out in the PARCOST C.D.I.", may not be applicable to all provinces. The SOC system employed by Saskatchewan, with a relatively small share of the Canadian market, may be inappropriate for the much larger markets where mandatory price selection might be more appropriate. Because of these differences the recommendation is of the following rather general nature,

> 8. Provincial governments should promote lower drug prices by the use of some or all of the following: certifying therapeutic equivalence of different brands of the same

drug; insuring that the physician and pharmacist bear no legal liability in selecting among these brands; mandatory price selection; mandatory product selection; formularies based on "realistic" prices; and tendering systems.

Specific suggestions, illustrating these points, are made with respect to British Columbia, Ontario, Quebec and Saskatchewan in Chapter VI, section 6.4.8 above. The provincial government has become the buyer on behalf of the population in the sense that it sets prices and the rules for selection, but still leaving a role for the market. The evidence suggests that this system has worked reasonably well but some modest changes can substantially lower drug prices, particularly of the multisource drug group.

All product selection laws allow the physician to write a specific brand name prescription which, when accompanied by the words "no substitution" across the precription, means that the pharmacist must dispense the brand named. (These were referred to as no substitution prescriptions in Chapter 1, section 1.2.3 above.) Such prescriptions are usually written for the patentee brand and enable the patentee to set a price substantially above the licensee. In the provincial retail markets this pricing behaviour was particularly apparent in Saskatchewan as Chapter IV, section 4.5 and Chapter VI, section 6.4.8 above demonstrated. In contrast to the retail market, in the hospital market the physician is often required to delegate brand selection to a Drugs and Therapeutic Committee. This therefore raises questions about the use by physicians of no substitution prescriptions in the retail market, especially when the province has already certified the brands listed in a formulary as therapeutically equivalent and all legal liability has been removed from the physician. Therefore, it is recommended

9. Provincial governments should seriously consider making physicians aware of the interchangeability of brands, quality control and price of different brands so that they be fully aware of the implications of no substition prescriptions.

In a number of instances such programmes have already been used, such as PARCOST in Ontario.

8.4.5 Some Concluding Remarks

The recommendations attempt to take into account the potential link between the dispensing fee and ingredient cost. Essentially the scheme advocates that government set the ingredient cost, but with a significant role for the market. One important element is that this system should incorporate an incentive such that the enterprising pharmacist has the

opportunity to adopt better inventory or purchasing techniques and thus realize lower costs than those in the formulary.[30] However, with a dispensing fee that can be advertised a substantial portion of these intra-marginal rents will probably result in pharmacists reducing their dispensing fees.[31] Hence it is important to remember the actual and potential connections between the dispensing fee and ingredient cost.

Two aspects of drug retailing, which really are outside the scope of this study, should be briefly mentioned, since they follow logically the sequence of recommendations already made. First, in a number of instances attempts have been made to restrict the sale of non-prescription drugs, particularly over-the-counter medicines which are advertised to the public and often available at a variety of outlets, exclusively to pharmacy outlets.[32] The rationale behind this is that sale through non-pharmacy outlets poses a serious health hazard. The available evidence is not consistent with this rationale. Rather, such restrictions seem to be chiefly in the economic interest of the pharmacists. Therefore, proposals to restrict the sale of non- prescription drugs, especially over-the-counter, solely to pharmacies, should only be allowed after the burden of evidence establishes that health hazards are caused by the present system and could be significantly reduced if sale of such drugs were confined to the pharmacy. Such a determination should be made by a body having a substantial representation from non-pharmacists. Second, in some provinces restrictions are placed on the ownership of pharmacies such that ownership and control must reside with the pharmacists, while in others non-pharmacists are allowed to own and control pharmacies.[33] (In these latter instances any intra-marginal rents will accrue to the non-pharmacist owner). Restrictions on ownership and control may inhibit the expansion of more efficient pharmacy operations from expanding and thus realizing economies of scale via price disclosure or employment of pharmacists to manage dispensaries in department or supermarket stores. In view of this, serious consideration should be given to relaxing such restrictions on ownership, with the exception of those authorized to prescribe medicines, where a potential conflict of interest arises.

8.5 Recommendations

The recommendations made here can be summarized as follows:

1. Compulsory licensing be retained in its present form.

2. The standards and quality of professional service supplied by the profession of pharmacy should be set and enforced by the professional body in

consultation with the provincial Minister of Health.

3. The dispensing fee should be defined in such a way that it is a standard service provided and monitored by the pharmacists' professional body in consultation with the provincial Minister of Health.

4. All restrictions on the disclosure of the price of dispensing fees, either over the phone, in the store, in newspapers, television and radio should be removed from provincial statutes and regulations.

5. The quantity dispensed by a pharmacist on receipt of a prescription should be that authorized by the physician, whether it is for 30, 60 or 100 days, for all sectors of the marketplace.

6. Provincial governments should consider, where practical, using the forces of the market for those currently receiving drugs free of charge so that greater utilization of pharmacies offering lower priced dispensing fees is made.

7. Pharmacists should be expressly permitted to provide information on drug prices over the phone or in the store; formularies should be available for inspection in the pharmacy (where the province publishes such documents); proposals for dissemination of pricing rules, which do not mention individual brands or generic names, used by pharmacists should be permitted.

8. Provincial governments should promote lower drug prices by the use of some or all of the following: certifying therapeutic equivalence of different brands of the same drug; insuring that the physician and pharmacist bear no legal liability in selecting among these brands; mandatory price selection; mandatory production selection; formularies based on "realistic" prices; and tendering systems.

Specific suggestions, illustrating these points for recommendation 8, are made with respect to British Columbia, Ontario, Quebec and Saskatchewan in Chapter VI, section 6.4.8. above

9. Provincial governments should seriously consider making physicians aware of the interchangeability of brands, quality control and price of different brands so that they be fully aware of the implications of no substitution prescriptions.

The first recommendation is addressed to the federal government while the remainder are within the jurisdiction of the provinces.

A P P E N D I X A

REGULATIONS RELATING TO THE

APPLICATION FOR A

COMPULSORY PATENT LICENCE

UNDER SECTION 41(4)

of the

PATENT ACT

Proceedings under Section 41 of the Act
(New P.C. 1969-1318, June 27, 1969)

116A. In this section and in sections 116B to 116M
(a) "applicant" means a person who makes an application as defined in paragraph (b);
(b) "application" means an application made to the Commissioner under subsection (4) of section 41 of the Act, together with any affidavit in support of such applicaion;
(c) "counter statement" means a counter statement filed with the Commissioner pursuant to paragraph (a) of section 116E, together with any affidavit in support of such counter statement;
(d) "drug" means a substance, whether in crude form, refined form, prepared dosage form or any other form whatever, intended or capable of being used for medicine or for the preparation or production of medicine;
(e) "invention" means the invention described and claimed in a patent in respect of which an application is made; and
(f) "statement in reply" means a statement filed with the Commissioner pursuant to paragraph (a) of section 116F, together with any affidavit in support of such statement.

116B. (1) An application shall be made in duplicate in Form 21A of Schedule A and shall

(a) be made only in respect of one or more patents
  (i) that, according to the records of the Office, are in the name of the same patentee, and
  (ii) that are for inventions that relate to or that may be used in the preparation or production of the same or substantially the same substance or thing, and
(b) specify, for each patent in respect of which the application is made,
  (i) the thing or things referred to in subsection (4) of section 41 of the Act that the applicant seeks a licence to do, and
  (ii) which of the things, if any, specified pursuant to subparagraph (i) in respect of the patent will be done, in whole or in part, on the applicant's behalf by another person;
(c) contain the following information:
  (i) the name of the applicant, the address of his principal office and his address for service;
  (ii) the name of the patentee, according to the records of the Office;
  (iii) a concise description of the nature of the business carried on by the applicant;
  (iv) where the applicant has had experience in or possesses skills specially relevant to the importation, manufacture, distribution, sale or supply of drugs, a concise description

of the nature and extent of such experience and skills;
(v) where the applicant employs, or proposes to employ if a licence is granted to him, persons with experience or skills described in subparagraph (iv), a concise description of the nature and extent of such experience and skills;
(vi) a concise description of the buildings and equipment available to the applicant to do the thing or things referred to in subsection (4) of 41 of the Act that are specified in the application and of any additional buildings and equipment that he proposes to obtain to do such thing or things if a licence is granted to him;
(vii) where the invention is a drug, or is used in the preparation or production of a drug, that the applicant proposes to import,
(A) the chemical name or proper name of such drug,
(B) the name and address of every person from whom the applicant proposes to obtain the drug for importation and where any such person is not himself the manufacturer of the drug that the applicant proposes to obtain from him, the name and address of the manufacturer of such drug;
(C) the form or forms in which the drug will be imported; and
(E) where there will be further preparation of the drug in Canada by the applicant or on his behalf, the nature of such further preparation and by whom it will be done;
(viii) where the applicant proposes to sell the invention or any medicine in the preparation or production of which the invention has been used, a concise description of the price structure that the applicant proposes to establish for the sale of such invention or medicine, including a description of the forms in which it will be sold and the prices or approximate prices at which each such form will be sold to each such class of customer;
(ix) where the applicant has previously requested the patentee voluntarily to grant to the applicant a licence under any patent in respect of which the application is made,
(A) the number of each such patent in respect of which a licence was requested, and
(B) in respect of each patent for which a number is given pursuant to subclause (A), whether the licence was granted or refused; and
(x) the royalty or royalties or other consideration that the applicant recommends should be fixed by the Commissioner for a licence to do the thing or things referred to in subsection (4) of the Act that the applicant seeks a licence to do under the patent or patents in respect of which the application is made.

(2) Where the applicant has previously been granted a

licence by the patentee under any patent in respect of which the application is made, copy of each such licence shall be submitted to the Commissioner with the application.

116C. An application shall be executed by the applicant and shall be supported by affidavit evidence of the material facts alleged in the application.

116D. (1) Upon receipt of an application that, in his opinion, complies satisfactorily with sections 116B and 116C, the Commissioner shall examine the application as soon as possible and

(a) if he sees good reason why the applicant should not be granted any licence whatever, reject the application and notify the applicant, the patentee and the Department of National Health and Welfare of his decision and the reasons therefor; or

(b) in any other case, instruct the applicant to serve a copy of the applicant on the patentee in the manner prescribed by subsection (2) and to file with the Commissioner proof satisfactory to him of such service.

(2) A copy of an application shall be served on the patentee by serving it in the following manner on the person who appears from the records of the Office to be the patentee:

(a) where such person is an individual who resides or carries on business in Canada, by leaving it with him or by mailing it to him by registered mail addressed to him at his residence in Canada or at the place where he carries on business in Canada;

(b) where such person is a corporation that has an office or place of business in Canada, by leaving it with an office manager, sales manager, general manager or other employee of the corporation in a position of authority in the corporation at such office or place of business; or

(c) where such person neither resides nor carries on business in Canada

(i) if he is represented in Canada with respect to the patent by a representative recorded as such in the Office, by leaving it with such representative or by mailing it to him by registered mail addressed to him at his last address recorded in the Office with respect to the patent, or

(ii) in any other case, by advertising the application once in the Canada Gazette and once in The Canadian Patent Office Record in Form 21B.

(3) Where a copy of an application is served on a patentee in accordance with subsection (2)

(a) by mailing it by registered mail addressed to a person, representative or corporation, it shall by deemed to have been served on the day on which receipt of the registered mail is acknowledged by or on behalf of such person, representative or corporation; and

(b) by advertising it once in the Canada Gazette and once in The Canadian Patent Office Record, it shall be deemed to have been served

(i) on the later of

(A) the day on which it is advertised in the Canada Gazette, or

(B) the day on which it is advertised in The Canadian Patent Office Record, or

(ii) where it is advertised on the same day in those two publications, on such day.

(4) Notwithstanding paragraph (a) of subsection (1), the Commissioner shall not reject an application pursuant to that paragraph without first

(a) informing the applicant of the reason or reasons why he proposes to reject the application; and

(b) giving the applicant a reasonable opportunity to make representations, or to have representations made on his behalf, as to why the application should not be rejected.

116E. The patentee may, within two months after service of the application on him or within such further period not exceeding three months as the Commissioner may, on application made to him by the patentee within those two months, allow, file with the Commissioner in duplicate

(a) a counter statement in Form 21C, executed by the patentee and supported by affidavit evidence of the material facts alleged in the counter statement; or

(b) a statement, executed by the patentee, that he does not intend to file any counter statement;

and, where a counter statement is filed with the Commissioner pursuant to paragraph (a), the patentee shall

(c) serve on the applicant, within such two months or such further period, a copy of the counter statement and of any affidavit filed with the Commissioner pursuant to that paragraph; and

(d) file with the Commissioner evidence satisfactory to the Commissioner of such service.

116F. Within one month after a counter statement is served on the applicant or within such further period not exceeding two months as the Commissioner may, on application made to him by the applicant within that month, allow, the applicant may file with the Commissioner in duplicate a statement, executed by the applicant

(a) in reply to any matter raised in the counter statement and supported by affidavit evidence of the material facts alleged in such statement in reply; or

(b) that he does not intend to make any reply to the counter statement;

and the applicant shall

(c) serve on the patentee, within such month or such further

period, a copy of such statement and of any affidavit filed with the Commissioner pursuant to paragraph (a); and

(d) file with the Commissioner evidence satisfactory to the Commissioner of such service.

116G. (1) The Commissioner shall dispose of an application in accordance with subsection (4) of section 41 of the Act not later than eighteen months after the day on which a copy of the application is served on the patentee in the manner prescribed by subsection (2) of section 116D.

(2) Subject to subsection (1) and to sections 116H, 116I and 116J, the Commissioner shall dispose of an application in accordance with subsection (4) of section 41 of the Act as soon as possible after the expiration of two weeks from the day after which no further steps may be taken with respect to the application by the applicant or patentee pursuant to sections 116C to 116F.

(3) Forthwith after disposing of an application in accordance with subsection (4) of section 41 of the Act, the Commissioner shall notify the applicant, the patentee, the Minister of National Health and Welfare and any other minister to whom he has given written notice of the application pursuant to subsection (1) of section 116I of the manner in which he has disposed of the application.

116H. (1) As soon as possible after an application, counter statement, statement in reply or other statement referred to in section 116E or 116F is filed with the Commissioner, he shall furnish a copy thereof to the Minister of National Health and Welfare.

(2) At any time after a copy of an application has been furnished to the Minister of National Health and Welfare, but not later than two weeks after the first day on which no further steps may be taken with respect to the application by the applicant or patentee pursuant to sections 116C to 116F, the Minister of National Health and Welfare may give written notice to the Commissioner of his intention to make representations with respect to the application.

(3) Where the Minister of National Health and Welfare gives written notice to the Commissioner pursuant to subsection (2), he shall, within two months after the day on which the notice is given,

(a) file with the Commissioner in writing any representations that he desires to make with respect to the application;

(b) serve on the applicant and patentee a copy of any such written representations; and

(c) file with the Commissioner evidence satisfactory to the Commissioner of service of the representations referred to in

paragraph (b).

(4) Where written representations are served on an applicant and patentee pursuant to subsection (3), the applicant and patentee may each file with the Commissioner, within one month after the day of such service on the applicant, or patentee, as the case may be, a reply in writing with respect to any matter raised in the written representations.

116I. (1) At any time before the expiration of fifteen months from the day on which a copy of an application is served on the patentee in the manner prescribed by subsection (2) of section 116D, the Commissioner may, if he deems it necessary or advisable, give written notice of the application to the Minister of Consumer and Corporate Affairs or the Minister of Industry, Trade and Commerce or to both.

(2) Where the Commissioner gives written notice of an application to a minister referred to in subsection (1), he may furnish to the minister copies of such of the documents described in section 116H as he considers it necessary or desirable for the minister to have.

(3) Where a minister referred to in subsection (1) receives a written notice pursuant to that subsection, he shall, within one month after the date of such written notice,

(a) file with the Commissioner in writing any representations that he desires to make with respect to the application;

(b) serve on the applicant and patentee a copy of any such written representations; and

(c) file with the Commissioner evidence satisfactory to the Commissioner of service of the representations referred to in paragraph (b).

(4) Where written representations are served on an applicant and patentee pursuant to subsection (3), the applicant and patentee may each file with the Commissioner, within one month after the day of such service on the applicant or patentee, as the case may be, a reply in writing with respect to any matter raised in the written representations.

116J. (1) At any time not earlier than two weeks after the first day on which no further steps may be taken with respect to an application by the applicant or patentee pursuant to sections 116C to 116F, the Commissioner may, if in his opinion a hearing in necessary or desirable, by written notice to

(a) the applicant;

(b) the patentee;

(c) the Minister of National Health and Welfare, if he has given written notice to the Commissioner pursuant to subsection (2) of section 116H; and

(d) any minister to whom the Commission has given written notice of the application pursuant to subsection (1) of section 116I,

designate a day for the commencement of a hearing at which evidence or representations or evidence and representations, as the notice specifies, may be adduced or made by or on behalf of any person to whom the notice is sent, at a time and place specified in the notice.

(2) The day designated pursuant to subsection (1) for the commencement of a hearing shall not be later than seventeen months after the day on which a copy of the application was served on the patentee in the manner prescribed by subsection (2) of section 116D.

(3) The procedure at and the form and manner in which evidence may be adduced at a hearing shall be as determined by the Commissioner, either before or at the hearing.

116K. An interim licence granted pursuant to subsection (6) of section 41 of the Act may be renewed by the Commissioner pursuant to subsection (9) of that section if

(a) the applicant requests that it be renewed; and

(b) on the basis of the information before him at the time the applicant so requests, the Commissioner can see no good reason why he should not grant a licence to the applicant pursuant to subsection (4) of the said section.

116L. Section 126 does not apply in respect of any time prescribed by or pursuant to section 116D to 116F, subsection (1) of section 116G, subsection (4) of section 116H, subsection (4) of section 116I or subsection (2) of section 116J.

116M. Any application, request, notice or other document referred to in sections 116B to 116K or in section 41 of the Act that may or shall be executed, made, served, forwarded or given by an applicant or patentee may or shall, as the case may be, be executed, made, served, forwarded or given on his behalf by his patent agent or solicitor.

APPENDIX B

REPORTED DECISIONS OF THE COMMISSIONER OF PATENTS AND THE COURTS CONCERNING SECTION 41(4) OF THE PATENT ACT

1. Frank W. Horner Ltd. v. Hoffman-La Roche Ltd. (1970), 61 C.P.R. 243 [diazepam; Commissioner of Patents.]

   Hoffman-La Roche Ltd. v. Frank W. Horner Ltd.; Attorney-General of Canada, Intervenant (1971), 64 C.P.R. 93 [diazepam; Exchequer Court of Canada.]

2. Compagnie Pharmaceutique Vita Ltee. v. Hoffman-La Roche Ltd. (1970), 63 C.P.R. 39 [diazepam; Commissioner of Patents.]

3. Merck & Co. Inc. v. Sherman & Ulster Ltd. and 11 other actions (1970), 63 C.P.R. 44 [general issues; Exchequer Court of Canada.]

4. Micro Chemicals Ltd. v. Hoffman-La Roche Ltd.; Attorney-General of Canada, Intervenant (1971), 64 C.P.R. 290 [diazepam; Exchequer Court of Canada.]

5. Novopharm Ltd. vs. Chas. Pfizer & Co. Inc. (1970), 62 C.P.R. 92 [oxytetracycline hydrochloride; Commissioner of Patents.]

   Charles Pfizer & Co. Inc. v. Novopharm Ltd. (1971), 65 C.P.R. 132 [oxytetracycline; Exchequer Court of Canada.]

6. Sterilab Corp. Ltd. v. Chas. Pfizer & Co. Inc. (1970), 62 C.P.R. 94 [oxytetracycline hydrochloride; Commissioner of Patents.]

7. Novopharm Ltd. v. Hoffman-La Roche Ltd. (1970), 62 C.P.R. 167 [chlordiazepoxide; Commissioner of Patents.]

8. Novopharm Ltd. v. Smith, Kline & French Inter-American Corp. (1970), 62 C.P.R. 206 [trifluoperazine hydrochloride; Commissioner of Patents.]

9. American Home Products Corp. v. Commissioner of Patents (1970), 62 C.P.R. 155 [benzathine, penicillin G; Ontario Court of Appeal.]

10. Sterilab Corp. Ltd. v. American Home Products Corp. (1970), 62 C.P.R. 213 [benzathine, penicillin G; Commissioner of Patents.]

11. Jules R. Gilbert Ltd. v. Societe des Usines Chimiques Rhone-Poulenc and Sandoz Patents Ltd. (1971), 64 C.P.R. 158 [thioridazine; Commissioner of Patents.]

12. Norwich Pharmacal Co. v. P.V.U. Inc., Attorney-General of Canada, Intervenant (1971), 2 C.P.R. (2d) 7 [furazolidone; Federal Court of Canada.]

13. Merck & Co. Inc. v. S & U Chemicals Ltd., Attorney-General of Canada, Intervenant (1971), 65 C.P.R. 99 [methyldopa; Exchequer Court of Canada.]

    Merck & Co. Inc. v. S.& U. Chemicals Ltd. et al. (1972), 4 C.P.R. (2d) 193 [methyldopa; Supreme Court of Canada.]

    Merck & Co. Inc. v. Sherman & Ulster Ltd.; Attorney-General of Canada, Intervenant (1972), appeal dismissed 5 C.P.R. (2d) 2 [methyldopa; Supreme Court of Canada.]

14. Lilly v. S & U Chemicals Ltd. (1973), 9 C.P.R. 17 [erythromycin estolate; Federal Court of Appeal.]

    Eli Lilly & Co. v. S & U Chemicals Ltd. (1976), 26 C.P.R. (2d) 141 [erythromycin estolate; Supreme Court of Canada; Commissioner of Patents judgement: p. 142.]

15. Beecham Group Ltd. v. Frank W. Horner Ltd. (1974), 13 C.P.R. (2d) 5 [ampicillin; Federal Court of Appeal.]

16. ICN Canada Ltd. v. American Cyanamid Co. and Laboratorio Chimico Farmaceutico Giorgio Zoja S.p.A. (1974), 15 C.P.R. (2d) 288. [ethambutol; Commissioner of Patents.]

17. Gruppo Lepetit S.P.A. and Ciba-Geigy A.G. v. ICN Canada Limited (1977), 15 N.R. 51 [rifampin; Federal Court of Appeal.]

18. Jerram Pharmaceuticals Ltd. v. Wellcome Foundation Ltd. (1978), 36 C.P.R. (2d) 143 [allopurinol; Commissioner of Patents.]

19. Novopharm Ltd. v. Beecham Group Ltd. and Koninklijke Nederlandsche Gist-en Spiritusfabriek N.V. (1978), 37 C.P.R. (2d) 258 [cloxacillin; Acting Commissioner of Patents.]

APPENDIX C

AN EXAMPLE OF A COMPULSORY PATENT LICENCE ISSUED PURSUANT TO SECTION 41(4) OF THE PATENT ACT BY THE COMMISSIONER OF PATENTS

IN THE CANADIAN PATENT OFFICE

Licence Under Section 41(4) of the Patent Act,R.S.C. 1952, C.203 as amended June 27, 1969.

IN THE MATTER of an application for a licence by Novopharm Limited of 1290 Ellesmere Road. Scarborough, Ontario, to import, manufacture and sell the medicine whose chemical or proper name is Trifluoroperazine Hydrochloride as prepared or produced under the following Canadian patents no. 698,838 issued December 1, 1964 for "Substituted Trifluoromethylphenothiazine Derivatives" and no. 612,204 issued January 10, 1961 also entitled "Substituted Trifluoromethylphenothiazine Derivatives" owned by Smith, Kline & French Inter-American Corporation of Ville St. Laurent, Province of Quebec.

WHEREAS Novopharm Limited whose place of business is 1290 Ellesmere Road, Scarborough, Ontario, has made an application dated the 8th day of August, 1969, to the Commissioner of Patents for a compulsory licence under Section 41(4) of the Patent Act as amended to import, manufacture and sell medicine under Canadian patent nos. 698,838 and 612,204;

AND WHEREAS the owner of the said patent(s) Smith, Kline & French Inter-American Corporation has objected to the grant of such licence;

AND WHEREAS the Department of National Health and Welfare, having been notified of the application filed by the Applicant, the counterstatement filed by the Opponent and the subsequent reply thereto filed by the Applicant, has not indicated that it objects to the granting of a licence to the Applicant;

AND WHEREAS after having considered the application, the counterstatement and the reply to the counterstatement and all material filed in accordance with the rules enacted 27th day of June, 1969, by Order in Council P.C. 1969-1318;

AND WHEREAS by a decision dated the 23rd day of March, 1970 I set out reasons why this licence should be granted and as to how royalty was to be assessed;

AND WHEREAS the question of my jurisdiction to act has been settled;

NOW THEREFORE, be it known that pursuant to the power vested in me by the Patent Act, R.S.C. 1952, C.203, as amended, and in particular Sections 4 and 41(4) thereof, I do grant the applicant Novopharm Limited a non-exclusive licence under Canadian patent(s) no(s) 698,838 and 612,204 for the unexpired term(s) thereof, to use the patented invention(s) and to do the things specified in the application, namely,

(1) With respect to any patents named above that are for an invention that is a process

(a) under patents numbers 698,838 and 612,204 to use the invention for the preparation or production of medicine;

(b) under patents numbers 698,838 and 612,204 to import medicine in the preparation or production of which the invention has been used; and
(c) under patents numbers 698,838 and 612,204 to sell medicine in the preparation or production of which the invention has been used,

the sale thereof not being restricted to Canada only, under the following terms and conditions:

1. Novopharm Limited shall pay to Smith, Kline & French Inter-American Corporation a royalty of 4% of the net selling price of the medicine sold in its final dosage form or forms, which medicine has been prepared or produced in accordance with the processes covered by Canadian patents nos. 698,838 and 612,204 pursuant to this licence and sold by Novopharm Limited. Such royalty shall be paid over the term of that patent named in this licence which expires last provided it is uses, with or without the other licensed patent, during the said term;

2. The term "net selling price" as used herein shall mean that price charged any arm's length customer after deduction of allowances for returns, sales tax or other tax forming part of the price and required to be remitted to any governmental authority;

3. Novopharm Limited as a term of this licence, if it itself does not manufacture the medicine into its final dosage form or forms, shall, in any agreement of sale with an associated company or any other person or company purchasing medicine prepared or produced from the inventions described in the patents herein set out, provide and require that such company or person will keep accurate records of the quantity, sales and prices of the medicine manufactured by it into final dosage form or forms and sold by it to customers. Such agreement shall be in writing and be binding upon the successors and assigns of the purchaser. Such agreement shall further provide that all sales of the medicine in its final dosage form or forms shall be made or calculated as having been made at arm's length and a certified copy of the agreement shall be made available to Smith, Kline & French Inter-American Corporation upon request;

4. The purchaser, in its agreement of purchase and sale, shall also be required to furnish Novopharm Limited with quarterly statements certified by its auditors within thirty (30) days of the end of each quarterly period during the continuation of this licence showing the description, quantity, net selling price and the royalty computations of its operation. The first such statement shall be made within thirty(30) days after the end of the

first full quarterly period following the issuance of this licence;

5. Novopharm Limited within thirty (30) days following the receipt of the statements referred to in paragraph 4 hereof, shall forward certified copies thereof to Smith, Kline & French Inter-American Corporation together with payment in full of the royalty as computed therefrom; or, if it itself manufactures the medicine into its final dosage form or forms, shall itself adhere to the same requirements demanded of the purchaser as set out in paragraph 4 hereof;

6. Novopharm Limited shall at all reasonable times but after forty-eight hours notice and until complete settlements of all transactions which have taken place during the existence of this licence permit an independent chartered accountant (a non-employee of the company) acting on behalf of Smith, Kline & French Inter-American Corporation but approved of by the licensee, to inspect and take copies of its records or books pertaining to its operations pursuant to this licence but not otherwise and such accountant shall only be entitled to report to Smith, Kline & French Inter-American Corporation as to whether the statements furnished pursuant to clause 5 are correct.

7. Novopharm Limited shall, within sixty days after each calendar year, transmit to Smith, Kline & French Inter-American Corporation a statement certified by its auditors showing the descriptions, quantity and selling price of the medicine produced in its final dosage form or forms using the patented processes and sold during the preceding calendar year;

8. If Novopharm Limited commits any breach of a term of this licence, Smith, Kline & French Inter-American Corporation may at its option terminate the licence by giving one month's notice in writing by registered mail, stating the particulars of the breach on which termination is based and the licence shall automatically be terminated upon the expiration of such period, unless Novopharm Limited within such period, has rectified the breach designated, but such termination shall not affect the right of Smith, Kline & French Inter-American Corporation to require a statement of the accounts and payment of accumulated royalties as of the date of termination;

9. In the event of a dispute concerning the breach and the licensee notifies the patentee in writing to that effect by registered letter, this licence shall not be terminated but the matter will be decided by arbitration prodedure. Each of the parties shall appoint a representative of its own choosing and the two so appointed shall appoint a third, and the majority decision of the three shall be

final and binding upon the parties hereto. Such decision shall be made within sixty (60) days following the date Novopharm Limited has notified the patentee. Costs of arbitration shall be apportioned between the parties;

10. Novopharm Limited may at any time give three months' notice in writing to Smith, Kline & French Inter-American Corporation of its intention to terminate the licence and the licence shall thereupon be terminated at the end of such period of three months and all accounts shall be adjusted as of the date of termination;

11. This licence is not transferable and Novopharm Limited is precluded from granting any sublicence;

12. Notices, statements, payments or any documents dealing with this licence shall be sent to the other party at its last known address notified by each party to the other party;

13. (a) The word "medicine" as used herein shall mean the products produced by the processes of the patents herein mentioned, known in the industry generally as "bulk material" or "active ingredient";

(b) The word "customer" or "customers" as used herein refers to any person or firm, as for example, a wholesaler, jobber, distributor, government agency, hospital, pharmacist or physician etc., and to whom the medicine in its final dosage form is directly sold or is calculated as having been sold at arm's length;

(c) The word "purchaser" as used herein refers to that person or company which purchases from Novopharm Limited medicine for the purpose of manufacturing or converting it into final dosage form or forms for sale to customers;

14. If the Canadian Government later prescribed factors that should be taken into consideration by the Commissioner in fixing the royalty or other consideration which would have an effect on this licence, then either party will be permitted to apply to me to have such royalty reassessed;

15. During the pendency of any appeal by the patentee from the granting of this licence, I direct that all royalty payments be made to the Exchequer Court to be held until all appeals shall have been finally disposed of. Also the provisions of clause 6 herein dealing with inspection of records or books will be suspended until such time as all appeals shall have been finally disposed of.

DATED and SIGNED at
Ottawa, Ontario, this
17th day of April, 1970.

A.M. Laidlaw,
Commissioner of
Patents

APPENDIX D

LICENCES GRANTED UNDER SECTION 41(4) OF THE PATENT ACT BY THE COMMISSIONER OF PATENTS BETWEEN 1970-1978

This Appendix provides in Table D-1 a complete list of all compulsory licenses issued under section 41(4) of the Patent Act by the Commissioner of Patents between 1970 and 1978. The table is largely self explanatory. It provides the identity of the licensee, the patentee, the name of the drug (i.e., generic not brand name), the patent numbers which are used in the Patent office, the date the licence was issued and, finally, whether the licence was to import and/or manufacture. In several instances the patents on a particular drug are owned by more than one patentee (e.g., ampicillin). In such instances a separate licence is usually acquired by the licensee against each of the patentees. Finally, subsequent to the licensee acquiring a licence from the Commissioner of Patents the licencee may have gone bankrupt, merged, or changed its name. None of these changes are reflected in Table D-1. The information contained in Table D-1 was provided by the Bureau of Intellectual Property, Department of Consumer and Corporate Affairs. It is, however, also readily available from the public files of the Commissioner of Patents.

TABLE D-1
LICENCES GRANTED UNDER SECTION 41(4) OF THE PATENT ACT
BY THE COMMISSIONER OF
PATENTS: 1970-1978

Licensee	Patentee	Drug	Patents	Date Issued	To Import	To Manufacture
Novopharm Ltd.	Hoffman-La Roche Limited	chlordiaze-poxide	612,497; 671,044	April 17, 1970	x	x
Frank W. Horner Ltd.	Hoffman-La Roche Limited	diazepam	647,701; 647,702 671,044; 725,187	April 17, 1970	x	
Sterilab Corp. Ltd.	American Home Products Corporation	benzathine (penicillin G)	501,583; 552,934	April 17, 1970	x	
Sterilab Corp. Ltd.	Etablissements Clin-Byla	acepromazine maleate	689,993	April 17, 1970	x	
Sterilab Corp. Ltd.	Chas. Pfizer & Co., Inc.	oxytetracycline	514,895	April 17, 1970	x	
Micro Chemicals Ltd.	Hoffmann-La Roche Limited	diazepam	647,701; 647,702; 647,703; 660,724; 725,187	Feb. 12, 1970		x
Micro Chemicals Ltd.	Ciba Company Limited	hydrochloro-thiazide	756,103	May 8, 1970		x
Novopharm Ltd.	Geigy Commonwealth Corp. Ltd.	imipramine	507,977	April 17, 1970	x	x
Novopharm Ltd.	Chas. Pfizer & Co., Inc.	oxytetracycline	514,895	April 17, 1970	x	x
Novopharm Ltd.	Smith, Kline & French Interamerican Corp.	trifluoperazine	612,204; 698,838	April 17, 1970	x	x
Novopharm Ltd.	Eli Lilly & Company	erythromycin estolate	743,952	April 17, 1970	x	x
Novopharm Ltd.	Sandoz Patents Limited	thioridazine HCl	617,343; 699,834	April 17, 1970	x	x
Laboratoire Medic Ltée	Hoffmann-La Roche Limited	chlordiaze-poxide	612,497; 647,701; 647,703; 660,724; 647,702	June 23, 1970	x	x
Compagnie Pharmaceu-tique Vita Ltée	Hoffmann-La Roche Limited	diazepam	647,701; 660,724	April 29, 1970	x	x
Mowatt & Moore Ltd.	Hoffman-La Roche Limited	diazepam	647,701; 647,702; 647;703; 660,724	May 1, 1970	x	x
Mowatt & Moore	Hoffman-La Roche Limited	chlordiaze-poxide	612,497; 671,044	May 1, 1970	x	x
S & U Chemicals Ltd.	Chas. Pfizer & Co., Inc.	oxytetracycline	514,895	May 12, 1970	x	x
S & U Chemicals	Merck & Co., Inc.	amitriptyline	730,697; 744,730	June 2, 1970	x	x
S & U Chemicals Ltd.	Dr. Karl Thomas G.m.b.H.	bisacodyl	543,125; 602,496	May 12, 1970	x	x
Trans-Canada Dermapeutics Ltd	American Cyanamid Company	triamcinolone acetonide	672,881	May 1, 1970	x	x
S & U Chemicals Ltd.	Hoffmann-La Roche Limited	diazepam	647,701; 647,702; 647,703; 660,724	May 6, 1970	x	x
S & U Chemicals Ltd.	Sandoz Patents Ltd.	thioridazine	779,890	May 12, 1970	x	x
S & U Chemicals Ltd.	Hoffmann-La Roche Limited	chlordiazepoxide	612,497; 671,044	May 14, 1970	x	x
S & U Chemicals Ltd.	Smith, Kline & French Interamerican Corp.	trifluoperazine	612,204	May 12, 1970	x	x
Neo Drug Company	Hoffmann-La Roche Limited	chlordiazepoxide	612,497; 671,044	July 10, 1970	x	x
Novopharm Ltd.	Hoffmann-La Roche Limited	diazepam	647,701; 647,702; 647,703; 660,724; 725,187; 767,115	May 22, 1970	x	x
Novopharm Ltd.	Société des Usines Chimiques Rhône-Poulenc	metronidazole	605,972	June 26, 1970	x	x
S & U Chemicals Ltd.	Henri Morren	hydroxyzine	568,379; 568,380; 568,381; 568,382; 576,356; 579,397	May 22, 1970	x	x

S & U Chemicals Ltd.	Merck & Co., Inc.	methyldopa	573,568; 707,354; 711,727; 724,687; 743,125; 743,128; 759,063; 759,073; 778,412; 778,413; 778,414; 797,869	June 11, 1970	x	x
S & U Chemicals Ltd.	Merck & Co., Inc.	indomethacin	769,732; 769,733; 769,734; 769,735; 769,736; 769,737; 769,738; 769,739; 769,740; 801,057; 816,091	July 21, 1970	x	x
S & U Chemicals Ltd.	U.S. Vitamin & Pharmaceutical Corporation	phenformin	637,147; 700,727	July 17,1970	x	x
S & U Chemicals Ltd.	Société des Usines Chimiques Rhône-Poulenc	methotrimeprazine	568,431; 568,432; 568,433; 568,434; 568,435	July 20, 1970	x	x
S & U Chemicals Ltd.	Merck & Co., Inc.	cyproheptadine	677,299; 730,712	July 23, 1970	x	x
S & U Chemicals Ltd.	Farbwerke Hoechst Aktiengesellschaft	furosemide	654,395	Oct. 30, 1970	x	x
S & U Chemicals Ltd.	Beecham Group Limited	ampicillin	649,545; 695,820	May 22, 1970	x	x
P.V.U. Inc.	The Norwich Pharmacal Company	furazolidone	569,571; 569,657; 578,435; 578,436; 582,645; 582,646; 584,778; 702,450; 702,451	Dec. 9, 1970	x	x
Sterilab Corp. Ltd.	The Upjohn Company	hydrocortisone sodium succinate	689,986	April 24, 1970	x	x
S & U Chemicals Ltd.	Geigy Commonwealth Corporation Limited	imipramine	507,977	May 15, 1970	x	x
S & U Chemicals Ltd.	Geigy Commonwealth Corporation Limited	oxyphenbutazone	575,915; 575,916	May 15, 1970	x	x
Jules R. Gilbert Ltd.	Sandoz Patents Limited	thioridazine	779,890	Nov. 19,1970		x
Jules R. Gilbert Ltd.	Société des Usines Rhône-Poulenc	thioridazine	713,063	Nov. 19, 1970		x
S & U Chemicals Ltd.	Geigy Chemical Corporation	chlorthalidone	651,833; 652,236; 682,155	May 22, 1970	x	x
S & U Chemicals Ltd.	Ciba Company Limited	glutethimide	543,568	June 23, 1970	x	x
S & U Chemicals Ltd.	Ciba Company Limited	methylphenidate	570,173	June 23, 1970	x	x
S & U Chemicals Ltd.	Eli Lilly and Co.	erythromycin estolate	743,952	Aug. 20, 1970	x	x
S & U Chemicals Ltd.	Société des Usines Chimiques Rhône-Poulenc	metronidazole	605,972	Aug. 20, 1970	x	x
Novopharm Ltd.	Beecham Group Limited	ampicillin	649,545; 695,820	Sept. 11, 1970	x	x
Neo Drug Company	Société des Usines Chimiques Rhône-Poulenc	metronidazole	605,972	Sept. 9, 1970	x	x
Sabra Pharmaceuticals Ltd.	Aktiebolaget Astra, Apotekarnes Kemiska Fabriker	lidocaine	503,645	April 15, 1971	x	
Sabra Pharmaceuticals Ltd.	Geigy Commonwealth Corporation Limited	imipramine	507,977	April 16, 1971	x	
S & U Chemicals Ltd.	Merck, Sharp & Dohme of Canada Limited	chlorothiazide	577,594; 577,595; 577,596; 577,597; 577,598; 577,599; 577,600; 577,938; 586,075; 584,334; 608,062; 611,130; 611,131; 611,132; 629,777; 630,166; 630,235; 649,116; 649,254; 651,206; 661,399; 683,451; 694,384; 766,752	Nov. 20, 1970	x	x
S & U Chemicals Ltd.	Troponwerke Dinklage and Co.	nylidrin	516,824; 530,946	Oct. 30,1970	x	x

W.E. Saunders Ltd.	Hoffman-La Roche Limited	chlordiaze-poxide	612,497; 671,044	Feb. 28, 1972	x	
Sterilab Corp. Ltd.	Farbwerke Hoechst Aktiengesellschaft vormals Meister Lucius & Bruning	furosemide	654,395; 724,655; 758,071	Nov. 27, 1970	x	x
Sterilab Corp. Ltd.	Beecham Group Limited	ampicillin	649,545; 677,603; 695,820	Nov. 19, 1970	x	x
Novopharm Ltd.	Merck & Co., Inc.	amitriptyline	730,697; 744,730	June 7, 1971	x	x
Sabra Pharma-ceuticals Ltd.	Bristol Myers Company	ampicillin	748,893	June 29, 1971	x	
Frank W. Horner Ltd.	Hoffman-La Roche Limited	chlordiaze-poxide	612,497; 671,044	Aug. 10, 1971	x	x
Frank W. Horner Ltd.	Rhône-Poulenc S.A.	chlorpromazine	519,525	Oct. 12, 1971	x	x
Frank W. Horner Ltd.	Farbwerke Hoechst Aktiengesellschaft vormals Meister Lucius & Bruning	halothane	650,600; 652,239; 692,039	Oct. 12, 1971	x	x
Frank W. Horner Ltd.	U.S. Vitamin & Pharmaceutical Corporation	phenformin	637,147; 700,727	Oct. 12, 1971	x	x
Frank W. Horner Ltd.	Sandoz Patents Limited	thioridazine	617,343; 779,890	May 18, 1972	x	x
Frank W. Horner Ltd.	Société des Usines Chimiques Rhône-Poulenc	thioridazine	713,063	May 18, 1972	x	x
Frank W. Horner Ltd.	Smith Kline & French Canada Ltd.	trifluoperazine	612,204	Oct. 12, 1971	x	x
Novopharm Ltd.	Merck, Sharp & Dohme Canada Limited	chlorothiazide	577,594; 577,595; 577,596; 577,597; 577,598; 577,599; 577,600; 586,075; 584,334; 611,131; 630,166; 651,206;	Nov. 8, 1971	x	
Novopharm Ltd.	Beecham Group Ltd.	ampicillin	649,545; 695,820; 677,603; 729,186	Mar. 30, 1972	x	x
Dymond Drugs Ltd.	Chas. Pfizer & Co. Inc.	chlorpropamide	592,352	Aug. 27, 1971		x
Dymond Drugs Ltd.	Smith, Kline & French Canada Ltd.	trifluoperazine	698,838; 692,220 734,461	Mar. 1, 1972		x
Jules R. Gilbert Ltd.	Sandoz Patents Ltd.	thioridazine	779,890	Oct. 21, 1971	x	
Jules R. Gilbert Ltd.	Société des Usines Chimiques Rhône-Poulenc	thioridazine	713,063	Oct. 21, 1971	x	
Gilcross Ltd.	Hoffmann-La Roche Limited	chlordiaze-poxide	612,497; 671,044	Oct. 21, 1971	x	
Gilcross Ltd.	Hoffmann-La Roche Limited	diazepam	647,701; 647,702; 647,703; 660,724	Oct. 21, 1971	x	
Gilcross Ltd.	Eli Lilly & Company	erythromycin estolate	634,240; 743,952	Nov. 1, 1971	x	
Gilcross Ltd.	Karl Thomas G.m.b.H.	bisacodyl	543,125; 562,723; 602,496	Nov. 1, 1971	x	
Sabra Pharma-ceuticals Ltd.	The Upjohn Company	hydrocortisone sodium succinate	689,986	Feb. 9, 1972	x	
Novopharm Ltd.	Sandoz Patents Ltd.	thioridazine	617,343; 699,834; 779,890	Nov. 30, 1971	x	
Novopharm Ltd.	Société des Usines Chimiques Rhône-Poulenc	thioridazine	713,063	Nov. 30, 1971	x	
Frank W. Horner Ltd.	Beecham Group Limited	ampicillin	649,545; 677,603; 677,959; 677,960; 695,820; 695,841; 698,010; 726,717; 729,186; 734,907; 746,505; 749,949; 770,601; 771,662; 772,612; 772,613; 797,803; 809,209; 837,081	Dec. 1, 1971	x	x

Frank W. Horner Ltd.	Bristol-Myers Company	ampicillin	720,116; 720,117; 746,001; 747,917; 748,893; 801,734; 837,578	Dec. 1, 1971	x	x
Frank W. Horner Ltd.	Farbenfabriken Bayer A.G.	ampicillin	698,688; 722,159; 736,918	Dec. 1, 1971	x	x
Frank W. Horner Ltd.	Koninklijke nederlandsche Gist-en Spiritus-Fabriek N.V.	ampicillin	838,120	Dec. 1, 1971	x	x
Mowatt & Moore Ltd.	Beecham Group Ltd.	ampicillin	649,545; 729,186	Feb. 4, 1972	x	x
Sterilab Corp. Ltd.	Bristol-Myers Co.	ampicillin	710,794; 720,116; 720,117; 747,917; 748,893; 801,734	Mar. 6, 1972	x	
Sterilab Corp. Ltd.	Beecham Group Ltd.	ampicillin	649,545; 677,603; 695,820; 809,209	Mar. 6, 1972	x	
M.T.C. Pharmaceuticals Ltd.	Bristol-Myers Co.	ampicillin	720,117	Jan. 27, 1972	x	
M.T.C. Pharmaceuticals Ltd.	Beecham Group Ltd.	ampicillin	649,545; 677,603; 695,820; 695,841; 729,186	Jan. 27, 1972	x	
W.E. Saunders Ltd.	Beecham Group Ltd.	ampicillin	649,545; 677,603; 695,820; 729,186	April 5, 1972	x	
S & U Chemicals Ltd.	Scherico Ltd.	perphenazine	711,250	Mar. 7, 1972	x	
Sabra Pharmaceuticals Ltd.	Merck & Co., Inc.	amitriptyline	730,697; 744,730	May 31, 1972	x	
Sabra Pharmaceuticals Ltd.	Hoffman-La Roche Limited	chlordiazepoxide	612,497; 671,044	Mar. 17, 1972	x	
Sabra Pharmaceuticals Ltd.	Hoffmann-La Roche Limited	diazepam	647,701; 647,702; 647,703; 660,724; 725,187; 767,115	June 7, 1972	x	
Delmar Chemicals Ltd.	Rhône-Poulenc S.A.	chlorpromazine	519,525	June 28, 1972		x
Novopharm Ltd.	Chas. Pfizer & Co., Inc.	oxytetracycline	514,895; 617,859	July 20, 1972	x	
Sterilab Corp. Ltd.	Hoffman-La Roche Limited	chlordiazepoxide	612,497; 671,044; 724,633	June 9, 1972	x	x
Jerram Pharmaceuticals Ltd.	Eli Lilly and Co.	erythromycin estolate	634,240; 743,952	Oct. 6, 1972	x	
Jerram Pharmaceuticals Ltd.	Sandoz Patents Limited	thioridazine	779,890	Jan. 22, 1973	x	x
Jerram Pharmaceuticals Ltd.	Hoffmann-La Roche Limited	chlordiazepoxide	612,497; 671,044	Oct. 3, 1972	x	
Jerram Pharmaceutical Ltd.	Hoffmann-La Roche Limited	diazepam	647,701; 647,702; 647,703; 660,724	Oct. 3, 1972	x	
Jerram Pharmaceuticals Ltd.	Merck & Co., Inc.	amitriptyline	730,697; 744,730	Jan. 9, 1973	x	
Novopharm Ltd.	Farbwerke Hoechst Aktiengesellschaft vormals Meister Lucius & Bruning	furosemide	654,395; 724,655 758,071	May 2, 1973	x	
Novopharm Ltd.	Geigy Chemical Corporation	chlorthalidone	651,833; 652,236; 682,155	May 2, 1973	x	
Novopharm Ltd.	Ciba Company Limited	methylphenidate	570,173	April 27, 1973	x	
Novopharm Ltd.	U.S. Vitamin & Pharmaceutical Corporation	phenformin	637,147; 700,727	April 25, 1973	x	
Jerram Pharmaceuticals	Société des Usines Chimiques Rhône-Poulenc	thioridazine	713,063	Jan. 22, 1973	x	x
Jerram Pharmaceuticals Ltd.	Etablissement Clin-Byla	acepromazine maleate	689,993	Aug. 28, 1973	x	x
Delmar Chemicals Ltd.	Sandoz Patents Limited	thioridazine	779,890	June 20, 1973		x
Delmar Chemicals Ltd.	Société des Usines Chimique Rhône-Poulenc	thiroidazine	713,063	June 20, 1973		x

Jerram Pharmaceuticals Ltd.	Farbenfabriken Bayer A.G.	ampicillin	698,688; 722,159; 736,918	July 30, 1973	x	
Jerram Pharmaceuticals Ltd.	Beecham Group	ampicillin	649,545; 677,603; 677,959; 677;960; 695,820; 695,841; 698,010; 726,717; 729,186; 734,907; 746,505; 749,949; 770,601; 771,662; 772,612; 772.613; 797,803; 809,209; 837,081	July 30, 1973	x	
Jerram Pharmaceuticals Ltd.	Koninklijke Nederlandsche Gist-en Spiritusfabriek N.V.	ampicillin	838,120	July 30, 1973	x	
Jerram Pharmaceuticals	Bristol-Myers	ampicillin	720,116; 720,117; 746,001; 747,917; 748,893; 801,734; 837,578	July 30, 1973	x	
Noco Drugs Ltd.	Smith, Kline & French Canada Ltd	trifluoperazine	612,204	Dec. 11, 1973	x	x
P.V.U. Inc	Pfizer Inc.	oxytetracycline	586,307; 641,352	Mar. 20,1974	x	x
Novopharm Ltd.	Beecham Group Limited	cloxacillin	649,545; 734,457	Aug. 28, 1973	x	
Madeau Laboratory Ltd.	Temler-Werke Vereinigte Chemische Fabriken	diethylpropion-hydrochloride	642,241	Dec. 12, 1973	x	
ICN Canada Ltd.	American Cyanamid Company	ethambutol	783,073; 845,192	Nov. 19, 1973	x	x
ICN Canada Ltd.	Laboratorio Chimico Farmaceutico Giorgio Zoja S.p.A	ethambutol	886,041; 897,190	Nov. 19, 1973	x	x
ICN Canada Ltd.	Imperial Chemical Industries Limited	primidone	548,079; 550,972; 569,908; 571,115; 586,947; 588,691; 586,948; 586,949; 681,332	Sept. 6,1974	x	x
M.T.C. Pharmaceuticals Ltd.	Pfizer Inc.	oxytetracycline	617,859; 618,861; 641,352	April 18, 1974	x	
M.T.C. Pharmaceuticals Ltd.	American Cyanamid Company	oxytetracycline	602,232	April 18, 1974	x	
Novopharm Ltd.	Merck & Co., Inc.	methyldopa	573,568; 707,354; 711,727; 724,687; 743,125; 743,128; 759,063; 759,073; 778,412; 778,413; 778,414; 797,869	Sept. 9, 1974	x	
Sterilab Corporation Limited	Chas. Pfizer & Co., Inc.	oxytetracycline	617,859	Sept. 6, 1974		x
Novopharm Ltd.	Merck & Co., Inc.	indomethacin	769,732; 769,733; 769,734; 769,736; 769,738; 769,739; 769,740; 801,057; 816,091; 769,735; 769,737	Oct. 15, 1974	x	
ICN Canada Ltd.	Beecham Group Limited	oxacillin and cloxacillin	725,161; 734,457	Oct. 15, 1974	x	x
Novopharm Ltd.	Imperial Chemical Industries Limited	clofibrate	707,737	Oct. 15, 1974	x	
Canapharm Industries Inc.	Merck & Co., Inc.	amitriptyline	730,697; 744,730	Oct. 24, 1974	x	
ICN Canada Ltd.	Scherico, Ltd.	perphenazine	711,250	Nov. 4, 1974	x	x
Jerram Pharmaceuticals	Chas. Pfizer & Co. Inc.	oxytetracycline and tetracycline	617,859	Oct. 24, 1974	x	x
Novopharm Ltd.	Imperial Chemical Industries Limited	propranolol	790,059; 791,191; 805,721	Nov. 4, 1974	x	
Canapharm Industries Inc.	Farbwerke Hoechst Aktiengesellschaft vormals Meister Lucius & Bruning	furosemide	654,395; 724,655; 758,071	Nov. 4,1974	x	

Canada Packers Ltd.	Beecham Group Limited	ampicillin	649,545; 677,603; 695,820; 695,841; 729,186	Oct. 24, 1974	x	
Canada Packers Ltd.	Bristol-Myers Company	ampicillin	720,117	Oct. 24, 1974	x	
Mowatt & Moore Ltd.	Farbwerke Hoechst Aktiengesellschaft vormals Meister Lucius & Brunning	furosemide	654,395; 724,655; 758,071	Nov. 4, 1974	x	
Jerram Pharmaceuticals Ltd.	Farbwerke Hoechst Aktiengesellschaft vormals Meister Lucius & Bruning	furosemide	654,395; 724,655; 758,071	Feb. 27, 1975	x	
Jerram Pharmaceuticals Ltd.	Imperial Chemical Industries Ltd.	clofibrate	707,737	Dec. 11, 1974	x	
ICN Canada Ltd.	Ciba Limited	rifampin	873,870	Sept. 19, 1975	x	x
ICN Canada Ltd.	Lepetit S.p.A.	rifampin	730,718; 730,719;	Sept. 19, 1975	x	x
ICN Canada Ltd.	Gruppo-Lepetit S.p.A.	rifampin	634,395; 634,476; 727,634; 778,786; 783,561; 840,430; 874,416	Sept. 19, 1975	x	x
Novopharm Ltd.	Beecham Group Limited	cloxacillin	649,545; 695,841; 725,161; 727,106; 734,457; 888,194	Dec. 4, 1975	x	x
Novopharm Ltd.	Koninklijke Nederlandsche Gist-en Spiritus-fabriek N.V.	cloxacillin	838,120; 854,710; 922,705	Dec. 4, 1975	x	x
Novopharm Ltd.	Beecham Group Limited	ampicillin	770,601; 771,662; 772,612; 772,613; 797,803; 649,545; 677,603; 677,959; 677,960; 695,473; 695,820; 695,841; 698,010; 713,553; 726,717; 727,105; 729,186; 734,907; 746,505; 749,949; 809,209; 835,979; 837,081; 888,194;	June 7, 1976	x	x
Novopharm Ltd.	Koninklijke Nederlandsche Gist-en Spiritus-fabriek N.V.	ampicillin	838,120; 854,710; 922,705	June 7, 1976	x	x
Novopharm Ltd.	American Home Products Corporation	ampicillin	751,435; 835,384; 916,699; 921,910; 926,390	June 7, 1976	x	x
Mowatt & Moore Ltd.	Ciba-Geigy Investments Ltd.	oxyphenbutazone	575,915; 575,916	Dec. 20, 1974	x	
Jerram Pharmaceuticals Ltd.	The Wellcome Foundation Ltd.	allopurinol	526,728; 908,168	Mar. 10, 1976	x	
Apotex Inc.	Sandoz Patents Limited	thioridazine	779,890	Aug. 7, 1975	x	
Apotex Inc.	Scherico, Ltd.	perphenazine	711,250	Aug. 7, 1975	x	
Apotex Inc.	Farbwerke Hoechst Aktiengesellschaft vormals Meister Lucius & Bruning	furosemide	654,395; 724,655; 758,071	Feb. 4, 1976	x	
Apotex Inc.	Geigy Chemical Corporation	chlorthalidone	651,833; 652,236; 682,155	Mar. 14, 1975	x	
Apotex Inc.	Merck & Co., Inc.	amitriptyline	730,697; 744,730	Aug. 7, 1975	x	
Apotex Inc.	Hoffman-La Roche Limited	diazepam	647,701; 647,702; 647,703; 660,724	Aug. 7, 1975	x	
Canada Packers Ltd.	American Home Products Corporation	ampicillin	751,435	April 28, 1976	x	x
Canada Packers Ltd.	Ankerfarm S.p.A.	ampicillin	828,748	Apr. 28, 1976	x	x
Canada Packers Ltd.	Koninklijke Nederlandsche Gist-en Spiritusfabriek N.V.	ampicillin	838,120	April 28, 1976	x	x

Canada Packers Ltd.	Beecham Group Ltd.	ampicillin	649,545; 695,841; 726,717; 770,116; 677,603; 695,820; 729,186	April 28, 1976	x	x
Ethica Ltée	Imperial Chemical Industries Limited	clofibrate of aluminum	707,737	Mar. 14, 1975	x	
Ethica Ltée	Laboratoire Solac S.A.	clofibrate of aluminum	771,177	Mar. 14, 1975	x	
Jerram Pharmaceuticals	Imperial Chemical Industries Limited	propranolol	790,059; 791,191; 805,721	June 13, 1975	x	
ICN Canada Ltd.	Ciba-Geigy A.G.	rifampin	867,947	Sept. 19, 1975	x	x
Frank W. Horner Ltd.	Farbwerke Hoechst Aktiengesellschaft vormals Meister Lucius & Bruning	furosemide	654,395; 724,655; 758,071; 759,438; 795,746; 881,522 884,316	July 10, 1975	x	x
Canada Packers Ltd.	Bristol-Myers Co.	ampicillin	720,117	April 38, 1976	x	x
Novopharm Ltd.	Glaxo Laboratories Limited	cephalexin monohydrate	888,195; 918,655; 928,293	Sept. 17, 1976	x	x
Novopharm Ltd.	Beecham Group Ltd.	cephalexin monohydrate	649,545	Sept. 17, 1976	x	x
Novopharm Ltd.	Koninklijke Nederlandsche Gist-en Spiritusfabriek N.V.	cephalexin monohydrate	838,120	Sept. 17, 1976	x	x
Novopharm Ltd.	Eli Lilly and Company	cephalexin monohydrate	856,786; 872,787; 872,788; 895,868; 932,325	Sept. 17, 1976	x	x
Novopharm Ltd.	Janssen Pharmaceutica Naamloze Vennootschap	haloperidol	632,437	Sept. 13, 1976	x	x
Novopharm Ltd.	The Wellcome Foundation, Ltd.	allopurinol	580,004; 908,168;	Nov. 8, 1976	x	
Novopharm Ltd.	G.D. Searle & Co. of Canada Ltd.	spironolactone	733,495	Dec. 8, 1975	x	
ERI Pharmaceuticals Ltd.	Hoffman-La Roche Limited	diazepam	647,701; 647,702; 671,044; 725,187;	Dec. 8, 1975	x	x
Medivet Products Inc.	Pfizer Inc.	oxytetracycline	617,859; 618,861; 641,352	April 28, 1976	x	
Medivet Products Inc.	American Cyanamid Company	oxytetracycline	602,232	April 28, 1976	x	
Novopharm Ltd.	Hoffman-La Roche Limited	flurazepam	752,394; 791,130; 881,525; 892,030; 904,283; 904,285; 910,905; 914,174; 945,989	Dec. 29, 1976	x	
Novopharm Limited	Glaxo Laboratories Limited	betamethasone 17-valerate	770,108; 787,915;	Dec. 30, 1976	x	
Novopharm Limited	Warner-Lambert Company	betamethasone 17-valerate	742,208; 914,665;	Dec. 30, 1976	x	
ICN Canada Ltd.	Imperial Chemical Industries Ltd.	clofibrate	707,737	Dec. 31, 1976	x	
Delmar Chemicals	Janssen Pharmaceutica Naamloze Vennootschap	diphenoxylate hydrochloride	633,032; 634,057;	Dec. 8, 1976		x
Apotex Inc.	Merck & Co., Incorporated	methyldopa	707,354; 711,727; 797,869	Oct. 20, 1976	x	
Apotex Inc.	Merck & Co., Inc.	methyldopa	778,412; 778,413; 724,687; 743,125; 743,128; 759,063; 778,414	Oct. 20, 1976	x	
K-Line Pharmaceuticals Ltd.	American Cyanamid Company	triamcinolone acetonide	751,411; 700,249; 672,881	Feb. 22, 1977	x	x
K-Line Pharmaceuticals Ltd.	Merck & Co., Inc.	triamcinolone acetonide	746,888	Feb. 22, 1977	x	x
K-Line Pharmaceuticals Ltd.	E.R. Squibb & Sons, Inc.	triamcinolone acetonide	715,087; 706,406	Feb. 22, 1977	x	x
K-Line Pharmaceuticals Ltd.	Richter Gedeon Vegyeszeti Gyar R.T.	triamcinolone acetonide	969,927	Feb. 22, 1977	x	x

K-Line Pharmaceuticals Ltd.	E.R. Squibb & Sons Inc.	fluocinolone acetonide	758,579; 710,330	April 7, 1977	x	x
Novopharm Ltd.	Beecham Group Limited	amoxicillin	649,545; 695,473; 695,841; 726,717; 727,105; 728,133; 729,186; 749,949; 772,612; 772,613; 825,162; 835,979; 837,081; 888,194; 911,433; 916,701; 948,650	April 7, 1977	x	x
Novopharm Ltd.	E.R. Squibb & Sons Inc.	fluocinolone acetonide	686,141; 710,330; 758,579	April 20, 1977	x	
Jerram Pharmaceuticals Ltd.	Merck & Co., Inc.	indomethacin	769,732; 769,733; 769,734; 769,735; 769,736; 769,737; 769,738; 769,739; 769,740; 801,057	June 21, 1977	x	
ERI Pharmaceuticals Ltd.	Hoechst Aktiengesellschaft	furosemide	654,395; 724,655; 758,071; 759,438; 796,746; 881,522; 884,316	Mar. 9, 1977	x	x
Jerram Pharmaceuticals Ltd.	Merck and Company, Incorporated	indomethacin	816,091	June 21, 1977	x	
Canada Packers Ltd.	Beecham Group Limited	amoxicillin	728,133; 911,433; 916,701	April 21, 1977	x	x
Canada Packers Ltd.	Beecham Group Limited	cloxacililn	725,161; 734,457	May 3, 1977	x	x
Neo Drug Company	Merck & Co., Inc.	amitriptyline	730,697; 744,730	May 5, 1977	x	
Neo Drug Company	Hoechst Aktiengesellsch	furosemide	654,395; 724,655; 758,071; 759,438; 796,746; 881,522; 884,316	May 16, 1977	x	
ICN Canada Ltd.	Beecham Group Limited	amoxicillin	649,545; 677,959; 677,960; 695,841; 698,010; 728,133; 729,186; 734,907; 772,612; 835,979; 837,081; 888,194; 911,433; 916,701; 948,650	April 29, 1977	x	x
K-Line Pharmaceuticals Ltd.	Delmar Chemicals Limited	allopurinol	968,797	Aug. 29, 1977	x	x
K-Line Pharmaceuticals Ltd.	EGYT Gyogyszervegyeszeti Gyar	allopurinol	905,962; 927,827	Aug. 29, 1977	x	x
K-Line Pharmaceuticals Ltd.	Ciba-Geigy Canada Ltd.	allopurinol	601,981; 813,902	Aug. 29, 1977	x	x
K-Line Pharmaceuticals Ltd.	Burroughs Wellcome & Co. (U.S.A.) Inc.	allopurinol	931,568	Aug. 29, 1977	x	x
K-Line Pharmaceuticals	The Wellcome Foundation Ltd.	allopurinol	908,168	Aug. 29, 1977	x	x
Novopharm Ltd.	Boots Pure Drug Company Limited	ibuprofen	812,843; 854,236; 881,565	April 21, 1977	x	
International Medication Systems of Canada Ltd.	Hoechst Aktiengesellschaft	furosemide	654,395; 724,655; 758,071; 796,746; 759,438; 881,522; 884,316	Sept. 13, 1977	x	
Frank W. Horner Ltd.	The Wellcome Foundation Ltd.	allopurinol	742,227; 908,168	Aug. 29, 1977	x	x
Frank W. Horner Ltd.	The Wellcome Foundation Ltd.	allopurinol	948,197; 975,297; 977,279	Aug. 29, 1977	x	x
Frank W. Horner Ltd.	Burroughs Wellcome & Co. (U.S.A.) Inc.	allopurinol	931,568	Aug. 29, 1977	x	x
ICN Canada Ltd.	Hoffman-La Roche Limited	chlordiazepoxide	612,497; 671,044	Aug. 29, 1977	x	x
International Medication Systems of Canada Ltd.	Sterling Drug Inc.	diatrizoate	667,983	Dec. 7, 1977	x	

International Medication Systems of Canada Ltd.	Imperial Chemical Industries Limited	propranolol	791,191; 805,721	Aug. 29, 1977	x	
ICN Canada Ltd.	Richter Gedeon Vegyeszeti Gyar R.T.	triamcinolone acetonide	969,927	Sept. 28, 1977	x	x
ICN Canada Ltd.	E.R. Squibb & Sons, Inc.	triamcinolone acetonide	715,087; 706,406	Sept. 28,1977	x	x
ICN Canada Ltd.	American Cyanamid Company	triamcinolone acetonide	672,881; 700,349; 751,411	Sept. 28, 1977	x	x
ICN Canada Ltd.	E.R. Squibb & Sons, Inc.	fluocinolone acetonide	710,330; 758,579	Sept. 21, 1977	x	x
Novopharm Ltd.	Bristol-Myers Canada Limited	amoxicillin	649,545; 695,841; 728,133; 1,012,136	Nov. 24, 1977	x	x
Frank W. Horner Ltd.	Janssen Pharmaceutical Naamloze Vennootschap	haloperidol	632,437	Jan. 8, 1978	x	x
ICN Canada Ltd.	Ivan Villax	betamethasone-17-valerate	932,321	Jan. 26/78	x	x
ICN Canada Ltd.	Glaxo Laboratories	"	770,108; 787,915	Jan. 26/78	x	x
ICN Canada Ltd.	Scherico Ltd.	"	780,852	Jan. 26/78	x	x
ICN Canada Ltd.	Merck & Co., Inc.	"	597,097; 615,184; 615,185; 616,975; 747,908	Jan. 26/78	x	x
ICN Canada Ltd.	Warner-Lambert Co.	"	742,208; 914,665	Jan. 26/78	x	
K-Line Pharmacy Ltd.	Hoffmann-La Roche	chlordiazepoxide	612,497; 671,044	July 5, 1978	x	x
K-Line Pharmacy Ltd.	Hoffmann-La Roche	diazepam	647,701; 647,702; 647,703; 660,724; 671,044; 725,187; 767,115	June 20/78	x	x
Canada Packers	Koninklijke Nederlandsche etc.	amoxicillin	838,120	Aug. 8/78	x	x
Canada Packers	Beecham Group Ltd.	amoxicillin	649,545; 695,820; 695,841; 728,133; 729,186; 770,116; 1,012,136; 916,701	Aug. 8/78	x	x
Canada Packers	Beecham Group	cloxacillin	649,545; 695,841; 725,161; 734,457; 770,116	Aug. 8/78	x	x
Canada Packers	Koninklijke etc.	cloxacillin	838,120	Aug. 8/78	x	x
Frank W. Horner	Hoffmann-La Roche	flurazepam	647,702; 647,703; 660,724; 715,115; 725,186; 752,394; 791,130; 892,030	Aug. 14/78	x	x
Novopharm Ltd.	Hoffmann-La Roche	trimethoprim	752,405; 930,739; 974,259; 986,937; 1,003,331	Nov. 17/78	x	x
Novopharm Ltd.	The Wellcome Foundation Ltd.	trimethoprim	689,179; 898,814; 904,865; 978,954	Nov. 17/78	x	x
K-Line Pharmaceuticals Ltd.	Nippon Soda Kabushiki Kaisha	tolnaftate	762,923	Dec. 12/78	x	x

Source: Information provided by Bureau of Intellectual Policy, Department of Consumer and Corporate Affairs.

APPENDIX E

SELECTED EXTRACTS FROM THE PATENT ACT

67. (1) The Attorney General of Canada or any person interested may at any time after the expiration of three years from the date of the grant of a patent apply to the Commissioner alleging in the case of that patent that there has been an abuse of the exclusive rights thereunder and asking for relief under this Act.

(2) The exclusive rights under a patent shall be deemed to have been abused in any of the following circumstances:

(a) if the patented invention (being one capable of being worked within Canada) is not being worked within Canada on a commercial scale, and no satisfactory reason can be given for such non-working, but if an application is presented to the Commissioner on this ground, and the Commissioner is of the opinion that the time that has elapsed since the grant of the patent has by reason of the nature of the invention or for any other cause been insufficient to enable the invention to be worked within Canada on a commercial scale, the Commissioner may make an order adjourning the application for such period as will in his opinion be sufficient for that purpose;

(b) if the working of the invention within Canada on a commercial scale is being prevented or hindered by the importation from abroad of the patented article by the patentee or persons claiming under him, or by persons directly or indirectly purchasing from him, or by other persons against whom the patentee is not taking or has not taken any proceedings for infringement;

(c) if the demand for the patented article in Canada is not being met to an adequate extent and on reasonable terms;

(d) if, by reason of the refusal of the patentee to grant a licence or licences upon reasonable terms, the trade or industry of Canada or the trade of any person or class of persons trading in Canada, or the establishment of any new trade or industry in Canada, is prejudiced, and it is in the public interest that a licence or licences should be granted;

(e) if any trade or industry in Canada, or any person or class of persons engaged therein, is unfairly prejudiced by the conditions attached by the patentee, whether before or after the passing of this Act, to the purchase, hire, licence, or use of the patented article, or to the using or working of the patented process;

(f) if it is shown that the existence of the patent, being a patent for an invention relating to a process involving the use of materials not protected by the patent or for an invention relating to a substance produced by such a process has been utilized by the patentee so as unfairly to prejudice in Canada the manufacture, use or sale of any such materials.

(3) For the purpose of determining whether there has been any abuse of the exclusive rights under a patient, it shall be taken, in relation to every paragraph of subsection (2), that patents for new inventions are granted not only to encourage

invention but to secure that new inventions shall so far as possible be worked on a commercial scale in Canada without undue delay.

68. On being satisfied that a case of abuse of the exclusive rights under a patent has been established, the Commissioner may exercise any of the following powers as he may deem expedient in the circumstances:

(a) he may order the grant to the applicant of a licence on such terms as the Commissioner may think expedient, including a term precluding the licensee from importing into Canada any goods the importation of which, if made by persons other than the patentee or persons claiming under him would be an infringement of the patent, and in such case the patentee and all licensees for the time being shall be deemed to have mutually convenanted against such importation; a licensee under this paragraph is entitled to call upon the patentee to take proceedings to prevent infringement of the patent, and if the patentee refuses, or neglects to do so within two months after being so called upon, the licensee may institute proceedings for infringement in his own name as though he were the patentee, making the patentee a defendant; a patentee so added as defendant is not liable for any costs unless he enters an appearance and takes part in the proceedings; service on the patentee may be effected by leaving the writ at his address or at the address of his representative for service as appearing in the records of the Patent Office; in settling the terms of a licence under this paragraph the Commissioner shall be guided as far as may be by the following considerations:

(i) he shall, on the one hand, endeavour to secure the widest possible user of the invention in Canada consistent with the patentee deriving a reasonable advantage from his patent rights,

(ii) he shall, on the other hand, endeavour to secure to the patentee the maximum advantage consistent with the invention being worked by the licensee at a reasonable profit in Canada, and

(iii) he shall also endeavour to secure equality of advantage among the several licensees, and for this purpose may, on due cause being shown, reduce the royalties or other payments accruing to the patentee under any licence previously granted, and in considering the question of equality of advantage, the Commissioner shall take into account any work done or outlay incurred by any previous licensee with a view to testing the commercial value of the invention or to securing the working thereof on a commercial scale in Canada;

(b) if the Commissioner is satisfied that the invention is not being worked on a commercial scale within Canada, and is such that it cannot be so worked without the expenditure of capital for the raising of which it will be necessary to rely on the exclusive rights under the patent, he may,

unless the patentee or those claiming under him will undertake to find such capital, order the grant to the applicant, or any other person, or to the applicant and any other person or persons jointly, if able and willing to provide such capital, of an exlusive licence on such terms as the Commissioner may think just, but subject as hereafter in this Act provided;

(c) if the Commissioner is satisfied that the exclusive rights have been abused in the circumstances specified in paragraph 67(2)(f), he may order the grant of licences to the applicant to such of his customers, and containing such terms, as the Commissioner may think expedient;

(d) if the Commissioner is satisfied that the objects of this section and section 67 cannot be attained by the exercise of any of the foregoing powers, he shall order the patent to be revoked, either forthwith or after such reasonable interval as may be specified in the order, unless in the meantime such conditions as may be prescribed in the order with a view to attaining the objects of this section and section 67 are fulfilled, and the Commissioner may, on reasonable cause shown in any case, by subsequent order extend the interval so specified; but the Commissioner shall make no order for revocation which is at variance with any treaty, convention, arrangement, or engagement with any other country to which Canada is a party;

(e) if the Commissioner is of the opinion that the objects of this section and section 67 will be best attained by making no order under the above provisions of this section, he may make an order refusing the application and dispose of any question as to costs thereon as he thinks just.

69.(1) In settling the terms of any such exclusive licence as is provided in paragraph 68(b), due regard shall be had to the risks undertaken by the licensee in providing the capital and working the invention, but, subject thereto, the licence shall be so framed as

(a) to secure to the patentee the maximum royalty compatible with the licensee working the invention within Canada on a commercial scale and at a reasonable profit, and

(b) to guarantee to the patentee a minimum yearly sum by way of royalty, if and so far as it is reasonable so to do, having regard to the capital requisite for the proper working of the invention and all the circumstanstances of the case;

and, in addition to any other powers expressed in the licence or order, the licence and the order granting the licence shall be made revocable at the discretion of the Commissioner if the licensee fails to expend the amount specified in the licence as being the amount that he is able and willing to provide for the purpose of working the invention on a commercial scale within Canada, or if he fails so to work the invention within the time specified in the order.

(2) In deciding to whom such an exclusive licence is to be granted the Commissioner shall, unless good reason is shown to the contrary, prefer an existing licensee to a person having no registered interest in the patent.

(3) The order granting an exclusive licence under section 68 operates to take away from the patentee any right that he may have as patentee to work or use the invention and to revoke all existing licences, unless otherwise provided in the order, but, on granting an exclusive licence, the Commissioner may, if he thinks it fair and equitable, make it a condition that the licensee shall give proper compensation to be fixed by the Commissioner for any money or labour expended by the patentee or any existing licensee in developing or exploiting the invention.

70. (1) Every application presented to the Commissioner under section 67 or 68 shall set out fully the nature of the applicant's interest and the facts upon which the applicant bases his case and the relief which he seeks; the application shall be accompanied by statutory declarations verifying the applicant's interest and the facts set out in the application.

(2) The Commissioner shall consider the matters alleged in the application and declarations, and, if satisfied that the applicant has a bona fide interest and that a prima facie case for relief has been made out, he shall direct the applicant to serve copies of the application and declarations upon the patentee or his representative for service and upon any other persons appearing from the records of the Patent Office to be interested in the patent, and the applicant shall advertise the application in the Canada Gazette and the Canadian Patent Office Record.

71. (1) If the patentee or any person is desirous of opposing the granting of any relief under sections 67 to 72, he shall, within such time as may be prescribed or within such extended time as the Commissioner may on application further allow, deliver to the Commissioner a counter statement verified by a statutory declaration fully setting out the grounds on which the application is to be opposed.

(2) The Commissioner shall consider the counter statement and declarations in support thereof and may thereupon dismiss the application if satisfaction that the allegations in the application have been adequately answered, unless any of the parties demands a hearing or unless the Commissioner himself appoints a hearing; in any case the Commissioner may require the attendance before him of any of the declarants to be cross-examined or further examined upon matters relevant to the issues raised in the application and counter statement, and he may, subject to

APPENDIX F

DRUGS FOR WHICH COMPULSORY LICENSES HAVE BEEN ISSUED BY THE COMMISSIONER OF PATENTS: 1970-1978

The Commissioner of Patents issued licences for 55 drugs over the period 1970 to 1978. (In the period subsequent to 1978 licences have been issued for a number of additional drugs including cimetidine and naproxen, the former being a particularly significant high selling drug). Of the 55, 47 were classified as prescription drugs for human use and these are presented in Table F-1. Drugs classified to Schedule F of the federal Food and Drugs Act are prescription drugs. Regulation C.01. 041(1) pursuant to that Act states,

> no person shall sell a substance containing a drug listed or described in Schedule F to the Regulations ... unless he has received a written or verbal prescription therefor.

Thus Schedule F drugs was used to determine whether a drug was prescription or non-prescription, in consultation with officials of the Department of National Health and Welfare. The remaining eight drugs consisted of one for veterinary purposes (i.e., acepromazine maleate) five human ethical non-prescription (i.e., bisacodyl, lidocaine, tolnaftate, nylidrin, and cyproheptadine) and two drugs for human use, which were not on sale to the public but used predominantly in hospitals for various purposes (i.e., diatrizoate and halothane).

TABLE F-1

Human Prescription Drugs for Which Compulsory Licences Have Been Issued, Classified by Pharmacologic - Therapeutic Classification, 1970-1978

Central Nervous System	Cardiovascular
amitriptyline	chlorothiazide
chlordiazepoxide	chlorthalidone
chlorpromazine	clofibrate
diazepam	furosemide
diethylpropion hydrochloride	hydrochlorothiazide
flurazepam	methyldopa
glutethimide	propranolol
haloperidol	spironolactone
hydroxyzine	
ibuprofen	Hormones & Substitutes
imipramine	
indomethacin	chlorpropamide
methotrimeprazine	hydrocortisone sodium succinate
methylphenidate	phenformin
oxyphenabutazone	
perphenazine	Skin and Mucous Membrane
primidone	
thioridazine	betamethasone-17-valerate
trifluoperazine	fluocinolone acetonide
Anti-infectives	triamcinolone acetonide
ampicillin	
amoxicillin	
benzathine (penicillin G.)	
cephalexin monohydrate	Unclassified Therapeutic
erythromycin estolate	allopurinol
ethambutol	
metronidazole	Gastrointestinal
rifampin	
oxytetracycline	diphenoxylate hydrochloride
trimethoprim/sulfamethoxazole	furazolidone

Note: In a number of instances the salts are also included.

Source: Appendix D, Table D-1 above, Schedule F to the Food and Drugs Act and advice from officials of the Department of National Health and Welfare.

FOOTNOTES

CHAPTER I

1. The material in this section is based upon Canada, Department of National Health and Welfare (1965, pp. 23-27); Canada, Director of Investigation and Research (1961, pp. 60-64); Hall Commission (1964, pp. 643-647); Harley Committee (1967, pp. 8-10); James (1977); OECD (1977, pp. 18, 77-78, 168-174); Scrip (1979); and Chapters IV, V, and VII below.

2. See Canada, Department of Industry, Trade and Commerce (1979a, especially pp. 11-26).

3. Scrip (1979, p. 2) is the source for the upper limit of 120. However, no account of ownership linkages would appear to have been considered in deriving this total. The lower limit of 66 is taken from Ontario, Minister of Health (1979a), and ownership linkages were taken into account. Official sources such as Canada, Statistics Canada (1978a) often refer to manufacturers of a wider array of products than prescription drugs.

4. See Saskatchewan, Department of Health (1978, Table XIII, pp. 21-22). National figures are unavailable. These percentages probably indicate the broad orders of magnitude at the national level.

5. Includes extemporaneous preparations which accounted for less than 1 percent.

6. On the physician and his role in prescribing, see Hall Commission (1964, pp. 671-674); Harley Committee (1967, pp. 16-17); and the RTPC (1963, pp. 453-469). See Chapter IV, section 4.4, below under "Brand Names" for a discussion of the terms "generic", "proper", and "brand" name.

7. On the pharmacist and his role see Canada, Director of Investigation and Research (1961, pp. 84-105); Downie Committee, (1970, pp. 216-243); Fevang (1980); Koffler (1980); Macdonald Commission (1971); and RTPC (1963, pp. 394-403. On the significance of compounding, see Macdonald Commission (1971, Table 12.6, p. 222) and Saskatchewan, Department of Health, (1978, Table XIII, pp. 21-22). The relative importance of the dispensing fee and the ingredient cost is based upon information provided by British Columbia, Ontario, Quebec and Saskatchewan and refers only to that part of the population subject to government reimbursement programmes. This detailed in section 1.4 below. The number of pharmacists and the ratio of population per pharmacist is taken from Canada, Department of National Health and Welfare (1979d, Table 20.1 p. 167 and Table 20.2, p. 168). The judgement against B.C. pharmacist is R. v. B.C. Professional Pharmacists' Society et al., 64 C.P.R. 129.

8. For sources of specific details, in this section, see: on the inelasticity of demand, Walker (1971, pp. 8-11); on the U.S. demand, by age group, for 1973, see Fisher (1980, Table 3, p. 67); on the significance of those over 65 years of age in Ontario the data was supplied by the Ontario Drug Benefit Programme, Health Insurance Division, Ministry of Health; and on the changing age structure, Economic Council of Canada (1979a, Chapter III, pp. 23-33). For a more general view of the patient's role or position, see Liefmann-Keil (1974).

9. On the hospital vs. retail market there is a relatively small amount of literature. See, for example, Canada, Department of Industry, Trade and Commerce (1979a, p. 11-22; 1980, p. 8, 13, 36). The estimates on the importance of the hospital market came from Scrip (1979, p. 3), Canada, Department of Industry, Trade and Commerce (1980, p. 8) and Canada, Department of National Health and Welfare (1979c, Table 18.31, p. 122 and supplementary information provided to author). Note these sources do not always refer to prescr-iption drugs but ethical or pharmaceutical products, of which prescription drugs is a significant component.

10. For a discussion of the issues raised in this paragraph see, for example, Cooper (1966, Chapter 4, pp. 87-117); Hall Commission (1964, pp. 671-674) and Harley Committee (1967, pp. 16-17). Note that sometimes the discussion is over the alleged lower quality of the smaller sellers while, alter-natively, the quality is considered acceptable, but the smaller firm is unable to enter the market successfully because of the brand loyalty built up by the originator through advertising, sales promotion and an admittedly proven record with a safe and efficacious drug. See Worthen (1973) for a survey of prescribing influences based on a series of articles published in the 1960's.

11. The federal response is based upon Bachynsky et al (1977), Canada, Department of National Health and Welfare (1972, 1974, 1975c, 1975d) and Munro (1971). The first of these is a review of the QUAD programme.

12. The provincial response is based upon communications with various federal and provincial government officials and an examination of provincial formularies (where published). The percentage figures cited in the last paragraph are drawn from Table 4-3 below. On the Ontario experience, the provincial leader in this respect with its PARCOST programme, see Dyer (1974) and Ferguson Committee (1973).

13. This section based upon the various provincial drug product selection legislation, which is usually found in the relevant provincial Pharmacy Acts. Additional information was provided by provincial and federal officials through the QUAD programme. On the reports which led to the introduction of

product selection in Manitoba, see Klass Committee (1972), for Ontario, Porter et. al. (1971) and Saskatchewan, Richards (1973). Comparable reports are not readily available for other provinces with such legislation.

14. For example, the first province to introduce product selection legislation, Alberta in 1962, presented a very detailed brief to the Harley Committee arguing drug prices were too high. (See, for details, Steele, 1967). Similarly the report which recommended product selection legislation for Ontario clearly had lower drug prices as a major objective. (See, for details, Porter, et. al. 1971). Finally, the full title of product selection legislation in Newfoundland, which was assented to on December 14, 1979, but not, as yet, proclaimed, is An Act to Provide for the Provision of Lower Cost Prescription Drugs.

15. Note that if the pharmacist decides not to product select then he dispenses the brand prescribed. In Ontario the PARCOST agreement between individual pharmacies and the provincial government supplements product selection legislation in such a way that when the pharmacist does not product select he charges no more than the price in the PARCOST Comparative Drug Index, discussed above. Although the participation rate in PARCOST has varied over time it is generally considered to guide non-PARCOST pharmacies in pricing the particular brand dispensed in such instances. PARCOST is a voluntary agreement.

16. In those instances in Manitoba where the pharmacist does not product select he can charge no more than the lowest price for that particular drug specified in the formulary. In other words, no matter which brand is dispensed of a given drug, the pharmacist can charge no more than the lowest priced interchangeable pharmaceutical product listed in the formulary. This is referred to as mandatory price selection and is discussed in section 1.4, below.

17. This explains the similarity between New Brunswick and Ontario noted in the previous paragraph and the table, but the difference in the treatment of open prescriptions mentioned below.

18. Details of the various provincial drug reimbursement programmes were provided by federal and provincial officials through the QUAD programme. See also Badgley and Smith (1979, pp. 79-91). More details may be found for the four provinces selected for study in Chapter VI, British Columbia, Ontario, Quebec and Saskatchewan.

19. For example, for methyldopa 250 mg. tabs, the highest and lowest price in the July 1979 provincial formularies were as follows:

Province	Price Per Tab ($) Highest	Lowest
Manitoba	0.0880	0.0630
New Brunswick	0.0874	0.0650
Ontario	0.0781	0.0616
Quebec	0.0704	0.0486
Saskatchewan	0.0896	0.0377

Source: Manitoba, Department of Health and Social Development (1979); New Brunswick, Department of Health (1979); Ontario, Minister of Health (1979b); Quebec, Régie de l'assurance-maladie du Québec (1979b); Saskatchewan, Department of Health (1979b).

Comparable information was not available for the non-formulary provinces. For Quebec the highest and lowest refer to brands commonly available in the other formularies. If this restriction were removed, then the highest and lowest for Quebec would be, respectively, 0.0830 and 0.0482. The information shows that the provinces with mandatory product selection do not necessarily have the lowest price, as indicated by the formulary, with the second lowest price after Saskatchewan being Quebec, rather than Ontario or Manitoba.

CHAPTER II

1. Previously called the Exchequer Court.

2. In voluntary licence agreements, the compensation may also consist of an exchange of know-how.

3. Several countries have compulsory licence provisions relating to only a certain class, not all, of patents. For details, see Neumeyer (1959, pp. 44-51), who uses the expression "public interest" in such instances.

4. For details and an overview of the patent system, see Economic Council of Canada (1971, pp. 45-85), Firestone (1971), Fox (1969) and Wilson (1970, pp. 14-17).

5. All citations, unless otherwise stated, refer to Chapter P-4 of the Revised Statutes, 1970, as amended.

6. Section 46 of the Patent Act.

7. The individual inventor who works for a corporation may assign all his patent rights to the corporation.

8. This qualification also applies to food patents.

9. For a discussion, see Canada, Department of Consumer and Corporate Affairs (1976, pp. 121-122), Fox (1969, pp. 44-49), and Ilsley Commission (1960, pp. 93-94). Note that "chemical processes" has been held to include some drugs largely based on a biological process according to Henderson (1970, pp. 187-188).

10. This followed the introduction of a similar provision in British patent legislation in 1919. However, in 1949 this was removed from the British patent legislation. (See Banks Committee, 1970, pp. 113-114, and Canada, Department of Consumer and Corporate Affairs, 1976, pp. 121-122.) In Canada, a similar recommendation was made by the Ilsley Commission (1960, p. 94) and Canada, Department of Consumer and Corporate Affairs (1976, pp. 250-251). However, these recommendations have not been implemented.

11. Section 41(2) reads as follows:

> In an action for infringement of a patent where the invention relates to the production of a new substance, any substance of the same chemical composition and constitution shall, in the absence of proof to the contrary, be deemed to have been produced by the patented process.

12. On general compulsory licensing under the Patent Act, see Economic Council of Canada (1971, pp. 64-68, 93-100), Fox (1969, pp. 541-565), Ilsley Commission (1960, pp. 74-82) and Neumeyer (1959, pp. 15-19); under the Combines Investigation Act see Economic Council of Canada (1971, pp. 70-72), Fox (1969, pp. 565-570), Ilsley Commission (1960, pp. 82-85) and Neumeyer (1959, pp. 19-20).

13. See Appendix E for details. In some instances, the Federal Court can become involved. See section 71(3) in Appendix E.

14. See Appendix E for details.

15. For details, see Appendix E below.

16. Ilsley Commission (1960, p. 77). Revocation of patent existed after 1923, but only as a last resort to the issuance of a compulsory licence.

17. See Economic Council of Canada (1971, Table 4-5, p. 68). Apparently, no records exist for the period prior to 1935, according to the Ilsley Commission (1960, p. 77).

18. See Economic Council of Canada (1971, pp. 95-97) for recommendation to liberalize the compulsory licence provisions.

19. Unless indicated to the contrary, all references are to Chapter C-23 of the Revised Statutes, 1970, as amended.

20. Section 29 of the Combines Investigation Act reads as follows:

> 29. In any case where use has been made of the exclusive rights and privileges conferred by one or more patents for invention or by one or more trademarks so as
>
> (a) to limit unduly the facilities for transporting, producing, manufacturing, supplying, storing or dealing in any article or commodity which may be a subject of trade or commerce, or
>
> (b) to restrain or injure, unduly, trade or commerce in relation to any such article or commodity, or
>
> (c) to prevent, limit or lessen, unduly, the manufacture or production of any such article or commodity or unreasonably to enhance the price thereof, or
>
> (d) to prevent or lessen, unduly, competition in the production, manufacture, purchase, barter, sale, transportation or supply of any such article or commodity,
>
> the Federal Court of Canada, on an information exhibited by the Attorney General of Canada, may for the purpose of preventing any use in the manner defined above of the exclusive rights and privileges conferred by any patents or trade marks relating to or affecting the manufacture, use or sale of such article or commodity, make one or more of the following orders:
>
> (e) declaring void, in whole or in part, any agreement, arrangement or licence relating to such use;
>
> (f) restraining any person from carrying out or exercising any or all of the terms or provisions of such agreement, arrangement or licence;

> (g) directing the grant of licences under any such patent to such persons and on such terms and conditions as the court may deem proper, or, if such grant and other remedies under this section would appear insufficient to prevent such use, revoking such patent;
>
> (h) directing that the registration of a trade mark in the register of trademarks be expunged or amended; and
>
> (i) directing that such other acts be done or omitted as the Court may deem necessary to prevent any such use;
>
> but no order shall be made under this section that is at variance with any treaty, convention, arrangement or engagement with any other country respecting patents or trademarks to which Canada is a party.

21. Except that a licence should not be at variance with foreign treaties entered into by Canada.

22. Ilsley Commission (1960, p. 83).

23. See Scherer (1977, Table 3, pp. 70-72).

24. Spectacles, 1951 (Neumeyer, 1959, pp. 19-20); air bubble extrusion process for producing polyethylene, 1969 (Canada, Director of Investigation and Research, 1970, pp. 54-56); the corona discharge process used for treating polyetheylene and other thermoplastic films or structures to make them ink adhesive for printing purposes, 1971 (Canada, Director of Investigation and Research, 1972, pp. 29-30); mechanical jointing of cast iron soil pipe and fittings, 1973 (Canada, Director of Investigation and Research, 1973, pp. 46-47). The date refers to the final disposition of the case in court.

25. Air bubble extrusion, process for producing polyethylene (the patentee was prepared to offer a royalty free licence to any manufacturer in Canada of polyethelene film by extrusion from resin) and mechanical jointing of cast iron soil pipe and fittings (the patentee was required to licence competitors to manufacture mechanical joints on terms no more onerous than set out in an agreement between the Crown and the patentee and filed with the Court).

26. Most investigations conducted by the Director are a response to a complaint, usually from a businessman. See Gorecki and Stanbury (1979) for details.

27. This section is based upon Economic Council of Canada (1971 pp. 69-70), Fox (1969, pp. 304-313), Harley Committee (1967, pp. 38-39), Ilsley Commission (1960, pp. 95-98) and various judgements.

28. This citation refers to Chapter 203 of the Revised Statutes 1952, as amended 1953-54 c.19, c.40, s.15.

29. Most of the applicants for compulsory licences under 41(3) concerned drugs.

30. Decisions of the Commissioner under 41(3) can be appealed to the Federal, then the Supreme Court.

31. Hoffmann-La Roche Ltd. v. Bell-Craig Pharmaceuticals Division of L.D. Craig Ltd., 48 C.P.R. 137, at 144. This statement has been quoted with approval in subsequent cases. (See, for example, Merck and Co. Inc. v. S & U. Chemicals Ltd., 65 C.P.R. 99, at 105).

32. Hoffmann-La Roche Ltd. v. L.D. Craig Ltd., 46 C.P.R. 32 at 50.

33. See RTPC (1961, p. 102) for details.

34. See RTPC (1961, p. 103) for details.

35. Frank W. Horner Ltd. v. Hoffmann-La Roche Ltd., 61 C.P.R. 243 at 260. Other rates were fixed, but 15 percent became the norm. See Fox (1969, pp. 311-312) for details.

36. The onus is on the patentee to justify the royalty rate requested to the Commissioner of Patents. In the words of Rand, J.,

> ...for that purpose it is not sufficient for the patentee to sit back and, if they only are available, keep important facts undisclosed as being private and confidential; once the Commissioner decides the case to be one for licence, it lies with the patentee, by whatever means are open to him, to present substantial support for the royalty which he claims; in the absence of that he will be in a weak position to complain of any holding by the Commissioner.

(Parke Davis and Co. v. Fine Chemicals of Canada Ltd., 30 C.P.R. 59, at 63). The royalty is fixed in the first

instance by the Commissioner. This decision can be appealed by either party (i.e., licensee or patentee).

37. As of 1969, when Fox (1969) was published.

38. See RTPC (1963, pp. 105-106) and Fox (1969, pp. 306-307) for details.

39. That is, a royalty different from the 15 percent usually awarded by the Commissioner.

40. The source is Economic Council of Canada (1971, Table 4-6, p. 70). This table refers to the period 1935-1969. However, since no applications, or perhaps one application, were received between 1923 and 1949, the table applies to the 1923-1969 period. For contrasting statements on whether one or no applications were made prior to 1949, see Harley Committee (1967, p. 38) and statement of Commissioner in RTPC (1963, p. 111). A list of licences granted to 1960 are to be found in Canada, Director of Investigation and Research (1961, pp. 34-37).

41. See RTPC (1963, p. 110-111) and Economic Council of Canada (1971, Table 4-6, p. 70).

42. See Macdonald Commission (1971, p. 25, footnote 7).

43. This, of course, is not unique but common to many Canadian manufacturing industries. See Gorecki (1976) for details.

44. Harley Committee (1967, p. 40).

45. The patentee usually had at least 4 to 5 years anyway to establish his product, because of New Drug Status. See Harley Committee (1965, pp. 38-39). This is explained in detail below.

46. See Pazderka (1976). This is much less likely to be a factor in the hospital market.

47. See Economic Council of Canada (1971, Table 4-6, p. 70).

48. It is true that the Commissioner came to process licence applications quickly. However, the first case under 41(4) that was appealed to the Supreme Court of Canada was not decided until after October 30, 1970.

49. See RTPC (1963, pp. 113-116).

50. However, the Harley Committee (1967, p. 38) did not seem to agree with this assessment:

> In summary, there seems no doubt that the present compulsory licensing provisions of

> the Patent Act, insofar as the more expensive and newer drugs are concerned, have assisted greatly in the lowering of prices of the particular drugs involved; and this is borne out by statistics which have been presented in evidence before this Committee.

This evidence is not referred to in the report, nor to which of the various briefs or proceedings in front of the Committee.

51. Frank W. Horner Ltd. v. Hoffman-La Roche Ltd., 61 C.P.R. 243 at 248-249.

52. Frank W. Horner Ltd. v. Hoffman-La Roche Ltd., 61 C.P.R. 243 at 250.

53. Frank W. Horner Ltd. v. Hoffman-La Roche Ltd., 61 C.P.R. 243 at 251.

54. The Act uses the terms interchangeably.

55. This is based upon several sources: Patent Office records; reported decisions of the Commissioner and appeals from such decisions (a listing is provided in Appendix B); Mr. Brown of the Patent Office.

56. Appendix A below contains the required facts.

57. One such case involved the Minister of Industry, Trade and Commerce. See Novopharm Ltd. v. Beecham Group Ltd. and Koninklijke Nederlandsche Gist-en Spiritusfabriek N.V., 37 C.P.R. (2d) 258 at 261.

58. This was established in Hoffman-La Roche Ltd. v. Delmar Chemicals Ltd., 45 C.P.R. 235

59. See, for example, Frank W. Horner Ltd. v. Hoffman-La Roche Ltd., 61 C.P.R. 243, perhaps the most important.

60. See, for example, Commissioner's views in Novopharm Ltd. v. Smith Kline & French Inter-American Corporation, 62 C.P.R. 206 at 207.

61. Hence the applicant will receive his licence that much more quickly.

62. These are listed in Appendix B below.

63. See Hoffman-La Roche Ltd. v. Frank W. Horner Ltd., 64 C.P.R. 93 at 116-118 and Micro Chemicals Ltd v. Hoffman-La Roche Ltd 64 C.P.R. 230 at 242. In Merck & Co. Inc. v. S & U Chemicals Ltd., 65 C.P.R. 99 at 110, the Federal Court referred back the royalty question to the commissioner.

However, on appeal, the Supreme Court of Canada set aside the Federal Court referral and reaffirmed the Commissioner's decision. See Merck & Co. Inc. v. S. & U. Chemicals Ltd., 4 C.P.R. (2d) 193 at 196.

64. American Home Products Corporation v. Commissioner of Patents, 62 C.P.R. 155 at 160.

65. See Lilly v. S & U Chemicals Ltd., 9 C.P.R. (2d) 17 at 18. See also Gruppo Lepetit S.P.A. and Ciba-Geigy A.G. v. ICN Canada Ltd., 15 N.R. 51 at 59-60.

66. See Frank W. Horner Ltd. v. Hoffman-La Roche Ltd., 61 C.P.R. 243 at 250.

67. American Home Products Corporation v. Commissioner of Patents, 62 C.P.R. 155 at 160. King, J., ruled that,

> The new law is by its terms applicable in respect of patents antedating the new law [i.e. 41(4)] because it provides for the issuance of licences "...in the case of any patent for an invention intended or capable of being used for medicine or for the preparation, or production of medicine... [emphasis in original]

See also Sterilab Corporation Ltd. v. Chas. Pfizer & Co. Inc., C.P.R. 94 at 96.

68. Sterilab Corporation Ltd. v. Chas. Pfizer & Co. Inc., 62 C.P.R. 94 at 96. The Commissioner's view on this issue was that,

> I consider this argument as one involving safety and medical acceptability which I am not competent to assess and, in any event, has no bearing on the fact as to whether or not a licence should be granted.

In general, on the safety issue of drugs, if the Minister of National Health and Welfare raised no objections then this was taken as approval by the Commissioner (see Step 6(b) in Figure 1).

69. Gruppo Lepetit S.P.A. and Ciba-Geigy A.G. v. ICN Canada Limited, 15 N.R. 51 at 58. The court found that,

> ...I must say that I have not been persuaded that the respondent [i.e. applicant for a licence] made any false statements, express or implies [sic] in its applications under section 51(4) nor have I been persuaded that there was any intention

> on the part of the respondent to mislead the Commissioner.

70. See Frank W. Horner Ltd. v. Hoffman-La Roche Ltd., 61 C.P.R. 243 at 251. The Commissioner stated,

> It is also well settled that the Commissioner's decision to grant a licence under the subsection must not depend on whether or not the patentee's prices for its product are reasonable.

71. Of reported cases, which are detailed in Appendix B.

72. See O'Connell (1978, pp. 7-8). Martin O'Connell was Liberal M.P. for Scarborough East in 1978 and former Minister of Labour, but was defeated in the May 22, 1979 General Election. Any factors prescribed under 41(4) would be by the Governor in Council on the advice of the Minister of Consumer and Corporate Affairs.

73. See Frank W. Horner v. Hoffmann-La Roche Ltd., 61 C.P.R. 243. The Commissioner's decision was appealed. See Hoffmann-La Roche Ltd. v. Frank W. Horner Ltd., 64 C.P.R. 93. Both of these decisions provide extensive arguments of the appropriate royalty to which the interested reader should turn.

74. Frank W. Horner v. Hoffmann-La Roche Ltd., 61 C.P.R. 243 at 262.

75. See, for example, Thurlow, J., in Charles Pfizer & Co. Inc. v. Novopharm Ltd., 65 C.P.R. 132 at 146.

76. In one reported case, the appeal court felt the royalty of four percent was too low and asked the Commissioner to reconsider the royalty level (see Merck & Co. Inc., v. S & U Chemicals Ltd., 65 C.P.R. 99 at 110). However, this was overturned on appeal and the Commissioner's four percent royalty reaffirmed (see Merck & Co. Inc. v. S & U Chemicals Ltd., 4 C.P.R. (2d) 193 at 196).

77. The only reported example of the applicant appealing the decision of the Commissioner with respect to the awarding of a four percent royalty is Novopharm Ltd. v Beecham Group Ltd. and Koninklijke Nederlandsche Gist-En Spiritusfabriek N.V., 37 C.P.R. (2d) 258.

78. Multiple patents may exist because there is more than one method of producing the drug, since, as pointed out above, drug patents are process-dependent. Alternatively, some of the patents may be on an intermediate process.

79. See, for example, Jules R. Gilbert Ltd v. Societe des Usines Chimiques Rhone-Poulenc and Sandoz Patents Ltd 64 C.P.R 158, Beecham Group Ltd. v. Frank W. Horner, 13 C.P.R. (2d) 5, and ICN Canada Ltd v. American Cyanamid Co. and Laboratorio Chimico Farmaceutico Giorgio Zoja S.P.A. 15 C.P.R. (2d) 289.

80. See Frank W. Horner Ltd. v. Hoffmann-La Roche Ltd., 61 C.P.R. 243 at 263.

81. This view was upheld by the Federal Court. See Merck & Co. Ind. v. S & U Chemicals Ltd., 65 C.P.R. 99 at 106-107.

82. See Frank W. Horner Ltd. v. Hoffmann-la Roche Ltd., 61 C.P.R. 243 at 263.

83. See Hoffmann-La Roche Ltd. v. Frank W. Horner Ltd., 64 C.P.R. 93 at 127-128.

84. See Hoffmann-La Roche Ltd. v. Frank W. Horner Ltd., 64 C.P.R. 93 at 128.

85. These are dated by when the application was made. Note that Table 2-2 refers to licences issued by the date of issue. The source was the Public Files of the Commissioner of Patents.

86. Assuming, of course, that it met any safety and efficacy tests prescribed by the relevant regulatory authority.

CHAPTER III

1. The four patentees were: Beecham Group Ltd.; Bristol-Myers Co.; Farbenfabriken Bayer A.G.; Koninklijke Nederlandsche Gist-en Spiritusfabriek N.V. See Appendix D below for full details.

2. For example, compulsory licences were issued to Novopharm Ltd. on two separate occasions (i.e., April 17, 1970 and Nov. 30, 1971) against Sandoz Patents Ltd. for the drug thioridazine. See Appendix D below for full details.

3. For example, on Nov. 19, 1970 and Oct. 21, 1971 compulsory licences were issued to Jules R. Gilbert Limited to manufacture and import, respectively, thioridazine. See Appendix D below for full details. Jules R. Gilbert Ltd., subsequently became Gilcross Ltd.

4. See, for example, Canada, Director of Investigation and Research (1961) which is concerned solely with two general types of drugs (i.e., antibiotics and tranquilizers), virtually all of which are prescription drugs; the Harley

Committee (1967, p. 80) which, when it compares prices in Canada with other countries, restricts its attention almost exclusively to prescription drugs.

5. The classification used here (see Table 3-1 for example) is based upon the system developed by the American Society of Hospital Pharmacists for the purpose of the American Hospital Formulary Service (Saskatchewan, 1979b, p. ix), and is used in the drug formularies released by Ontario, Quebec, and Saskatchewan, the provinces with the most comprehensive formularies (see Chapter I above for a discussion of provincial formularies). The categories may be further sub-divided: for example, within the cardiovascular category there are four sub-categories. See Ontario, Minister of Health (1979b, pp. X-X11).

6. The columns headed "Significance of Each Classification" in Table 3-1 will be discussed below.

7. Extemporaneous preparations are not included in either of these numbers.

8. Delmar Chemicals Ltd. and Micro Chemicals Ltd. with a total of five licences.

9. In Chapter IV below, some discussion of working/non-working of licences by licensee is presented.

10. These numbers were based upon the background material to Table 3-3.

11. Discussed below under "acceptability."

12. See Ontario, Minister of Health (1977b, p. 36).

13. Saskatchewan, Department of Health (1978, p. 18) shows that total sales and number of prescriptions, classified by pharmacologic-therapeutic classification, are quite similar for the province of Saskatchewan.

14. Note the results obtained using the data for compulsory licences which were worked are also in accordance with *a priori* expectations.

15. A number of studies have shown a positive relationship between market growth and profitability for the manufacturing sector. For example, see Jones *et al* (1973) and McFetridge (1973) for Canadian work in this area.

16. This refers to 45 of the 47 drugs for which licences were issued. Insufficient data were available in the remaining two instances. If several patentees marketed the drug,

the date used is the earliest introduction of the drug; similarly for licensees.

17. See Table 3-5 for details.

18. See Bond and Lean (1977, especially Chapter V, pp. 57-74).

19. "Market" is defined as a physician being allowed to prescribe the drug for a patient.

20. Chapter F-27 of the Revised Statutes of Canada, 1970, as amended. For a current and historical examination of the Act see Pugsley (1967) and Morrison (1975), respectively.

21. Sellers and Sellers (1978, p. 70). This refers to the U.S. The authors suggest the lag in Canada would be an extra five to eight months.

22. See, for example, Canada, Department of National Health and Welfare (1973, 1975b, 1979b), Pernarowski and Darrach (1972), and Sellers and Sellers (1978).

23. Based on conversations with officials of Bureau of Drugs, Health Protection Branch, Department of National Health and Welfare.

24. These are likely to include bioavailability tests on humans (final dosage form) and toxicity tests performed on animals (raw material). Specialist firms often conduct these tests for the licensee. Once the licensee is granted a Notice of Compliance and markets the drug, the same reporting requirements, noted above for the patentee, concerning "... unexpected reactions... or failure to produce the desired effect", apply. (Information supplied by officials of Bureau of Drugs, Health Protection Branch, Department of National Health and Welfare).

25. The Department of National Health and Welfare will inspect the manufacturing facilities of the licensee whether the drug is New or Old. The licensee has to provide evidence to the Health Protection Branch that the raw material is not contaminated and of the proper quality, while the final dosage form is produced by a valid manufacturing process. The costs entailed, however, are small compared to those required if the drug is on New Drug Status, since no animal or human tests are conducted. (Information supplied by officials of the Health Protection Branch, Department of National Health and Welfare).

26. It should be noted that if the drug is on Old Drug Status tests may have to be conducted to satisfy some provincial authorities that the licensee product is therapeutically equivalent to that of the patentee. Even if the drug is

on New Drug Status the provincial authorities may require duplicate copies of all material submitted by the licensee to the Health Protection Branch. (This comment also applies to the patentees). This additional barrier to entry is discussed in more detail in Chapter IV below. The classic discussion of barriers to entry may be found in Bain (1956).

27. Another supply side constraint deserves to be mentioned. A drug can be prepared by the manufacturer in a variety of dosage forms: solid and liquid (which can be administered either orally or intravenously). The easier forms to manufacture are the solid dosage forms, requiring less sophistication and technical "know-how." Hence, the percentage of total sales accounted for by solid dosage forms should be positively related to "worked" and "licences." Unfortunately, it was not possible to estimate the former variable for the 47 licensed drugs. However, it would appear that solid dosage forms constitute the bulk of sales of any given drug. An early commentator on this study made this point.

28. Data not available for later years. IMS data used for market size and growth.

29. Data was not available for two of forty-seven drugs: furazolidone; trimethoprim.

30. Although the denominator and numerator of the growth variable were available for 45 licensed drugs, the denominator was zero in six instances. Hence the variable was not defined in these instances.

31. If equations 3 and 4 are estimated for the maximum number of observations (i.e., 45) the results are as follows:

$$\text{License} = \underset{(4.98)***}{1.56} + \underset{(8.40)***}{0.0014} \qquad R^2 = 0.6216, \; F = 70.6***$$

$$\text{Worked} = \underset{(2.94)**}{0.68} + \underset{(9.00)***}{0.0011} \qquad R^2 = 0.6532, \; F = 81.0***$$

32. The direction of these correlations is not surprising. The positive correlation between status and laglic is explained by the fact that for drugs on New Drug Status, which are usually relatively recent in terms of appearance on the market, the lag between the licence being issued and the patentee marketing the drug is short while the converse applies to drugs on Old Drug Status. The negative correlation between growth and status implies drugs on Old Drug Status have a lower growth rate than drugs on New Drug Status. Since drugs on New Drug Status are relatively recent arrivals on the market their growth rate is likely to be greater than the older more mature drugs on Old Drug Status.

33. Unless the market size is very large.

34. These figures were provided to the author in mid-1980. The $10,000 refer to bioavailability tests, with this sum being required for each strength (e.g., 10 mg., 5mg.). The $400,000 refer to not only bioavailability tests, but long-term toxicity tests which are likely to be particularly expensive if the drug has suspected carcinogenic side effects. The licensee has recently been granted a number of Notices of Compliance by the Health Protection Branch so these estimates should be reasonably accurate.

35. That is, August, 1979.

CHAPTER IV

1. Two of the licensees listed in Table 4-1, P.V.U. Inc. and Medivet Products Inc. are veterinary firms. Hence their use of the licensed drug is in the non-human, rather than the human, prescription drug market. As noted above, interest centres in this study only on prescription drugs. These two firms are, nevertheless, included in both Tables 4-1 and 4-2 for the sake of completeness, because the major use of the drugs for which they have obtained licenses is in the human prescription drug market. None of the results or statistics presented in the chapter with respect to licensees changes significantly if these two firms are excluded from consideration.

2. These were all, however, approved under the Foreign Investment Act as being of "significant benefit" to Canada See Foreign Investment Review Agency (1976, 1977, 1978, 1979) for details.

3. Measured in terms of the number of licences worked as of August 1979. See Table 4-1 for details.

4. This largely reflects the lack of publicly available annual reports since the licensees are usually private firms or else part of large conglomerates.

5. These tests are, however, often performed for the licensee by a third party.

6. There may, of course, be costs to entering or getting listed in the formulary.

7. For a discussion of formularies see Chapter 1 and also section 4.4 below.

8. There is some data available, however, for these two firms from the financial statements which they have to file with the Bureau of Corporate Affairs, Department of Consumer and Corporate Affairs. The evidence is consistent with the inference drawn in the text at least for Frank W. Horner. Net income or earnings after tax as a percentage of shareholder's equity is as follows:

	FIRM	
Year	Frank W. Horner Ltd.[a]	ICN Canada Ltd.[b]
1979	8.70	n.a.
1978	9.57	8.60
1977	12.09	-0.93
1976	14.29	8.80
1975	14.30	-2.65
1974	16.17	13.86
1973	23.85	n.a.
1972	28.28	n.a.
1971	21.85	n.a.
1970	12.83	n.a.

a. Financial year ending March 31.
b. Financial year ending November 30.
n.a.= not available.

The table shows the maximum number of years for which data are available.

9. Through its parent Canada Packers Ltd. There are three other members none of which are licensees.

10. In the sense it represents licensee interests.

11. Some patentees, however, acquired licences in the mid/late 1970's as Table 4-2 indicates. The reasons for this are discussed in Chapter V, section 5.3.4, below.

12. There were four: Canada, Director of Investigation and Research (1961), Restrictive Trade Practices Commission (1963), Hall Commission (1964), and Harley Committee (1967).

13. A similar conclusion was reached by a number of U.S. studies. These are summarized in Jadlow (1979), see also Temin (1979). Most of these studies were based upon the U.S. Senate hearings into the drug industry, chaired by Senator Estes Kefauver. See, for example, Comanor (1966), and/or Steele (1962, 1964).

14. See, for example, Harley Committee (1967, pp. 63-64) or Canada, Director of Investigation and Research (1961, pp. 245-248, pp. 257-258).

15. The Harley Committee (1967, p. 54, recommendation #18) and the Hall Commission (1964, p. 42, recommendation #67) both recommended that compulsory licensing to import be introduced, while the Restrictive Trade Practices Commission (1963, pp. 525-6, recommendation #6) recommended that drug patents be abolished. The Health Commission (1964, p. 43, recommendation #68) stated that if compulsory licensing to import had not reduced drug prices significantly five years after introduction, then the RTPC recommendation concerning drug patents be implemented. Finally, Canada, Director of Investigation and Research (1961) made no recommendations with respect to drug patents. In fact this report contained no recommendations at all.

16. The licensee typically offers no therapeutic advantage on the patentee's product so price is the only competitive variable which remains.

17. Typically the patentees are much larger than the licensees and more well-known to physicians and pharmacists and hence have easier access to those making the decisions as to which brand of drug to prescribe or dispense.

18. See James (1977, Table 2.1,p. 7) for details.

19. See, for example, Walker (1971), Bond and Lean (1977).

20. Note we are not concerned here with the validity or factual accuracy of these perceptions.

21. At the federal level the corresponding program was called QUAD. This is discussed in Chapter 1.

22. Ontario, Quebec, New Brunswick, Manitoba and Saskatchewan.

23. See Canada, Department of National Health and Welfare (1975a, Table 47, p. 57) for details. The table refers to sales of prescription drugs through retail stores only.

24. This appears to be particularly true of Ontario. Quebec relies on federal government testing since it lists brands of acceptable quality and does not certify interchangeability.

25. See, for example, the criteria used in Ontario (Ontario, Minister of Health, 1979b, pp. VIII-IX).

26. The listing of interchangeable drugs in the provincial government formularies is that of July 1979. Exceptions occur if a drug had been included for a number of years prior to July 1978, but for some reason had been dropped from the formulary within the last 6 months to a year. Then, for the purposes of Table 4-3, it is considered to be listed in the formulary. When a licensee had been included

or excluded from the formulary for a number of years, reference to the fact is made in the footnotes to Table 4-3.

27. See bottom line of Table 4-3 for significance of provincial drug markets.

28. Another possible reason is that although the licensed drug is listed in the provincial formulary the licensee did not apply for a listing of its particular brand. At least one instance of this is cited in the text below. This would seem to have limited applicability, however, as a general explanation for the discrepancies observed in Table 4-3, especially for the large markets of Ontario and Quebec. It should also be remembered that just because a licensee does not apply for a listing in a provincial formulary does not necessarily imply that the licensee would not like to be listed. As mentioned in the text some provinces apply more stringent requirements for listing than others, thus discouraging the smaller licensees. It seems irrational for a profit maximizing licensee to acquire a compulsory licence, begin manufacturing and then not attempt to market the drug in as many provinces as possible.

29. See footnotes to Table 4-3 for information upon which this was based.

30. Information provided by R.U. Sheikh, Technical Director and Vice-President of Jerram Pharmaceuticals Ltd.

31. This inference is based upon the following passage of a Quebec, Ministry of Industry, Commerce and Tourism (1979, p. 95) study:

> The sales stuctures of firms in Ontario and Québec lead one to believe that the former are more aggressive on the Québec market and the latter less aggressive on the Ontario market. Moreover, Québec firms, for a number of reasons, do not always meet the standards required by Ontario, be it at the product or the distribution level. The fact that Québec accepts federal standards, which is not always the case in Ontario, and the fact that Ontario has its own inspection service, constitute a considerable handicap for the native companies in the other provinces.
>
> For several years now, Ontario has had an implicit purchasing policy which, to all intents and purposes and in actual fact, protects its native firms. In the pharmaceutical field, Ontario uses "The Drug Benefit Formulary" and "The Parcost

> Comparative Drug Index" to keep the province's physicians informed of the quality of pharmaceutical products, to guide its pharmacists in their choice of drugs to keep in stock, and to advise the various professional committees responsible for the choice of drugs to be purchased for hospitals. Although it is not openly mentioned, native Ontario products are given precedence and it is fairly difficult for other provinces to get their pharmaceutical products included on the various formularies and indexes. Thus it is through the discretionary use of quality standards and its own proprietary products, and not through a purchasing policy per se, that Ontario can protect its native industry.

Since the other provinces are often alleged to follow Ontario's example, this may account for the non-listing in Manitoba, Saskatchewan and New Brunswick, reported in Table 4-3.

32. Oxyphenabutazone.

33. Ethamethmbutal, rifampin, betamethasone-17-valerate and methylphenidate.

34. Clofibrate.

35. Triamcinolone acetonide and fluocinolone acetonide.

36. These five were listed in Quebec over the period of July 1977 to July 1979.

37. Ethambutol.

38. Methylphenidate.

39. The information in this sentence re listing in Ontario was provided by J. Kay, Marketing Manager of ICN Canada. Note that Table 4-3 refers to provincial formularies for 1979.

40. Hence, the system should be well established. It should be noted that Apotex Inc. agrees that the references and explanation in this paragraph are accurate.

41. Data are available on the year of introduction from the print-out of current (i.e., August, 1979) drugs on the market supplied by the Bureau of Drugs, Department National Health and Welfare.

42. The corresponding time lag for Ontario for these six was 10.

43. This was confirmed in conversations with various licensees and Quebec drug plan representatives.

44. Except Quebec, of course.

45. At least Quebec and Ontario, given their economic significance in the industry.

46. See the quotation above from an official of Cyanamid of Canada Ltd.

47. See Saskatchewan, Department of Health (1979b, p. 49).

48. See Ontario, Minister of Health (1979b, pp. 11-111).

49. A drug firm can obviously call its drug by the generic name, but receives no trademark protection.

50. Evidence of the usefulness of brand names was reported above in Chapter II for Hoffman-La Roche Ltd. which attempted to impose, as a condition of the Commissioner of Patent's issuing a licence that the licensee should not be allowed to use a brand name. The Commissioner rejected this suggestion. See also footnote 43 of Chapter V, below.

51. Information concerning sample selection was provided by PMAC, the source for Table 4-4.

52. Amoxicillin, ampicillin, diazepam and methyldopa.

53. Ethambutol, perphenazine, rifampin, and trifluoperazine.

54. This inference is based upon:

Drug	Number of Licenses Issued June 1969-Dec. 1978[a]	Market Share of Licensees[a]
chlordiazepoxide	11	32.8
diazepam	11	28.3
furosemide	11	13.2
ampicillin	8	25.2
thioridazine	7	28.1
Average	9.6	25.5

a. See Chapter III, section 3.3 above, for details.
b. Based on Table 4-4, above.

The five drugs are ranked by number of licences issued.

55. Popular in this context refers to value of sales. These ten were as follows: amitriptyline 25 mg. tabs; diazepam 5 mg. tabs.; clofibrate 500 mg. caps.; furosemide 40 mg. tabs.; methyldopa 250 mg. tabs.; ampicillin 250 mg. caps.;

amoxicillin 250 mg. caps.; cloxacillin 250 mg. caps.; erythromycin estolate 25 mg. susp.; and chlorpropamide 250 mg. tabs.

56. The drug would appear to have been excluded from Table 4-4, because the patent had expired.

57. Two points can be made in this connection. First, the lack of success for permissive product selection is consistent with the results of a survey conducted in Saskatchewan in the early 1970's, prior to the introduction of the present system in 1974. See Richards (1973) for details. Second, in Quebec the law requires the pharmacist to notify the patient that product selection is taking place, in order to get the patient's permission. However, since such exercises are likely to be time consuming and may work to the economic disadvantage of the pharmacist, there is little, if any, incentive to product select.

58. Other things are not equal. For example, the price of a given brand is not necessarily lower in Ontario than Quebec because of the way prices are estimated for inclusion, in the formulary. See Chapter 1, section 1.4 above and Chapter VI, sections 6.4.5 to 6.4.7 below for details.

59. Then factors may be elaborated as follows: Inclusion of all dosage forms and strengths (Table 4-4) compared to only a high selling dosage form and strength (Table 4-5); refers to all of Canada (Table 4-4) which includes provinces such as Alberta, British Columbia, New Brunswick, Newfoundland, Nova Scotia and Prince Edward Island which either have no or only permissive product selection legislation (although Newfoundland intends to introduce mandatory price selection). None of these provinces are included in Table 4-5 which refers mainly to provinces or markets with strong product and price selection rules; different data sources are used for each table, with Table 4-4 relying on a sample, but Table 4-5 using the universe; and, finally for Ontario and Quebec, in Table 4-5, reference is made only to those persons covered under the provincial drug reimbursement programme (see Chapter I, Table 1-2 above) which, although constituting a significant percentage of the provincial market, may not be representative of the entire provincial market. Nevertheless, this would not seem to be the case. For Ontario information, comparable to that in Table 4-5, data was obtained for May 1979 and May 1980 from a private prescription drug benefit programme, Green Shield Prepaid Services Inc. of Windsor, Ontario. Green Shield is relatively small compared to ODB, with, in 1979, 12.3 percent of the number of eligible recipients. The average licensee market shares were as follows:

Year	Units	Sales
1979	80.4	84.2
1980	73.1	75.9

These percentages show that the licensees are much more successful in penetrating Green Shield than ODB prescriptions. The disparity in the size of the schemes, the concentration of Green Shield business in southern Ontario and the coverage of different population groups probably explains the difference in licensee market shares. For Quebec, no market share data is available outside that in Table 4-5. However, given the general product selection laws of the province and the rules of the government reimbursement scheme both detailed in Chapter 1, section 1.3 above, it seems unlikely that licensees would experience markedly higher market shares outside the provincial drug reimbursement scheme.

CHAPTER V

1. See, for example, Cooper (1966), James (1977), RTPC (1963), Schwartzman (1976), Pazderka (1976) and Walker (1971). Given the international character of the industry reference to foreign studies may be of considerable use.

2. Recall the discussion in Chapter II. Drug patents are process dependent.

3. Based upon Appendix D, below.

4. 34 of the drugs had but a single patentholder (i.e., 47-13 = 34). The remaining 13 drugs had a total of 40 patentholders, as detailed in the previous paragraph. The maximum figure of 74 is derivated on the assumption that each patentholder is a separate firm.

5. Brand name used by Hoffman-La Roche Ltd. Bactrim, it should be noted, is a combination drug, sulfamethoxazole and trimethoprim. The compulsory licence was issued, however, for trimethoprim, since there is no patent extant on sulfamethoxazole.

6. See Appendix D, Table D-1, below under "patentee."

7. In a small number of instances the patentee does not have a Canadian subsidiary. Instead, the patent rights are assigned to a representative in Canada, usually another drug firm. In such instances, reference is made to the "subsidiary" being a representative in a footnote.

8. It is more difficult to interpret the corresponding size distributions for licensed drugs with multi-patentholders,

since information is lacking in Table 5-1 on the number of patentees which share in the ownership of the licensed drug. On average, 3.1 patentees jointly owned the patents relating to the 13 multi-patentholder licensed drugs. The actual distribution was presented at the beginning of this chapter.

9. Similar percentages are recorded for those licensed drugs which the licensees, as a group, were marketing as of August 1979.

10. A similar conclusion would appear to apply to the 12 patentees outside the leading 80 drug firms, with the single exception of Delmar Chemicals Ltd. This is a Canadian owned firm, which owns patents relating to a multi-patentholder drug.

11. See Canada, Statistics Canada (1976, Table 3, p. 64-65) for details. The percentages refer to 1970. U.S. owned firms accounted for 73.1 percent of industry sales.

12. The five patentees are Bayer, Beecham, Imperial Chemical Industries, Dow and Boots. The fact that these patentees entered into voluntary license arrangements was deduced from the fact that the patentee's licensed drug was sold by a third party not a licensee or subsidiary of the patentee. In some instances, these patentees did have subsidiaries in Canada, but those were not engaged in prescription drug sales. However, while Beecham is listed in this category, it did start selling the licensed drugs for which it owned the patents toward the end of the 1970-1979 period.

13. These data are taken from Drug Merchandising (1979). In the case of a patentee with several subsidiaries the aggregation process assumed each subsidiary was in the midpoint of the size grouping which appeared in the data source.

14. Although there were 26 licensees, data on size was available only for 16. It seems safe to assume that the excluded 10 licensees had sales of less than $15 million. See Chapter IV above for details.

15. Sales of the leading 11 patentees, ranked by their worldwide sales for 1973 is taken from James (1977, Appendix 1, pp. 248-249) while the size of the retail prescription drug market is taken from Canada, Department of National Health and Welfare (1975a, Table 4-7, p. 57).

16. Three of the leading four suppliers of prescription drugs in Saskatchewan are patentees while the fourth is not. However, the four firm concentration ratio is only marginally higher, 35.7 percent. Such a "low" degree of concentration is not surprising since industry 374 (Manu-

facturers of Pharmaceuticals and Medicines), which includes prescription drugs recorded a four firm concentration ratio in 1970 of 29.5 percent. (See Canada, Statistics Canada, 1975, Table 1, p. 49).

17. On specialization, see James (1977, Table 3-4, p. 36), while an industry vs. therapeutic category concentration see Grabowski and Vernon (1979, Table 3-1, p. 31, Table 3-2, p. 32 and Table 3-3, p. 33) and references cited therein. On the general question of industry and product market concentration see Gorecki (1971).

18. See previous footnote. A second source are the documents submitted in the Hoffman-La Roche Ltd. court case concerning predatory pricing, which is mentioned in section 5.3.2 below. The market share of various patentees, for which data was presented, for 1966 to 1969 was as follows:

	Year			
Patentee[a]	1966	1967	1968	1969
Merck & Co.	8.3	7.5	7.4	7.7
Hoffman-La Roche Ltd.	5.1	5.4	5.8	6.4
American Home Products	5.8	6.0	6.1	6.2
Ciba-Geigy	4.7	4.8	4.8	4.7
Warner Lambert/ Parke Davis	4.0	3.5	3.2	3.1
Eli Lilly & Co.	3.1	3.1	3.0	3.1
Sandoz-Wander	2.6	2.2	2.5	2.4
Smith, Kline	3.2	2.9	n.a.	n.a.
Total	36.8	35.4	32.8	33.6

a. Patentees ranked by market shares for 1969.
n.a. = not available.

Source: Hoffman-La Roche Ltd. (1970) Forecast for Pharmaceutical Speciality Products (Montreal: mimeo, pp. 106-109.).

Note that "market" refers to both all drug sales, whether via the retail or hospital sectors. No explanation is provided in the data source as to why market share data is presented for a small number of drug firms, albeit the highest ranking ones.

19. See Drug Merchandising (1979) for details.

20 For details of research and development activity in Canada see Canada, Director of Investigation and Research (1961, pp. 120-141), Hall Commission (1964, pp. 666-671), Harley Committee (1967, pp. 24-28) Moriarity (1972, esp. pp. 12-15), PMAC (1976b, pp. 12-13; 1978, pp. 17-18) and RTPC (1961), pp. 120-141). On a more general level see

Steele (1967, pp. 16-30). See also the discussion in Chapter VII, below.

21. See PMAC (1976b, Table II, p. 13).

22. See Garton (1978, p. 4). The other major firm conducting research in Canada is Connaught Medical Research Laboratories which in the early 1970's had a scientific staff of around 600 (Moriarity, 1972, p. 12). However, Connaught, a Canadian owned firm, was neither a patentee nor licensee nor a member of PMAC, CDMA or AFQPP.

23. See PMAC (1978b, p. 18).

24. Nevertheless, via tax incentives the government may be funding such activities, albeit indirectly.

25. This is referred to as basic research, and accounts for 8 percent of research and development expenditures by PMAC members in 1975 (see PMAC, 1978b, p. 18). Most of the patentees' basic research and development is not conducted in Canada, but rather abroad.

26. See RTPC (1963, p. 81, 94) Harley Committee (1967, p. 25) for comments on regulatory induced R & D expenditures.

27. See PMAC (1978b, p. 18).

28. For details of advertising expenses see Canada, Director of Investigation and Research (1961, pp. 106-119), Hall Commission (1964, pp. 658-666), Harley Committee (1967, p. 20-23) PMAC (1978b, pp. 34-35) and RTPC (1963, pp. 182-303). See also for a critical appraisal Silverman and Lee (1974, pp. 48-80)

29. This is a commonly used index to measure advertising intensity.

30. Taken from PMAC (1978b, p. 34).

31. The Harley Committee (1967, p. 21), for example, commented, "No one disputes the fact that money spent on marketing by the drug industry far exceeds money spent for similar purposes by other industries."

32. On the level of profitability in Canada see Harley Committee (1967, pp. 12-13, 72-75) and RTPC (1963, pp. 362-377). Note that these two sources referred to periods in the 1950's and 1960's and used measures of profitability different from those in Table 5.3 above, thus making comparisons difficult. Broadly similar findings are also reported for the U.S. See, for example Schwartzman (1976, Table 7-8, p. 154) and Walker (1971, pp. 25-29). These two sources refer to the 1960's and

early 1970's, while Schwartzman uses the rate of return on equity as in Table 5-3 above.

33. The available evidence is somewhat sketchy but seems broadly consistent with this generalization. The following data refer to five licensed drugs and three patentees:

Patentee	Drug(s)	Sales Percentage	Profits Percentage	Year
Merck & Co.	methyldopa indomethacin	25	40	1975
Smith, Kline	cimetidine	33	50	1979
Hoffman-La Roche Ltd.	diazepam	49	n.a.	1970
	chlordiazepoxide	20	n.a.	1970

n.a. = not available.

Source: Hoffman-La Roche Ltd. (1971) Market Position of Librium and Valium (Montreal: mimeo, Enclosure #2, p. 26). James (1977, p. 36) and Louis (1980, p. 63).

Note that while the figures for Hoffman-La Roche Ltd. refer to Canada the data for the other two patentees refers to the U.S. and probably worldwide operations. Athough cimetidine is a licensed drug, this did not occur until 1980. Appendix F below details the sample of licensed drugs used in this study, which consists of all those for which licenses had been issued by Dec. 1978. The PMAC (1979, p. 11) agrees with the importance of a few products: "Few companies obtain the majority of their profit from more than three or four product groups."

34. See Pharmaceutical Manufacturers Association of Canada (1978b, pp. 43-45) for a list of members. Note that not all of the subsidiaries of the patentees in Canada are members of the PMAC. Information concerning Hoffman-La Roche Ltd. rejoining the PMAC noted at the end of the paragraph, was provided by the association. Despite the fact that the patentees constitute only 45.9 percent of the membership it is likely that non-patentee members will share the views of the patentees concerning compulsory licensing, since they themselves, should they become owners of a patent relating to a large volume selling drug, will likely find themselves subject to a licences application and competition. It should be noted that Sabex International Ltd. and Desbergers Ltd. which are members of the PMAC own licensees. However, these are small licensees, some of which no longer market the licensed drug. See also footnote 47 below.

35. The PMAC was not, however, able to stop the introduction of section 41(4) in 1969 or the various provincial product selection laws discussed in Chapter I, above. For full details concerning section 41(4) see Lang (1974).

36. This information was provided by S. Jackson of the Department of National Health and Welfeare. The data source was IMS.

37. R. vs. Hoffman-La Roche Ltd., unreported judgement handed down on February 5, 1980 by Linden, J., of the Supreme Court of Ontario. The accused were fined $50,000. See R. vs. Hoffman-La Roche Ltd., reasons for sentence, unreported, handed down on June 18, 1980 by Linden, J., of the Supreme Court of Ontario. No appeals have been or are expected to be filed.

38. Discretion as to whether or not to hold a hearing is that of the Commissioner.

39. See Appendix B for a list of decisions.

40. Although the Exchequer Court (later renamed the Federal Court) ruled in favour of the licensee the possibility of a reversal at the Supreme Court still would make it risky for Horner to sell the licensed drug.

41. See Lilly v. S & U Chemicals Ltd., 9 C.P.R. (2d) 17 at 18.

42. See Gruppo Lepetit S.P.A. and Ciba - Geigy A.G. v. ICN Canada Ltd., 15 N.R. 51 at 59-60.

43. It should be also noted that there has been, admittedly on a very small scale and quite recently (i.e., one case, Hoffman-La Roche Ltd. vs. Novopharm Ltd., an unreported judgement handed down August 8, 1980 by O'Driscoll, J. of the Supreme Court of Ontario), some litigation concerning infringement of trademarks by licensees. However, it would appear to be of very limited significance. Hoffman-La Roche Ltd. filed an application on June 14, 1976 that the colour combinations used for its brand of flurazepam, Dalmane, be registered as trademarks. This application was granted by the Registrar of Trademarks. (However, this is currently under dispute, by a party unrelated to Novopharm Ltd). Novopharm Ltd., after obtaining a compulsory licence for flurazepam and a Notice of Compliance from the Department of National Health and Welfare, launched its brand of flurazepam, Novofluram, in the spring of 1980. The colour combinations were the same as those used for Dalmane. Hence Hoffman-La Roche Ltd. brought an action for infringement of its trademark against Novopharm Ltd. In this case Roche was successful. All facts from the aforementioned judgement. (It should be noted that Hoffman-La Roche Ltd. in 1970

unsuccessfully brought a similar case against Rocke-William Cie Ltée. with respect to chlordiazepoxide. However, Roche did not have the black and green colour combination registered under the trade mark legislation. For details, see Hoffman-La Roche vs. Rocke-William Cie Ltée. 62 C.P.R. 23).

44. Hoffman-La Roche Ltd.(1971) Market Position of Librium and Valium (Montreal, mimeo, p. 13).

45. Hoffman-La Roche Ltd. (1974) Restrictive Government Practices Affecting Research-based Drug Industry (Montreal, mimeo, Attachment III, no page number).

46. The only period for which reliable information is available.

47. Based on industry sources. It should be noted that the one patentee, American Home Products Ltd., owns a firm, Elliott-Marion Co. Ltd., which acquired licences under section 41(3) of the Patent Act. (See Chapter II, section 2.4 above for a discussion of section 41(3) of the Patent Act). However, no licences were taken out under 41(4).

48. See Canada, Foreign Investment Review Agency (1975) for details.

49. The issue arose over sulfinpyrazone, a drug for which the patent expired long ago. Ciba-Geigy Canada Ltd. has found a new indication for this old drug. See Hollobon (1979) and Canada, Department of National Health and Welfare (1979b).

50. The drug is returned to New Drug Status.

51. On the product selection laws in Manitoba see Owen (1975) while many of the reasons cited by Lang (1974) for the PMAC's failure to prevent section 41(4) would appear to be equally valid today.

52. In the United Kingdom, where these conditions did not exist, compulsory licensees for diazepam and chlordiazepoxide have had little influence in the market-place. For details, see U.K., Monopolies Commission (1973).

CHAPTER VI

1. The difference is likely to be larger the further in time one moves away from 1969.

2. IMS pays the pharmacist to examine and report information.

3. In some instances, of course, the drug firm distributes the drugs itself.

4. In Tables 6-1 and 6-7, attention is paid only to the ingredient or drug cost component of the prescription price. This necessitated deducting the dispensing fee from the total price of a prescription. The 1977 Ontario survey was taken early in the year when the ODB dispensing fee was $2.70 and the PARCOST dispensing fee $2.95. A glance at footnote d, of Table 6-1 and a, of Table 6-7 shows that a dispensing fee of $2.85 was used. This is derived as follows: if it is assumed that ODB prescriptions, accounting for approximately 28-30 per cent of all prescriptions in Ontario, are priced to include a $2.70 dispensing fee, while the non-ODB market follows the PARCOST guideline and charges $2.95, then the weighted average is approximately $2.85. The actual average dispensing fee may differ from this, probably being less. This does not seem, however, to materially affect the results. In Table 6-1, indices 1 and 3 were re-estimated using a $2.70 dispensing fee and the results changed by about 1 percentage point at most. For the indices in Table 6-7, although they were not re-estimated for a lower dispensing fee, if such a dispensing fee is appropriate, then the indices as presented, are biased upwards, thus understating the savings from compulsory licensing and associated provincial policies.

5. See Chapter 1, section 1.2.7 above for details.

6. See discussion in section 6.4.5 below on wholesale/retail price distinction with respect to Ontario.

7. IMS data would require funds not presently available.

8. Most of the patent expiration dates were taken from PMAC (1976b Appendix A, pp. 36-47). In a number of instances, howwever, PMAC (1976b) contained no information on the licensed drug. In such instances (11) the year of patent expiration was estimated by taking the year the patentee first marketed the drug (taken from a print-out of current drugs on the market (i.e., August, 1979) supplied by Bureau of Drugs, Department of National Health and Welfare) and adding 10 years. This assumes that, given a patent is granted for 17 that the patentee takes 7 years to market the drug. This is almost certainly an overestimate. Hence the expiration date is biased downwards. (If 5 years to market the drug from the granting of the patent is used instead then the present/past 1979 expiration does not change for these 11 drugs).

9. An individual patent lasts seventeen years. However, the patentee may discover improvements in the product which are patentable, hence effectively prolonging the period of the patent life. For example, the patent on furosemide was

originally taken out in 1962 by Hoechst, but the date of expiration is not 1979, but rather 1984, because additional patents were taken out in 1967. (See PMAC, 1976b, Appendix A, p. 41 for details).

10. The licences issued by the Commissioner of Patents refer to 1970-1978. The use of August, 1979 is the date for working, to allow for the time lag between the granting of the licence and the marketing of the drug. August was the latest date for which information was available at the time of writing. It should be noted that if index is redefined as the percentage of the total drug prescription drug bill accounted for by licensed drugs for which at least one licensee is marketing a brand as of August, 1979 (as opposed to by) then the numbers in Table 6-1 change only slightly, - by 1 percentage point or less. (A licensee was considered to be marketing a licensed drug if it appeared in the Quebec formulary or on the print-out of current (i.e., August, 1979) drugs on the market, from the Bureau of Drugs, Department of National Health and Welfare).

11. No explanation was apparent for the "contradictory" finding for 1977 using Ontario data in Table 6-1.

12. Information provided to author by licensees.

13. This may reflect the fact, of course, that the patentee has lowered the price sufficiently to make entry unattractive for the licensee. In such instances the use of index A will be the more appropriate for evaluating scope and coverage.

14. The focus of attention in this study has been upon the prescription drug market, for reasons presented and discussed in Chapter III, section 3.2.2 above. However, if attention is paid to the more broadly defined ethical drug market (i.e., drugs usually sold through a pharmacist, but not advertised to the public) the results still indicate that the scope and coverage of compulsory licensing is substantial, though somewhat less. For example, reading from left to right in Table 6-1 the corresponding percentages for index 1 are 17.9, 20.8 18.7 and 20.2, respectively, for index 2, 15.0, 16.4, 13.7 and 11.7. The same data sources are used to estimate those figures as for Table 6-1. Note that these percentages refer to all licensed ethical drugs whether prescription or not. However, as Chapter III, section 3.2.2 above makes clear most licensed drugs fall into the prescription category.

15. See Harley Committee (1967, Appendix F, p. 80) which relates to 1966. See Canada, Director of Investigation and Research (1961, pp. 203-213) for price comparisons relating to the year 1959.

16. See Canada, Statistics Canada (1976, Table 3, pp. 64-65). The 70-75 per cent figure refers to industry 3740, Manufacturers of Pharmaceuticals and Medicines for 1970. Industry 3740 includes other products besides prescription drugs, such as non-prescription ethicals and proprietory goods. However, drug firms are usually engaged in these other facets of industry 3740, so that the 70-75 per cent figure is probably fairly accurate.

17. In terms of pricing policy.

18. For example, the U.K. has drug prices set by the National Health Service negotiating with the industry. An account of the institutional and regulatory environment in major European countries may be found in Abel-Smith and Grandjeat (1978, pp. 35-65)

19. Assuming, of course, that a decline actually takes place.

20. Statistics Canada publishes industry selling price indices for various groups of prescription drugs. The selling price index is based upon actual manufacturer's prices and not listed prices. Unfortunately the prescription drug price indices are either too heterogeneous to be used in evaluating the effect of compulsory licensing on drug prices or are too narrow, in that no licensed drugs are included. (The categories are: penicillin preparations, other antibiotics, dosage forms; vitamin preparations; biologicals and vaccines excluding sex hormones; oral antiseptics; ethical preparations for human use. See Canada, Statistics Canada, 1979, Table 1, p. 58). For example, Penicillin Preparations includes several patentee brands of drugs for which compulsory licenses have been issued and worked, but non-compulsorily licensed drugs accounted for by far the largest weight in the price index. (Information provided by G. Flynn, Prices Division, Statistics Canada.) Hence, the decline in this index from 100 in 1971 to 79.4 in 1978 cannot, without further information, be attributed to compulsory licensing. (See Canada, Statistics Canada, 1979, Table 1, p. 58 for details of this price index.)

21. In a number of instances information is provided in the text and footnotes cannot be found in Fulda and Dickens (1979). Such information was provided by Fulda to the author or on the basis of an earlier version of Fulda and Dickens.

22. Derived from IMS data supplied by the Bureau of Intellectual Property, Department of Consumer and Corporate Affairs.

23. The eleven drugs selected by Jackson were amitriptyline, hydrochlorothiazide, ampicillin, erythromycin, ethambutol, diazepam, chlordiazepoxide, metronidazole, imipramine, thioridazine and trifluoperazine. All of these eleven were the sample selected by Fulda and Dickens except hydrochloro-

thiazide and ethambutol for which the licensees had by 1974 gained at least 10 per cent of the market. On the other hand Fulda and Dickens' sample contains seven drugs not in Jackson sample. The differences in sample size and composition reflect the different criteria used. (These are detailed in the text). However, in spite of different sample criteria selection the results are consistent.

24. Note that Plet's sample is larger than that of either Jackson or Fulda and Dickens. This reflects different sample selection criteria. In particular Plet only required that the licensee market the drug whereas Jackson required that significant licensee competition should exist.

25. No explanation for the absence of two of the 43 drugs from either category was available. Several reasons may be offered including perhaps the most obvious, lack of data.

26. The U.S. data source was Drug Topics Red Book (1975) while for Canada Plet used list prices as collected by the Consumer Research Branch for the federal QUAD program. The list price was always used except for Valium and Librium. Although the list price remained constant throughout the period 1969 to 1975 its national price to wholesales had fallen 28.4 per cent. This was used instead of the list price.

27. These analysis all relate to 1969-1975. Some doubt may thereby be thrown on their relevance to the late 1970's. It was not possible, due to resource constraints, to undertake exercises similar to those of Fulda and Dickens, Jackson or Plet for the 1975-1979 period. However, using the same brand name drug dosage forms as Plet used for the sample of drugs for which a licensee had marketed a competitive product, average price changes were estimated between 1975 and 1978 using the July Ontario formulary. Plet usually used units of 100 to compare prices between the U.S. and Canada. The Ontario formulary records unit prices, based on package sizes of 100. The average change in the patentee's price for the 19 drugs was -1.5 per cent. Hence the price reductions which have taken place because of compulsory licensing in the 1969-1975 period do not seem to have been nullified in the subsequent three years. In any event the United States in the late 1970's began to introduce measures to promote price competition, such as product selection laws and the federal MAC programme. (See U.S., Federal Trade Commission, 1979, and Gagnon and Jang, 1979). Hence, comparisons in the late 1970's between the U.S. and Canada would be less valid, for the purposes at hand, than the early 1970's.

28. New licensees will have entered the market. On the supply side, Manitoba (1974), New Brunswick (1975) and Saskatchewan (1975), all introduced formularies in the mid 1970's which may not have fully affected prices for a number of years.

29. i.e., (70 + 10 + 20)/(70 + 10 + 40) = 100/120 = 83.3

30. i.e., (70 + 10 + 16)/(70 + 10 + 40) = 96/120 = 80.0.

31. The information concerning HPI in this paragraph is drawn from HPI Annual Reports, records and conversations with officials.

32. It is perhaps worth quoting a letter from HPI dated Aug. 29, 1978 concerning these factors to a licensee who, despite having the lowest price, was not awarded a particular contract:

> When our Pharmacy Standardization Committee meets to award contracts, it reviews many factors before deciding on a particular product. These factors, to name but a few, include whether the product:
>
> (1) is listed in the [Ontario] drug benefit formulary
> (2) is therapeutically effective
> (3) is available in the variety of strengths required
> (4) is produced by a firm with a sound service record and proper facilities
> (5) is properly identified
> (6) requires a great deal of costly inservice
> (7) and is price competitive.
>
> The fact that I have listed the products' price as our last consideration is by design not accident. The majority of contracts we let are not for the least expensive products but for those that combine most favorably all the factors listed.

33. Strictly speaking when there is no licensee competition index B is not defined. However, under such circumstances, by assumption, index B is set equal to index A since the only price is that of the patentee.

34. As noted in section 6.2 above in 32 instances by August 1979 the licensee had marketed a product to compete with the patentee. However, the sample of 22 experiencing licensee competition in Table 6-5 includes two which were marketed by a licensee subsequent to 1979 - propranolol and flurazepam. Hence the 64.7 percent is derived as 22/34, not 20/32.

35. There are usually a number of different prices which can be taken in comparing patentee and licensee prices, depending upon the package size (e.g., 100's 250's, 1,000's) selected and which licensee's price is chosen. In general for both indices A and B, the price of the licensee awarded the contract is selected and where the licensee did not succeed, the licensee price closest to the patentee. The package size was selected which minimized the difference between patentee and licensee price per unit (e.g., tab., or cap.).

36. The propranolol contract was not awarded to the licensee in large part because its brand was not listed in the Ontario formulary as interchangeable with the patentee brand at the time of decision to grant the contract. Subsequently the licensee successfully obtained a listing and hence stands a better chance of being awarded the contract in 1981/82.

37. See Canada, Department of National Health and Welfare (1975a, Table 47, p. 57). Percentages refer to 1973.

38. The data is described in footnote b of Table 6-6. As noted there, the sample refers to the 95 highest selling drugs, by brand name, dosage forms and strength, ranked by a number of prescriptions. Included in the top 95 were a number of licensed drugs for which only the patentee's brand appeared, yet extensive licensee competition existed elsewhere in Canada. However, it cannot be assumed that such competition is absent in B.C. because the licensee brand may rank lower than 95th.

39. See Chapter IV, Table 4.3 above for details.

40. The survey would appear to include a small number of ethical non-prescription drugs for which the purchaser used a prescription, probably because it was covered under a drug plan and hence free of charge to the person concerned.

41. Unpublished work by A. Klymchuk of the federal Department of Consumer and Corporate Affairs indicates formulary prices are followed in the non-ODB market. See also the Bailey Committee (1978) for details.

42. This applies particularly to licensed drugs experiencing licensee competition. Where there is only one supplier the variation in unit price by package size is likely to be much less, since the pharmacist has to purchase that particular manufacturer's brand. (See footnotes 46 and 48 below).

43. See Baily Committee (1978) and Porter et al (1971).

44. Quebec formulary prices refer to the wholesaler's price for the most frequently purchased (by the pharmacist) package size (typically larger than 100), according to officials of the Quebec government. (See also Baily Committee, 1978,

p. 9). Several comparisons were made using the Ontario quantities but using Ontario as well as Quebec prices. (See Quebec, Régie de L'Assurance maladie du Quebec, 1977, for details of prices). The results for index B are as follows:

	Where Licensee Competition Exists for a Licensed Drug
Ontario Prices	38.1
Quebec Prices	36.0

Since actual expenditure for licensed drugs and all drugs was not available for Quebec, index A could not be estimated, nor could index B for the "total drug bill" or "all licensed drugs". As can be readily observed, index B estimated for those licensed drugs where licensee competition existed was much the same for both Quebec and Ontario, despite large differences in the numerator and denominator, as between Ontario and Quebec. For example, the denominator of index B for Ontario was 33 percent larger than that for Quebec.

45. Each entry consisted of a drug, by dosage form and strength, such as diazepam 2 mg. tabs. In other words different brands of the same drug were not counted as separate entries toward the 36.

46. The cost to the pharmacist for a particular drug, by dosage form and strength (e.g., diazepam 2 mg. tabs.) was derived by taking the average cost as reported by IMS survey; the price selected as representative of that the pharmacist receives for the sale of the drug to the patient was that of the manufacturer most often identified by pharmacists as the brand dispensed according to the May 1978 Drug Benefit utilization reports. The manufacturer's price was then taken from the July formulary for each year. The result of using these prices was to yield the following average percentage mark-up over cost to the pharmacist:

1976	97.9
1977	139.2
1978	238.2

The manufacturer selected was usually a licensee, particularly ICN Canada Ltd. and Novopharm Ltd. In a number of instances the manufacturer's price does not correspond with the lowest in the formulary. This latter price is used in estimating the mark-up as presented in the text. Not surprisingly, it is smaller.

47. The 10 were as follows: methyldopa 250 mg. tabs.; amitriptyline 25 mg. tabs.; chlordiazepoxide 10 mg. caps.; diazepam 10 mg. tabs.; diazepam 5 mg. tabs.; diazepam 2 mg. tabs.; furosemide 40 mg. tabs.; hydrochlorothiazide 25

mg. tabs.; hydrochlorothiazide 50 mg. tabs.; and chlorpropamide 250 mg. tabs.

48. As explained in footnote 45 above, each of the 36 consisted of a drug, by dosage form and strength. Hence one drug could count more than once because of different dosage forms and strengths. The seventeen consisted of: propranolol 40 mg. tabs.; propranolol 10 mg. tabs.; ibuprofen 200 mg. tabs.; indomethacin 25 mg. caps.; ibuprofen 300 mg. caps.; flurazepam 30 mg. caps.; spironolactone 25 mg. tabs.; and the 10 listed in the previous footnote. The first seven were all single source. The percentage mark-up over cost to the pharmacist was as follows for this group:

1976	21.4
1977	9.9
1978	13.9

Not surprisingly these are much lower than the figures in the text and footnote 46 above for the 10 multisource licensed drugs.

49. The mark-up was estimated in a similar way to footote 46. The retail price that the pharmacist received was taken to be the lowest price for that particular dosage form and strength of the drug as listed in the formulary; the cost to the pharmacist was based upon actual prices of the drug, by dosage form and strength, as given to the author by a successful licensee in the Ontario market. In a number of instances the lowest price in the formulary was not that of the licensee. If the licensee's prices are used, then the mark-up is 430.7 percent.

50. The eight included all those in footnote 47 above except methyldopa 250 mg. tabs. and chlordiazepoxide 10 mg. caps.

51. Based on same sources as in footnote 46 above. See also footnote 52 below.

52. This reflects the different data sources employed in estimating mark-ups for 1976-78 and 1980. In both instances the price to consumer, charged by the retailer, is taken to be, the lowest price for that particular drug, by dosage form and strength. The cost to the pharmacist for 1976-78 is based upon IMS data, which is the average actual acquisition cost, while 1980 is based upon the actual prices to the pharmacists as supplied by a successful licensee in Ontario. These latter prices are usually in units of 1000. However, since the sample is of 36 high volume drugs, then 1000 is not an unreasonable quantity upon which to base the cost to the pharmacist. The licensee in providing the data remarked, "Most of our large customers pay prices identical to or comparable to [those provided to the author] ... and most

smaller customers pay prices which are only slightly higher" (letter to author, July 10, 1980).

53. See Chapter IV, Table 6-3 above for details. The remaining material in this paragraph is drawn from Chapter I, sections 1.3 and 1.4 above, while the 25 percent figure is detailed in the text below.

54. Data was provided by the Régie de l'assurance-maladie du Quebec for all 47 licensed drugs, but, for various reasons, only 40 were used in the preparation of Table 6-8.

55. Rifampin.

56. See Chapter III, section 3.3 above for details.

57. Methylphenidate, phenformin and pencillin G (benzathine).

58. See Quebec, Régie de l'assurance-maladie du Quebec (1980, pp. i-iii). Although a similar method calculating prices was used earlier (Baily Committee, 1978, p.9) the actual method and list of drugs, by dosage form and strength, did not appear in formularies prior to 1980. Some of the high volume drugs refer to non-prescription ethical drugs.

59. The additional four were amitriplyline 10 mg. tabs., furosemide 20 mg. tabs., and thioridazine 10 and 25 mg. tabs. This was the maximum sample for which Chart 6-3 could be estimated.

60. Based on a memo by a rival licensee supplied to the author.

61. Several other factors should be mentioned, in addition to those in the text, in interpreting Chart 6-3. First, the package sizes used to estimate the unit cost to the pharmacist are not always the same as those used to derive the licensee and patented prices in the formulary, as stated in Quebec, Régie de l'assurance-maladie du Québec (1980, pp. i-iii). The latter is smaller than the former in some instances. However, in view of the comments made at the end of footnote 52 above, the package sizes used for estimating the cost to the pharmacist seem quite reasonable for the purposes at hand. Second, Chart 6-3 refers to the Quebec formulary for July-December 1980 while Chart 6-2 refers to the Ontario formulary for January-July 1980. Since the patentee prices in the Ontario formulary showed little, if any, change (January-June 1980 to July-December 1980) and the lowest priced licensee brand showed a slight increase during 1980, a comparison of Chart 6-2 and Chart 6-3 for July-December 1980 would show a slight increase in the intra-marginal rent for Ontario. Third, the eight drugs, common to both Charts 6-2 and 6-3, are arranged in the same order for purposes of comparison. Fourth, patentee prices were much the same in Quebec and Ontario for the eight drugs common to

Charts 6-2 and 6-3. For five of the drugs, by dosage form and strength, the Ontario prices fell within 10 percent above or below the Quebec prices. In the case of the three dosage forms and strengths of diazepam the Quebec price was approximately two-thirds of the Ontario price.

62. The 3 percent figure is taken from Chapter IV, Table 4.3 above. The remainder of the material in this paragraph is taken from Chapter I sections 1.3 and 1.4 above. Further details concerning the Saskatchewan drug programme may be found in the annual reports of that province's Prescription Drug Plan.

63. The prices are based upon the July-December 1979 formulary of both provinces (Ontario, Minister of Health 1979b and Saskatchewan, Department of Health 1979b). All eight drugs were subject to standing-offer-contracts in Saskatchewan for the July-December 1979 formulary. As pointed out in the text in section 6.4.6 above Ontario has priced 36 high volume drugs, by dosage form and strength, on the basis of 1000's package sizes since the January-June 1979 formulary.

64. The sample was selected as follows: all dosage forms and strengths of a particular drug for which January-March 1979 sales (patentee and licensee) were less than $10,000 were excluded. For example, no information was provided for imipramine because for each dosage form and strength (10 mg. tabs., 25 mg. tabs., and 50 mg. tabs.) sales did not exceed $10,000. Broadly speaking, using the aforementioned cut-off, the highest selling dosage form of a licensed drug was then included in the sample. However, if more than one dosage form and strength of a particular drug or different drugs within the same therapeutic classification (e.g., several dosage forms and strengths of both diazepam and chlordiazepoxide met the $10,000 criteria) only the largest selling dosage form and strength was included.

65. The decrease in the significance of these drugs reflects the success of the Saskatchewan drug reimbursement programme in lowering expenditure on these drugs despite an increase in the number of units of each drug sold between 1976 and 1979.

66. Similar results hold even if the index A is estimated using actual patentee price, with no factor adjustment for the influence of section 41(4). The results are as follows for 1979:

INDEX A

Drug	Patentee price unadjusted	Patentee price adjusted upward 20%
amitriptyline	39.2	32.7
diazepam	31.5	26.6
furosemide	40.1	33.4
chlorpropamide	48.7	40.6

67. Confidentiality prohibits mentioning to which of the four drugs these percentages refer.

68. See, for example, footnote 66 above.

69. It is realised that pharmacists are encouraged in both provinces to engage in more efficient purchasing and hence may purchase drugs for prices lower than those in the formulary. For example, the following paragraph typically appears in the first few pages of the Ontario formulary,

> Where more than one package size is available, the one selected for listing indicates the most economic and efficient size for an average community pharmacy to purchase. It is recognized that lower prices will be realized through efficient operational practices and bulk purchasing, and improvements in this regard will be stimulated and encouraged.

Nevertheless it is felt that a markup of several hundred percent for a very significant percentage of pharmacists suggests that this needs re-examination. In Ontario, of course, this was what the Baily Committee (1978) was designed to address. See Chapter VIII below for a further discussion of these issues.

70. See Baily Committee (1978) and Porter et al (1971) for details. Several persons involved in the drug market in Ontario confirmed those findings to the author.

71. In view of this discussion concerning Ontario, it might be thought that Chart 6-3 for Quebec should also be compared with Chart 6-2 estimated for the non-ODB sector of the Ontario market. In this case, for Ontario instead of "lowest price in formulary to patentee price" the appropriate ratio is, "licensee price in formulary to patentee price," where, of course, the licensee is that which provided data on the cost to the pharmacist of the drugs in Charts 6-2 and 6-3. The latter ratio averages for the eight drugs in Chart 6-2, 33.1 percent for Ontario and 38.6 percent in Quebec (as shown in Chart 6-3). The former ratio averages for the eight drugs in Chart 6-2 for Ontario is 20.1 (as shown in Chart 6-2). Since the "cost to pharmacist to patentee price" was very

similar in both Quebec and Ontario for the eight drugs, it

would appear that the intra-marginal mark-up is larger in Quebec compared with either the ODB or non-ODB market in Ontario.

72. Only two such estimates are available. The Department of Industry, Trade and Commerce in a discussion paper on the health care products sector makes the following statement:

> While the 1969 amendment has brought about some moderation of prescription drug prices, it has been estimated that the overall reduction has been only of the order of five percent at the manufacturer's level since less than 20 percent of prescription drug sales have been involved. It would appear that the market for most pharmaceuticals sold in Canada has not been large enough to encourage potential licenses to enter the business. (Canada, Department of Industry, Trade and Commerce, 1980, p. 13).

Neverthelss, despite the presence of several background papers, no further discussion of the derivation of the estimate is presented. Somewhat more baldly the following statement is made without any supporting documentation by a recent task force report,

> Although the original intention of Section 41 was to reduce the cost of pharmaceuticals to the consumer, in fact, the overall saving is less than one dollar per capita per year at the manufacturer's level. (Canada, Task Force on Biotechnology, 1981, p. 27).

CHAPTER VII

1. See PMAC (1976a, 1976b, Nov. 1977, 1977, 1978a, 1978b) as well as Garton (1978). These briefs were principally made in response to the federal governments's Working Paper on Patent Law Revision. (See Canada, Department of Consumer and Corporate Affairs, 1976). See Gorecki and Henderson (1981) for a discussion of the PMAC position and that of the Department of Industry, Trade and Commerce.

2. For full details see Chase Manhattan Bank (1977a, 1977b).

3. Based on the same sources as Table 7-1 below.

4. This assumes, of course, that there are no other factors that would have influenced the balance of trade for these commodities.

5. It could be argued that a more appropriate test of the impact of compulsory licensing is upon Pharmaceuticals and Medicines (i.e., industry 374) as a whole rather than just prescription drugs. This is the position of the patentees, as expressed through their trade asociation, the PMAC. The general arguments in the text as to the trend in the import/export ratio apply equally well to Pharmaceuticals and Medicines, while those concerning the effect of compulsory licensing also refer to the small number of licensed human non-prescription and veterinary drugs discussed in Chapter III, section 3.2.2 above. The average import/export ratio for Pharmaceuticals and Medicines for periods comparable to those in Table 7-1, is as follows:

Period	Average of Import/Export Ratio
1964-1968	2.24
1969-1977	2.69

Source: PMAC (1976b, p. 15; 1979, Appendix 7, p. 2).

Hence, it would appear that the general forces impacting on the Pharmaceuticals and Medicines industry have resulted in an increase in imports vis à vis exports. However, although the increase in the ratio seems relatively small, the difference in the average over the two periods is statistically significant at the .01 level, the t-value being 3.59.

6. See, for example, Britton and Gilmour (1978) and Palda (1979).

7. See, for example, Canada, Ministry of State, Science and Technology (1978b, p. 17).

8. OECD (1977, p. 81).

9. OECD (1977, pp. 80-81).

10. OECD (1977, p. 82).

11. See Schwartzman (1976, pp. 136-161) and Clymer (1975).

12. See Grabowski et al. (1978).

13. See Grabowski (1976, pp. 44-48).

14. Scrip (1979) and Canada, Department of Industry, Trade and Commerce (1979b, p. 19).

15. See Taylor and Silberston (1973, pp. 231-266) for the results of a survey evaluating the effects of patent protection for the U.K. drug industry.

16. Scrip (1979) also makes the same point.

17. GNE is a commonly used price index to deflate R & D (see for example, Mansfield, 1980) while the industry selling price index for industry 374 would seem most appropriate for industry sales. These two indices recorded substantially different gains. Setting each to 100 in 1963 (based on price indices expressed in terms of 1971 dollars), by 1976 GNE had reached 214.4, the industry selling price index for industry 374, 139.3.

18. See Canada, Ministry of State, Science and Technology (1978a, Table 2, p. 6).

19. See Economic Council of Canada (1979b, pp. 119-120) for the terms of reference.

20. Other things may not be equal. In particular, the average time to approve a new drug (i.e., issue a Notice of Compliance) differs considerably between the U.S. and Canada for those fourteen drugs. (16 months in Canada as opposed to 23 in the U.S.). (See, for details, U.S., Comptroller General, 1980, p. 7). However, since Canada accepts clinical and other tests done in the U.S. this difference may reflect no more than the fact once a certain stage in the approval process has been started in the U.S., the procedure is then started in Canada.

21. See, for example, Wardell (1978). On the issue of U.S.-discovered drugs often being introduced first in the U.K. see Grabowski (1980, Table 6, p. 20, and pp. 19, 21).

22. See, for example, Chapter I, section 1.2.5 above and OECD (1977, p. 52).

23. See, OECD (1977, p. 52) and Teeling-Smith (1975).

24. Economist (1980).

25. See Chapter 3, section 3.2.2 above for a discussion of ethical prescription and non-prescription drugs.

26. The industry selling price index for Ethical Preparations for Human Use is taken from various issues of Canada, Statistics Canada, Industry Price Indexes, Cat. No. 62-011, a monthly publication. The price change data in the text for Ontario comparisons refer to the second part of 1974 (Sept.-Dec.) and 1980 (July-Dec.). Hence the price index for Oct. was selected. However, published data was only available up to Oct. 1979. It was therefore assumed that the rate of increase between Oct. 1979 and Oct. 1980 was the same as between Oct. 1978 and Oct. 1979.

27. This was based on the same sources as mentioned in the previous footnote. The years 1978/79 and 1980/81 varied, but usually started July 1. The price changes for the index were based upon Oct, 1978 and 1980. The same approximations as used in the previous footnote were used to generate Oct. 1980 level of prices.

28. See Lang (1974) and Abel-Smith and Grandjeat (1978, p. 45) for details.

29. See, for example, Gagnon and Jang (1979).

30. See U.S., Federal Trade Commission (1979, p. 7).

31. See Chapter I, section 1.4 above, for a brief account of the various provincial government reimbursement programmes.

32. These percentages were based upon information made available by federal and provincial officials through the QUAD programme. Unfortunately administrative and prescription costs were available only for British Columbia, Manitoba, New Brunswick, Ontario and Saskatchewan. It should be noted that it did not appear a common definition of administrative costs was used by these provinces.

CHAPTER VIII

1. These were the only provincial retail markets studied in any detail in Chapter VI, above.

2. These modifications included measures for speeding up the process by which a licence is granted and codifying into law the 4 percent royalty that the Commissioner of Patents had set in issuing licences. See Canada, Department of Consumer and Corporate Affairs (1976, pp. 250-251) for details. No evaluation of compulsory licensing was presented by the department.

3. This position was adopted by the CDMA (1978, 1979) which, as mentioned in Chapter IV, section 4.2 above represents several Canadian owned licensees. The CDMA with respect to compulsory licensing suggested that the status quo remain unchanged, but specific incentives be given to encourage R & D expenditures on new drug innovation in Canada. Although the CDMA does not specify in great detail the nature of these incentives the overall thrust is apparent from the following:

> It would make good sense for the Commissioner of Patents to delay the issuance of compulsory licenses or increase royalties for those drugs which were DISCOVERED predominantly in CANADA by multinationals or a Canadian-owned company. We see, however, no reason to offer added economic

> protection to those companies which are NOT INTERESTED to do R & D here. After all, the costs of developing and launching pharmaceuticals are being amortized in every country of the world, why should Canada carry an excessive and burdensome load? (CDMA, 1979, pp. 8-9).

A somewhat similar position was taken by the Harley Committee (1967, p. 28). Two points can be made concerning the CDA position. First, it is not clear why special incentives should encourage R & D expenditure in Canada on drug innovation. Chapter VII above, suggests that there are very good reasons for the present location of R & D, such as scale economies in drug innovation. Second, if the criteria by which the Commissioner of Patents awards periods of exclusive right to work the patent to the patentee are not specified clearly in the legislation, such that for a given set of facts the period of exclusivity can be predicted with a reasonable degree of certainty, then the potential for expensive and extensive litigation in front of both the Commissioner and, possibly, the courts, arises. These criteria include the need to identify the total amount of the R & D which led to the development of the drug and what proportion of the outlay was conducted in Canada. Such information is in the possession of the patentee not the federal government or the licensee. Since the licensees tend to be smaller sized firms, as detailed in Chapter IV, court costs could impose a potential barrier to the application for compulsory licences. However, if the Commissioners' decisions under section 41(4), discussed in Chapter II, section 2.5 above, are any guide to the future, then CDMA inspired legislation, even if ambiguous in the criteria, would not necessarily result in long and costly legal arguments. Hence, the danger may be more apparent than real.

4. The PMAC view is as follows:

> 1) an amendment to the Patent Act to allow a ten-year period of exclusivity for a pharmaceutical product before a compulsory licence to import would be granted. This period would commence on the date that the HPB [Health Protection Branch] issued a Notice of Compliance;
>
> 2) at the end of this ten-year period, compulsory licences could be granted as a matter of right;

3) a compulsory licence to manufacture the pharmaceutical chemical in Canada could be granted at any time;

4) a licence to import could be granted in the case of patent abuse under Section 67 (PMAC, 1979, Appendix 6, p. 6, emphasis in original).

It should be noted, however, that the PMAC would not have made their recommendations retroactive, hence existing licences to import would not be revoked if these four proposals were incorporated in the Patent Act. The only differences between the PMAC position and the law as it stood prior to 1969, apart from the "grandfather" clause implied by the lack of retroactiveness, are minor. For example, while item 1) refers to a 10 year period of exclusivity, this should not be construed as reducing the effective length of time for which a patent is valid from the customary 17 years to 10. There is usually a period of about 3 years (CDMA, 1979, p. 2) between the granting of a patent by the Commissioner of Patents and the issuing of a Notice of Compliance, which entitles the patentee to legally sell the drug in Canada, by the Health Protection Branch of the Department of National Health and Welfare. Hence the reduction is more in the order of from 17 to 13 years. It is assumed that the PMAC position means that patentable improvements to the drugs made subsequent to the issuance of the Notice of Compliance would be included in any compulsory licences to import issued at the end of the 10 year period of exclusivity. If this is not the case then the period of patent protection could easily and substantially exceed 10 years. The Canadian Drug Manufacturers Association made the point, as follows, in the context of re-introducing full 17 year patent protection,

> Most drugs are covered not by one patent but by numerous subsequent patents which appeared years later. Therefore, if the 17 years of patent protection is re-introduced, a drug product could be protected for a much longer period of time by the addition of new patents, unless the competitor wishes to go to the courts and challenge the validity of the patents. For example, a product like Methyldopa has approximately 13 different patents. The first one was issued April 7, 1959, while the last one issued was on October 29, 1968 and expires in 1985. Therefore, the product has a potential patent protection of 26 years (CDMA, 1978, p. 9).

The PMAC view is discussed in Gorecki and Henderson (1981).

5. See Canada, Task Force on Biotechnology (1981, p. 6, 26-27, 32-33). The views of this task force are discussed in Chapter VI, section 6.4.8 especially footnote 71 and Chapter VII, section 7.3, above.

6. This conflicts with the suggestions, noted above, of several groups concerning section 41(4). Each of these briefs and reports was examined critically, together with supporting material (see last three footnotes for details). In not one instance was a pursuasive case made in favour of changing section 41(4).

7. See Canadian Pharmaceutical Association (1966, p. 58).

8. See, for example, Canadian Pharmaceutical Association (1980) Downie Committee (1970, pp. 221-25), Fevang (1980) and Comité Hould (1980, pp. 201-08). The emphasis on such services reflects, in part, the virtual disappearance of the traditional function of the pharmacist, compounding medications, which are now supplied or manufactured by the drug firms. See Chapter I, section 1.2.4 above for details.

9. These are somewhat stylized but nevertheless useful for exposition purposes.

10. One of the major issues in the recent review of health care system by Special Commissioner E.M. Hall was that of compensating physicians within the framework of a government operated insurance system. For details see Hall (1980).

11. For example, the recently completed negotiations over a new dispensing fee and related matters in Ontario have taken two years to complete. One agreement between the Ontario Pharmacists Association and Ministry of Health was rejected by the provincial pharmacists in a referendum in 1980.

12. Recent studies in Quebec suggest the need for such monitoring. The results are summarized as follows by Comité Hould (1980, p. 151, translated from original)

> Finally, the study by the School of Pharmacy [at Université Laval] examined the detection and prevention of possible side effects of a medicinal treatment. It was found that when the survey-taker presented a prescription for two medicines that, when taken simultaneously, could have serious side effects (tranylcypromine and a decongestant), 78.8 percent of the pharmacists visited failed to detect the interaction or, at the least, made no attempt to prevent it. When the survey-taker obtained a prescribed medicine liable to have a dangerous interaction

> with another product prescribed a week earlier and purchased at the same pharmacy, 95.7 per cent of the pharmacists failed to detect the interaction (or to attempt to prevent it).

13. The Comité Hould (1980) results indicate the need for such surveys. It should be noted these were confined to Quebec and do not necessarily apply to all of Canada.

14. See Fielding et al. (forthcoming, 1981) for details.

15. Restrictions vary from province to province. The following summary was prepared by the Consumer Research Branch of the federal Department of Consumer and Corporate Affairs in 1979. I should like to thank T.K. Gussman for permission to reprint it here.

> In summary, Quebec expressly permits the activity, while four provinces, Alberta, Saskatchewan, Manitoba, and Ontario, which prohibit other forms of disclosure, do not appear to prohibit telephone disclosures, British Columbia, New Brunswick, Newfoundland, Nova Scotia, Prince Edward Island, and the Territories appear to have no specific prohibitions on telephone disclosure.
>
> Posters are mandatory in Quebec and allowed in British Columbia and Ontario. Posters are prohibited in Alberta, Manitoba, and Saskatchewan, and do not appear to be prohibited in the remaining four provinces and two Territories.
>
> Printed price lists, while apparently not prohibited in New Brunswick, Newfoundland, Nova Scotia, Prince Edward Island and the Territories, are not allowed in the remaining six provinces.
>
> Media advertising, only of the fact that a pharmacy posts prices, is allowable in British Columbia. Media advertising is not allowed in Alberta, Manitoba, Ontario, Quebec, and Sackatchewan. The remaining four provinces and Territories do not appear to have specific prohibitions.
>
> This information was drawn from the latest available regulations, by-laws, and professional codes of ethics available at the time of writing. It is possible that subsequent amendments could have altered some of the information.

It should be noted that although price posting is allowed in some provinces the detailed rules and regulations have the effect of making such price posting uneconomic. For example,

in Ontario the regulations specify that price information should be made available on not less than 25 drugs, but there shall be at least 15 included in a series of 20 pharmacologic-therapeutic categories, many of which have very small drug sales (See Chapter III, Table 3-1 above for details).

16. See Benham (1972), Bond et. al. (1980) and Feldman and Begun (1978).

17. See Cady (1975, 1976) for the U.S. and for Canada, Muzundo and Pazderka (1980, Table 6.13, p. 127).

18. See, in particular, Bond et. al. (1980) and Cady (1975).

19. See also Tidball (1980, p. 163).

20. This agrees with the view of the Quebec, Office des Professions (1978, esp. pp. 54-73).

21. This is consistent with the view of Evans (1980, p. 226. 234-35, 262). The Bailey Committee (1978, p. 15) made a similar proposal to recommendation 4.

22. See Tidball (1980, p. 316) and Ontario, Standing Committee on Public Accounts (1980, p. 37).

23. This can be illustrated with respect to Ontario for one section of the reputation. Suppose all Ontario senior citizens were to receive a grant equal to the modal expenditure for senior citizens on drugs, defined to include both ingredient cost and dispensing fee, plus (say) 10 percent, with prompt payment over this amount. In 1979-80 ODB costs for senior citizens for the provincial government were $105 million. The number of beneficiaries were 800,000. Although the modal payment is not available, the average implied by these figures is $131.25 per capita. (For details see Ontario, Minister of Treasury and Economics, 1980, Table 3, p. 5).

24. Under the Saskatchewan, Prescription Drug Plan the pharmacist receives a dispensing fee for each prescription and in addition is reimbursed for the cost of the drug dispensed. The patient pays a prescription charge (co-payment) for each prescription. For example, at present the maximum dispensing fee is $3.70 per prescription. The maximum prescription charge is $2.80. A patient receiving a prescription pays the pharmacist the prescription charge and the pharmacist submits a claim to the Drug Plan for a 90¢ dispensing fee subsidy and for the cost of the drug material dispensed. The maximum dispensing fee is negotiated with the Saskatchewan Pharmaceutical Association; the maximum prescription charge is set by government policy. Pharmacies are permitted to charge less than the maximum prescription charge. In fact, as of

March 31, 1980, 110 out of 340 pharmacy outlets discounted the prescription charge, with some charging as low as 95¢ per prescription. The competitive influences on the market result in substantial savings accruing to the consumer. In addition to the above discounts, most Saskatchewan pharmacies offer a courtesy discount (usually 10%) to senior citizens. (This information was provided by officials of the Saskatchewan drug plan).

25. For details see Canada, Bureau of Competition Policy (1976, pp. 60-64).

26. See Trebilcock et al. (1979), Ontario, Professional Organizations Committee (1980), and Quebec, Office des Professions (1978). Note these first two reports do not refer to pharmacists but nevertheless their recommendation (i.e., greater competition through price disclosure) seem equally applicable to pharmacists.

27. See, for example, U.S., Federal Trade Commission (1975, pp. 321-473).

28. For details see footnote 15, above for details of existing legislation.

29. See Cady (1975, 1976).

30. In Ontario the Baily Committee (1978, p. 15) suggests 10 to 20 percent. However, in the case of Ontario and Quebec the mark-ups on multisource drugs are, as demonstrated above in Chapter VI, sections 6.4.5 and 6.4.6 above are considerably above this.

31. It should be noted that it is argued by some pharmacists that the dispensing fee is lower than it otherwise would be in some provinces because of the presence of such mark-ups. Although no systematic study was undertaken of this, of the four provinces studied in Chapter VI their dispensing fees as of May 1981 were as follows: British Columbia, $4.60; Ontario $3.90; Quebec, $3.00; and Saskatchewan $4.05. (These prices were given by the officials of the various provinces to the author. In all instances they refer to maximums with some discounting in some provinces. In B.C. the $4.60 represents the 15 percent markup over an average of $3.97-$4.01). The two provinces where the intra-marginal rents or markups would appear to be the most significant (Ontario and Quebec) do indeed have lower dispensing fees particularly Quebec. Nevertheless the Ontario and Saskatchewan fees are very close together despite the SOC system in the latter province. Hence there is not a very strong relationship between dispensing fees and the presence of mark-ups, especially given the difference between Quebec and Ontario of 90¢

32. These comments are based upon Lalonde (1973), Oliver (1980) and Quebec. Chamber of Commerce (1975, pp. 25-28). The Department of National Health and Welfare is presently conducting a study into the use and misuse of non-prescription drugs. (For details, see Oliver). One example of confining non-prescription drugs to pharmacy only sale is the schedule C regulations in Ontario which led to the purple sticker system.

33. On the evidence concerning economies of scale see Cady (1975, p. 125) who finds scale economies in the U.S. in pharmacy operation, while the Saskatchewan Prescription Drug Plan acknowledges this by permitting a lower dispensing fee after a given number of prescriptions have been filled by a pharmacy. (See Saskatchewan, Department of Health 1978, p. 8). See also Evans and Williamson (1978, p. 69). Concerning restrictions on ownership details on the four provinces studied in Chapter VI are as follows: British Columbia allows non-pharmacists to own a pharmacy but the majority of directors must be pharmacists. (See section 18 of the B.C. Pharmacists Act). Thus, chain pharmacies can and do exist; in Ontario under section 141(4) of the Health Disciplines Act only pharmacists may own and control pharmacies, although non-pharmacists may take a minority position. However, a grandfather clause, 141(4), allows pre-1954 pharmacy charters to be owned by non-pharmacists. It is this which accounts for the operation of pharmacies in department or other stores in Ontario. Apparently the charters trade for money, which suggests some liberalization is called for in Ontario. Nevertheless, in 1977, 66.1 percent of all pharmacists were classified as "independent" in Ontario. (B.C. had a similar system to Ontario but the 1974 changes, now in force, abolished such charters); in Quebec, only a pharmacist may own a pharmacy. There is no limit placed on the number of pharmacies that can be owned by an individual pharmacist except, that on his death the pharmacies must, within three years, come under the ownership of a pharmacist(s). (See Quebec, Pharmacy Act, sections 27 to 30); in Saskatchewan the situation is somewhat similar to Ontario, except instead of 1954 charters being "grandfathered" the date is 1936. (For details see Saskatchewan, Pharmacy Act, sections 61 to 64). In all instances the above interpretation was discussed with officials in each of the provinces concerned. Note that the provincial Acts and regulations referred to were those in force in 1980.

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GLOSSARY

AFQPP	Association des Fabricants du Québec de Produits Pharmaceutiques
Bailey Committee	Ontario Drug Benefit Formulary Pricing Committee
Banks Committee	U.K. Committee to Examine the Patent System and Patent Law
CDMA	Canadian Drug Manufacturers Association
Comité Hould	Quebec. Comité sur la Rémuneration des Professionels de la Santé du Québec
Downie Committee	Ontario. Committee on the Healing Arts
Ferguson Committee	Ontario. Task Force on PARCOST Review
Hall Commission	Canada. Royal Commission on Health Services
Harley Committee	Canada. Special Committee of the House of Commons on Drug Costs and Prices
HPI	Hospital Purchasing Incorporated
Ilsley Commission	Canada. Royal Commission on Patents Copyright and Industrial Design
IMS	Intercontinental Medical Statistics
Klass Committee	Manitoba. Advisory Committee on Central Drug Purchasing and Distribution
licensee	a firm that has taken out a compulsory license(s) under the Patent Act
Macdonald Commission	Commission on Pharmaceutical Services

ODB	Ontario Drug Benefit Programme
OECD	Organization for Economic Co-operation and Development
patentee	a firm that owns a patent(s) for which a compulsory licensee has been issued by the Commissioner of Patents
PMAC	Pharmaceutical Manufacturers Association of Canada
QUAD	Drug Quality Assurance Programme of the Department of National Health and Welfare
RTPC	Restrictive Trade Practices Commission
SOC	Standing Offer Contract