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A Review of the Pharmaceutical Industry of Canada

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Abstract

This paper discusses three important aspects of the Canadian pharmaceutical industry-viz. compulsory licence, price control on patented drugs and the R&D scenario. Unlike other developed countries, which have adopted the route of providing higher Intellectual Property Rights (IPR) protection to promote the growth of the domestic pharmaceutical industry, Canada chose to limit the IPRs on important pharmaceutical products. Till early 1990s, Canada stood alone among the developed countries in using CL for pharmaceutical patents held in Canada, which helped the promotion of domestic generic industry. However, it had not resulted in active price competition since, in Canada, price of the generic product is generally fixed at 70 per cent of the branded drug and all the prices of the subsequent generics are also invariably fixed at this level. Prices of the patented products are controlled and monitored by the Patented Medicines Prices Review Board. Besides analysing the patented products, this agency also gives a detailed account of the R&D carried out in Canada. R&D in Canada is dominated by the multinationals, which have been investing 10 per cent of their sales revenue. However a sizeable amount is invested towards applied research rather than basic research, which is, reflected in the number of real breakthrough drugs that appeared in the market. Interestingly, though the pharmaceutical industry of India and Canada share a few common points of comparison, the most important point of divergence between Canada and India is that while the Indian pharmaceutical industry is supported by a well-established homegrown fine chemical industry, Canada lacks this advantage.

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1. Introduction

Among the various intellectual property rights system, patents concerning the pharmaceutical innovations are the widely and passionately debated issue all over the world for their positive and negative impact on welfare of the people. A patent on a drug effectively postpones all or some of the social benefits associated with an invention. Patents in pharmaceuticals has been heavily argued against on the grounds that it prevents spread of knowledge and scientific advances and more importantly tries to cash on from the diseases people suffer. These arguments stem from the fact that pharmaceutical patents create conflicts because of the public good nature of the product created by private with profit intentions. In the knowledge based pharmaceutical industry, while new inventions are difficult to arrive at and costly, technological advancements made in the information technology and the information provided in the patent applications makes it relatively cheaper to imitate the innovation. This often results in eroding the profit made by the first innovator while the subsequent `innovation' benefits from not having to invest in research and development (R&D) and other developmental costs related with the development of a drug. Hence, to minimize the loss over the intellectual creation of the first innovator, intellectual property rights (IPRs) have been created. Thus, industrially developed countries with a strong R&D protected their pharmaceutical innovations by choosing to protect the `product', countries which did not have a strong industrial base chose either to ignore property protection for pharmaceutical innovations or provided limited protection (protecting the process of such innovations), which paves way for further innovations around the original innovation. More importantly, while product patents result in a temporary monopoly, process patents create a competitive situation and particularly in pharmaceutical industry such competition results in reduction in prices.

Unlike other consumer goods, prices of medicines are inelastic in nature in the sense, rise or fall in the price of medicine is not going to significantly alter the demand for a medicine because often people go by what they have been prescribed. Exception to this however is the fact that in government programmes such as AIDS control, significant reduction in the price of the drug would lead to more number of patients brought under the programme coverage.

Many developed and developing countries also had the provision to issue compulsory license (CL) in pharmaceuticals to make it accessible, affordable or to introduce price competition. CL refers to the act of government conferring the right to produce a medicine to a third party. US and Canada are the two countries, which have used the CL maximum number of times. Though the US is against any country using the CL and the drug cartel of the US is against the issuance of the CL, ` the US's own patent legislation is far more liberal than that which it is trying to impose on developing countries. Under the US law, if the government wants to use a patent, it can do so without the need for a CL and without negotiating with the patent holder. The patent holder can ask for compensation but has no other rights. In addition, the Bahy Dole Act gives the government wide ranging powers to issue CL' (Scrip's Year Book, 2000, Vol. 1. P165). The German patent law has provided that CL could be issued in the interest of public, while the Brazilian patent law allows for CL in cases of insufficient working of the patent. Canada has used the CL in the pharmaceutical sector to introduce price competition. In the pharmaceutical context, Canada became a model for other countries to adopt the route of CL, which played a significant role in promoting generics.

In this paper, a review of the pharmaceutical industry of Canada is made, where in section 2 following this introduction the role of compulsory licensing in the Canadian pharmaceutical industry is detailed. In Section 3, the method of controlling the price of patented drugs is discussed and Section 4 discusses the R&D scenario in Canada. Section 5 briefly compares and contrasts the Canadian pharmaceutical industry with that of a developing country's experience such that of India. Section 6 presents the conclusions.

2. Compulsory Licensing and the Pharmaceutical Industry of Canada

Before we actually describe the pharmaceutical industry scenario, a few points on health care in Canada would be ideal. According to the OECD statistics of 2004, Canada has a total population of 3.16 crore. Of this 18.3, 68.9, 12.8 percent of the population is in the age group of under 15, 15-64 and over 65 respectively. As per the Human Development Report of 2002, Canada ranks 3 in terms of human development index. Canada is the only country in the OECD group that outlaws privately funded purchases of core health services. Governments do not own most of the hospitals in Canada. Most of them are private owned but function as not for profit institutions. Canada has a small number of physicians. It has 2.1 doctors per 1000 people (interestingly this figure has not changed between 1992 and 2002). Health care spending in Canada is expected to be $121.4 billion or more than $3, 800 per person, which is 10 per cent of its GDP. Pharmaceutical expenditure as percentage of total expenditure on health accounted for 16 per cent in 2002 (Table 1). The epidemiological data show that the four major diseases, which the people of Canada suffer from are hypertension, diabetes, depression and respiratory diseases (Table 2). As far as the Canadian pharmaceutical industry is concerned, it constitutes 2 per cent of the world market (Lexchin, 2003).

Three points of time are important for the pharmaceutical industry of Canada. 1. Late 1800s – 1969, 1969-1993 and the time since 1994. A highlight of these periods is made in the following paragraphs. The origin of the pharmaceutical industry in Canada dates back to 1870s. The period between the World wars saw the emergence of the pharmaceutical sector in Canada boosted by the introduction of sulpha and penicillin drugs. The policy of the government then was to attract foreign investment, promote R&D, competition and employment in Canada by and large through the tariff route. The tariff policy was framed in such a way that units set up by multinationals for products where there were no alternatives, attracted lower tariff and higher tariff was levied if there were many alternatives. This resulted in lot of investment particularly from the US, who first set up their sales subsidiaries and once the market picked up manufacturing facilities were set up. Setting up of sales subsidiaries was found to be attractive because the market and the standard of living of people were similar to that of the US. Table 3 presents the details of the composition of pharmaceutical

industry in 1969. Interestingly, this table reports that at this point of time, the percentage of pharmaceutical units under domestic control was 57 and those under foreign control was 43. Nevertheless, the number of production workers, wages, total employees and the value added from manufacturing were more in the foreign controlled firms. Here again, the US controlled firms were more than the European controlled firms. Gordon and Fowler (1981) observe that because of the multinationals presence, Canadians enjoyed products of the same quality at comparable prices, but it did not result in reducing the import of fine chemicals. The high technology based manufacture of the fine chemicals remained abroad. They also observe that the secondary manufacturing operations carried out in the Canadian industry was quite inefficient and the methods of production were widely known in Canada even before the presence of the multinationals. However, the basic chemicals, which are the backbone of pharmaceutical industry, were limited in their presence. Many of the fine chemicals even now come from Ireland and Puerto Rico. Both these places have attracted a great deal of pharmaceutical manufacturing because of strong tax incentives provided for companies to set up units in those places. Perhaps this factor contributes to the negative balance of pharmaceutical trade of Canada. For instance, the data show that while exports of pharmaceuticals increased from $1.58 billion in 1998 to $1.81 billion in 2000, imports increased from $4.15 billion to $5.88 billion. Table 4 shows the import penetration in the domestic pharmaceutical market of Canada, which has increased from 0.55 per cent in 1983 to 6.1 percent in 2000.

One of the efforts taken in the early years (1923) to strengthen the domestic industry and promote price competition was the decision to introduce compulsory licensing (CL). CL refers to the act of a third party obtaining license to produce a patented product through the intervention of the government. Unlike other developed countries, which have adopted the route of providing higher IPR protection to promote the growth of the domestic pharmaceutical industry, Canada chose to limit the IPRs on important imported pharmaceutical products. However, the policy that the compulsory license had to be obtained on the products that were manufactured in Canada, did not help in increasing the competition and lower the prices. During the ‘60s, there was a review of prices of pharmaceutical product took place in the US, Canada, UK and India and perhaps in other countries also. Harley committee, which reviewed the prices in Canada, concluded that the prices prevailing were very high and emphasized the need to introduce price competition through more number of firms operating in the

market. The then prevailing CL practices were reviewed and a decision to amend the CL law to make it applicable on imported products was taken in 1969.

2.1 The Period Beginning 1969

The decision to adopt CL on imported products started benefiting the domestic industry and a turnaround occurred for the generic producers. Licensees at this point of time tend to be smaller Canadian owned firms who imported the bulk raw material and manufactured the final drug in Canada. Between 1970 and 1983, 181 CL were taken against 58 drugs by 30 firms. In 1983, 66 licenses were worked which the firms sold in their brand name. Under CL, the licensee had to establish the bioequivalance and conduct purity tests alone, which means that the generic producers save on the enormous sunk cost of R&D and the expensive clinical trials. Two domestic companies Novopharm and Apotex became very strong in the field of producing generic drugs. Between the 70s and 80s, Apotex got 16 licenses out of 181 licenses and worked 13 of them. Importantly, after obtaining CL, the generic versions of the drugs were introduced within a period of 2 or 3 years. Drugs using CL were brought out in the category of central nervous system, cardiovascular drugs and gastrointestinal category. Soon the local generic manufacturers made available ampicilin and diapezem. Generic products also entered those areas of branded drugs, which had strong sales.

Till early 1990s, Canada stood alone among the developed countries in using CL for pharmaceutical patents held in Canada. At this time, though the domestic Canadian industry was still emerging, the role of the multinationals in pharmaceutical innovations was high as evident from the number of patents granted to Canadians and others in Canada (Table 5). Her trading partners France, Germany, Sweden, Switzerland, the United Kingdom and the United States however did not favour CL and discouraged R&D expenditures in Canada. The Canada-United States Free Trade Agreement lead to the first modification of compulsory licensing in 1987, through the Bill C 22[1]. As per this amendment, protection from compulsory licensing was accorded to companies introducing

[1] The Conservatives' commitment to free trade deal with the United States brought in immense pressure from the US government through the Pharmaceutical Manufacturers Association of Canada (consisting of MNCs and their subsidiaries) to remove the compulsory licensing system from the Canadian patent law.

new drugs for a minimum period of seven years. However, in order to get the CL after seven years, the company receiving the license would have to manufacture the necessary fine chemicals within Canada. If the chemicals were imported (as was the case with most drugs) then such drugs can be produced only after ten years of protection. Lexchin (2003) observes that prior to Bill C 22, generics were coming into market at regular intervals, however after this amendment there was a prolonged delay by more than 7 years. Finally when the generics appeared in the market, sales of the brand name drugs were already on the decline making no effective difference for the generic products. However, the pressure on Canada by her trading partners continued to increase through the NAFTA first and later through the TRIPS Agreement to increase the patent term to 20 years and abolish CL. Canada remained on the US's `super 301' watch list because of compulsory licensing. Besides, the internal pressure from the Pharmaceutical Manufacturers Association of Canada (PMAC, comprising of multinationals and their subsidiaries) to do away with any form of compulsory licensing was also mounting on the government of Canada. The US pharmaceutical manufacturers association commented that Canada's patent protection was no better than the protection offered by many third world countries. All these pressures resulted in passing the Bill C 91, which lead to the abolition of CL. In return for withdrawing CL, PMAC committed on an investment of 10 percent of its sales in R&D and a $400 million in new investments. In order to safeguard the interest of consumers against unduly raise in the prices of patented products, Bill C 22 also created the Patented Medicines Prices Review Board. This bill also introduced the system of notice of compliance regulation, which is discussed later. In 1994, Canada also adopted the TRIPS Agreement and therefore committed to protect the products in the pharmaceutical sector.

In 2003, Canadian government approved Bill C 56, now known as bill C 9 to amend the Patent Act and the Food and Drugs Act. This amendment would allow limited CL of drug, enabling generic manufacturers to produce and export patented medicines to those developing countries which do not have sufficient domestic manufacturing capabilities as deemed by the WTO. This bill also specifies the countries that are eligible to apply for the import of Canadian generics and also specifies the range of pharmaceuticals that are eligible for patent exemption. Though this measure at the first glance looks like it would benefit the generic industry, there is a clause, which will rule against the generic industry. This clause says that the right of first refusal is with the patent holder. In

other words, a brand name company (patent holder) has the right to take over a contract, that a generic producer has already negotiated with a developing nation and block the CL. This controversial aspect `right of first refusal' was however eliminated when the final version of the bill was passed.

2.2 Impact of CL

Several studies have looked at the impact of CL on Canadian pharmaceutical prices and competition. Eastman committee observed that CL saved a $211 million for Canadians out of a total drug bill of $1.6 billion in 1983 without affecting the profitability of the multinational drug companies. However, Gordon and fowler (1981) observe that CL did not result in flood of competition among different drugs and a widespread fall in prices. This is because, the entry of new firms had to compete with an established brand names. Secondly, a source of supply for the fine chemical ingredients had to be found. Finally, federal and provincial approval of the new facilities and of each product had to be obtained, which required paper work and resulted in time over run.

Lexchin (1997) analysing the impact of withdrawing of CL and introducing longer patent term on pharmaceutical industry of Canada, argues that the domestic industry got a fillip after the CL was made applicable on imported products too. He points out while the introduction of generic drugs lead to the saving of about $211million to the Canadian public, the multinationals lost only 3.1 per cent of their market. He also showed that as the number of suppliers of a drug increased, price of the drug as compared to the expensive brand decreased (Table 6).

In a country like Canada where government plays a prominent role in providing health care, promotion of generics depends on the selection of drugs and pricing policy adopted by the provinces in the selection of drugs. From this context, CL did not quite promote generics because the prescription practices of the physicians did not change towards prescribing generics and the `don't substitute' prescriptions actually discouraged promotion of generics[2]. Table 7 presents

[2] In 1962, Alberta was the first province to allow a pharmacist to substitute a generic or brand equivalent written in the prescription. The Swiss multinational CIBA unsuccessfully challenged the legislation in the court.

interesting information on the use of brand and generic drugs in different provinces where the Quebec region tops the list with the highest percentage of brand drugs use.

Generally in Canada, price of the generic product is fixed at 70 per cent of the branded drug and prices of the subsequent generics are also invariably fixed at 90 per cent of the first generic. Hollis's study (2002) observes that since the price fixation policy of the provinces have a set level of prices for different therapeutical products, generics charging a higher price than this price do not get selected for the provincial formulary. Hence under this reference pricing system, role of price competition is very less. Further, only the first generic entrant gets roughly 30 percent of the branded drugs' market and subsequent entrants get less and less share due to the following reasons. First, pharmacists try to sell the first entrants generic products. Otherwise they have to explain the bio-equivalence of the different generic products with that of the branded products to make the consumer switch from one product to the other. Hence, getting a market share for the subsequent entrant becomes extremely difficult. The second aspect is that though both the brand and the generic producer give incentives to the pharmacist for increasing the volume sales of a particular drug, the different generic producers within a therapeutical group have to compete with each other. Also to minimize the cost of inventory, the pharmacists do not keep many generic drugs. Thus Hollis observes that the prevailing pricing practices do not result in generating adequate price competition. In 1999, generics formed 40.6 per cent of the prescriptions but only 16 per cent of the sales at drug stores (Hollis, 2002) which points to the fact that prices of the generics are substantially lower than branded drugs. On the other hand, we observe that the average household expenditure on prescription drugs was increasing (Table 8). It only implies that (a) drug expenditure would be more for cash paying customers and (b) introduction of generics did not lead to a fall in the prices of branded drugs (Lexchin, 2003).

However, entry of the generic product depends on the expiry of different patents on the drug and in cases where the patent has already been extended, the generic industry has to wait till the expiry of the extension. Thus the first generic entrant has to incur higher costs both to face legal charges and to place his drug in the market along with the branded drug. Unlike the US, where legally the first generic producer is protected from competition for 180 days, no such incentives

are prevalent in Canada[3], to create niche market for the early entrant. In fact the regulations only discourage the generic entry. For instance, to get the generic product approved for sale by Health Canada, the generic producer will have to obtain a `no objection certificate' from Health Canada. In the Canadian regulatory environment it takes between 3 to 6 years to develop and obtain regulatory approval for a generic drug[4]. Further, the generic producer will have to send a `notice ' to the brand drug producer (patented drug) to the effect that none of his patents are infringed. This requirement leads to the brand name producer pre-empt the move of the generic producer. Hollis's (2004) study brings out that often since the patent holder gets to know of the generic producers strategy, he brings out his own generic version of the drug through his own subsidiary or through a third party contract which Hollis terms as `pseudo generics'. Such pseudo generics, account for 25 per cent of the prescription sales in Canada. Such practices again do not result in promoting effective post patent competition.

The Romanow committee (2002) on the Future of Health Care in Canada recommends a national formulary be developed by the national drug agency that would provide consistent coverage, objective assessment and help contain costs. The advantage of such a national formulary is that a certain percentage of drugs can be set aside to be drawn from the list of generic drugs, which will help the domestic industry. It will contain costs for cash paying consumers and the government, which faces fiscal deficit. Such a national formulary will also help the consumers, since consumers shifting base from one province to another can continue with the same drug.

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[3] In a private communication Lexchin observes that, in the US because of this rule brand-name companies do indulge in paying the first generic producer (to get approval for his product) to pursue him not to offer the product for sale in the market. This is because, since the first company has the monopoly for 180 days, no other generic producer can enter the market during this period.

[4] Canada is one country among the OECD countries with a median time of 650 days compared to 464 days of the US and 439 days of the UK which delays the introduction of generic and patented drugs. The longer time taken is attributed to the lack of resources for some of the technical work done by health Canada.

3. The Patented Medicines Prices Review Board

As mentioned earlier, the Patented Medicines Prices Review Board (PMPRB) was set up in 1987 to protect the interest of the consumers and contribute to Canadian health care by ensuring that prices charged by manufacturers for patented medicines are not excessive. This agency is unique in the sense it is set up exclusively to monitor the prices of patented drugs. Besides it also analyses the therapeutical contribution of the patented drugs and documents the pharmaceutical R&D investment in Canada. Though the data provided by this agency are rich, yet PMPRB's area of operation is restricted to the patented medicines marketed or distributed under voluntary licenses. It does not regulate the prices of generic drugs and prices charged by wholesalers or retailers. Thus, PMPRB regulates the price of each patented drug product including the strength of each dosage form of a patented medicine. Patentees will have to inform the PMPRB of the first sale of the patented product on the first and last month of every year. The price of the patented product in Canada at no time can exceed the highest price for the same drug in countries such as France, Germany, Italy, Sweden, Switzerland, the UK and the US. Sale of patented drugs accounted for 67 per cent of total sales in 2001 as compared to 43 per cent in 1990 (Table 9). Interestingly, PMPRB while fixing the price of the patented drugs classifies the drugs in to three categories. Category 1 comprises of those drugs, which are comparable with an existing medicine, or alternatively these are usually a new strength of an existing drug. Category 2 drugs are the new drugs to treat effectively a particular illness or which provides a substantial improvement over existing drug products often referred to as breakthrough or new drug. Category 3 drugs are new dosage forms of an existing medicine that provides moderate, little or no improvement over existing medicines. From 1996 to 2000, 455-patented drugs were introduced of which only 25 were the new improved drugs (Lexchin, 2003). In 2001, 24, 3, and 21 drugs belonged to category one, two and three respectively, which means that real breakthrough drugs in 2001 were just 3 drugs which implicitly indicates the R&D distortion that is taking place in the Canadian pharmaceutical industry. Nevertheless, as Table 10 shows, of the 933-patented drugs reviewed by PMPRB till 2001, 827 drugs have been within the price guidelines. In the year 2002 alone, of the 94-patented drugs introduced 48 were within guidelines and the rest are under review. This implies that the PMPRB does keep the prices of the patented drugs under control. Lexchin, (1997) observes that the prices of those drugs, which had voluntarily surrendered the

patents, were above the prices of patented medicines. Once this was brought to the notice of PMPRB, the rules were changed and now, even if companies voluntarily surrender their patents, such products still come under the scrutiny of PMPRB, until the expiry of the patents. Critically analysing at the PMPRB's methodology of comparing the prices with the prices of US, Japan, France, Germany and Switzerland, he observes that the basis of selection of these countries is not clear, since Canada's prices are indeed higher, if the prices are compared with New Zealand, Belgium type of other OECD countries. It may be added here that, since the prices of the generics is fixed at 70 per cent of the patented drugs, both generics and the patented drugs tend to be costlier in Canada.

4. Research and Development in Canada

Redwood (1994) observes that pharmaceutical R&D inevitably reflects the ground rules of public policy under which industry operates. This is because, the difference between innovative and imitative strategy is in large part a reaction to the dictates of public policy. If the system rewards imitation more than innovation either deliberately or inadvertently then imitation will flourish while innovation will not grow at all. He further observes that the `perverse signals of public policy have helped to squeeze originality out of R&D in a number of countries with strong scientific infrastructure from whom one would normally have expected pharmaceutically innovative results of a high order during the past twenty years. The notable of these are Canada and Australia where no innovative results were achieved during this period; also Italy and France where the innovative (as distinct from imitative) content of newly developed drugs was below average in relation to the magnitude of their pharmaceutical R&D expenditures '(Redwood, 1994, P.82).

Though the above quotation doesn't explicitly talk about CL of Canada, yet it can be understood that the CL policies are referred to here, which did not promote domestic R&D in Canada. Before the passage of Bill C 22, R&D spending in Canada as percentage of sales was below 5 per cent. The Eastman Committee (as quoted in Lexchin, 1993) observed that `Canada does not now possess either the scientific manpower or the physical infrastructure that would make it a major world centre for pharmaceutical research. Nor in the opinion of the

Commission, would it be wise for governments to seek to create such an environment in competition with heavily supported long established centres in other countries'. One impact of the dominance of the multinationals in Canada is that they also dominate the R&D investment, with the effect that Canada is the net importer of intellectual property. According to the Business Enterprise Expenditure in R&D, the high tech industries, medium high tech industries, medium low tech and low-tech industries and service industries accounted for 53.5 per cent, 9.1 per cent, 7.2 per cent and 26.4 per cent respectively[5] (OECD, 2004). According to the same source, basic research in Canada accounts for 16 per cent as compared to 24.5 per cent in the UK and 36 per cent in the US. In terms of innovation, the number of patents filed by resident Canadians is less than that of the patents filed by the foreigners in Canada as shown in Table 5. As far as the pharmaceutical industry is concerned, predominantly it is the multinationals, which dominate the R&D scenario of Canada. The Patented Medicines Prices Review Board is the only source of statistics on R&D expenditure in pharmaceuticals in Canada. One problem with this data is that it reports R&D expenditure of only those companies, which reported sales of any patented drugs. In other words, even if a company had invested substantial investment in R&D but not had sale of patented drugs in that year then their investment is not reported. The same is applicable for generic companies and the biotech companies that have not brought out any drugs in the market[6]. Hence, to that extent the investment in R&D could be under reported by this data. Since PMPRB came into being in 1987, we have data from 1988. In the initial years in return for the restriction and later for abolition of CL, the pharmaceutical industry promised a 10 per cent investment in R&D. Table 11 reports the R&D expenditure over the past decade. This table reports that though the number of companies reporting R&D increased only by mere 8 in number, total R&D expenditure of these companies increased from $165 mn in 1988 to $1060.1mn in 2001 registering an impressive 539 per cent. As compared to this,

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5 High tech industries are aerospace, office and computing equipment, drugs and medicines, radio, TV and communication equipment and professional goods: motor vehicles, electrical machinery, other transport, machinery and equipment constitute medium and high tech industries: rubber and plastics, nonmetallic mineral products, shipbuilding, ferrous and nonferrous metals, metal products, petroleum and other manufacturing industries constitute medium low tech and low tech industries.

6 Thanks to Lexchin for bringing notice of this point.

sales revenue increased by 295 per cent over the same period. Interestingly, R&D expenditure as percentage of sales revenue increased from 8 per cent reached a peak of 12 per cent in late 90s. But for the past few years it is stagnating at 10 per cent. Stephen Li and Tamolin in their (2002) work using the PMPRB data observe that though the multinationals achieved the 10 per cent target rate of R&D investment as percentage of sales as agreed while signing the Bill C 22, R&D had not increased further. Interestingly, a few 10 companies consistently account for the major R&D expenditures in Canada. The top 10 companies which have been investing consistently in the past decade are: Boehringer Ingelheim (Canada) Inc, Connaught Laboratories Ltd, Ferring Inc, Pharmacia (Canada) Inc, Solvay Kingswood Inc, Adria Laboratories of Canada Ltd, Hoffman-La Roche Ltd, Sandoz Canada Inc, Merck Frost-Canada Inc and Johnson and Johnson. According to these authors, while attractive tax incentives offered by Canada could be one of the reasons for attracting R&D expenditure, the lengthy regulatory procedures could prove obstacles for operationalising R&D. By and large these investments are concentrated in Quebec and Ontario regions. Table 12 reports the therapeutical concentration of this research, which is largely in the area of cardio vascular system, nervous system disorders and alimentary tract metabolism in that order.

However, the issue which causes concern is that as much as 50 per cent of the research expenditure is spent on applied research (i.e. about 70 per cent of investment on manufacturing process, pre clinical trials and clinical trials) as against about 17 per cent on basic research (Table 13). Basic research is defined as work that advances scientific knowledge without a specific application in view reduced from 17.8 per cent in 2000 to 16.1 percent in 2001. Perhaps due to this, `me too' drugs are large in number and truly innovative drugs are small in number, in spite of the huge R&D spending, which indicates that the productivity of pharmaceutical R&D is declining. According to Reuters 2002, on an average only 1 out of 10,000 substance become a marketable product. And only 3 out of 10 drugs generate revenues that meet or exceed average R&D costs. R&D costs are increasing because of the complex clinical studies and the long clinical trials, which reduce the marketed shelf life of patented products. Further, since the `me too' drugs do not adequately compensate the revenue[7] lost through patent expiry which is the major issue with the multinationals presently, any patented drug

[7] In a private communication Lexchin observes that there are exceptions to this, whereby the `me too' drugs like Lipitor have contributed to large sales.

comes into the market is priced higher irrespective of the therapeutical contribution. The high concentration on applied research can also be explained by the fact that the patentees or companies account for as high as 55 per cent of R&D compared to academic universities and hospitals (Table 14) which as mentioned earlier are under constant pressure to find a blockbuster drug to support their R&D. This is the prevailing R&D scenario in Canada. There are a number of pharmaceutical firms, which are engaged in biotechnology-based pharmaceuticals, which is the fast emerging area in Canada though the extent of R&D in this sector is not known.

It is observed that though R&D in Canada has increased as a result of withdrawal of the CL, the foreign payments made by the pharmaceutical companies are also increasing indicating their dependence on imports. For instance, the payments by the Canadian companies to their foreign affiliates increased from $7 million in 1987 to $30 million in 1989 (Lexchin, 1993). The inward and outward stocks of foreign direct investment in Canada in 1990 and 1996 indicate that while the inward FDI increased from $113 billion in 1990 to $129 billion in 1996, the outward FDI increased from $85 billion to $125 billion respectively. On the other hand, withdrawal of CL had resulted in improving the indices of perceived strength of IPR of Canada, which improved from 58.4 in 1990 to 72.3 in 1995[8] (Maskus, 2000).

5. Comparison with the Indian Pharmaceutical Industry

A few points emerge in common for the pharmaceutical industry of both the countries. Like Canada, in India also, three points of time are very important. These are 1900-1970, 1970-1990 and the decade of 1990s, (Lalitha, 2002) which more or less coincides, with the trends observed in the Canadian industry. The first period signifies the dominance of the multinationals in this field that were basically importing bulk drugs and formulations from abroad and the domestic units were engaged in repacking the formulations produced by the multinationals. At this point of time, the Patents Act of 1911 was in practice, which facilitated

[8] This survey is conducted by the World Economic Forum whereby the MNE managers are asked to provide answer to the question of whether IPRs in each country is adequate to meet their needs of security. Their responses are compiled into numerical index ranging from zero to 100 with higher numbers indicating stronger faith in the system of IPRs.

patenting all the known and possible processes of manufacturing of the said drug besides patenting the drug itself. The policy instruments of independent India emphasized on creating a strong public sector with specific areas of production defined for the public, private and the domestic sector, though the performance of the multinationals allowed them some leeway in the production of drugs reserved for other sectors also. In the second period 1970-1990, important policy changes occurred. The Patent Act of 1911 was amended in 1970, which came into force in 1972. The 1970 Patent Act protects the processes of manufacturing the drug for seven years from the date of filing the application or for five years from the date of the grant of the patent. This change brought a renaissance to the pharmaceutical industry of India. More units larger in size and capacity set up in the 1970s and 1980s started producing drugs, which were primarily imported till then. Thus, while the adoption of compulsory licensing on imported products helped the Canadian domestic pharmaceutical industry in the 70s, adoption of process patents helped the Indian pharmaceutical industry. However, the further step adopted by the Indian government, which aimed at reducing the concentration of economic power with few units, brought the control in favour of the domestic pharmaceutical industry. To elaborate, through the Monopolies and Restrictive Trade Practices Act and the Foreign Exchange Regulation Act, the Indian government forced the units, which were not bringing in any new technology to reduce their foreign equity and renewal of their license was also subject to their bringing in new technology. Such a measure was not adopted in Canada, though some studies had observed that the technology adopted by the multinationals was not new to Canada.

Multinationals were also not permitted to produce a list of drugs, which were set-aside for the public and private sector units. This list was delicensed in favour of the private sector during the late 80s and early 90s. One immediate impact of delicensing of the drugs was that production increased manifold. For instance, production of bulk drugs increased from Rs.900 crore in 1991-92 to Rs.4344 crore in 2000-01 and formulations increased from Rs.4,800 crore to Rs.17, 843 crore in 2000-01.

There prevails tough price competition, which benefits the consumers. Prices of the drugs are controlled through the Drug Price Control Order whereby a list of drugs is brought under control. The National Pharmaceutical Pricing Authority also monitors the prices of the drugs. The most important point of divergence

between Canada and India is that while the Indian pharmaceutical industry is supported by a well-established homegrown fine chemical industry, Canada lacks this advantage. Because of this advantage, India could attain positive balance of trade in pharmaceuticals from the year 1988-89 (Table 15). Though, the domestic industry developed skills to reverse engineer and invent around a new product, India could not attract large foreign direct investment in this sector due to the `inadequate patent protection'. But, now as a signatory of the WTO, India has adopted stronger patents and further, as part of domestic reform, now the government allows 100 per cent foreign equity in pharmaceuticals. These measures should lead to increase in foreign direct investment. The amendments made to the patent law will enable the Indian government to issue a compulsory licensing on a product, which is required in case of health emergency or epidemic. Also India can be authorized to produce a patented drug under compulsory licensing to supply for a country without adequate domestic manufacturing facility under specific circumstances. As far as the supply of drugs to the government health care, in India, different state governments are responsible for delivering health care. These governments more often procure generic drugs through tender process by which the one quoting the lowest price gets selected for supplying drugs which promotes healthy price competition among the pharmaceutical units.

To summarize this section India like Canada adopted process patents and the presence of multinationals was more before the '80s. However, policy measures taken by the Indian government and the support of the domestic fine chemical industry has resulted in the growth of the Indian pharmaceutical sector, which is at present introducing patent law reforms as per the TRIPS Agreement.

6. In Lieu of Conclusion

This paper presented a review of the pharmaceutical industry in Canada where the presence of multinationals is dominant in production, R&D and innovations. Canada is one country, which had frequently exercised the CL option in the pharmaceutical sector. Though this resulted in generic products being manufactured in all major therapeutical area, it did not result in desired price competition between generics and branded drugs due to the pricing policies of the government. Proportion of branded drugs is higher than the generics in the

provincial purchases. Canada spends 10 per cent of its GDP on health expenditure and 16 per cent of the health expenditure is on drugs. However, in view of the fiscal deficit faced by the government promoting generics in different provincial formulary would help the government in controlling the drug expenditure and also help the consumers who have to pay on their own.

It is interesting to note that the multinationals invest about 10 per cent of their sales revenue in R&D in Canada. But the large number of `me too' drugs getting patents necessitates a closer look at the patent granting criteria for these drugs which distorts and reduces the productivity of R&D investment. After signing the TRIPS Agreement, Canada has amended its Patent Law to provide for CL to produce drugs for the developing countries. This is a welcoming trend set by a developed country, which will immensely benefit the developing countries without manufacturing facilities and will also benefit the generic producers of Canada. In India where the price of the drugs is a sensitive issue, setting up of an agency like the PMPRB that would continuously monitor and review the price of the patented drugs and their contribution to research would be useful. Besides providing useful statistics on pharmaceutical industry such an agency can also inform the public about the kind of drugs that are patented and their usefulness to the society.

Table 1: Health Expenditure in Canada by Category ($ million)

	1999	2000	2001	2002	2003
Health Expenditure	90066.6	97696.5	105953.6	113396.0	121430.8
Hospitals	28301.7	30638.6	32396.7	34171.5	36392.0
Other institutions	8524.1	9222.0	9979.0	10681.7	11557.7
Physicians	12223.8	12977.3	13978.4	14964.4	15640.2
Other professionals	10845.9	11585.3	12575.5	13441.3	14476.8
Drugs prescribed and non prescribed	13520.0	15093.2	16669.7	18140.8	19619.1
Drugs as % of total health Expenditure	15.01	15.4	15.7	16.0	16.2
Other Expenditure	16651.1	18180.1	20354.3	21996.3	23745.0
Health Expenditure as % of GDP	9.2	9.1	9.6	9.8	10

Note: Health Expenditure include spending by federal provincial and local governments, worker compensation boards and the private sector

Source: Statistics Canada.

Table 2: Profile of Leading Diagnoses, 1999

(Figures are in percentages)

By age Group	All Diagnoses	Hyper Tension	Diabetes	Depres-sion	Respira-tory Infections	Ear Infection	Anxiety
Under 10	10	<1	<1	<1	35	64	1
10-19	8	<1	1	3	16	12	4
20-39	25	5	7	31	23	11	30
40-59	29	35	32	48	14	7	43
60+	28	58	59	17	10	3	21

Note: Totals by age group may not equal 100 per cent due to rounding off.

Source: IMS Health (Annual report on diagnoses, treatments, and the pharmaceutical industry in 1999).

Table 3: Pharmaceutical Establishments Operating in Canada

Category	Under Foreign Control 1969 (%)			Under Domestic Control (%)	Under Domestic Control in 2004
	US	Euro-pean	Total		
Number of establishments	34.7	8	42.7	57.3	257*
No of production workers	61.2	10.5	71.7	28.3	
Total production wages	63.5	10.8	74.3	25.7	
Number of non-production Employees	69.9	14.1	84.0	16.0	
Total salaries	71.2	14.1	85.3	14.7	
Total employees	66.2	12.6	78.8	21.2	25013*
Total remuneration	68.8	13.1	81.9	18.7	
Shipment of goods of own Manufacture	72.5	13.5	85.9	14.1	
Value added from manufacturing	74.5	13.1	87.5	12.5	

Note: * Numbers and pertain to the year 2001.

Source: 1969 data from Gordon M J and Fowler D J `The Drug Industry-A Case Study of the Effects of Foreign Control on the Canadian Economy, p.36, Canadian Institute for Economic Policy, Ottawa 1981.

Table 4: Import Penetration in the Domestic Pharmaceutical Market of Canada

Year	Import as a Per Cent of Domestic Market	% Annual Increase
1983	18.0	0.55
1987	20.2	
1988	23.9	2.1
1993	34.4	
1994	39.2	6.1
2000	75.5	

Source: Lexchin, (2003).

Table 5: Patent Applications Filed and Patents Granted During 2000 for Selected Countries

Details	Application for Patents Filed by			Grant of Patents to		
Country	Residents	Non-Residents	Total	Residents	Non-Residents	Total
Canada	5518	80408	85926	1117	11008	12125
India	90	60852	60942			
France	21471	138707	160178	10303	26101	36404
US	175582	156191	331773	85071	72425	157496
Re.Korea	73378	98806	172184	22943	12013	34956
Japan	388879	97325	486204	112269	13611	125880
Germany	78754	183796	262550	16901	24684	41585

Source: World Intellectual Property Organisation, 2000.

Table 6: Effect of Competition on Drug Prices in Canada

No of suppliers of drug	2	3	4	5	6
Price*	76.2	61.2	45.1	34.4	37.9

Note: * price of least expensive brand as percent of most expensive brand

Source: Lexchin, (1993).

Table 7: Brand Vs. Generic Drug Usage*

	Brand %	Generic%
Canada	59.5	40.5
Quebec	65.9	34.1
Ontario	57.9	42.1
British Columbia	53.0	47.0
Alberta	58.1	41.9
Manitoba	53.4	46.6
Saskatchewan	52.9	47.1
Nova Scotia	55.7	44.3
New Brunswick	54.3	45.7
Pei and Newfoundland	53.4	46.6

Note: * Percentage of prescriptions dispensed through retail pharmacies

Source: IMS Health (Annual report on diagnoses, treatments and the pharmaceutical industry in 1999)

Table 8: HH Spending on Health Care Prescription (Average Expenditure in $)

Year	Expenditure
1997	198
1998	202
1999	205
2000	225
2001	226

Source: CANSIM

Table 9: Manufacturers Sales of All Drugs and Patented Drugs for Human Use

Year	Total Drugs		Patented		Patented Drugs as % of Total
	Sales $bn	Change (%)	Sales $bn	Change%	
2002	13.1	13.9	8.8	17.3	67.4
2001	11.5	15.0	7.5	18.9	65.0
2000	10.0	12.4	6.3	16.7	63.0
1999	8.9	16.8	5.4	27.0	61.0
1990*	3.7		1.7		46.0

Note: *Includes the human and veterinary drugs

Source: PMPRB 2002

Table 10: Patented Drug Products for Human Use Sold in 2002- Status of Price Review as of March 31, 2003

Number	New Drugs Introduced in 2002	Existing Drugs	Total
Total	94	933	1027
Within guidelines	48	827	875
Under review	34	48	82
Under investigation	12	55	67
Notice of hearing		3	3

Source: PMPRB, 2002

Table 11: Total R&D Expenditure and R&D to Sales Ratio of Reporting Companies

Year	No of Companies Reporting	Total R&D Exp Mn$	Total Sales Revenues $ mn	% Of R&D to Sales of Patentees*
2002	76	1183.5	11908.3	10.0
2001	74	1060.1	10732.1	10.6
2000	79	941.8	9309.6	10.6
1999	78	894.6	8315.5	11.3
1998	74	798.9	6975.2	12.7
1997	75	725.1	6288.4	12.9
1996	72	665.3	5857.4	12.3
1995	71	625.5	5330.2	12.5
1994	73	561.1	4957.4	11.6
1993	70	503.5	4747.6	10.7
1992	71	412.4	4164.4	9.8
1991	65	376.4	3894.8	9.6
1990	65	305.5	3298.8	9.2
1989	66	244.8	2973	8.1
1988	66	165.7	2718	6.5

Source: PMPRB, Annual Reports 2001, 2002

Table 12: Patented Drug Products by Anatomical Therapeutic Chemical (ATC) Classification, 1995 and 2001

Classification	Value $Mn 1995	Value In mn 2001	Contribution to Total Exp Growth (%) in 200l
Alimentary tract and metabolism	412	1010.1	19.8
Blood and blood-forming organs	261	372.1	7.4
Cardiovascular system	419	1957.4	22.2
Dermatological	76	70.7	-1.6
Genito-urinary system and sex hormones	112	229.9	2.9
General anti-infective for systemic use	395	903.9	8.3
Antineoplastics and immunomodulating agents	134	553.1	9.5
Musculo-skeletal system	101	608.6	9.0
Nervous system	396	1100.0	12.2
Antiplastic products	0		
Veternary products	86		
Respiratory system	170	508.2	7.8
Sensory organs	16	80.1	1.0
Various	36	30.1	
Totals	2637	7492.8	

Note: Current R&D Expenditures by organisations performing R&D 2002 and 2001

Source: PMPRB

Table 13: Current R&D Expenditure by Type of Research, 2002 and 2001

Type of Research	2002		2001		% Change in Expenditures 2002-2001
	$ Million	%	$ Million	%	
Basic research	198.6	17.6	163.1	16.1	21.8
Chemical	104.5	9.3	84.3	8.3	24.0
Biological	94.1	8.4	78.8	7.8	19.4
Applied research	626.3	55.6	604.8	59.9	3.6
Manufacturing process	110.9	9.8	79.5	7.9	39.5
Pre clinical trial 1	46.4	4.1	56.5	5.6	-17.9
Pre clinical trial 2	30.2	2.7	23.0	2.3	31.3
Clinical trial phase 1	37.1	3.3	23.2	2.3	59.9
Clinical trial phase 2	103.7	9.2	96.2	9.5	7.8
Clinical trial phase 3	298.0	26.5	326.4	32.3	-8.7
Other qualifying R&D**	301.6	26.8	242.6	24.0	24.3
Total	1126.4	100.0	1010.5	100.0	11.5

Note: Current expenditures exclude capital equipment and depreciation expenditures
** Includes drug regulation submissions, bio availability studies and phase IV clinical trials

Source: PMPRB table 10, 2002.

Table 14: R&D Performers in Canada

R&D Performer	2002		2002		% Of Change in Expenditure 2002-2001
	$Million	%	$Million	%	
Intramural					
Patentees	612.4	54.4	545.2	54	12.3
Extramural					
Universities and hospitals	139.9	12.4	159.6	15.8	-12.3
Other companies	273.7	24.3	227.5	22.5	20.3
Others	100.4	8.9	78.2	7.7	28.4
Total	1126.4	100.0	1010.5	100.0	11.5

Note: Current expenditures exclude capital equipment and depreciation expenditures

Source: PMPRB 2002

Table 15: Balance of Trade in Pharmaceutical Sector

Year	Export of Drugs	Imports of Drugs	Balance of Trade
1987-88	289.99	349.44	-59.75
1989-90	856.8	652.12	204.68
1990-91	1254.6	604.0	650.6
1992-93	1541.5	1137.4	404.1
1994-95	2465.3	1537.0	928.3
1996-97	4340.0	1039.2	3300.8
1998-99	6153.0	1446.8	4706.2
1999-00	6631.0	1502.0	5129.0

Source: IDMA annual publications.

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