A BRIEF HISTORY OF DRUG PATENTING

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The dispute over drug patents and the monopoly power it bestows on the multinational drug giants began some 50 years ago.

From 1957 to 1967, Senator Estes Kefauver chaired the Senate Sub-Committee on Anti-Trust and Monopoly. Formal hearings did not begin until 1959 with the intervening two years taken up by conducting investigations into the drug industry. When these initial probes indicated a monopoly situation, the Sub-Committee reached a decision whereby any bill, if it was to be successful, must destroy the monopoly by injecting into the drug manufacturing industry a greater degree of price competition.

The Sub-Committee's recommendations were aimed at the patent, compulsory licensing, trademarks, brand name versus generic and the promotional practices of the brand name drug companies.

Bill S-1552, accordingly, reduced patent protect from seventeen (17) to three (3) years upon the payment of a royalty based on sales (under 5%) to a licensor and not to exceed 8%.

As the hearings progressed, Kefauver found that once a particular company had developed a new drug, some of the competing houses would quickly move into the field, modify the chemical structure, patent the result (with a new trade name), and put it on the market –

> *"This plethora of poor compounds and of new mixtures of old agents that appear each year confuses physicians. It raises the cost of drugs, and may harm patients, either through keeping them from adequate therapy or by causing them serious side effects."*

Kefauver, therefore, recommended that combinations and modifications of existing drugs be patentable only if their effects had been proved to be therapeutically better than the effects of old drugs.

Kefauver made a number of other recommendations that would curtail the brand name corporations marketing and promotional practices which only further enforced their monopoly position.

Taken in total, Kefauver's findings and recommendations in Bill S-1552 were a direct condemnation of the marketing, pricing, manufacturing and distribution policies of the multinationals in the United States.

The multinationals mounted a devastating attack on Bill S-1552 which they vowed *"...to fight to the death."* In the end, that part of the legislation which Kefauver considered to be crucial to the reduction of drug costs – the sections governing patents and licensing procedures – was removed.

The testimony of evidence filled thirteen (13) large volumes and covered 12,885 pages.

THE CANADIAN EXPERIENCE

The first inquiry into the cost of drugs in Canada began on April 14, 1958. (This was 18 months before the Kefauver Sub-Committee began its public hearings in September 1959.)

Certain statements made by Jules Gilbert, (a generic drug manufacturer from Toronto) about the monopoly practices of the brand name multinationals, is credited with giving impetus to a Canadian investigation. A few initial enquiries by the then Director of Investigation and Research in the Combines Division (Mr. T. D. MacDonald, Q.C.) a full investigation into drug costs was launched. It was completed by his successor, Mr. D. H. Henry, Q.C.

The result of their work was continued in the findings of the Green Book which was presented to the Restrictive Trade Practices Commission (RTPC) as evidence on February 28, 1961. Using the Green Book as the basis for further investigation, the government then launched a public enquiry under the authority of the RTPC. This body held public hearings from Halifax to Victoria and presented its findings to the then Minister of Justice, the Honourable Donald Fleming, MP, on January 24, 1963. (The authority to appoint this inquiry was

Section 42 of the Combines Investigation Act and was concerned with the Manufacture, Distribution and Sale of Drugs.)

The RTPC found, as did the Green Book, that:

> *"The dominance of branches and subsidiaries of United States drug firms and the widespread use in Canada of drug products originated in the United States mean that the drug trade in Canada in effect operates under the United States patent system..."*

In brief, Canada had become an extension of the U.S. market and that drugs supplied to the Canadian market are *"at least as high a price as that charged in the United States."*

In Canada at this time, patents were on the process, not the product, and like the U.S. were for a seventeen (17) year period.

Unlike Canada, the U.S. had no compulsory licensing. The purpose of Parliament in providing compulsory licensing was to modify *"...the exclusive monopoly conferred by a patent...to ensure that drugs would be available to the public at the lowest possible prices consistent with due reward to the discoverer..."*

Because over 95% of all drug patents are owned by foreign multinationals, the RTPC found that the compulsory licensing provisions were used very infrequently. This is not surprising since generic drug firms, which were wholly Canadian-owned, were shut out from using them by the foreign multinationals. Furthermore, for the Canadian subsidiaries of the foreign multinationals it was not practical for them to secure licensing to allow them to manufacture and sell a particular drug. To do so it would have to develop, manufacture and market the product on its own in competition with its own parent company.

The RTPC considered changing the compulsory licensing provisions of the Patent Act (Section 41[3]) to make them issuable "as of right" but concluded this in itself would make no appreciable difference. The RTPC therefore recommended that *"...patents with respect to drugs be abolished. In the opinion*

of the Commission, this is the only effective remedy to reduce the price of drugs in Canada."

With this single recommendation, the RTPC had set the government of Canada on a collision course with the U.S. dominated Pharmaceutical Manufacturers Association of Canada (PMAC).

There were a number of other recommendations dealing with dumping duties, generic versus brand names and the advertising surrounding them. The major battle was, of course, on changes to patent life and compulsory licensing.

On November 30, 1962, the Honourable J. Waldo Montieth, Minister of Health, announced that a Special Parliamentary Committee would be established to make a full-scale investigation into Canada's drug industry.

In 1963, the Liberals came to power and the Committee was reconstituted under the Chairmanship of Dr. Harry Harley.

THE HARLEY COMMITTEE

Prior to the Harley Committee's hearings, Mr. Guy Favreau established an Inter-Departmental Committee, chaired by Mr. D. H. Henry of the Combines Branch. This Committee was initially composed of three (3) departments – Patents, Justice and Health and Welfare. It was later expanded to include Industry, Finance and Trade and Commerce.

This Committee began work in earnest in January 1965 and completed its final draft by April of the same year. This draft included simultaneous action to modify the effects of all the economic factors involved: patents, trademarks, tariffs and dumping duties.

Also included was a programme of loans and guarantees to strengthen the generic drug manufacturers which were Canadian. This latter proposal was also designed to help ensure an adequate supply of lower priced drugs.

Upon receiving this Committee's Report, Mr. Guy Favreau took it to Cabinet where a decision was reached to establish a Cabinet Ad Hoc Committee of those

Ministers whose Departments were involved. This Cabinet Committee's task was to coordinate and expedite the work of the Harley Committee on Food and Drugs.

When Dr. Harley's Committee began its public hearings the government had already reached a decision on what set of actions must be taken to reduce drug costs.

Throughout the Harley Committee's hearings, members – particularly the Liberal and New Democratic Party (NDP) members – were fully briefed by the Interdepartmental Committee. (These government public servants were at the most senior levels of their respective departments.)

Because the government knew the power of the drug companies, it was not about to leave anything to chance. The Harley Committee had to be one of the most closely monitored Parliamentary Committees in Canadian history. Cabinet had written the script and it left nothing to chance that might derail the final outcome.

The 1963 hearings by Harley concerned itself with the use of pesticides and their control.

The 1964 hearings looked at the safety of drugs.

The 1965 hearings received their terms of reference from Cabinet *"...to consider and recommend, as it may deem expedient...a comprehensive and effective program to reduce the price of drugs."*

Without going into all the details the government produced witnesses to counter the PMAC's spokespersons. Not a single claim from the competitive position to the equivalency of generic drugs versus brand names was left unchallenged.

The real problem was the final report of the Harley Committee which reflected the intense negotiations between not only the Tory members who sided with the PMAC and the Liberals and NDP, but also those Liberal members of the Committee from Toronto and Montreal who had large multinational drug companies in their constituencies.

The Harley Committee's Report did not reflect the full intent of Cabinet but nevertheless it did go far enough for the subsequent legislation to reflect the Green Book's and the RTPC's recommendations on the "package approach."

BILLS C-190 AND C-102

Bill C-190 was introduced by then Registrar General John Turner on December 15, 1967. It was an amendment to the Patent and Trade Marks Act.

Bill C-190 received Second Reading on February 14, 1968 and died when Parliament adjourned on March 27th for the Liberal Leadership Convention and the eventual dissolution of Parliament on April 23, 1968.

On September 23, 1968, Turner's successor, the Honourable R. Basford tabled Bill C-102, an Act to Amend the Patent Act, the Trademarks Act and the Food and Drugs Act.

On March 28, 1969, Bill C-102 was read the third time and passed. It received Royal Assent on June 22, 1969.

Bill C-102 amended the Patent Act to allow compulsory licensing as of right on the payment of a royalty to the patent holder. The previous period had been seventeen (17) years.

From this period to 1987 when the Patent Act was amended to the previous seventeen (17) years, Canada enjoyed the lowest drug prices in the world.

In 1993, the Patent Act was again amended to increase it to twenty (20) years along with the "evergreening" regulations.

SOME OBSERVATIONS

Having done my Masters Degree at the University of Waterloo on the drug industry in Canada and my Doctorate at the London School of Economics on the drug industry in Great Britain, I offer the following observations:

1) Any attempt by your Committee to make meaningful inroads on reducing drug costs will be met by fierce resistance by the multinational drug companies. They will protect their monopoly position at all costs. If the senior bureaucracy, which I fear has and does side with the brand name companies have their way, nothing will come of your Committee's work. The Cabinet must be persuaded of the value of your work.

2) The last thing the multinationals want is competition. While kneeling at the alter of free-enterprise, competition is for others, not for themselves.

3) The multinationals do little, if any, research in Canada on the development of new drugs. Any research they do is directed at that research which is required to have their drugs approved for marketing in Canada by the Health Protection Branch. Canadian subsidiaries of these multinationals only import the active ingredients from the parent companies and package them into final dosage form. Less than 5% of drug patents are issued to Canadian firms. It is in the nature of research that it is conducted at a central location, i.e., at the parent company's research facilities in the home country. That is why 95% of all drug patents are owned offshore.

4) The claims by the drug companies that x millions of dollars are needed to develop and research new drugs cannot be substantiated. Third parties are completely dependant on the figures supplied by these corporations. Even so, it is misleading for them to apply these developmental costs to a single country which is the impression they give. Since they operate on a worldwide basis, these costs should be apportioned on the same basis.

5) These multinational corporations have to use the argument that drug costs are not too high because they have led to shorter hospital stays for patients. This is a false claim. The length of stay in hospital has nothing to do with the cost of developing new drugs. To link the two is a fallacious argument. Contrarily, the shorter hospital stay may indeed be due to more potent and therapeutic drugs but the higher cost to the patients, it could

also be argued, is in fact a transfer benefit to the drug company gained from its monopoly.

6) If the government does not take action to bring down drug costs prior to bringing in a national Pharmacare Programme, it will pay a heavy price. These multinationals will plunder the government coffers as they did in Great Britain and elsewhere. The provinces have found this out and took action where and when they could, given their limited legislative authority in this area. The multinational drug companies would like nothing better than to have direct access to the public purse!

As the Sainsburg Committee was quick to point out –

> *"...medicines are developed, manufactured and supplied by the pharmaceutical industry; they are prescribed by doctors; they are consumed by patients; and, through the National Health Service, the taxpayer eventually pays for them. But neither the doctor who prescribes nor the patient who consumes is immediately concerned with prices."*

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