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Technology and Public Policy: Patent Protection for New Drugs in Canada

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Abstract

Technology and Public Policy: Patent Protection for New Drugs in Canada

Robert J. Collins

In November 1987 the Conservative government passed Bill C-22, restoring patent protection to new drugs in Canada and reversing a 1969 Liberal government decision to allow the compulsory licensing of patented drugs, which had reduced costs to the consumer. This thesis examines this new policy from the perspective of a "technological imperative." A comparison is made between the public policy process leading up to the 1969 and 1987 changes, which shows that there has been a shift in approach by the main lobby group (the Pharmaceutical Manufacturers Association of Canada) involved in attempts to restore patent protection. This group has engaged in an appeal to the benefits of "technology" in order to have patent protection restored, which is seen as an acknowledgement that a rhetoric of technology can succeed in the accommodation of group interests. The conclusion is that sufficient analysis of the social costs involved has been screened out of this policy revision, because of the privileging of technological means over ends.

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Introduction

The Mulroney government, on November 7th 1986, introduced legislation in the House of Commons to amend Canada's Patent Act. The main effect of such amendments was to restore (up to) ten year patent protection for new brand name drugs introduced to the Canadian market, with the corollary that higher prices might be expected owing to the (enforced) absence of competition from so-called "generic" drug companies. These companies will be barred under the new Patent Act from making copies of such drugs, removing their right to demand from patent holders a license to import or manufacture a generic version of any brand-name drug marketed in Canada.[1]

Such a licensing arrangement had existed since the Trudeau government had amended the Patent Act in 1969, in response to concerns over the high cost of prescription pharmaceuticals; the 1969 Act in effect abolished the seventeen year patent protection previously available, by allowing the imposition of such arrangements on proprietary drug companies in exchange for a 4% royalty on sales of the copied drugs. The Mulroney Act, which

received Royal Assent November 19th 1987, also set up a new Federal regulatory agency (the Patented Medicine Prices Review Board) with a mandate to monitor, and to some extent control, the prices of drugs in Canada.[2]

The intent of this thesis is to examine this new drug policy, with an analysis of both the background to the original (1969) Act, and the revision of the public policy adopted therein in the latest (1987) Act. It will be demonstrated that drug companies were unsuccessful in lobbying (on the grounds of product safety and sanctity of patent rights) against the 1969 Act. It will also be shown that an ultimately successful lobbying effort was carried out for the adoption of the 1987 Act, on the basis that this was necessary in order to obtain, and to thus benefit from, technological advances resulting from expanded research and development activities both in the pharmaceutical field and in allied areas.

It will be demonstrated that the driving force behind government support of the latest changes to the Patent Act is the perception that these will foster an increased level of research and development within Canada by multinational pharmaceutical companies. This is seen

as necessarily favourable both to the Canadian scientific establishment and thus, by extension, to Canada. The government supporters of the legislation also state that such research and development is "inevitable" if the benefits of future progress in the relatively new and rapidly expanding field of biotechnology are to be felt in Canada.

These elements have combined to form a type of technological imperative expressed succinctly, though awkwardly, by Harvie André (Minister of Consumer and Corporate Affairs, whose department is responsible for the legislation). He explained to Parliament why the changes to the Patent Act were seen as necessary in the following terms: "We need to do this for the benefit of Canadian research and development so that Canadian scientists can have that research and development in this high-tech biotechnology area here in Canada, and that is why we are proceeding."[3]

This statement must be analyzed to determine whether a public policy discussion has taken place to "clarify the full range of choices to be made, and their possible impact on values, so that enlightened decisions

about the future directions of social change may be made."[4] It will be contended that a process of interest group pressure has in this case privileged a normative acceptance of what has been expressed as the legitimation of technological means without any rational discussion of their goals, if they exist at all. This can be summed up in the phrase "technology is imperative," which in essence assumes that society must accommodate technology, rather than the reverse, and further assumes that rational discussion can only be focused on the (technological) means that are to be employed, rather than the ends which they are designed to serve.[5]

The hypotheses that will be advanced, and examined, in the thesis will be as follows:

1. The interests of the business groups affected by the Patent Act (1969) were suborned to a coalition of interests representing consumers and provincial governments, without any explicit causality being accorded to technological concerns.
2. The acceptance by a post-industrial society that a fundamental role should be accorded to technological development creates a rationale for revisionism in public policy amongst groups that

can reformulate their interests in terms of research and development for technological ends.

3. Implicit recognition of the latter was the impetus for articulation by specific groups of their interests couched in terms of a rhetoric of technology which privileged accommodation of technological means over ends, to the detriment of social welfare.

The object of the research is to examine whether it can be determined if there exists a driving force to public policy change, in the shape of a technological imperative. This would tend to support the second hypothesis if it can be demonstrated that this has led to the moulding of interest articulation by certain groups into a technology nexus that can prevail over competing interests in the process of accommodation.

The first chapter of the thesis will examine the notion of a technological imperative. This will be placed in the theoretical framework of two of the most noted polemicists against modern technological society. First is the French philosopher Jacques Ellul, whose discourse on technology will be described in some detail

as an introduction to critical reflections on technology from a North American perspective. This will be drawn from George Grant, the Canadian thinker whose work parallels in some ways, and extends in others, that of Ellul. The second chapter will set forth the process and analyse the results of the efforts in the 1960's to make drug prices more affordable, from the Kefauver hearings in Washington and the Harley Committee in Ottawa to the Canadian Patent Act amendments in 1969. The third chapter will present the background to the efforts in the 1980's to reverse, in Canada, the results of the process outlined in the second chapter. The concluding chapter will integrate these three themes and will test the hypotheses advanced.

It remains to be seen whether what is going to be described as a technological imperative can be demonstrated to exist or not. The thesis will, however, examine the new drug policy in this light and will include an empirical analysis of the rhetoric of technology employed during the debate by the principal actors involved, combined with a theoretical reflection on the implicit ideology contained therein.

Although it remains to be shown, the contention of this thesis is that the impetus for the revisions to the Canadian Patent Act (1987) was a recognition, in this case by the Pharmaceutical Manufacturers Association of Canada, that interest articulation in the form of a technological imperative would lead to accommodation of their aims by the government. As has been mentioned, it is necessary to examine further the notion of a technological imperative, to define both its origins and its meaning in the fields of sociological and political theory. This examination will be carried out in the next chapter, and it will be couched in the framework of the thought of Ellul and Grant, who have written extensively on the subject of technological society.

Notes to Introduction

[1]Gazette (Montréal), 8 November 1986, p. A-13.

[2]Canada, Statutes, Patent Act (An Act to Amend) 35-36 Eliz. 2, ch. 41, Canada Gazette, Part III, vol. 10, no. 6 (Statutes of Canada, 1987). The sections of the Act establishing the Patented Medicine Prices Review Board were proclaimed in force 7 December 1987. Canada Gazette, Part II, Consolidated Index of Statutory Instruments, January 1, 1955 to March 31, 1988 (Ottawa: Supply & Services, 1988), p. 254.

[3]Canada, Parliament, Hansard's Parliamentary Debates, 33rd Parlt., 2nd sess., 1986, 129, pt. 5:101.

[4]William Leiss, "The Information Society: A New Name for Some Old Tricks," paper presented at the annual 1982 Departmental Colloquium, "The Social Responses to Technological Change and Environmental Impact," Dept. of Sociology, University of Calgary, March 24-26 1982.

[5]Marike Finlay, "William Leiss on Technology," Canadian Journal of Political & Social Theory 10 (1986): 185.

Chapter I

The Mulroney government had informed Parliament that changes to the Patent Act were necessary not just so as to provide the means for research and development in the pharmaceutical field, but also so that this would in turn provide the means for further research and development in the "high-tech" biotechnology area.[1] This, it will become evident, is an example of what will be shown as the technological imperative being invoked to justify public policy change. It meshes neatly with the following definition supplied by Langdon Winner:

> The technological imperative contains a logic that accounts for much of the way change occurs in modern society. The logic is not that of syllogistic inference. Rather, it is the pragmatic rationale of necessary action. If you desire X and if you have chosen the appropriate means to X, then you must supply all of the conditions for the means to operate. To put it differently, one must provide not only the means but also the entire set of means to the means. . . . once the original choice has been made, the action must continue until the whole system of means has reached its proper alignment.[2]

It must of course be understood that the imperative of technology is recognised as a function of the overall autonomy of technology, in which "technologies are structures whose conditions of operation demand the

restructuring of their environments."[3] This autonomy is not a given; it is rather a point of heated debate on the part of those who view technology as either the possible liberator, or the enslaver, of humanity. Autonomous technology and free human will are seen by some as a dichotomy which cannot be resolved other than by the victory of one over the other; pessimistic viewpoints such as those of Jacques Ellul state unequivocally that "there can be no human autonomy in the face of technical autonomy."[4]

The writings of Jacques Ellul on technology and its relation to society have prompted much discussion since the appearance of La Technique, ou l'enjeu du siècle in 1954. This was heightened after its translation into English as The Technological Society in 1964, and his subsequent works, such as L'illusion politique (1965, English version The Political Illusion, 1967) and more notably Le Système technicien (1977, English version The Technological System, 1980) have added to the debate on his tendency to view technology as both degenerative and dispossessive.[5] These perspectives will be examined in more detail as an attempt is made to contextualize the technological imperative within Ellul's framework of the absorption of contemporary life by technology.

One should first offer what Ellul regarded as his simple definition of technique, which he saw as strictly a sociological phenomenon; he is explicit that he studied it as such. This definition stated that technique (or, in American-English usage, technology) is "the totality of methods rationally arrived at and having absolute efficiency (for a given stage of development) in every field of human activity."[6] This definition has been adopted by North American philosophers such as George Grant,[7] although the Ellulian concept of the autonomy of technology would be denied on an ontological basis by Grant, who sees the "pure will to technology" as a facet of the deep nihilism of technological society, in relation to the Nietzchean will to power of those "last men" who govern such a society.[8] Grant's perspectives will be returned to at a later point in this thesis.

Whilst on the subject of defining "technique," it should be noted that although it is generally the practice to use "technology" interchangeably with the term "technique" (indeed, some English translations of Ellul's works did so), Ellul himself insisted at a later date that this was unacceptable. In an interview he demanded that the word "technique" should be used rather

than "the totally incorrect use of 'technology' in imitation of North American vocabulary."[9] In his view, technology is a discourse on technique, but it is not technique itself.[10] With that caveat in mind, the use of the word "technique" will in this chapter be consistent with Ellul's usage; however, the usage of the word "technology" by North American commentators will also be followed even when this should be semantically treated as within the rubric of Ellul's "technique."

It was stated earlier that Ellul's interpretation of technique was pessimistic; however, it must be pointed out that he claimed (in The Technological Society) that this work was descriptive and should not be seen as pessimistic from his standpoint.[11] Although he foresaw that the probable outcome of a technicised society would be the triumph of technical automatism,[12] the thrust of his early work was to incite a debate which, by recognizing the technological phenomenon as "the most dangerous form of determinism," would be the first step toward the transcending of the "blind mechanism" of technique.[13] The pessimism inherent in his work must therefore be seen as a function of the psycho-semiotic interpretation of his work by others, who obviously do

not see it as a "concrete and fundamental interpretation of technique" without "ethical or aesthetic judgement" as he claimed.[14]

Ellul saw the historical development of technique as following two parallel paths from its Eastern origins. The first path was that of primitive technical operation as expressed by concrete means, that of homo faber; the second that of what he terms technical operation by supernatural means, or that of homo magicus. The latter path is one which attempts to influence a course of events by occult control of nature or of spirits; the techniques of such a path are assumed to have disappeared with the civilizations which utilized it.[15] With the Ancient Greeks one sees the first recorded separation of science and technique; this is the apex of civilization for Ellul, because the Greeks succeeded in subordinating technique, using it sparingly as a means to a more philosophical end. This is seen as a deliberate rejection of technique, in an awareness of the danger inherent in its unrestrained development.[16] This is clearly a warning that modern society should also reject technique or, more precisely, at least resist its teleological dominance.

With the Roman era, one finds the perfection of social technique in its relationship to Roman law, in its refinement of means, and respect for the individual.[17] As long as technique remained subordinated to the end of the internal cohesion of society, as expressed in Roman law, the society survived. The fall of Rome came about due to its "drift into a technical vertigo"[18] which was compounded by the rise of Christianity. Due to the other worldly nature of the latter, the social technique of Rome, based on its judicial system, was undermined; as well, the ethos of Christianity from its beginnings until the Renaissance acted as a brake on technical progress unless the latter could be shown to be morally just. This is a fundamental point because technique was thus measured "by other criteria than those of technique itself" during the period when Western society was united in "the search for justice before God."[19]

The crossroads between the modern technological society and that of the Middle Ages was the sixteenth century. The Reformation and the Renaissance had seen a measure of technical progress and the rise of humanism, which in the sixteenth and seventeenth centuries saw the flowering of the universalist in the intellectual field.

A new spirit of individualism, linked to a profound humanism, "believed not only in knowledge and respect for the human being but in the genuine supremacy of man over means. This humanism, bound up with the idea of universalism, did not allow techniques to grow."[20]

Where, then, were the beginnings of the enormous proliferation of technical advances which have led to our modern society? From the early to the late part of the eighteenth century, in England and in France, a breakdown of received prohibitions, both social and religious, in Ellul's view contributed to a receptive atmosphere for technique; from this preliminary phase blossomed the Industrial Revolution. Ellul offers as explanation for this phenomenon the necessary simultaneous existence of five other phenomena; to understand his historical theory of the development of technique, these phenomena must be recognized.[21]

First, there must have been a long enough period of continuity within a civilization for the progressive evolution of as yet disparate technical processes. This has an eventual effect somewhat akin to the fermentation of wine; eventual evolution and change of its properties

takes place up to the point where an explosion must occur unless the bottle is uncorked. Second, an expansion in the population is necessary. This has the implication that there then will exist a large pool of urbanized and under-utilized labour (although this latter effect may more properly belong in a later phenomenon as the result of radical social change). Third, a receptive economic climate is required. This must be composed both of a stable infrastructure, to support technical research, and at the same time also be volatile enough to absorb the practical applications of that research.

Fourth, and seen as the key element, a society must exist whose complete pliancy (in Ellul's terms, plasticité) makes it open to the development of technique. This pliancy was achieved in England by the disintegration of widely accepted beliefs, such as in the social order represented by the church and state hierarchies founded on the sovereign power. This was caused by the Civil War and the execution of Charles II, the Monmouth Rebellion, the Glorious Revolution and the forced abdication of James II, and the successive Jacobite Rebellions. The struggle between the Church of England and the Puritans further confused and undermined

the previously accepted religious strictures, which had up until then not been conducive to the development of technique.

In the French system, the pliancy was achieved by a series of shocks, the most profound of which was that of the Revolution, with the execution of Louis XVI and the complete breakdown of the established order. Coupled with a concerted attack on natural social groupings, and the prevailing philosophy of individualism, was a drive by the state for technical means to survive and to extend its control over those same individuals. The atomization of the population and its concentration in an urban environment (as had earlier occurred in England under the impetus of agricultural reform promoted for the profit of the landowners) bred a receptive attitude to technical change as an agent of improvement of the dismal conditions of life for the majority.

The fifth and final condition was the appearance of "a clear technical intention, which combines the other factors and directs them toward the pursuit of the technical objective."[22] This was expressed in England by the bourgeois self-interest in pursuit of profit, and

later by the state when it could see its own self-interest in technical improvement in the wars against the French. In France itself, this intention was first clarified by the monarchy to promote scientific advance, and later refined during the Revolution more specifically to promote technical progress in the self-interest of the state. Only at the birth of the Industrial Revolution had all five of these determining factors been present at the same time, and with this conjunction of phenomena the seeds of the modern technological society were sown. It is from this that technique grew into the characteristics which Ellul portrays in his work: technical automatism, self-augmentation, monism, universalism, and autonomy.[23] This brought Western civilization to the situation in which it finds itself today, to "a destiny which enfolds us in its own conceptions," so that "[i]t has been truthfully said, 'Technology is the ontology of the age.'"[24]

It was stated earlier that George Grant would dispute Ellul's concept of the autonomy of technology on an ontological basis, because Grant saw the drive to technology in relationship to the will to power of those who governed a technological society. However, the

Ellulian perspective is important because it provided Grant with a conceptual framework that he could utilise to formulate a critique of modern society that went beyond his previous work. With the development of Grant's thought, we see a clear thread connecting the initial definitions that he adopted at first uncritically from Ellul; Grant is explicit on this in Technology and Empire.[25] However, Grant went on from this definition and in the remainder of Technology and Empire he implied what he termed a critique of Ellul. It is from this development of a Grantian perspective, intimately woven into a penetrating analysis of the place of Canada within North America, that we are able to arrive at what is most relevant to this thesis. This is what Arthur Kroker has demonstrated is Grant's most basic methodological claim: "that the meaning of technological society can only be disclosed by means of a critical understanding of the 'all-encompassing world-view' which is embodied in and carried forward under the name of technology."[26]

What must be demonstrated is that there is indeed a Weltanschauung which ascribes to technology a liberating possibility, but which is actually a means to domination and is the basic impulsion of the modern project, which

is the essence of Grant's definition, and critique, of the "technocratic imperative."[27] That the combination of Western science and technology does form a project of control and domination is a theme that has also been explored by the Frankfurt School critical theorists, most notably by Herbert Marcuse and Jurgen Habermas.[28] The reflections of Marcuse on Max Weber's concept of rationality conclude with the statement that "the very concept of technical reason is perhaps ideological. Not only the application of technology but technology itself is domination (of nature and men)-methodical, scientific, calculated, calculating control."[29] Habermas pointed out that the challenge of technical control lay in how it could be subjected "to the consensus of acting and transacting citizens" in which the social potential of technology could in turn be harnessed to "a defined and controlled relation to our practical knowledge and will."[30]

Habermas also illustrates that the problematic of the relationship between science and politics is the development of a long-term research policy, and the need for public opinion to mediate the direction that future technological development should take. This is seen as

the necessary form for a rational society, although he is pessimistic that this can occur, because of the tendency for technical decisions to be dictated by "the logic of objective exigency" and because the public is effectively excluded from general discussions amongst scientists and politicians.[31] The implications of this critique will be explored further in the final chapter, as part of the general conclusions that will be drawn from the empirical observations that will be made in Chapters II and III.

As Stanley Aronowitz has pointed out, much of the critical discourse on technology has its roots in the European thinkers such as Ellul or the Frankfurt School, and Americans "have been blinded to the dangers of modern technology because it has been central to building a world empire that has sustained material prosperity and political and economic domination over others."[32] We must turn to Canadian thinkers for reflections which can illustrate a critical North American perspective on the technological society, precisely because Canada itself is "caught between its partial integration into technological society and the past of European culture . . . [a]ccording to Arthur Kroker it is precisely owing to Canada's existence in the interstices of this conflict

that technology is the Canadian discourse, and Canada's identity is inextricably bound up with technology."[33]

Although Kroker has focused on Harold Innis and Marshall McLuhan, as well as George Grant, it is the latter that perhaps best illustrates the theme of the Canadian technological dependency on the United States. It is ironic that the rhetoric of what purports to be an attempt to strive for technological sovereignty in the field of biotechnology, which was discussed earlier, in effect simply strengthens the dependency of Canada on the pharmaceutical technology of American multinationals, as will be seen at a later stage. This may be an intimation of the validity of what Michael Weinstein sees as Grant's perspective, that "Canada's fate is to be an auxiliary of American projects," which is epitomised in the view that "Canadians are caught up, willingly or not, as integral participants in the adventures of the American empire."[34]

What this thesis will attempt to show is that the actors involved in the policy process in Canada were caught up in an adventure of the American multinational pharmaceutical companies. It will be seen that those

policy participants have indeed adopted a rhetoric which purports to demand acceptance of the furtherance of technology because of its inherent "good"; this is the essence of what has been referred to as the technological imperative, in which possibilities of refusal are negated. Refusal (of technology) is itself equated with the absence of "the good" in such a discourse, and cannot even be thought if indeed Grant is right and "technique is ourselves."[35] Whether we can recognize that such a distortion of our choices exists, in that we are effectively deprived of the possibility of refusal in the technological dynamo, depends on whether we are following the advice of Grant. As he states: "Only in listening for the intimations of deprival can we live critically in that dynamo."[36]

Group activity might be seen as the wrong level of analysis for examination of the nature of a technological imperative as the impetus for technologically inspired public policy revision. Surely, it could be said, the individual machinations of any particular interest group must be subsumed under the overarching drive towards technology, and all resulting policy changes must after all be considered as having been determined by the very

nature of an imperative: that it cannot be refused. What need, then, is there to look within the interstices of the process for an explanandum, when the process itself is the explanans? For the purposes of this thesis, it must be acknowledged that this is a relevant, and very powerful, argument. There is, unfortunately, no measure that one can easily grasp that would enable the validation of such an imperative; this was alluded to before, and shows that it is still difficult to escape the restrictive confines of the North American social science paradigm, trapped in the logical empiricist's forced denial of the untestable. From this same tradition, however, one can induce alternative, and testable, hypotheses; the caveat must remain that these may themselves reduce us to the blinded state that was referred to by Aronowitz. This in some measure describes the development of the third hypothesis, which is based on the observed articulation of the pharmaceutical lobby interests couched in terms of a rhetoric of technology which privileged accommodation of technological means over ends, to the detriment of social welfare. What follows in the next two chapters is an empirical description of the process which is to be investigated; the final chapter, as noted earlier, will analyze and integrate the themes elaborated upon above.

Notes to Chapter I

[1]Canada, Parliament, Hansard's Parliamentary Debates, 33rd Parlt., 2nd sess., 1986, 129, pt. 5:101.

[2]Langdon Winner, Autonomous Technology: Technics-out-of-Control as a Theme in Political Thought (Cambridge: MIT Press, 1977), pp. 101-2. Emphasis in Winner.

[3]Ibid., p. 100. Emphasis in Winner.

[4]Ibid., p. 16, quoting Jacques Ellul, The Technological Society, trans. John Wilkinson (New York: Knopf, 1964), p. 138.

[5]Jacques Ellul, The Technological Society, trans. John Wilkinson (New York: Knopf, 1964); idem, The Political Illusion, trans. Konrad Kellen (New York: Knopf, 1967); idem, The Technological System, trans. Joachim Neugroschel (New York: Continuum, 1980).

[6]Idem, The Technological Society, pp. xxv-xxvi. Emphasis in Ellul.

[7]George Grant, Technology and Empire: Perspectives on North America (Toronto: House of Anansi, 1969), p. 113.

[8]Ibid., pp. 38-40.

[9]Jacques Ellul, In Season, Out of Season, trans. Larii K. Niles (New York: Harper & Row, 1982), p. 30.

[10]Ibid., p. 177.

[11]Ellul, The Technological Society, p. xxvii.

[12]Ibid., p. 79-80.

[13]Ibid., pp. xxvii-xxxiii.

[14]Ibid., p. xxxv.

[15]Ibid., pp. 23-24.

[16]Ibid., pp. 27-28.

[17]It must be noted that Ellul was a professor of history at the University of Bordeaux from 1938, and that he wrote his dissertation on Roman law; his perspective on this period is thus both conditioned and enhanced by his academic background. See Ellul, In Season, Out of Season, passim.

[18]Idem, The Technological Society, p. 29-32.

[19]Ibid., p. 38.

[20]Ibid., pp. 41-42.

[21]Ibid. Ellul explicates these five phenomena at length; a summary is given here. See pp. 47-60.

[22]Ibid., p. 60.

[23]Ibid., p. 79.

[24]George Grant, Technology and Justice (Toronto: House of Anansi, 1986), p. 32.

[25]Grant, Technology and Empire, p.113.

[26]Arthur Kroker, Technology and the Canadian Mind: Innis/McLuhan/Grant (Montreal: New World Perspectives, 1984), pp. 40-41.

[27]Ibid., pp. 37-40, passim.

[28]Herbert Marcuse, One Dimensional Man (London: Sphere, 1968); idem, An Essay on Liberation (Boston: Beacon Press, 1969); Jurgen Habermas, Toward a Rational Society: Student Protest, Science and Politics, trans. Jeremy J. Shapiro (Boston: Beacon Press, 1970).

[29]Herbert Marcuse, "Industrialization and Capitalism in the Work of Max Weber," in Negations: Essays in Critical Theory, trans. Jeremy J. Shapiro (Boston: Beacon Press, 1968), p. 223, quoted in Habermas, "Technology and Science as 'Ideology'," p. 82.

[30]Habermas, "Technical Progress and the Social Life-World," pp. 60-61.

[31]Habermas, "The Scientization of Politics and Public Opinion," pp. 72-80.

[32]Stanley Aronowitz, "Technology and Culture," Canadian Journal of Political and Social Theory 9 (Fall 1985):127.

[33]Ibid. Aronowitz is referring to Arthur Kroker, Technology and the Canadian Mind, (see note 26 supra).

[34]Michael A. Weinstein, "Lament and Utopia: Responses to American Empire in George Grant and Leopoldo Zea," Canadian Journal of Political and Social Theory 5 (Fall 1981):48.

[35]Grant, Technology and Empire, p. 137, quoted in Kroker, p. 28.

[36]Grant, Technology and Empire, p. 141, quoted in Kroker, p. 31.

Chapter II

Prior to amendments to the Patent Act in 1969, the companies that produced pharmaceuticals for sale in Canada enjoyed the same level of patent protection as other owners of patent rights, namely 17 years. However, it must be noted that the Patent Act, even prior to the changes that will be the subject of this chapter, already had a provision for the compulsory licensing of patented products at the discretion of the Commissioner of Patents of Canada. This provision was intended to ensure that patents were not abused, usually by refusal of the patent holder to actually exercise use of the patent; there also existed the possibility for the Exchequer Court of Canada to grant compulsory licenses if patents were used in the restraint of trade. This latter provision could be invoked after an offence under the Combines Investigation Act had been proved.[1]

It is interesting to note that the Patent Act already contained a mechanism intended to regulate the price of drugs through a compulsory licensing process; it was not a completely new system that was proposed later.

The relevant section is quite specific as to the aims of the legislators, as can be seen below:

> 41(3). 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 [of Patents] shall, unless he sees a 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 <u>available to the public at the lowest possible price</u> consistent with giving to the inventor due reward for the research leading to the invention.[2]

This would seem a fairly straightforward method of ensuring that drug prices would be subject to the laws of competition, by removing patent protection completely in exchange for royalty payments. This, in fact, was the essence of the 1969 legislation, which is commonly assumed to have been the first attempt by any Western industrialised nation to control drug prices through a system of compulsory licensing. Why, then, did the Patent Act not fulfill the legislators' intentions? That it did not is obvious from the fact that in the twenty years following the Second World War, drug prices in Canada rose 150% until they were among the highest in the world.[3]

To understand why the provision did not achieve its objective, it is necessary to examine the nature of the drug industry in Canada at the time. Most of the large pharmaceutical companies producing prescription drugs (known as "ethical" drug manufacturers) were Canadian subsidiaries of foreign multinationals. Data obtained by the Royal Commission on Health Services (the Hall Commission) showed that 90% of ethical drug sales in Canada in 1960 were attributable to 40 companies. Of these, only 4 were Canadian owned and controlled; the remainder were subsidiaries of large U.S. or European companies.[4] The Hall Commission studies came to the conclusion that: "It is evident that conditions in the drug industry in Canada are largely related to and influenced by conditions in the industry in the United States; in fact in many respects the Canadian market may be considered as simply an extension of the United States market."[5]

This perception of the Canadian drug industry was also one held by other government commissions charged with investigating it. In 1961, the Restrictive Trade Practices Commission published the results of its own inquiry into the drug industry in Canada, known as the

"Green Book."[6] This noted that as far as the drug market in Canada was concerned, ". . . the North American area was spoken of as the domestic area. . . . The great majority of large ethical drug firms operating in Canada are branches or subsidiaries of United States firms and import not only basic drugs from the U.S. but, in many instances, prepared dosage forms and simply package them in Canada."[7]

This market structure must be understood so that the nature of the patent process, or specifically the failure of the compulsory licensing provisions, can be clarified. The Royal Commission on Patents, Copyright and Industrial Design, which reported in 1960, found that in the 24 years between 1935 and 1959, there were only 14 applications for compulsory licences under Section 41 of the Patent Act, "of which four licences have been granted and three licences have been refused, the remaining applications being either abandoned or withdrawn and pending."[8] The key to the dearth of applications for compulsory licences can be found in the fact that any drug process licenced in such a way carried with it a responsibility to <u>manufacture</u> the drug in Canada.[9] The problem was that there were no large scale manufacturers

prepared to infringe other patent-holders' rights by demanding licences; this would expose them to similar action by others. Hardly any patents were held by the few Canadian drug companies, nor was the industry one geared to the manufacturing of substances, as opposed to "packaging" them. This is graphically illustrated in evidence given to the Banks Committee, which investigated United Kingdom patent laws in the 1960's, and reported that:

> prices of commonly-prescribed drugs in Canada were substantially higher than in the United Kingdom, that the cost of drugs was usually borne directly by the consumer, that 85% of drug manufacture in Canada was confined to the conversion of imported material into final-dosage form, that at least 95% of Canadian drug patents were owned by residents of foreign countries, and that expenditure on pharmaceutical research in Canada was at a comparatively low level.[10]

To summarise, the Canadian drug industry did not avail itself of the compulsory licencing provisions of the patent act because of the monopolistic nature of the industry at that time, where although 57% of companies were Canadian controlled, they only accounted for 14% of shipments of goods of own manufacture.[11]

The reasons for the lack of interest in compulsory licences were highlighted by the Restrictive Trade Practices Commission; they were based on the reluctance

of the Canadian subsidiaries which had the facilities to manufacture drugs to enter into competition with either their own parent firms, or those of other multinational pharmaceutical firms, that were the patent holders. The Commission came to the conclusion that the problem of high drug prices rested with the patent system itself, and it recommended stringent measures as a remedy. It found that:

> The compulsory licence provision of the Patent Act has been used infrequently and in the opinion of the Commission cannot be relied upon to achieve the purpose intended by Parliament of ensuring that medicines should be made available to the public at the lowest possible price consistent with giving to the inventor due reward for the research leading to the invention. The Commission has considered whether such an objective would be assured if compulsory licences under Section 41(3) of the Patent Act were made issuable as of right and has concluded that such a change would make no appreciable difference in the present situation. As the Commission believes that close control exercised by patents has made it possible to maintain drugs at levels higher than would have obtained otherwise and that such patent control has produced no benefit to the public of Canada which would outweigh the disadvantages of the monopoly, the Commission recommends 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.[12]

By removing the need to manufacture drugs in Canada under the terms of a compulsory licence, through the abolition of the patents themselves, the Commission would have thus paved the way for the smaller Canadian controlled drug companies to import the necessary chemical substances; these were available from foreign companies that were

able to supply to markets that were not protected by third party patents.

The notion that perhaps prescription drugs could be supplied by other than the patent holders, through the importation of the material from "foreign" countries, was already being raised both in Canada and in the United States in the late 1950's. This was due to the actions of a U.S. Senate Subcommittee on Antitrust and Monopoly, chaired by Senator Estes Kefauver, which began inquiries into the U.S. drug industry in January 1957; the pricing and marketing policies of this industry were to be the subject of the Subcommittee's investigations for over ten years, until October 1967.[13] The initial phase of the Senate hearings ended in 1962, when a bill was proposed (S.1552) which would remove 17 year patent protection in exchange for 3 year exclusivity, followed by 14 years of licensing rights; the patent holder in this latter phase would be required to grant a license to manufacture the patented drug in exchange for a royalty, not to exceed 8% of sales.[14]

The terms of S.1552 will be seen to be remarkably similar to attempts by Canadian civil servants and

legislators in the 1960's to break the monopoly of the drug industry, something that the U.S. bill was not able to do; the section regarding patents and compulsory licensing was removed on the Senate floor.[15] Although the Kefauver Committee had begun initial investigations in 1957, formal hearings did not take place until the end of 1959. However, the Canadian civil service had begun its own inquiry into the cost of drugs in April 1958, and this took place under the auspices of the Director of Investigation and Research of the Combines Division;[16] the results were presented to the Restrictive Trade Practices Commission in 1961 (the above mentioned Green Book).

In the midst of these official examinations of the drug industry, there was no lack of effort by its representatives to defend its prerogatives even before these were attacked. The problems with compulsory licensing under the Canadian Patent Act were shown earlier in this thesis, in that the requirement to manufacture substances in Canada effectively made the process redundant. This was recognised by many as leading inevitably to demands that the importation of chemical entities should be allowed in order to carry out

the intent of the legislators. A comment typical of the industry's reaction to such possibilities was made by the President of one of the largest Canadian pharmaceutical companies (Ayerst, McKenna & Harrison), itself a part of American Home Products, one of the largest U.S. drug firms.[17] His statement, made to the Ontario Retail Pharmacists' Association in 1960, was clear on the points made above:

> There is a movement on foot to undermine the North American pharmaceutical industry by the importation of foreign-made chemicals and compounds of obscure origin produced at lower costs than possible in North America. . .
>
> This movement to the prescription and sale of generic-name drugs from unknown foreign manufacturers versus trade name drugs is being promoted . . . by selfish motives and interests in the guise of a crusade to improve the lot of the Canadian public.[18]

At this point the distinction between generic name and trade, or brand name should be clarified, as these terms are important in discussions of the drug industry. Although generic name is not the correct term in Canada (it should be called the "proper name") it is the most widely used term for the "abbreviated scientific name for a drug and is generally used in prescribing, naming and identifying drugs."[19] The trade, or brand name of a drug is the registered trademark of a particular company for the drug identified in the generic name. There is a

third level of nomenclature, which is the one actually indicative of the composition of the drug; this is the chemical name, which is the true scientific name. These three different naming conventions are best illustrated by an example which demonstrates the complexity of the matter. For instance, the trade name of Aureomycin is held by Cyanamid for a drug which has the generic name of chlortetracycline HCL, the chemical name of which is expressed as "The hydrochloride of 7-chloro-4-dimethylamino - 1, 4, 4a, 5, 5a, 6, 11, 12a - octahydro - 3, 6, 10, 12, 12a - pentahydroxy - 6-methyl - 1, 11 - dioxo-2-napthacene carboxamide."[20]

It has been stated that one should only apply the term "generic" when referring to the prescribing of a drug; if the physician uses the generic name, such as chlortetracycline HCL, on the prescription, he is in effect delegating responsibility to the dispensing pharmacist for the selection of the actual brand given to the patient. If, on the other hand, the physician uses the trade name on the prescription, Aureomycin in this case, then the pharmacist would have to dispense that particular brand.[21] In fact, a concerted campaign by the National Pharmaceutical Council, composed of the

largest U.S. brand name drug manufacturers, in the 1950's and early 1960's led to the adoption by 48 U.S. states of "antisubstition laws" which made it a criminal offence for a pharmacist to dispense a generic equivalent if the physician specified a brand name drug.[22] The fact that these laws were not passed in Alaska, Missouri, or the District of Columbia without any detrimental effects on public health, and the belief that they were utilized by the major brand name companies to protect themselves from price competition,[23] coupled with the investigations by the Senate subcommittee on Monopoly and its attendant publicity, led to the eventual rescinding of these antisubstitution laws in all but six states.[24]

One must be careful in the use of the term generic, because the only official definition is that given above, i.e. the abbreviated name given to all drugs. However, a more general usage outside the drug industry is that where generic is taken to mean drugs produced by other than a major brand name manufacturer. Even this is a misconception, because many of the major manufacturers also produce "generic" versions of their competitors' products that are no longer protected by patent; these are sometimes marketed under the generic name only, but

the "copier" version is also sometimes given a brand name of its own. This leads to the confusing presence of not only brand name drugs, but generic versions of them which are also brand name drugs! Suffice to say that popular conceptions are that generic drugs are produced mainly by those "generic houses" that are not themselves the manufacturers of major brand name drugs, and which do not generally engage in research and development of new chemical entities (NCE's).[25]

The presence of such generic houses in the United States, and to a very limited extent in Canada, was the impetus for the political interest in drug pricing in the two countries. The revelation in the Kefauver hearings that brand name companies were charging up to twenty times more than the equivalent generic product,[26] was confirmed in the Restrictive Trade Practices Commission hearings in Canada, which were referred to earlier. The Canadian investigations into the drug industry were carried forward throughout this period by upper-echelon civil servants, who had formed an interdepartmental committee at the request of the Justice Minister, Guy Favreau, after the reports of the Hall Commission on Health Services and the Restrictive Trade Practices

Commission had been published. The committee was chaired by D. H. Henry, Q.C., who had been the head of the initial inquiry into the drug industry, in 1958, held under the Combines Investigation Act.[27] The other departments involved in this committee were Patents, Health & Welfare, and later Industry, Finance, and Trade & Commerce. The committee was to be instrumental in the policy decisions of the Pearson and Trudeau governments, as will be seen in this chapter. However, prior to the formation of the committee, the Conservative government had, in November 1962, announced its intention to form a special parliamentary committee "to make a full-scale investigation into Canada's drug industry."[28] As was the case in the U.S., the political involvement came in the wake of the thalidomide tragedy; thalidomide control legislation to ban the sale of this drug, "blamed for birth malformations of about 60 infants in Canada and thousands in Germany and other countries,"[29] was in its final stages in the Canadian parliament at the time the special committee was announced.

The context of the formation of the parliamentary committee, that is the thalidomide tragedy, is important in the development of the debate on the drug industry in

Canada. Because of this tragedy, the pharmaceutical manufacturers were able to focus attention on the issue of drug safety, rather than on drug pricing. In fact, the issue of price became unimportant in the light of the dangers to public health of such drugs as thalidomide, and the terms of reference of the committee demonstrated this in that "the prime purpose of the committee was safety and quality of drugs rather than costs."[30] The major manufacturers attempted to focus the debate on the lack of quality control, and thus dubious safety, of the generic houses, even though thalidomide had been made by a major pharmaceutical company, Merrell, and was sold as a brand name drug (as Kevadon), under licence from the inventors, Chemie-Grunenthal of West Germany.[31]

The major drug manufacturers in the United States had also attempted to excoriate generic houses during the Kefauver hearings, and there were indeed some generic companies that were known as "schlock" houses, described as "dreadfully unhygienic operations - something like two men and a bathtub - turning out dreadful products."[32] However, some of the opponents of generic drugs could be described as partisan to say the least; one example is that of Dr. Austin Smith who, as president of the U.S.

Pharmaceutical Manufacturers Association, in 1959 was against the use of generic equivalents. Yet, when he was editor of the Journal of the American Medical Association as long ago as 1944, he "had come out strongly in favour of generic prescribing, mentioning the 'enormous profits' to be made from brand name drugs, and condemning the 'absurd practice' of prescribing them when less expensive generic equivalents were available."[33]

The initial stages of the special parliamentary committee's activities were, therefore, concerned more with the safety and efficacy of drugs, with the focus being forced onto generic equivalents. This process was aided amply by senior members of the regulatory agencies charged with overseeing the drug companies, in both the United States and Canada. In the former case, Dr. Henry Welch, head of the antibiotic division of the Food and Drug Administration, was found to be working with major drug companies "with what seemed to some observers to be undue closeness," which on further investigation led to the revelation that he had received "a small honorarium" for "editorial duties" with two medical journals. When this was shown to amount to $287,142.40 over a seven year period, his resignation from the FDA was accepted.[34]

In the case of Canada, the head of the Food & Drug Directorate (FDD), Dr. Morrell, did not seem disposed to condemn high drug prices per se. The report prepared by the Department of National Health & Welfare for the Hall Commission included as its only appendix a copy of an article in the Canadian Medical Association Journal, that was basically an attack on a law passed (in 1962) by the Province of Alberta allowing pharmacists to substitute a generic equivalent even where a brand name drug had been prescribed. Dr. Morrell, as Chief of the FDD, was quoted as follows: "When it comes to buying top-quality drugs, the things to check are the ability, facilities, personnel and conscience of the manufacturer. . . . The real point is who makes the drug and how it's made."[35] The conclusion of the article's author was that: "It is not within the function of the Food & Drug Directorate to guarantee the quality of drugs sold in Canada, this assurance normally being provided in the trademark adopted by the manufacturer."[36]

The opinion of Dr. Morrell was thus being used as a vindication for brand name drug manufacturers, as they were being promoted as the only companies that would be able to guarantee quality, in part because of their need

to maintain their reputation. This analysis of course ignores the fact that some of the worst cases of abuse in the form of marketing of unsafe drugs could be laid at the door of the brand name manufacturers, including the cases of thalidomide, MER/29, Chloramphenicol and other drugs whose toxic effects were deliberately ignored, and in some cases the records of which were falsified, in order to bring to market drugs which had very high profit potentials.[37]

The analysis also ignores a fundamental role of all corporations, which is the need to make a profit; the juxtaposition of the need for safety and the need for profit is succinctly demonstrated in quotations from the Pharmaceutical Manufacturers Association of Canada. In its Principles and Code of Marketing Practice it is stated that: "The calling of a pharmaceutical manufacturer is one dedicated to a most important public service, and such public service shall be the first and ruling consideration in all dealings." Contrast this with the words of a past President of the Association: "The pharmaceutical industry has never claimed to be motivated by altruism, but rather by profit for survival."[38]

The role of Dr. Morrell, as Chief of the FDD, was therefore important in the public perception of the major manufacturers; that they are indeed motivated, whether through conscience or profit, to produce safer drugs than the generic manufacturers. In the Canadian parliamentary committee hearings, "the PMAC had been allowed to make its case for brand name superiority without challenge. It had received support on this point . . . when Dr. Morrell had told this same special committee that 'he personally would always buy a brand name drug, to ensure that he obtains the quality and efficacy guaranteed by the reputation of a well-known manufacturer.'"[39]

The correlation between the roles played by senior members of the FDA and the FDD is that public policy, in this case a desire to ensure that "fair" drug prices were being charged to consumers, was being influenced by regulatory agencies which had become closely intertwined with, and sympathetic to, the regulated industry; this has been described as a truism for most Western societies.[40] This perspective has been noted with particular clarity in a study of the Federal Communications Commission in the U.S.A., and its "capture" by the industry it is meant to oversee.[41]

The parliamentary committee continued throughout 1963 and 1964, with the emphasis on drug safety, as was elaborated above. However, in 1965, it was announced in the throne speech that the committee would be given new terms of reference, and would now be "empowered to consider and recommend, as it may be deemed expedient, respecting a comprehensive and effective program to reduce the price of drugs."[42] This change in focus has been attributed to the work of the interdepartmental committee mentioned earlier, which had submitted its own version of the "Green Book" recommendations to the new Cabinet, and actively promoted the reduction of drug costs by alteration of the patent laws.[43] From this point on, the Pharmaceutical Manufacturers Association of Canada was put on the defensive, and had to change its tactics from the promotion of safety only, to one of justification for patent protection in general, as will be seen below.

The parliamentary committee, known as the Harley Committee, conducted hearings in 1965 which "did not accomplish much that was useful,"[44] but after it was reconstituted early in 1966, it finally began hearings which were to provide the basis for the legislation that

would in effect abolish patent protection for drugs in Canada. The hearings are important in the context of this thesis, as it is here that one would expect the technological imperative of research and development to be called forth to justify the continuation of patent protection, even though we have seen that this had not so far been done when the question of product safety could be kept at the forefront of debate by the pharmaceutical manufacturers. The record of the hearings has been made the subject of scrutiny to determine this very point, and it has been found wanting.

The main representations of the Pharmaceutical Manufacturers Association of Canada took place in June 1966, and consisted of a voluminous brief which covered 14 sections with an additional 15 appendices.[45] The cost and value of research[46] is elaborated upon by the Association, in which the world pharmaceutical market is shown to expend $400 million annually on research and development, the fruits of which are made available to the Canadian subsidiaries of the major manufacturers. However, it is also shown that the Canadian component of this research activity amounted to only $6.5 million in 1965, and was only $2.5 million in 1959. Although there

was a separate (and much larger) section on the need for patent protection in the brief,[47] this point was also addressed under cost and value of research. The PMAC stated that "it is our strong contention that a research based industry develops its maximum potential only under the spur of sustained competition. In this connection patent laws are valuable . . ."[48]

This contention, of course, could be debated by economists, and had been addressed in a seminal paper by K. J. Arrow in 1962, where it was "concluded that the incentive to invent is less under monopolistic than under competitive conditions."[49] It has already been shown that the Canadian drug industry was operating under conditions of near monopoly, and it will be shown in the next chapter that patent protection enhances this position, and would thus tend to counter the PMAC contention, which in and of itself was intended to strengthen the monopoly position of the industry by retaining, and even increasing, the level of patent protection available in Canada.

Even though the pharmaceutical industry had only nine major manufacturers operating research laboratories

in Canada, the PMAC foresaw further growth as long as the necessary investment was not "precluded" by any adverse treatment of the industry. The brief refers to this expansion of research & development activity as a reflection of "the growing scientific maturity of this country," but elsewhere it notes that it would not be realistic to expect any significant outcome from this research effort, as although we would remain "worthy collaborators in an international venture, [t]his must remain an international industry, with the main foci on endeavour in those countries where the major companies have been long established."[50]

The main thrust of the PMAC brief was that "the public interest is not limited to the provision of drugs at the lowest possible price. Quality and safety are extremely important."[51] Although this is a statement which would be accepted by most observers, the linkage that is made to the retention of patent protection may not be as acceptable. The above quotation is to be found in the section of the PMAC brief dealing with patents, and it is in the same paragraph as the contention that "the growth of a research based industry that makes large scale investments and provides good employment

opportunities is extremely important." The brief goes on to state that: "There is ample evidence of Canada's recognition that it can enhance its industrial status only if it encourages innovation through research and development . . . [a]nd of course, a patent system provides industry with the very primary incentive to innovation."[52] This is then linked to the long term industrial growth of Canada, and its national interest, in that "[i]f the development of pharmaceutical research is held to be a national interest for Canada, the denial to the industry of reasonable patent protection calls for the closest scrutiny. Canada can ill afford decisions that could endanger its long term interests as a rising industrial power."[53]

The issue of whether or not patent protection would indeed lead to all the benefits claimed for it was not seriously addressed by the Harley Committee, and the PMAC was allowed to make such claims without serious attempts at rebuttal. This was not the case for the issue of brand name superiority over generic equivalents, however. This had already been apparently resolved in favour of the PMAC by the earlier hearings, in which it will be recalled that Dr. Morrell had come out in favour of bran

name drugs. The FDD now had a new Director, Dr. R. A. Chapman, who did not share his predecessor's viewpoint. In January 1967, he appeared before the Harley Committee and stated: "There does not appear to be any significant difference between drugs sold under a generic name and those sold under a brand name. Similarly, imported drugs appeared to be of the same general quality as domestic production."[54] Dr. Chapman's appearance before the Harley Committee was followed by that of D. H. Henry, Q.C., the head of the interdepartmental committee which was by now highly critical of the PMAC. Within a short space of time, the case for brand name superiority was completely discredited by the government representatives that appeared before the Harley Committee, which produced its final report with a recommendation that the Patent Act be amended to allow the issuing of "compulsory licences to import drug products in all forms."[55]

The Liberal government proposed legislation based on the Harley Committee's recommendations, as Bill C-190, in December 1967. An intensive campaign against the bill was mounted by PMAC, which "was not satisfied to limit its activities to pressurising Members of Parliament and the influencing of public opinion. It actively attempted

to influence and enlist the aid of other interests in the country and approached both legislators and public servants, from every flank."[56]

However, the thrust of the attack against the proposed changes was that generic drugs would not be manufactured to the same high standards as the brand name drugs, lacking their therapeutic quality and possibly even dangerous. This was disproved by the Department of National Health and Welfare which had conducted studies on this subject; studies which a member of the drug lobby had tried to suppress, or at least have withheld from discussion, during the Special Committee proceedings.[57]

Although the PMAC lobbying campaign managed to delay the initial legislation (Bill C-190 dying with the dissolution of the House prior to the 1968 election), the new Trudeau government reintroduced changes to the Patent Act which became law as Bill C-102 March 28th 1969. Following what was described, in view of the "extent and degree of the pressure applied," as perhaps "one of the best examples of present-day lobbying in Canada,"[58] the multinationals were forced to give licences on request to any "generic" drug company for their products, which

could then either be manufactured, or imported into Canada, in return for a 4% royalty of the sales of the copied drug(s).

Throughout the campaign, the issue as presented to the general public seems to have been one of safety, in the terms of the product made available. As presented to private industry, in particular in the attempt to foster support in the dying stages of their campaign, the focus was on the precedent that could be set in removing patent protection from any industry:

> . . . the PMAC sent a letter to each of the association's 56 members enclosing short biographies of 100 chief executive officers of the largest companies in Canada. This letter urged that drug company presidents should contact their counterparts in other industries and urge them to write to selected Cabinet Ministers, with copies of such correspondence going to the Prime Minister, expressing their opposition to any legislation which would endanger or weaken patents or trade marks in Canada.[59]

Nowhere can one readily find references to technology, or of the harmful impact of reduced profits on research and development. The drug lobby knew that the public perception at the time was one of a profitable industry, and arguments that were related to the profit-motive were not cogent enough in the face of a

rising awareness amongst consumers that they were paying too much for drugs.

Arguments on the imperative of technological advance within Canada needed to await a climate more conducive to a remoulding of public policy; a climate allowing a re-allocation of resources, that is of consumers' costs being inflated by re-imposition of patent protection with the concomitant restoration of profits to the multinational drug companies. This was to arrive in the form of a Conservative government with an agenda that was prepared to favour an industry that could assert that research & development <u>within Canada</u> would allow the emergence here of the "biotechnology revolution" necessary for "progress"; this will be examined in the next chapter. Meanwhile, if one may paraphrase one analyst, they had to await, or inculcate, that technocratically inspired remoulding of public policy which would "serve historical inevitability by facilitating a social response to it."[60]

Notes to Chapter II

[1]Canada, Dept. of National Health & Welfare, Provision, Distribution, and Cost of Drugs in Canada (Ottawa: Queen's Printer, 1965), p. 27. The above study was prepared by the Research & Statistics Division of the Dept. of National Health & Welfare, at the request of the Royal Commission on Health Services (Hall Commission), in 1962-63. [Hereafter referred to as Cost of Drugs in Canada.]

[2]Ibid., p. 28. [Emphasis added.] The Patent Act cited is the 1952 version [R.S.C., 1952, ch. 203]. The compulsory licensing provision was in operation in previous versions also. "The origin of Section 41(3), which was introduced in 1923 having been modelled on a similar section of the English Patent Act of 1919, was the danger of a shortage of drugs in England." Canada, Parliament, House of Commons, Special Committee on Drug Costs and Prices, Minutes of Proceedings and Evidence, No. 5, June 23 1966 (Ottawa: Queen's Printer, 1966), p. 108.

[3]CBC, "The Journal," 18 November 1986, "Political Prescription."

[4]"Submission to the Royal Commission on Health Services by the Canadian Pharmaceutical Manufacturers Association, Toronto, 18 May, 1962," p. 117, cited in Cost of Drugs in Canada, p. 31. Of the 36 foreign owned companies, 28 had parents based in the U.S., and 8 were subsidiaries of European drug manufacturers.

[5]Cost of Drugs in Canada, p. 31.

[6]Canada, Dept. of Justice, Restrictive Trade Practices Commission, Report Concerning the Manufacture, Distribution and Sales of Drugs (Ottawa: Queen's Printer, 1963). See note 7 infra for details of the "Green Book." This inquiry was made under Section 42 of the Combines Investigation Act. [Hereafter referred to as the Report, RTPC.]

[7]Report, RTPC, Appendix Q, quoted in Ronald W. Lang, The Politics of Drugs (Lexington, Mass.: Lexington Books, 1974), pp. 28-29. This Appendix is what is known as the "Green Book"; the title is "Material Collected for Submission to the Restrictive Trade Practices Commission in the Course of an Inquiry under Section 42 of the Combines Investigation Act, Relating to the Manufacture, Distribution and Sales of Drugs." [Hereafter referred to as the Green Book.]

[8]Canada, Royal Commission on Patents, Copyright and Industrial Designs, Report on Patents of Invention (Ottawa: Queen's Printer, 1960), cited in Cost of Drugs in Canada, p. 30.

[9]Andrew H. Wilson, Background to Invention: A Summary of Views on the Canadian Patent System and on Industrial Research and Development Activities in Canada (Ottawa: Science Council of Canada, 1970), p. 25.

[10]Great Britain, Parliament, The British Patent System: Report of the Committee to Examine the Patent System and Patent Law, Cmnd. 4407 (London: HMSO, 1970), p. 116, quoted in Lang, p. 27, (emphasis added by Lang).

[11]Myron J. Gordon & David J. Fowler, The Drug Industry: A Case Study of the Effects of Foreign Control on the Canadian Economy (Ottawa: Canadian Institute for Economic Policy, 1981), pp. 36-37.

[12]Report, RTPC, pp. 525-26, quoted by Lang, p. 30, (emphasis added by Lang).

[13]Lang, pp. 13-16. Senator Estes Kefauver died in August 1963; the Kefauver-Harris Amendments had been signed into law at the end of 1962 after "the thalidomide tragedy swept across the country." The work of the Senate subcommittee continued under the chairmanship of Senator Gaylord Nelson. Milton Silverman & Philip R. Lee, Pills, Profits and Politics (Berkeley: University of California Press, 1974), pp. 115-16, 145-51.

[14]Lang, p. 14.

[15]Ibid., p. 16.

[16]Ibid., p. 28.

[17]Ayerst was acquired by American Home Products in 1943. Gordon & Fowler, p. 35.

[18]E. Clyde Gregory of Ayerst, McKenna & Harrison Globe & Mail (Toronto), 7 June 1960, cited in the Green Book, p. 14. Quoted by Lang, p. 20, (emphasis added by Lang).

[19]Joel Lexchin, The Real Pushers (Vancouver: New Star Books, 1984), p. 17.

[20]Lang, p. 31.

[21]John W. Egan, Harlow N. Higinbotham, & J. Fred Weston, Economics of the Pharmaceutical Industry (New York: Praeger, 1982), p. 53.

[22]Silverman & Lee, pp. 142-43.

[23]Ibid., p. 143.

[24]Egan, Higinbotham, & Weston, p. 54.

[25]Ibid., p. 53.

[26]Silverman & Lee, p. 144.

[27]Lang, pp. 132-36. See also note 6, supra.

[28]Ibid., p. 130. The announcement was made in the House of Commons by J. Waldo Monteith (PC, Perth), the Minister of Health, on November 30 1962.

[29]Ibid.

[30]Ibid., p. 131.

[31]Silverman & Lee, p. 95.

[32]Ibid., p. 144.

[33]Ibid.

[34]These revelations were made in the Saturday Review, at a time when Senator Kefauver felt he was not receiving adequate support from the Food and Drug Administration (FDA). Kefauver's investigators found out the full extent of the "small honorarium" in 1960, and they offered Dr. Welch the opportunity to appear before the Senate committee following his demand to clarify the record. He never appeared, pleading illness. Silverman & Lee put it succinctly: "He offered to retire from FDA. The offer was accepted." Ibid., p. 113.

[35]Cost of Drugs, Appendix A, pp. 125-28.

[36]Ibid., p. 125.

[37]For thalidomide, see Silverman & Lee, pp. 37, 94-96, and Lexchin, pp. 191-93. For MER/29, Silverman & Lee, pp. 79, 92-96, and Lexchin, pp. 74-79. For the case of Chloramphenicol, see Silverman & Lee, pp. 15, 59-61, 88-89, and Lexchin, pp. 70-74. Thalidomide was estimated to have produced up to ten thousand deformed babies; it was never approved for use in the U.S. because a new FDA medical officer was suspicious of the data provided by the Merrell Company; she felt that something was being held back. Merrell was still trying to have the drug approved in the U.S., and indeed marketed it in Canada, up to March 1962, even though the original innovator had withdrawn thalidomide from the market and warned all its licencees, in November 1961, that it caused birth defects when taken by pregnant women. Tragically, a large number of victims in the U.S. were born to the wives of American physicians who had been given free samples of the drug by Merrell representatives, even though it was unapproved by the FDA for sale to the public.

[38]Lexchin, p. 29.

[39]Lang, p. 196. The viewpoint of Dr. Morrell here must be considered in the light of the fact that shortly after this, in 1965, he retired from the FDD and was made a director of the board of CIBA, one of the world's largest drug manufacturers.

[40]Robert Presthus, Elite Accommodation in Canadian Politics (Toronto: Macmillan 1973), pp. 197-97.

[41]Thomas Redburn, "Wedding Presents, Cigars and Deference," in Inside the System, 4th ed., eds. Charles Peters & Nicholas Lemann (New York: Holt, Rinehart, 1979), pp. 180-88.

[42]Lang, p. 190.

[43]Ibid., pp. 190-91.

[44]Ibid., p. 192.

[45]Canada, Parliament, House of Commons, Special Committee on Drug Costs and Prices, Minutes of Proceedings and Evidence, No. 5, June 23 1966 (Ottawa: Queen's Printer, 1966), pp. 282-84, gives the table of contents for the brief. An abstract appears in ibid., Minutes of Proceedings and Evidence, No. 4, June 16 1966, pp. 97-116. [The proceedings are hereafter referred to as the "Harley Committee."]

[46]Ibid., No. 4, June 16 1966, pp. 102-3.

[47]Ibid., pp. 106-12.

[48]Ibid., p. 102.

[49]K. J. Arrow, "Economic Welfare and the Allocation of Resources for Invention," in R. R. Nelson, ed. The Rate and Direction of Inventive Activity (Princeton: Princeton University Press, 1962), cited by Michael K. Berkowitz & Yehuda Kotowitz, Research & Development Under Competition & Monopoly: Arrow Revisited (Toronto: University of Toronto, Institute for Policy Analysis, 1979), pp. 1, 5.

[50]Harley Committee, No. 4, June 16 1966, p. 103.

[51]Ibid., p. 106.

[52]Ibid.

[53]Ibid., p. 107.

[54]Ibid., Report, Appendix B, No. 30, January 26 1967, p. 2101, quoted by Lang, p. 197.

[55]Lang, p. 198-99.

[56]Canada, Library of Parliament, Research Branch, "Pressure Groups in Canada," Parliamentarian 51 (January 1970):15-16.

[57]Ibid. The studies are summarised in the Harley Committee Report, Appendix B, No. 30, January 26 1967, p. 2101. Presthus also cites the studies, which were not prepared until after the previous director had retired (see also note 39, supra). Presthus, p. 197.

[58]Canada, "Pressure Groups," p. 16.

[59]Ibid.

[60]William Leiss, "The Information Society: A New Name for Some Old Tricks," paper presented at the annual 1982 Departmental Colloquium, "The Social Responses to Technological Change and Environmental Impact," Dept. of Sociology, University of Calgary, March 24-26 1982, p. 2. (Mimeographed.)

Chapter III

On May 22nd 1985, the Mulroney government made public the report of the Eastman Royal Commission, established by the previous Liberal administration to make recommendations on the pharmaceutical industry. The main points of the report were that 1) the royalty rate paid by generic licencees should be raised from 4% to 14% of sales, with the increase being diverted to a special royalty fund, and 2) the fund would make payments to brand name companies based on the value of licenced sales and the amount of research they performed in Canada. As an example of the latter, royalty payments in 1983 under this proposal would have ranged from 6.6% of sales for a company that did no research in Canada, to 39.5% of sales for the one that did the most. The third main recommendation was to impose four year patent protection for newly-developed drugs; this period was to allow innovators to recoup the research and development costs incurred.[1]

The report, and especially the proposal to increase patent protection, soon became the focus of yet another

lobbying campaign by the drug industry, with the PMAC in favour of even more patent protection (ten to twelve years), and the more recently formed Canadian Drug Manufacturers Association (CDMA), which represented 17 smaller Canadian generic drug companies, in opposition to any protection. What has been described as a "cut-throat lobbying war" raged both behind the scenes and in the media, and allegations were soon made that the government was preparing to "sell-out" Canadian consumers because of pressures from the U.S. in the context of the concurrent free-trade discussions.[2]

During the Eastman Commission hearings,the question of research became an issue. The president of multinational drug company Smith, Kline & French advised Canadian doctors not to allow "generic companies to cash in, while doing no original research," and threatened that his firm "envisages leaving Canada and not putting our discoveries at the disposal of Canadians."[3] Before long, the research aspect became the nexus for all the interests seeking to re-impose patent protection. The Dean of Pharmacy at the Université de Montréal claimed that Canadian pharmaceutical research was diminishing, and graduating researchers were having to

leave Canada to work, or else had to stay in Canada and work at desk jobs - a terrible waste. The current law was also cited as one reason why multinational Ayerst, McKenna & Harrison closed its Montréal research centre and moved the operation to the U.S., with the loss of 300 scientific and technical jobs.[4] Underlying these hieratic pronouncements is the implicit acceptance that it is of course proper and necessary for scientists to be employed in research, and that they should carry out such research in Canada if at all possible (although they will happily go elsewhere to perform it if induced). Thus the threats to remove scientific research become much more potent, as this is seen as striking at the heart of the autonomy of the scientific establishment; with the possible loss of development centres, Canadian pharmaceutical research scientists would be much diminished in status, as well as in number.[5]

It is at this juncture that one finds the emergence of the concerted effort to link pharmaceutical research in Canada with the so-called biotechnology revolution. It has been claimed that this will be to the 1990's what the microchip was to the developed world in the 1980's, and that this will be tied into the future of the

pharmaceutical industry, which has been the catalyst (in the form of the multinationals) for national development in biotechnology in other countries.[6] However, the Canadian regulations which permit the compulsory licencing of drugs, unique amongst developed countries, are seen as contributing to the fact that Canada is last amongst OECD countries in per capita investment in both pharmaceutical research and biotechnology.[7]

There are claims that Canadian research, running at about $85 million annually in 1984 (4%-5% of sales),[8] is not high enough. Yet it has been stated that most multinationals perform the majority of their research in their "home" country.[9] Considering that U.S. based pharmaceuticals spend between 7.35% and 8.93% of sales on research (and the higher figure is for companies whose main patents have expired[10]), one can speculate that the Canadian figures are fairly high in view of the fact that no major multinational is based here; possibly because lack of patent protection actually stimulates research, as one cannot "sit back and enjoy" the benefits of new products without competition. This would seem to be borne out by the case in the United States (see table 1 overleaf), at least where major patents have expired.

One of the hallmarks of profitability for any company is its return on equity. The U.S. based multinationals mentioned above average about 19% return on equity, as shown in table 1. The Eastman Commission reported that Canadian multinational drug companies, even with compulsory licencing, have produced a return on equity averaging 17% - higher than that for any manufacturing industry in Canada.[11]

Table 1: 1984 Composite Financial Performance of U.S. Pharmaceutical Companies.

	GROUP I Primarily Patent-Protected	GROUP II Primarily Off-Patent
	%	%
Return on Equity	19.85	18.70
Net Income on Total Assets	12.25	9.50
Net Income on Sales	11.68	10.45
Cost of Goods as Percent of Sales	38.38	42.78
Research and Development to Sales	7.35	8.93

Source: Tamara J. Erickson, "The Next Decade in Pharmaceuticals," Business Quarterly 50 (Fall 1985):81.

With comparable profitability to U.S. based multinationals, and with research and development expenditure which is certainly not as low as is suggested, considering the size of the Canadian drug market, why is it that such resolute lobbying has been

conducted to restore patent protection? After all, as almost all drug research and development is concentrated in the U.S., U.K., Switzerland and Japan (the "homes" of the multinationals or the largest markets), there is not very much likelihood of any massive expansion in that field within Canada.[12] Perhaps the real reason can be found by looking at one example of drug pricing. In the U.S., one prescription fill-up of the proprietary drug "Tagamet" costs $70 cdn; whilst in Canada the same drug costs $30 cdn because of competitive pressure, and the generic equivalent costs only $9 cdn. This is equivalent to a discount of 87% or, conversely, the U.S. price is inflated by more than 130% compared to the Canadian proprietary brand sold by the same manufacturer, or by 677% when compared to the generic version. Recalling that Canada's compulsory licencing is unique in the developed world, and also realizing that the total world drug market at stake is in excess of $100 billion US (as table 2 overleaf shows), one can easily appreciate that the multinationals view the Canadian system as a threat. The real fear of the multinationals is that other countries, including the U.S., will enact similar legislation with enormous harmful potential for their corporate profits.[13] The leading pharmaceutical

companies worldwide are shown in table 3: note that their average research spending is $180 million US annually.

Table 2: Pharmaceutical Sales by Major Geographic Region.

Region	Prescription (U.S. $MM)	Over-the-Counter (U.S. $MM)	Total (U.S. $MM)
United States	17,650	4,760	22,410
Japan	11,920	2,750	14,670
Western Europe	25,565	2,750	28,315
Rest of the World	34,595	1,950	36,545
Total	89,730	12,210	101,940

Source: Arthur D. Little, Inc., cited by Tamara J. Erickson, "The Next Decade in Pharmaceuticals," Business Quarterly 50 (Fall 85):80.

Table 3: Leading Pharmaceutical Companies Worldwide

Rank	Company	"Home Base" Country	1984 Sales (U.S. $MM)	1984 R & D (U.S. $MM)
1	Merck	USA	2,658	290
2	American Home Products	USA	2,613	90
3	Bristol-Myers	USA	2,427	162
4	Pfizer	USA	2,211	159
5	Ciba-Geigy	Switzerland	2,153	230
6	Hoechst	Germany	2,039	274
7	Warner-Lambert	USA	1,894	162
8	SmithKline-Beckman	USA	1,686	158
9	Eli Lilly	USA	1,664	n/a
10	Bayer	Germany	1,575	200
11	Upjohn	USA	1,449	200
12	Takeda	Japan	1,448	125
13	Hoffmann-LaRoche	Switzerland	1,379	363
14	Sandoz	Switzerland	1,373	181
15	Johnson & Johnson	USA	1,296	187
16	Boehringer-Ingelheim	Germany	1,170	176
17	Abbott	USA	1,100	110
18	Squibb	USA	1,090	114
19	Schering-Plough	USA	1,057	129
20	Rhone-Poulenc		855	110

Source: compiled from tables cited in Tamara J. Erickson, "The Next Decade in Pharmaceuticals," Business Quarterly 50 (Fall 1985):81.

There have been various claims made by the participants on both sides in the debate over the proposed legislation. One claim is that multinationals do their research where it is cheapest, and that it would be very difficult for Canada to compete with the U.S., which has very generous research and development tax credits. In fact, the U.S. multinational drug companies perform 85% of their research in the United States.[14]

In February 1986 the lobbying efforts intensified. The PMAC offered to increase research expenditures from $85 million to $300 million within four years, creating up to 2,000 new jobs in the process,[15] although two days previously they had threatened to reduce the $35 million [sic] spent on clinical research in Canada unless patent protection was restored.[16] Within a month, they were stating they would double research from $85 million over four years if the law was changed.[17] Soon, pressure was applied from other quarters. In April, U.S. Trade Representative Clayton Yeutter was claiming that the Canadian government had promised to give brand name manufacturers more patent protection and that the U.S. had so far shown "uncommon patience" in waiting for these changes. This brought denials from Mr. Mulroney that

there had been any "arm-twisting," but he did say that Canada was acting as a "scavenger in the area of intellectual property," and referred (obviously incorrectly) to "a total absence of research and development in Canada."[18]

Shortly thereafter, following his leader's thought process, (then) Minister of Consumer & Corporate Affairs Michel Côté said that "intellectual property must be protected so that research and development can flourish." He went on to state that he would not force the multinationals to increase research in return for patent protection, but would instead rely on promises, thus ignoring the demands from some quarters for guarantees, and the fact that the introduction of compulsory licencing had not had any discernible adverse effects on the levels of research.[19]

It did not take long for the facts of the debate to become obfuscated by the appeal to the imperative of technology. The Health Minister, Jake Epp, declared that our health system "demands the very best in technology . . . [w]e cannot continue that system if we simply decide we can buy the best technology offshore."[20] As an

exercise in elementary logic, this statement is nonsensical.

Michel Côté announced in June 1986 that he would shortly introduce legislation which would result in an "unprecedented" $1.4 billion in research and development, and 3,000 new jobs, over the next ten years. Unfortunately, due to a "procedural" mistake by the Speaker's office, the bill was not tabled when the parliamentary session ended on June 27th.[21] Apparently unaware of this, the PMAC held a press conference that day extolling the new legislation, which led Consumers' Association spokesperson Kathleen Stephenson to comment: "whenever you see multinational drug companies this happy, you should check your wallet." The PMAC did, however, assure the press that announcements of their research plans "may come as early as next week."[22] Before any such announcements were forthcoming, opposition to the proposed legislation continued, with both the CDMA and the New Democratic Party (NDP) marshalling their forces against the new bill. On the subject of research spending in Canada in the context of the world market, the CDMA argued that the assumption that Canadian drug companies had been spending too little

on research and development was wrong, because "when the spending is compared with Canada's share of the global sales market, 'Canada is paying its fair share'."[23] A composite of this market can be found in table 4.

Table 4: Leading Pharmaceutical Markets Worldwide

Country	1984 Sales (U.S. $MM)
United States	22,410
Japan	14,670
West Germany	6,100
France	5,600
China	4,550
Italy	4,390
United Kingdom	3,150
Canada	**1,600**
South Korea	1,400
Spain	1,385
India	1,350
Mexico	1,220
Brazil	1,100
Argentina	800
Australia	640
Indonesia	550
Others	31,025
Total	101,940

Source: Arthur D. Little Inc., cited by Tamara J. Erickson, "The Next Decade in Pharmaceuticals," Business Quarterly 50 (Fall 1985):80.

Although the multinationals had promised to announce $200 million in new investment "during the summer," there was only one company that actually committed itself. This was Merck Frosst, whose President and Chairman, John Zabriskie, happens to chair the PMAC Board of Directors. Even this announcement was only for $20 million, and 50 scientific jobs, in an expansion of Merck's existing Kirkland, Montréal, research facility.[24] By now, the PMAC is quoted as promising investment in research and development over the next ten years to the amount of $700 million (a reduction of 50% over the earlier reports).[25] These disparities will be examined at length later in this Chapter.

Once again (November 6th 1986), the government attempted to table the new legislation, and once again it was unable to do so due to opposition parties using House rules to delay first reading. Not surprisingly, the PMAC had already scheduled their news conference, where they announced plans for increases in research expenditures to $3 billion by 1995, still with a target of 3,000 new jobs. At the same time, the generic opposition in the form of the CDMA was claiming that increased costs to consumers under the new law were likely to climb to $650

million annually by 1995.[26] Finally, after a deft maneuver in the House which caught the opposition with fewer than the 25 M.P.'s necessary for the procedural blocking to continue, the Deputy Prime Minister (Don Mazankowski), won approval for the House to give first reading to the long-awaited legislation. Coincidentally, on the same day, three brand name drug firms announced expansion plans in research and development entailing investment of $102 million.[27]

It is clear from the range of promises by the PMAC that there is some manipulation of numbers involved as far as increased research expenditure claims are concerned. Their promises have produced ten year figures of:

(1) $700 million, which is actually less than current levels of spending,

(2) $1.4 billion, somewhat less than double current levels, and

(3) $3 billion, between three and four times current levels. The number of claimed scientific or technical jobs promised have ranged from 2,000 to 3,000, with the latter figure being the apparent consensus lately.

Let us examine the figures a little more closely. One can determine elsewhere that research spending is actually divided in various ways; of the $85 million currently spent, about $20 million is contract work given to hospitals and universities for clinical trials. Actual research is carried out in only a few companies, six in 1985, employing a total of some 1,000 personnel involved with research and development.[28] As to the absolute dollar values, little mention is made of the fact that this will include figures for investment in physical plant and equipment, and replacement of (depreciated) facilities. This of course is not a net investment, and a proportion would have taken place in any event. In written commitments said to have been delivered by the Chairperson of the PMAC to the federal government, which are the only commitments one should really consider, promises were made to create 2,000 "high-tech" jobs by 1990, and to invest $1 billion (also by 1990). This would be divided into $650 million in actual research and development, and $350 million in new plant and equipment.[29] Taking current levels of expenditure into account, this would produce a net increase in research investment of 50%, or $45 million annually; certainly a respectable amount, but one must

relate this to claims that consumers may have to pay up to $650 million annually (by 1995) in increased prices - or fourteen times the net increase in investment. Of course, we are given to understand that research personnel will increase by between 100%-200% over the next five to ten years; no wonder that the scientific establishment is so eager to help this development take place.

Where then does this leave us? It would seem from an investigation of the facts that the government is prepared, nay adamant, to allow Canadian drug prices in the future to begin that spiralling path they once followed; in the twenty years after the Second World War, they rose 150% until they were amongst the highest in the world, now they are amongst the lowest.[30] The benefits we are to enjoy to offset this would seem to be only a modest increase in investment and scientific employment, and a chimaerical involvement in the "biotechnology revolution." It has been stated, however, that

> it will probably not be until the next century that we will see the true potential of biotechnology spanning several industrial sectors. Many of the companies targeting biotechnology have invested in pharmaceuticals, but the more significant impact will be in plant agriculture, food processing, and specialty chemicals.[31]

Looking more closely at some projected figures for the biotechnology market in Canada, we see that even without any patent protection being provided to drug companies, it is expected that this market segment will increase to $850 million annually by 1990, and to $2.3 billion annually in 1995.[32] This latter figure is more than the total drug market in Canada, and it most certainly does not seem to justify the apparent insistence by the government that the success of "biotechnology revolution" in Canada is contingent upon the proposed legislation.

To paraphrase one analyst, one can perceive that the government is perhaps indulging in a rhetoric of technological nationalism in Canada, which ascribes to technology the capacity to create a "biotechnology revolution" by enhancing the profits of multinational drug companies, ostensibly to foster research and development.[33] It is unclear whether the government has realized fully the implications of the path it has been guided upon by the lobbying of the drug companies and the scientific establishment, or whether it has been mesmerised by what has been seen as the magical aura of the instruments and procedures of science and technology.[34] Perhaps one should accept that the

members of the government are indeed fully aware, and are pursuing their own "drive to technology" so admirably described by George Grant, though one would agree that this public policy revision does not seem to be an expression of "a will to mastery governing the vacuous masses" that such a drive may become.[35]

However, if the government truly expects that Canada will be able to participate in the world drug market to a greater level than the current 2% of world sales, or create a "biotech" industry of world stature, they should perhaps take note of the views (admittedly biased) of a Canadian generic drug company president:

> There is unlikely to be a major Canadian-owned and located pharmaceutical industry. Canada will continue to be dependent on multinational companies carrying out some research in Canada, but introducing products which have been discovered and developed elsewhere. The new biotechnology will undoubtedly provide opportunities for specific products and "niche" markets to be addressed by smaller Canadian companies.[36]

We must of course acknowledge that in the face of such an intense pressure from the drug lobby, it was necessary for the government to make a decision. As one commentator on technology has pointed out, "inasmuch as knowledge and technology have become the central resource

of the society, certain political decisions are inescapable."[37] However, his corollary to a decision to allow use of public resources (in this case higher consumer drug costs), is meant to be "some public claim" on the institutions using them. The government, unfortunately, has abrogated this claim by refusing to place any conditions in the new law to ensure that the promises of the multinationals will be kept. Even the prices of new drugs, which are ostensibly to be regulated by a new price commission headed by Professor Eastman, will be set by the drug companies based on world prices that they can reasonably expect. We have already seen how high are the prices that they claim to be reasonable in the U.S.; the price commission can hardly argue effectively against prices that may as well have been plucked out of the air as far as their relation to actual costs are concerned, as the argument will simply be that high prices are necessary to recoup the costs of research and development, even though such costs may have been incurred (and tax credits received?) elsewhere. It would seem that we must trust the multinationals implicitly to perform in a fair and equitable manner, although there are not any guarantees that they will in fact do so.

One of the proponents of increased patent protection has noted that "knowledge is international, so science and technology are international. Mankind and its diseases transcend artificial national boundaries, so any industrial activity based on the above will be international."[38] Another has stressed that we must "preserve intellectual property, in order to stimulate Canadian research," and that there must be a "strong academic research base in Canada [with] close links . . . between academia and industry."[39] Here we see echoes of the new vision of the post-industrial society, with its privileging of the role of science in the university and in industry, and the increased interdependence of the world economy.[40]

Mention has been made of the "cut-throat lobbying war" involving this issue. In a Foucauldian sense, the war-strategy of the multinationals and their allies has so far carried the field, abetted by the truth-strategy employed which has embodied the normative acceptance that research & development are fundamentally "good." The Technology employed does not need an "end," in terms of specific goals, which is indicative of technology as "means" triumphing in Ellulian terms. One must accept,

therefore, that this public policy revision has not been shaped in the terms of a rational debate on the implications of social change, but has rather come into being under the aegis of "technology is imperative."

The attitude of the government, especially as expressed by the haughty pronouncements of Harvie André when addressing this issue in Question Period at the House of Commons, appears to have hardened against discussions of the social cost of this public policy. André had denied that there would be any adverse effect on consumers, other than possibly "a few dollars a year extra per household," because (new) drug prices will need approval by the proposed Eastman "watchdog" body, and because the drug companies deny that they will try to "gouge" consumers. In fact, by the time the bill was in committee in January 1987 (as Bill C-22), the government had begun to claim that the new law would mean lower drug costs, because the drug-prices review board would also monitor existing prices to ensure that price increases remained within the rise in the consumer price index. Note that this does not mean that the existing prices would be subject to revision, but only increases. It does not require great mathematical skill to calculate

that an already inflated price (remember the Tagamet example) plus an increase limited to the rise in the CPI, is still more than the generic competition would charge. Given that copying would be allowed after seven years if the generics manufacture the active ingredients of the copied drug in Canada, rather than after ten years if the ingredients are imported, there is still a massive time-lag between the period when a new drug is introduced to the market at the brand name price, and the first appearance of a reasonably priced alternative in Canada.[41] While the government on the one hand denies the possibility of increased social costs, at the same time it proposes to compensate provincial governments to the amount of $100 million for "foregone savings" because of the absence of future competition from the generic companies as far as new drugs are concerned.[42] This is obviously a contradiction; it appears that Harvie André can therefore ordain what God cannot. This attitude recalls the words of J. S. Mill: "Absolute princes, or others who are accustomed to unlimited deference, usually feel this complete confidence in their own opinions on nearly all subjects."[43]

The combined efforts of the NDP and the Liberals

were unable to prevent Bill C-22 from receiving its final reading in the House,[44] and it was sent to the Senate for what was expected to be the normal rubber-stamp of the upper chamber. To the chagrin of the government, the Senate embarked on a lengthy process of public consultation on the legislation, and succeeded in retaining it "in committee" until the House had recessed for the summer. The Prime Minister was concerned enough about this delay to request that Speaker John Fraser recall the House, in the hope presumably of embarrassing the (appointed) Senate into approving Bills passed by the (elected) Commons. The Speaker initially refused this request, although the House was eventually recalled five weeks early for a special sitting, ostensibly "to deal with immigration legislation, two transportation bills and the Patent Act changes."[45]

Even at this late stage, the government and the Pharmaceutical Manufacturers Association of Canada were offering different versions of the benefits that would accrue to Canadians as a result of the changes. Harvie André told the Commons in August that the pharmaceutical companies had announced $900 million in new research projects based on the government's plans to amend the

Patent Act. In fact, the PMAC had only announced up to that point $553 million worth of new commitments, although the PMAC president noted that $280 million could be added to that because of general commitments to university based research in various provinces.[46]

Two days after the special sitting commenced, the Senate rejected Bill C-22, offering instead amendments based on the recommendations of the Eastman Commission. This began what was to come to be seen over the next few months as a minor constitutional crisis, as the Senate had not rejected a Bill passed by the Commons in 40 years; however, this aspect is not relevant to this thesis. In the final analysis, after again rejecting Bill C-22 after it was passed once more by the House, the Senate eventually gave way to external pressures and adopted the government's Patent Act legislation as outlined in the Introduction.

Notes to Chapter III

[1]Gazette (Montréal), 23 May 1985, p. B-1.

[2]"Even U.S. Trade Representative William Brock, trying to tie the drug-pricing question to the broader issue of Canada-US trade negotiations, has intervened on behalf of Canadian subsidiaries of large US firms by bending International Trade Minister James Kelleher's ear at every opportunity." Globe & Mail (Toronto), 2 July 1985, p. 10.

[3]Ibid.

[4]Gazette (Montréal), 4 September 1985, p. E-4.

[5]Daniel Bell, The Coming of Post-Industrial Society: A Venture in Social Forecasting, (New York: Basic Books, 1973), p. 379. As Bell states, science as a self-directed community is autonomous

> ". . . in the decisions about what research would be undertaken, in the debates about what knowledge was valid, in the recognition of achievement and the granting of status and esteem. This very autonomy is the heart of the ethos - and organization - of science."

[6]Donald N. Thompson, "What Future for the Pharmaceutical Industry in Canada?" Business Quarterly 50 (Fall 1985):68.

[7]Ibid., pp. 68-69.

[8]William A. Cochrane, "Biotechnology and the Canadian Pharmaceutical Industry," Business Quarterly 50 (Fall 1985):91.

[9]Glen Williams, "Still Not for Export," Canadian Forum, October 1983.

[10]Tamara J. Erickson, "The Next Decade in Pharmaceuticals," Business Quarterly 50 (Fall 1985):80-81.

[11]CBC, "The Journal," 18 November 1986, "Political Prescription."

[12]Murray Elston, Ontario Minister of Health, interview with Barbara Frum, CBC, "The Journal," 20 November 1986.

[13]This fear was expressed by G. Joe Stettler, until recently the Chairperson of the American Pharmaceutical Manufacturers Association. CBC, "The Journal," 18 November 1986, "Political Prescription."

[14]Globe & Mail (Toronto), 23 January 1986, p. A-14.

[15]Gazette (Montréal), 22 February 1986, p. H-7.

[16]Globe & Mail (Toronto), 20 February 1986, p. A-4.

[17]Financial Post, 80:3, 29 March 1986, p. 3.

[18]Gazette (Montréal), 12 April 1986, p. A-7.

[19]Financial Post, 80:8, 3 May 1986, p. 8.

[20]Financial Post, 80:34, 10 May 1986, p. 34.

[21]Gazette (Montréal), 28 June 1986, p. A-3.

[22]Globe & Mail (Toronto), 28 June 1986, p. A-2.

[23]Globe & Mail (Toronto), 5 July 1986, p. A-3.

[24]Gazette (Montréal), 9 July 1986, p. D-1.

[25]Gazette (Montréal), 30 August 1986, p. B-13.

[26]Gazette (Montréal), 7 November 1986, p. B-1.

[27]Gazette (Montréal), 8 November 1986, p. A-13.

[28]Cochrane, pp. 91-93.

[29]Thompson, p. 70.

[30]CBC, "The Journal," 18 November 1986, "Political Prescription."

[31]Nanette Newell, "The Next Decade in Biotechnology," Business Quarterly 50 (Fall 1985):90.

[32]Cochrane, p. 92.

[33]Maurice Charland, "Technological Nationalism," Canadian Journal of Political and Social Theory 10 (1986):197. Charland discusses a rhetoric "which ascribes to technology the capacity to create a nation by enhancing communication." I have borrowed this ascription with another "aspect," which is in keeping with his argument that this rhetoric is insidious.

[34]William Leiss, The Domination of Nature, (New York: Braziller, 1972), p. 28.

[35]George Grant, "In Defence of North America," in Technology and Empire, (Toronto: Anansi, 1969), p. 27.

[36]Cochrane, p. 94.

[37]Bell, p. 263.

[38]Michael S. Barber, "Beyond the Millenium: Canada and the World Pharmaceutical Industry," Business Quarterly 50 (Fall 1985):71.

[39]Sir John Vane, "Government, Science and Industry," Business Quarterly 50 (Fall 1985):108.

[40]Bell, p. 43, pp. 483-84.

[41]Gazette (Montréal), 31 January 1987, pp. A-1, A-2.

[42]CBC, "The Journal," 18 November 1986, "Political Prescription."

[43]John Stuart Mill, On Liberty, (Indianapolis: Hackett, 1982), p. 17.

[44]"[D]espite the soundness of the arguments against it, [Bill C-22] was passed because of the numbers in the Conservative benches opposite." Letter from Ed Broadbent, Leader of the Federal New Democratic Party, to the author, June 3 1987.

[45]Gazette (Montréal), 11 August 1987, p. A-1.

[46]Gazette (Montréal), 15 August 1987, p. A-10.

Chapter IV

To what, then, can be attributed the success of the multinational drug companies' lobbying efforts in this revision of public policy? To what extent can this be demonstrated as determined by the "drive to technology" elaborated upon in the first chapter? Or is there in fact another discourse woven into the rhetoric that was employed by the various actors in the process that has been described? It will be recalled that a hypothesis was advanced that the interests of business groups affected by the Patent Act (1969) were suborned to a coalition of interests representing consumers and provincial governments. Chapter 2 described the process that led up to the enactment of the legislation which forced the granting of compulsory licensing in Canada for the manufacture of drugs, even from imported ingredients, as long as a small royalty was paid to the patent-holder. It will be recalled that unsuccessful attempts were made in the United States to introduce similar legislation at about the same time, seeking compulsory licensing after three years of patent exclusivity.

The claims made by the major pharmaceutical firms in the Canadian policy arena were similar to those that were advanced in the United States: these were in essence that product safety was of overriding concern to the public, and patent protection per se was vital to private industry. One cannot find strong evidence that there was any concern expressed over the needs of technology; the references made to research and development did not offer any realistic intentions to expand this beyond the levels already reached in Canada. The hypothesis advanced would seem to be supported, in that the policy process unfolded and was eventually resolved (by the passage of the Patent Act amendments in 1969), without any explicit causality being accorded to technological concerns.

What of the second hypothesis, which was predicated on the acceptance by a post-industrial society that a fundamental role should be accorded to technological development? One can demonstrate that certainly by 1984, when the Conservative government was elected, technology had become, as Professor Kroker put it, "the keyword of advanced industrial societies."[1] It can be argued that both the United States and Canada were advanced industrial societies during the 1960's, at the time that

the policy process described in Chapter II was unfolding: Why then did the second hypothesis not apply at this time?

To answer this, one must emphasize that the premise of the hypothesis is that there must be acceptance by the society overall that technological development should be accommodated as a necessary condition of that society. A review of the literature produced by thinkers such as Ellul and Grant, some of which was mentioned in Chapter I,[2] shows that the period of the 1950's and 1960's was one of struggle against that very thesis by philosophers who refused to accept the inevitability of technological society, and its "descent" into popular acceptance[3] and a position where policy makers might incorporate it subliminally as a worthwhile, or even necessary, goal. It is this transmutation of the technological imperative into part of the teleology of society that is required for one to be able to even begin to claim any relevance for the second hypothesis that was advanced.

G. Bruce Doern has shown that the period of the 1960's was a transitional one for policy makers who would have been involved in science and technology decision

making. The Pearson government had developed much of its legislative program from the "thinkers' conference" held in Kingston in 1960: this had not mentioned science and technology.[4] There had been a federal body since 1917, the National Research Council, with a responsibility for overall policy advice on science. This body had been created to meet the demands of a wartime experience, and its role had been reinforced by the exigencies of the Second World War. However, by the 1960's it did not function as was originally intended, having turned away from concerns of broad national policy to the promotion of university research through scholarship funding, and to support of its own individual scientific laboratories. The Council was meant to advise the Privy Council Committee on Scientific and Industrial Research, and an interdepartmental committee of deputy ministers (the Advisory Panel for Scientific Policy); the former had not met at all between 1950 and 1958, and the latter had hardly met more than once a year from 1950 to 1960.[5]

This was pointed out by the Royal Commission on Government Organization (Glassco Commission) in its 1963 report, which showed that science policy decisions tended to fall to Treasury Board staff who lacked technical

expertise. From the Glassco Report, Doern traces the Liberal party's 1968 election promise to create a science secretariat, and the acceptance by the party of the links between technology and the future economic well-being of Canada:

> Innovation and research are major keys to Canada's economic growth. In this era of rapid technological change, our industrial development and the evolution of our society will depend increasingly on our scientific effort. . . .
>
> To achieve these goals, your new Liberal government will:
>
> Give vigorous support to science in both pure and applied forms as a basis of modern economic development.[6]

Similar policy proposals were being made in the United States, where technological progress was being described in the late 1960's as having "contributed mightily to the improvement of health, the spread of leisure, and the enrichment of life generally."[7] A Presidential Commission on Technology, Automation and Economic Progress reported optimistically that the use of appropriate government policy could ensure that high employment could continue even with rapid technological advances, despite popular fears that technological change might lead to unemployment.[8] Policy proposals were made that advocated the creation of a cabinet department responsible for integrating all government programs that

fostered research and development; this would be the responsibility of a Secretary of Science and Technology, with the parallel establishment of a National Institute of Technology, with a mandate to guide the "scientific underpinnings" of technology through research grant programs.[9]

Thus we see the parallel development of politically similar policy initiatives in both the United States and in Canada; the decade of the 1970's led to even more of a role being attributed to the positive propensities of technology in shaping economic well-being. These must be seen as tendencies which had moved beyond the realm of prescriptions for action by technocratically inspired, and thus biased, actors such as the Science Council, or the Brookings Institution. Instead, one witnessed the development of the social acceptance of technology, and this was in turn a factor which shaped the direction and potential of technological change. Although thinkers such as Ellul attributed the development of technology to its own internal dynamic, through a form of technological determinism which was explicated in Chapter I, it must be acknowledged that other writers on technology look beyond what they regard as such a naive view.[10]

Whether such a view is naive may depend in part on what particular perspective on technology one seeks to illuminate. One of the criticisms of American writers on technology that was alluded to in the discussion on Grant in Chapter I, is precisely the fact that they tend to reflect the biases of social scientists brought up in the traditions of logical empiricism, which would consign to what Mach described "the pit of uncertainty" any such untestable premise as an imperative of technology. What one sees instead is a concern with the social and the economic forces which shape specific instances of the changing patterns of technology; indeed, this thesis may well have been modelled on such a pattern by focusing on the patterns of interest group interaction, or on the bureaucratic politics involved, or the role of the state as an agent of instrumental change. But this would have been to acknowledge that there could be nothing beyond these elements which may have constituted a dynamic which is clearly expressed in the writings of Ellul, and beyond him of Grant. It is not possible to prove or disprove the existence of such a dynamic, but it is possible to attempt to demonstrate that it exists in the received wisdom of a society that has come to accept the notion of the inevitability of technological change. Without

wishing to fall into the logical fallacy of misplaced concreteness, one can then arrive at the justification of the second hypothesis: that the acceptance by society that a fundamental role should be accorded to technological development created a basis on which certain groups could reformulate their interests in terms of promoting research and development for the "good" of technology.

That such an acceptance of a fundamental role for research and development had been accepted by the time the Mulroney government attained office can be seen in the various manifestations of policy recommendations which had been made in the years between the formation of the Liberal commitment in their 1968 election handbook and the 1980's. For example, the Minister of State for Science and Technology received, in 1979, a report from the Science Council of Canada entitled Forging the Links: A Technology Policy for Canada. This report emphasised that the only way Canada could maintain a semblance of competition with other advanced industrial nations was through a policy of technological sovereignty, and outlined four main objectives to attain this. These were "1) increase the demand for Canadian technology within

the industrial system; 2) expand Canadian industry's potential to develop technology; 3) strengthen the capacity for the absorption of technology at the level of the firm; and 4) increase the ability of Canadian firms to import technology under conditions favourable to Canada."[11]

Here we see positive indications that technology is necessary not just for economic growth and international competitiveness, but is essential for survival of the Canadian economy. One may note also that the creation of a Ministry of State for Science and Technology could be seen as acknowledging the importance of the active promotion of technology; however, from its inception up to the advent of the Mulroney government, one must bear in mind Peter Aucoin's judgement that this "had always been a junior portfolio and ministry of state agency with little clout in federal decision-making."[12] A similar arrangement could be said to exist at that time in the United States, where an Office of Science and Technology Policy had been set up as part of the Executive Office of the President,[13] but which did not have the status that would be required to direct and channel the development of technology in the manner envisaged by the Brookings

Institution in their recommendation that a Department of Science and Technology be created at cabinet level.[14]

G. Bruce Doern has argued that throughout this period (the 1970's), the Canadian government had very inadequate processes for obtaining scientific and technical advice, which resulted in controversies over science and technology being accorded at best only a peripheral status.[15] It is interesting that in his case studies, Consumer and Corporate Affairs particularly showed an inability to unravel the complexities of the technological controversies which they were empowered to regulate. This is relevant to this thesis because this was the Department with lead responsibility for Patent Act revision, which was undertaken in part through the representations of multinational pharmaceutical firms on the basis of an appeal to technology, as was shown in Chapter III. Whether these firms were aware of the Doern Report and couched their lobbying efforts in the more obscurantist technical manner in the hope of confusing the Consumer and Corporate Affairs decision makers is perhaps too Machiavellian a notion to put forward in a serious way; it would of course directly support what has been articulated as evidence for the third hypothesis that was advanced.

Returning to the junior status previously accorded to science and technology within a ministry of state, the Mulroney Government created a more powerful Cabinet Department, by merging the portfolios of industrial policy (the "target" for a technology policy) and of science and technology into a new Department of Industry, Science and Technology. Thus the general direction of the trend toward ("the drive to") technology was being reinforced at the policy making level, even though there were indications from prominent economists that there was in fact little theoretical or empirical justification for the conventional wisdom that increased government support for research and development was worthwhile. Yehuda Kotowitz, who wrote a background study on pharmaceutical patents for the Eastman Commission, had earlier completed a report for the Ontario Economic Council that stated: "The causal connection between R&D performed in Canada and the degree of competitiveness and profitability of Canadian industry, either in general or in high-technology industries in particular, has not been conclusively established."[16] Nevertheless, government rhetoric continued to urge the necessity of technological advance, as was shown in Chapters I and III.

The implication of the existence of such rhetoric on the testing of the third hypothesis is that it created the necessary environment in the policy arena for the major pharmaceutical lobby group to be able to adopt the same rhetoric in pursuit of its goals. It was stated in the Introduction that the second hypothesis (accordance of a fundamental role to technological development by society) had to be demonstrated. One could then develop the corollary, that this created a rationale for public policy revision amongst groups that could reformulate their interests in terms of research and development for technological ends. The third hypothesis rested on the implicit recognition of the latter by, in the case under study, the Pharmaceutical Manufacturers Association of Canada, who could be assumed to adopt the same rhetoric in order to attain their policy goals.

We have seen in Chapter III the description of what one may describe as a technology nexus; the emergence of a concerted effort to link the restoration of patent protection to pharmaceutical products with a concomitant increase in scientific research, with claimed benefits in the field of biotechnology. It will be recalled that the claims themselves were questioned, and competing views

were identified which tended to negate, or at least to reduce, such benefits. However, it may still be argued that such claims were made in good faith, and that in and of itself, invalidation of such claims cannot be used as support of the third hypothesis. This is an argument which is not conducive to refutation; one must therefore look elsewhere for such support. Nevertheless, what if one could identify a policy process being undertaken by essentially similar actors, namely pharmaceutical groups and a national government, which was intended to address similar concerns, namely patent protection for drug products, and which took place in the same time frame, namely around 1984? Would it not be logical to expect that claims made in good faith in Canada, would also be the claims made in this other policy arena? We speak, of course, of the United States, and we shall now test the third hypothesis by investigating whether discrepancies exist between the American policy process and that which took place in Canada; if they do exist, we may have found evidence which points to a deliberate articulation of goals within a rhetoric of technological progress, and which shows that this is but a superstructure built upon the foundations of actual intent: the protection of the corporate profits of multinational pharmaceutical firms.

In 1984, there had been concerted efforts in the United States to address the problems of ever-increasing drug costs to American consumers. It will be recalled that in Chapter III, evidence was presented which showed that the American Pharmaceutical Manufacturers lobby group was concerned that the Canadian compulsory licence system might be adopted by Congress, with what could be enormous harmful potential for corporate profits in the American drug market, worth over $20 billion annually. The thrust of the lobbying effort against such a system can be found in the various representations made in the Congressional hearings which took place to debate changes to the Federal Food, Drug, and Cosmetic Act, which had been proposed separately by both the Senate and the House of Representatives.[17]

It is interesting to note that in this particular policy arena, the multinational pharmaceutical companies and the generic manufacturers both supported the proposed legislation (which will be described shortly); it will be recalled that in Canada these were protagonists and antagonists. Only consumer advocates (notably Ralph Nader) remained in opposition in both countries. The Congress in essence recommended a compromise solution to

address the problem of high drug costs, which had already seen a 32% increase in the 1981-1983 period on name-brand drugs.[18] This solution was to offer an accelerated process for the approval of off-patent drugs that the generic companies could produce after the expiry of the innovator's patent. This was a key point, because up to this stage, generic companies had to go through the same detailed approval process, which could take many years, if they wished to produce a drug which had recently come off-patent; the Food and Drug Administration treated the generic "copy" as a "new" drug. Obviously, this was a disincentive to generic production, and introduced an extended time-lag before "cheaper" generic versions of a drug could be produced to the benefit of consumers. The original innovator in effect continued to enjoy a market monopoly even after patent expiry, because of the length of time it took to approve a generic version; court cases had determined that this process could not begin whilst the original patent was valid.

The compromise solution was that an "Abbreviated New Drug Application" (ANDA) would be allowed, which would drastically reduce the time-frame for approval of a generic version of an already marketed drug that had gone

off-patent, as long as the original drug was approved after 1962, when more stringent procedures had been put in place by the government to ensure the safety of new drugs. In return for the support of the innovators, (the Pharmaceutical Manufacturers Association, whose members produced 90% of new drugs in America each year), the Congress proposed acceding to their demands that an extension to the statutory seventeen year patent term be given, to offset the time-lag between original patenting of a new drug and final approval for sale, which could take as much as from seven to ten years out of the patent life. This provision could extend patent protection by up to five years, as long as this did not result in an effective remaining patent life of more than 14 years. Even though this compromise had the support of the Reagan Administration, with the Commissioner of Food and Drugs making a statement in Senate Hearings to that effect,[19] there were still concerns that it might be defeated, which led the drug lobby to make specific claims as to the benefits that would accrue if the legislation was passed.

Here we arrive at the crux of the matter, as far as comparisons between the rhetoric employed by the American

and Canadian drug lobbies are concerned. Lewis Engman, President of the Pharmaceutical Manufacturers Association of America (PMA), did indeed claim that the legislation would provide research incentives, but this was a point which was made in relation to the fact that the current practice penalised the pharmaceutical industry, because the lengthy approval process resulted in "only a fraction of the related investment incentives provided innovators in other industries. This is neither fair nor good public policy."[20] This is reminiscent of the approach which had been used in Canada in the 1960's, which was described in Chapter II. It will be recalled that this had failed in Canada, and patent protection had been in effect removed, but it must be remembered that the same approach had succeeded in America, and legislation based on a compulsory licensing system had been altered so as to remove this aspect. What had worked before, an appeal to the basic rights of an industry to accrue to itself the return on investment guaranteed by patent law, was thus being used again in the rhetoric employed in the United States; there were no emotional appeals to the necessity of accommodating a drive to technology in the recommendations made to the Congress.

Interestingly enough, an illuminating aspect of these same hearings on the research intentions of the major manufacturers was provided when discussion turned to another part of the legislation. This was a proposal to allow pharmaceutical firms to manufacture drugs in the United States for export that were not currently approved by the FDA for sale in America, as long as they had been approved in another country (anywhere in the world) that had certain minimum regulatory standards which were seen as providing an assurance that the drug would be "safe." Aside from the ethical implications involved in allowing drug companies to export products that might not be given approval in the U.S. (remember the Thalidomide example), certain claims were made that this would enable greater employment in the United States, by stimulating research and manufacturing. American Cyanamid asserted that net benefits could equal 50,000 extra jobs, and increased capital investment of $400 million. These figures were completely disproved by a study completed by the Labor Institute, whose analysis of the same figures resulted in a net benefit of less than 2,500 jobs; one wonders what would be the result of a similar analysis on the figures provided by the Canadian drug lobby for their claimed employment benefits?[21]

Another enlightening comment was made by a Vice-President of Merrell Dow Pharmaceuticals, who was also lobbying for the ability to manufacture and export drugs unapproved for sale in the U.S. In view of the claims being made by the Canadian branch plants of this and other manufacturers, that patent protection would result in more research and development in Canada, with all the claimed benefits to technology, it might be interesting to note the answer to a question posed to this executive, Robert Ingram, who had also stated that benefits would accrue in the form of more U.S. jobs. The transcript is as follows:

> Senator Hatch: Question for Mr. Ingram:
> Your testimony states "our preference would be to expand or build new facilities here in the U.S." Patriotism aside, why do you prefer to invest in the U.S.?
> Mr. Chairman:
> Patriotism aside, we prefer to invest here in the United States because it's simply good business for us as well as beneficial for the United States economy.
>
> As we stated in our testimony, we currently have reached capacity at our plants overseas. In order to handle increasing volume requirements for current products plus new volume requirements for products in the R&D pipeline we must make a decision now to expand or build new manufacturing facilities. Our choice is whether to expand the existing facilities overseas or do it here in the United States. Our preference would be to expand existing facilities here in the United States as they offer us much lower costs in terms of production costs and at the same time utilize existing facilities and manpower in a much more productive fashion.

> The end result would be that our manufacturing would be consolidated with our current U.S. technology centers thus utilizing our total employee base more productively. We would also be creating new jobs at both the Midland Michigan and Cincinnati Ohio facilities. Thus aiding the economy in both of these locations through new tax revenue and capital expenditures.[22]

In the interest of objectivity, it must be reported that the discussion on the removal of export restrictions did include a submission from a biotechnology firm, whose representative argued against such restrictions on the basis that it created a disadvantage for American firms in competition with biotechnology companies abroad, which was endangering the American world leadership "in this new technology."[23] However, this was not linked to the discussion of patent protection, which was the revision of public policy that this thesis has been concerned with, and therefore it is not seen as offering more than weak evidence that a linkage could be made between calls for policy change based on a technological imperative as we have defined it. We therefore must take the remainder of the submissions to the Senate Hearings, based on the sanctity of patents and inherent right of innovators to recoup their investments, as the substantial form of the rhetoric employed in the United States policy arena. Even consumer advocates such as Ralph Nader did not argue

against patent rights as such. His point of contention was that the pharmaceutical industry "are not asking for equitable treatment under the patent law; they want a radical new form of patent. Not satisfied with patents that delay competition for seventeen years after patent issuance, the proponents have been advocating a restructured patent under which a monopoly sales period of less than seventeen years is considered an urgent problem requiring immediate legislative attention."[24] Nader also pointed out that the United States Office of Technology Assessment, in a 1981 report, concluded that there was no evidence that additional revenues derived from patent extension would increase the percentage of research and development activity. Indeed, because patent holders would be insulated from competition for longer, there was a possibility that innovation would actually decline because of a lessened demand for any ingenuity to retain market dominance.[25] It will be recalled that this perspective was also explored with the discussion of Canadian pharmaceutical companies' claims for restoration of patent protection in Chapter III, with a similar conclusion being posited.

We seem therefore to have described an essentially

similar public policy problem in the two countries, and the policy outcomes were different in each. In the U.S. case, the drug companies were successful in averting any threat to existing patent protection, and were even able to achieve Congressional support for extension of such protection under certain circumstances. Yet in all of this, there cannot be found any strong evidence that there was an appeal to the "drive to technology" that was demonstrated in the Canadian public policy process. We have already seen that the American process in essence duplicated a successful strategy from the 1960's, whereas the Canadian process saw the development of a radically different approach based on a discourse which predicated the "good" of technology. It must be stressed that the majority of the actors involved in the Pharmaceutical Manufacturers Associations of these two countries are in essence the same corporate entities; how then can one explain the different strategies employed, assuming that corporate principles enjoy a transitivity of preference which should have seen a similar purpose expressed in both Canada and the United States? For this explanation, one can turn to the third hypothesis and claim with some justification that the pharmaceutical manufacturers had identified in Canada the presence of a government that

would be more prepared to accommodate their interests if they were couched in the terms of what we have described as a rhetoric of technology. Once the premise on which this hypothesis was based was identified, it could then be used, as it indeed seems to have been, to support the privileging of these interests even to the detriment of social welfare.

As implied in the Introduction, it seems that one cannot demonstrate in this process the existence of a technological imperative as <u>determinant</u>, but it is felt that the very ethos of such an imperative is that it pervades the social fabric to such an extent that it does allow the use of strategems which can only be inculcated to the extent that society allows itself to accept the inevitability of the truth-claims that can accompany such penetration. Ellul made the point that technology for the ancients was magic; Arthur C. Clark stated that "any sufficiently advanced technology is indistinguishable from magic."[26] If a function of magical properties is their ability to transmute our critical faculties into unquestioning acceptance of the chimaerical result of the magical act, then perhaps we are no further advanced than the ancients in the face of promises made on behalf of

the necessarily beneficial nature of a process that few of us can understand. Habermas disputed the assertion that "politically consequential decisions are reduced to carrying out the immanent exigencies of disposable techniques and that therefore they can no longer be made the theme of practical considerations,"[27] but one must wonder whether such a process may not have taken place in this instance, if not deliberately then at least by the absence of struggle against the technological assumptions that underlay the rhetoric employed. In closing, perhaps we should remind ourselves of an insight expressed by George Grant in his final work. If we adopt this, then whenever we hear a call to action based on a "necessity" ascribed to technology, we should bring this "necessity" before us and put it to the question, reminding ourselves that: "a posse ad esse non valet consequentia."[28]

Notes to Chapter IV

[1]Arthur Kroker, "Japanese Perspectives on Technology & Rationalization," Canadian Journal of Political and Social Theory 8 (Autumn 1984):5.

[2]See also George Grant, Philosophy in the Mass Age (Toronto: Copp Clark, 1959); idem, Lament for a Nation: The Defeat of Canadian Nationalism (Toronto: McClelland & Stewart, 1965); idem, Time as History (Toronto: Canadian Broadcasting Corporation, 1969). An exegesis of these works can be found in Arthur Kroker, Technology and the Canadian Mind: Innis/McLuhan/Grant (Montreal: New World Perspectives, 1984).

[3]"An indication of the degree to which the ideology of technological progress grips the popular imagination is the fact that among the cartoon heroes which are popular today in children's comic books and television programs, human beings are overwhelmingly outnumbered by robots." Charles Lummis, "Japanese Critiques of Technological Society," Canadian Journal of Political and Social Theory 8 (Autumn 1984):12.

[4]G. Bruce Doern, Science and Politics in Canada (Montreal: McGill-Queen's University Press, 1972), p.158.

[5]Ibid., pp. 3-6.

[6]Liberal Federation of Canada, Liberal Candidates' Handbook, 1968, quoted in ibid., pp. 158-59. Emphasis in Doern.

[7]Richard R. Nelson, Merton J. Peck and Edward D. Kalachek, Technology, Economic Growth and Public Policy (Washington, D.C.: Brookings Institution, 1967), p. 171.

[8]National Commission on Technology, Automation and Economic Progress, Technology and the American Economy, vol. 1 (Washington, D.C.: Government Printing Office, 1966), cited in ibid., p. 134.

[9]Ibid., pp. 175-77.

[10]Langdon Winner, "Do Artifacts Have Politics?" in The Social Shaping of Technology, eds. Donald MacKenzie & Judy Wajcman (Philadelphia: Open University Press, 1985), pp. 26-27.

[11]Science Council of Canada, Forging the Links: A Technology Policy for Canada, Report No. 29 (Ottawa: Supply & Services, 1979), p. 7.

[12]Peter Aucoin, "The Mulroney Government, 1984-1988: Priorities, Positional Policy and Power," in Canada Under Mulroney: An End-of-Term Report, eds. Andrew B. Gollner & Daniel Salée (Montreal: Véhicule Press, 1988), p. 340.

[13]James Q. Wilson, American Government: Institutions and Policies (Toronto: D.C. Heath, 1980), p. 321.

[14]See note 7.

[15]G. Bruce Doern, The Peripheral Nature of Scientific and Technological Controversy in Federal Policy Formation, (Ottawa: Supply & Services, 1981), pp. 88-89.

[16]Yehuda Kotowitz, Positive Industrial Policy: The Implications for R & D (Toronto: Ontario Economic Council, 1985), p. 33.

[17]U.S., Congress, Senate, Committee on Labor and Human Resources, Drug Price Competition and Patent Term Restoration Act of 1984, Hearing before the Committee on Labor and Human Resources on S. 2748, 98th Cong., 2nd. sess., 1984. [Hereafter cited as Senate Hearing 98-1102 on S. 2748.] The companion House of Representatives Bill was H.R. 3605.

[18]Ralph Nader, Private Citizen, Statement, Senate Hearing 98-1102 on S. 2748, pp. 358-59.

[19]Mark Novitch, M.D., Food & Drug Administration, Statement, Senate Hearing 98-1102 on S. 2748, pp. 11-19.

[20]Lewis A. Engman, President, Pharmaceutical Manufacturers Association, Statement, Senate Hearing 98-1102 on S. 2748, p. 46.

[21]Richard Miller, The Labor Institute, Statement, Senate Hearing 98-1102 on S. 2748, pp. 287, 296.

[22]Senate Hearing 98-1102 on S. 2748, p. 76.

[23]Robert A. Swanson, President, Genentech, Inc., Statement, Senate Hearing 98-1102 on S. 2748, p. 77.

[24]Ralph Nader, p. 357.

[25]Ibid., p. 362.

[26]Tom Darby, "Nihilism, Politics and Technology," Canadian Journal of Political and Social Theory 5 (Fall 1981):65.

[27]Jurgen Habermas, "Technical Progress and the Social Life-World," Toward a Rational Society: Student Protest, Science and Politics, trans. Jeremy J. Shapiro (Boston: Beacon Press, 1970), p. 59.

[28]"I take this to mean: just because something can be, it does not follow that it should be." George Grant, Technology and Justice (Toronto: House of Anansi, 1986), p. 33. For the purposes of the question which is to be put, one might say: Is this necessarily worthwhile, just because it is possible for it to be?

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