Drugs In Canadian Patent Law

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A. *Introduction*

In the second half of the twentieth century, drugs have assumed a position in the social economy of the world which they have never possessed in the long history of their existence. From the earliest times, drugs in some form or another have been employed by man to alleviate human suffering in the hands of the conscientious physician, and to confound the uninitiated in the hands of the charletan. It is hardly surprising, therefore, that in an age in which technicological advances in almost all branches of science have taken place with almost unbelievable speed, progress in the field of drugs has been no less startling and momentous. The major breakthrough in the field of drugs can be said to have taken place with the discovery of the sulpha drugs and, particularly, with the discovery of the antibiotics. Since that time, the search for ever newer and better drugs has been the principal occupation of the drug industry, and their labours have been neither unsuccessful nor unrewarded. But, as with every major advance in science, the coin has two sides. With the undoubted benefits conferred by the perpetually growing number of antibiotics, tranquilizers, antihistamines and similar drugs, there have grown doubts and misgivings in the minds of many serious students of the problems involved in the administration of drugs as to the relative advantages flowing from this Pandora's Box.[1] The industry has been suspected, and publicly accused, of making exorbitant profits at the expense of the helpless consumer; and, in reply, the industry has painted a sad picture of the crushing burden of perpetually rising research costs. The larger firms of drug manufacturers have prospered and become giants; many of the smaller firms have perished in the struggle for survival. Not very long ago, two of the biggest wholly Canadian firms were swallowed up by two of the larger American drug houses.

Fortunately it is not within the scope of this paper to explain, analyze or justify these events, or to pass judgment on them. But for a proper appraisal of the position of drugs in the field of Canadian patent law, they are facts which cannot be ignored.

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[1] See, *e.g.*, *Drugs in Our Society*, ed. Paul Talalay, The Johns Hopkins Press, 1964; *The Therapeutic Nightmare*, Morton Minz, Houghton Mifflin Co., 1965.

B. *History*

Ever since the year 1923, drugs have occupied a special position in the field of Canadian patent law. In that year an amendment was introduced [2] into the existing law which, with an important and far-reaching change, incorporated into the Canadian patent law a provision which had been added to the English Patents and Designs Act, 1907[3], by section 11 of the Patents and Designs Act, 1919.[4] In that year, shortly after the conclusion of the First World War, and for reasons which may have been good or bad, the English patent law was changed by providing that henceforth an inventor could no longer obtain a claim to a product *per se* in respect of any invention relating to substances prepared or produced by chemical processes or intended for food or medicine.[5] Furthermore, it was also provided that in the case of any patent for an invention intended for a capable of being used for the preparation or production of food or medicine, any person could apply for a compulsory licence on terms to be fixed, if necessary, by the appropriate officer of the Patent Office.[6] Having deprived the patentee of the right to obtain a claim to the product *per se* for the result of his invention, the sub-section contained a *proviso* that in an action for infringement of a patent where the invention relates to the production of a new substance, any substance of the same chemical composition and constitution should be deemed to have been produced by the patended process.[5] This *proviso* was intended to alleviate the task of the patentee in discharging the *onus* of proving infringement, which is always on the patentee in such an action. As the product was now protected only when made by the patented process, a patentee would have to prove not only that the alleged infringer had the product, but also that the product in question had been made by the patented process. As such proof is generally extremely difficult, if not impossible, to adduce, the law provided the patentee in such cases with the benefit of a statutory presumption in his favour, leaving it to the infringer, if he could do so, to prove that the otherwise infringing substance had not been made by the infringing process, and thus escape the charge of infringement.

When this provision was taken over into Canadian law in 1923,[2] an apparently insignificant, but in fact a very important, change was made in the wording of the English section. The word "or" in

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[2] Statutes of Canada, 1923, c. 23, s. 17.
[3] 7 Edw. 7, c. 29.
[4] 9 & 10 Geo. 5, c. 80.
[5] Patents and Designs Act, 1907, s. 38A(1).
[6] *Ibid.*, s. 38A(2).

sub-section (1) was changed into "and". The result was that, whereas in England the sub-section applied to substances that were either intended for food or medicine on the one hand or prepared or produced by a chemical process on the other, in Canada the section has always applied, and still applies, only to substances that are both intended for food or medicine and prepared or produced by a chemical process. In Canada, therefore, drugs were, and are, subject to the restricted form of product-by-process claim only if they are prepared or produced by a chemical process; and in respect of any drug not so produced or prepared, e.g. drugs produced and prepared solely by micro-biological processes, the patentee can generally obtain a product claim without any restriction as to the method of manufacture. Similarly, chemical substances not intended for food or medicine can be protected by unrestricted product claims.

Apart from this important distinction, the other provisions of the English section were incorporated in the Canadian Patent Act without any fundamental change. In 1935, when the Statutes of Canada were revised,[7] the relevant section became section 40, and at that time the *proviso* in sub-section (1) relating to the statutory presumption as to the method of manufacture, became a new sub-section (2). At the present time the section is to be found as section 41 of the 1952 edition of the Revised Statutes of Canada,[8] and is identical with section 40 of the 1935 statute.

The additional restriction imposed on drug patents by the original English section by providing for compulsory licences was also incorporated in the new section of the Canadian Act,[9] and is now found in section 41 (3) of the current Patent Act.[8]

There are, thus, two serious and far-reaching limitations to the monopoly which can be obtained in Canada in respect of drug patents.

C. *Section 41 (1)*

> In the case of inventions relating to substances prepared or produced by chemical processes and intended for food or medicine, the specification shall not include claims for the substance itself, except when prepared or produced by the methods or processes of manufacture particularly described and claimed or by their obvious chemical equivalents.

The sub-section applies only to drugs "prepared or produced by chemical processes", and in order to determine whether the restrictive

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[7] R.S.C. 1935, c. 32. For a discussion of the historical development of the English and Canadian sections, see *Commissioner of Patents* v. *Winthrop Chemical Co.* (1948), 7 C.P.R. 58.

[8] R.S.C. 1952, c. 203.

[9] Statutes of Canada, 1923, s. 17; R.S.C. 1935, c. 32, s. 40.

provisions of a product-by-process claim are applicable, it is necessary to establish in the first instance whether the drug in question has been prepared or produced by a "chemical process". In the case of drugs produced by chemical synthesis, there is generally no problem, since, whatever may be the precise meaning of the words "chemical process", there can be little doubt that such drugs are produced and prepared by a chemical process. In the case of antibiotics, however, the problem is a very real one. Most antibiotics are produced by the fermentation of micro-organisms, and the view has been generally taken that this is not a chemical process within the meaning of section 41 (1). There are Canadian patents for such products which contain unrestricted product claims, on the footing that the fermentation process for their production is not chemical. The matter is further complicated by the fact that in the case of some of these drugs part of the "invention" relates to the step of isolating the active substance from a crude culture medium, a process which involves the use of, at any rate, chemical techniques.

In the earlier English cases it was held that the words "chemical process" must be given their popular, and not a limited technical, meaning.[10] In Canada the question first came up in connection with the production of a bleaching agent by the fermentation of an enzyme, and it was held that this was not a chemical process.[11] More recently, the Canadian courts were concerned with the chloramphenicol patent. The substance was claimed in an unrestricted product claim, but the disclosure indicated that the substance was produced by fermentation and then isolated by the use of chemical techniques. Puddicombe, J. held [12] that the isolation was a chemical process, and that accordingly the claim was invalid. With regard to the fermentation as such, he expressed the view that this was not a chemical, but a biological, process.

In view of the fact that the sub-section uses both the words "produced" and "prepared", it is reasonable to assume that different meanings must be ascribed to each word. Although the "production" of an active medical substance may be the result of a non-chemical fermentation process, it is frequently impossible for such a substance to be "prepared", i.e. made ready for use, without the use of some chemical techniques. The fact that the Patent Office may allow an

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[10] See *e.g.*, *Re S. Co's Application* (1921), 38 R.P.C. 399; *Re H.E.P.'s Application* (1925), 43 R.P.C. 150. But see *Re Levy and West's Application* (1945), 62 R.P.C. 97, where the earlier decisions were not followed.

[11] *Continental Soya Co. Ltd.* v. *J.R. Short Milling Co. (Canada) Ltd.* [1942] S.C.R. 187.

[12] *Parke, Davis & Co.* v. *Laboratoire Pentagone* (1966), 46 C.P.R. 171.

unrestricted product claim is no guarantee of its validity if it is challenged in court, and the more prudent course, where there is any element of doubt, would be to include a product-by-process claim even if a bare product claim is allowed.

A further question may arise whether the drug in question is a "substance" within the meaning of the sub-section. There can be little doubt that a chemical compound is a "substance"; and it would now appear that even a mixture is a "substance" within the meaning of the sub-section. Thorson, P. had held that a mixture of a novel compound with a carrier was a substance,[13] and although the Supreme Court of Canada reversed his decision that such a mixture was not prepared or produced by a chemical process,[14] Judson, J., delivering the judgment of the Court stated [15] that the mixing of a patented chemical substance with a carrier is, "of course, a substance, as the learned President has found, but it is still a substance identical in all respects except dilution with a substance produced by a chemical process . . .". It would appear, therefore, that if any significant ingredient of the mixture has been prepared or produced by a chemical process, only a limited product claim can be obtained.

The next requirement of the sub-section is that the substance of the invention must be "intended for . . . medicine". In general, this requirement does not give rise to serious problems, but there are some drugs which also find application in agriculture or other than strictly medical fields. The better view would appear to be that if the invention discloses any medical use, it is intended for medicine, irrespective of the fact that it may also have other non-medical uses. The word "medicine" must be interpreted broadly, and has been held to include the active ingredient in bulk form.[16] Recently, an inhalent, volatile anaesthetic was held to be a substance intended for medicine in respect of which only a product-by-process claim could be obtained.[17]

If the sub-section applies, then there cannot be a claim for the substance itself except when prepared or produced by the methods or processes of manufacture particularly described and claimed or

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[13] *Farbwerke Hoechst A.G.* v. *Commissioner of Patents* (1963), 39 C.P.R. 105.

[14] *Commissioner of Patents* v. *Farbwerke Hoechst A.G.* (1964), 41 C.P.R. 9.

[15] *Loc. cit.* at p. 14.

[16] *Parke, Davis & Co.* v. *Fine Chemicals* (1959), 30 C.P.R. 59, *per* Martland, J.

[17] *I.C.I. Ltd.* v. *Commissioner of Patents* (unreported, Exch. Ct., June 29th, 1966). A schedule to the Reasons for Judgment contains a comprehensive and useful list of definitions of the words "Anaesthetic", "Drug", "Medicine", "Remedy" and "Therapy".

by their obvious chemical equivalents. The operation of the sub-section has recently been the subject of two decisions of the Supreme Court of Canada,[18] and on the basis of these decisions the following propositions would now appear to be established. In the first place, the process claim which limits the product claim must be a valid claim. If, for one reason or another, it is not, the product claim cannot stand and falls with it.[18] Secondly, the process which is claimed must be "particularly described";[19] and, thirdly, the process which has been particularly described must be claimed as such. It would seem to be implicit in these decisions that a general process claim for a class of compounds, even if valid, is insufficient to support a section 41 (1) product claim for a specific compound, and that even a specific process claim, even if valid as such, is not sufficient to support a product-by-process claim, unless the specific process claimed has been particularly described.

A particular problem in connection with chemical patents in general, and drug patents in particular, is the practice of claiming a whole group of analogous compounds on the basis of an invention of one or a number of such compounds. In view of the recent decisions of the Supreme Court of Canada referred to,[18] it may well be that the Patent Office will no longer allow such broad claims; but even if it does, patentees will have to consider very seriously whether it is worthwhile obtaining a monopoly which is so wide that it is unsupportable. It is inherent in the philosophy of patents as a whole that an inventor is entitled to protection only in respect of what he has in fact invented; and there would appear to be no reason why there should be any exception to this rule in the field of drugs. The doctrine of chemical equivalency should be wide enough to prevent others from stealing a meritorious invention by attempts at specious circumvention. In fact, section 41 (1) expressly provides, insofar as the process is concerned, that the ambit of any such claim extends to processes which are "obvious chemical equivalents". Insofar as processes which are not chemical equivalents are concerned, it appears to be one of the purposes of the sub-section to encourage others to find alternative processes for the production of useful drugs and to prevent the patent monopoly from closing up other avenues of research. What is and what is not an obvious chemical equivalent is in every case a question of fact; but it should be remembered that an alternative process may be a chemical equivalent and yet not be

[18] See *C.H. Boehringer Sohn* v. *Bell-Craig Ltd.* (1964), 41 C.P.R. 1; *Hoechst Pharmaceuticals of Canada Ltd.* v. *Gilbert & Co.* [1966] S.C.R. 189.

[19] See *per* Thurlow, J. in *C.H. Boehringer Sohn* v. *Bell-Craig Ltd.* (1963), 39 C.P.R. 201 at p. 240.

an "obvious" chemical equivalent.[20] In such case the process would not fall within or infringe the product-by-process claim, but might nevertheless infringe the process claim.

D. *Section 41(2)*

> In an action for infringement of a patent where the invention relates to the production of a new substance, any substance of the same chemical composition and constitution shall, in the absence of proof to the contrary, be deemed to have been produced by the patented process.

Although this sub-section is now a separate sub-section, it must not be forgotten that it was originally a *proviso* to sub-section (1); and it is clear that its purpose is to facilitate proof of infringement by a patentee.[21] In view of the limited claim permitted by sub-section (1), it is not enough for a patentee to prove that the alleged infringer has used the patented substance; he must also prove that it was made by the patented process. But once proof has been adduced that the infringer's substance has the same chemical composition and constitution as the substance to which the invention relates, the sub-section operates to shift the *onus* of proof to the defendant, who may then produce evidence to the contrary to establish that the substance in question has not been made by the patented process. It is not necessary for this purpose for a defendant to prove how the substance was in fact made. It is conceivable that he might be able to establish by expert evidence that, for one reason or another, the substance could not in fact have been made by the patented process.[22]

Although the purpose of the sub-section is comparatively simple and straightforward, its wording can give rise to difficulties in practice, particularly in the case of patents which, contrary to the provisions of section 38, contain more than one invention. Many chemical drug patents disclose in the specification not a single compound, but a number of classes, sub-classes and preferred compounds, each of which may be a different "invention".[23] The first difficulty in applying the sub-section in such a case is to determine what is the invention to which the patent relates. By virtue of the Interpretation Act[24] the singular includes the plural "unless the context

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[20] See *per* Thurlow, J. in *C.H. Boehringer Sohn* v. *Bell-Craig Ltd., loc. cit.* at p. 255.

[21] See *per* Thurlow, J. in *Société des Usines Chimiques Rhône-Poulenc* v. *Jules R. Gilbert Ltd.* [1966] Ex. C.R. 59.

[22] *Parke, Davis & Co.* v. *Allan & Hanburys* (1953), 70 R.P.C. 123.

[23] See *per* Thurlow, J. in *Farbwerke Hoechst* v. *Commissioner of Patents* (1965) 31 Fox Pat. c. 64.

otherwise requires"; but it is difficult to see how the section can be properly construed as applicable to several inventions in view of the express prohibition against claiming more than one invention in section 38. Similar problems arise in connection with the words "the production of *a* new substance" and "*the* patented process", although section 41 (1) does refer to "methods or processes" in the plural. Perhaps these problems have, at least to some extent, been resolved by the recent decision of the Supreme Court of Canada in *Société des Usines Chimiques Rhône-Poulenc* v. *Jules R. Gilbert Ltd.*[25] In that case the patent contained a product-by-process claim involving three alternative processes. In an infringement action the patentee chose to rely in his pleadings on only one of the three process claims, and Thurlow, J. dismissed the action on the narrow ground that in those circumstances the section could not apply.[21] On appeal, the Supreme Court of Canada allowed the appeal and held that there was no reason "why when the plaintiff frames its action in this way that [*sic*] the presumption in section 41 (2) should not apply."[25] The Supreme Court also held that section 41 (2) did not require three separate applications for the same substance, one by each process. It would seem to follow from the decision that the presumption applies *a fortiori* where the patentee in his pleadings relies on all processes claimed in the alternative.

E. *Section 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 shall, unless he sees good reason to the contrary, grant to any person applying for the same, a licence limited to the use of the invention for the purposes of the preparation or production of food or medicine but not otherwise; and, in settling the terms of such licence and fixing the amount of royalty or other consideration payable the Commissioner shall have regard to the desirability of making the food or medicine available to the public at the lowest possible price consistent with giving to the inventor due reward for the research leading to the invention.

This sub-section constitutes the second limitation imposed on the monopoly granted to the owners of drug patents. It applies in the case of any patent in respect of which the invention is either intended, or capable of being used, for the preparation or production of medicine; and accordingly the section is not limited to substances within section 41 (1),[26] or indeed to drugs at all, but extends to any kind

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[24] R.S.C. 1952, c. 158, s. 31(1) (j).

[25] Unreported, October 24th, 1966.

[26] *Charles E. Frosst & Co.* v. *Carter Products* (1958), 29 C.P.R. 145.

of invention capable of being used for the preparation or production of medicine. There is no reason, for example, why it should not apply to an invention for a machine for making tablets or pills.

"Any person" is entitled to apply for a compulsory licence, and the Commissioner of Patents "shall" grant a licence limited to the use of the invention for the purposes of the preparation or production of a medicine but not otherwise. The Commissioner will not, however, grant a licence to import.[27]

The obligation on the Commissioner to grant a licence is mandatory, and he can refuse a licence only if the patentee can show "good reason to the contrary". The *onus* is, therefore, on the patentee to show why a licence should not be granted. Unlike in the case of compulsory licences under section 68 of the Patent Act, there is no procedure prescribed under the Patent Rules, and the Commissioner is entitled to determine his own procedure.[28]

As to what is "good reason to the contrary", the matter is one for the discretion of the Commissioner, and unless, on the evidence, his decision is manifestly wrong, or he acts on a wrong principle of law, his decision will not be reversed on appeal.[29] Generally speaking, if the applicant has a reasonably permanent organization, if he is qualified to work the patent, the Canadian market is not already over-supplied with the product and the public interest will benefit, or at least will not suffer, the Commissioner must grant a licence.[30] In recent years applications for compulsory licences have been bitterly opposed by some of the larger drug manufacturers, principally on the alleged ground that the smaller Canadian applicant companies do not maintain strict quality controls as established by the larger drug companies. This has been rejected as a good ground for refusing a licence,[31] although a recent Parliamentary Special Committee has suggested that there should be closer co-operation between the Commissioner of Patents and the Food and Drug Directorate in the granting of compulsory licences.[32] It would seem that however praiseworthy and desirable a high degree of control in the manufacture

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[27] *Gilbert Surgical Supply Co.* v. *Parke, Davis & Co.* (1958), 30 C.P.R. 21, 55.

[28] *Parke, Davis & Co.* v. *Fine Chemicals of Canada Ltd.* [1959] S.C.R. 219; *Hoffman-La Roche* v. *Delmar Chemicals Ltd.* [1965] S.C.R. 575.

[29] See cases cited in note 28, and *Hoffmann-La Roche* v. *Bell-Craig* (1966), 32 Fox Pat. c. 106. See also *The King* v. *Irving Air Chute Inc.* [1949] S.C.R. 613.

[30] *Frank W. Horner* v. *Sharp & Dohm (Canada) Ltd.* (1952), 15 C.P.R. 68. No exclusive licence can be granted; *ibid.*

[31] See *per* Thurlow, J. in *Hoffmann-La Roche* v. *Delmar Chemicals Ltd.* (1965), 27 Fox Pat. c. 178. See also *J.R. Short Milling Co. (Canada) Ltd.* v. *George Weston,* [1941] Ex. C.R. 69 at p. 94 *per* Maclean, J.

[32] Report of the Special *Ad Hoc* Committee Studying Matters Involving the Patent Licensing of Drug Manufacturers; chairman, Dr. I.M. Hilliard.

of drugs might be, the recommendation is a confusion of the respective functions of the Patent Act and the Food and Drugs Act;[33] nor is there any reason why special considerations as to quality control should apply to drugs which happen to be patented.

As a matter of pratice, an application for a compulsory licence under section 41 (3) is answered by a counter-statement filed by the patentee, to which the applicant is entitled to file a reply. The Commissioner then decides whether or not he requires a hearing; but he is not obliged to hold one.[28] If the Commissioner grants a licence, and the parties cannot agree on the terms or the royalty, the Commissioner will settle both. In this connection the second half of the sub-section contains a direction that in so doing he shall have regard to the desirability of making the medicine available to the public at the lowest possible price consistent with giving the inventor due reward for the research leading to the invention. Until recently, the Commissioner had been fixing a royalty of something between ten and fifteeen per cent calculated on the net price of the bulk raw material, i.e. the bulk medicine before being tabletted or capsulated and packaged. This method of arriving at the royalty was recently challenged; and, although reversed by the President of the Exchequer Court,[34] the Commissioner's practice of calculating the royalty on the bulk ingredient was affirmed by the Supreme Court of Canada.[35] Furthermore, the Supreme Court seems to have suggested that where the actual inventor, as opposed to the patentee, would receive no reward at all from the royalty, perhaps no royalty should be payable at all.[36]

F. *Section 41 (4)*

> Any decision of the Commissioner under this section is subject to appeal to the Exchequer Court.

This sub-section provides for an appeal to the Exchequer Court from any "decision" of the Commissioner under this section. It has recently been held that where the Commissioner only grants a licence, but does not fix the terms or the royalty, there is no "decision", and that therefore no appeal lies at that stage of the proceedings.[37]

Under the provisions of section 41 (3) the decision both as to the grant of the licence as well as the royalty and other terms is for

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[33] See Statutes of Canada 1952-53, c. 38 and amendments, and Regulations made thereunder.

[34] *Hoffmann-La Roche Ltd.* v. *Bell-Craig* (1965), 29 Fox Pat. c. 123.

[35] (1966), 32 Fox Pat. c. 106.

[36] *Ibid.* at p. 111.

[37] *Hoffmann-La Roche Ltd.* v. *Delmar Chemicals Ltd.* (unreported, Exch. Ct., February 4th, 1966).

the Commissioner to make, and an appellate court cannot interfere with his decision unless he can be shown to be manifestly wrong on the evidence or to have acted on a wrong principle.[38]

Pending an appeal, an applicant who has obtained a licence can operate under it if he is willing to take the chance that he may ultimately be held not to be entitled thereto. The Exchequer Court has recently refused to grant a "stay" of such a licence pending an appeal.[39]

G. *The Future*

For some years section 41 of the Patent Act has been subjected to attacks from many sides. On the part of patentees, on the ground that it constitutes an unjustifiable interference with monopoly rights granted in other industrial areas, and that it tends to stifle research; on the part of the so-called "copiers", on the grounds that the procedure for obtaining compulsory licences is unnecessarily cumbersome, takes unduly long and can be utilized to embroil an applicant in protracted and costly litigation by a patentee who wishes to avail himself of every possible legal manoeuver to delay the grant of a fully effective licence. Most recently, the views of various interested groups and parties have been put forward with varying degrees of vehemence before the Harley Committee inquiring into drug prices in Canada.[40] Perhaps the most legitimate and serious criticism of the section is that, in the context of modern technology and modern conditions, it is unnecessarily ambigous and unclear, and that it leaves too many loose ends and too many opportunities for unnecessary litigation. There may be legitimate disagreement as to what, in the public interest, the law should be; but once Parliament has made up its collective mind on that issue, the public and the legal profession are entitled to expect that its intention be expressed clearly and without ambiguity.

Several recommendations for changes to the section have been made during the past few years by various bodies. Initially, the Ilsley Commission [41] recommended that product claims unlimited as to process of manufacture should be allowed in respect of substances prepared or produced by chemical processes and substances intended for food or medicine, but that compulsory licences under food or medicine patents should be retained in a somewhat modified form,

[38] *Hoffmann-La Roche Ltd.* v. *Bell Craig* (1966), 32 Fox Pat. c. 106 at p. 108.

[39] *Hoffmann-La Roche Ltd.* v. *L.D. Craig Ltd.* (1966), 46 C.P.R. 30. *Quaere* whether the court has any authority to grant a "stay" of the licence; *ibid.*

[40] Standing Committee on Drug Costs and Prices, chairman, H.C. Harley.

[41] Royal Commission on Patents, Copyright and Industrial Design, Report on Patents of Invention, Queen's Printer, 1960, pp. 92-97.

but without any proof of misuse.[42] Later, the Restrictive Trade Practices Commission[43] advocated the complete abolition of drug patents, on the ground that "the control over drugs exercised through patents in Canada is disadvantageous to the users of drugs in this country . . .".[44] More recently, the Hall Report[45] recommended a modification of the existing system of compulsory licensing by permitting compulsory licensing of imports,[46] streamlining generally procedures as they relate to compulsory licensing,[47] and establishing a standard royalty.[47] The Report also recommends a delay of five years in any decision to implement the recommendations of the Restrictive Trade Practices Commission[43] that drug patents be abolished.[48] Finally, the recommendations of the Harley Committee[40] will be awaited with interest and anticipation by all interested parties.

Prophecy has always been an unprofitable past-time; and if it has been corerctly said that "there is no pre-vision in chemistry", it is equally fruitless to make predictions in the field of drug patents. Assuming that it is in the public interest that drug prices should be kept at a reasonable level, and that drugs, insofar as they constitute a necessity of life rather than a luxury, occupy a position in the community different from other commodities, it would seem that the only effective solution is either the imposition of price control by Government authority or the creation of free competition in the market place. Assuming that the former alternative is not acceptable in a free society, the only remaining alternative would appear to be some degree of limitation on the monopoly otherwise afforded by the Patent Act. Whether such limitation should be absolute or partial, and, if so, how far it should extend, is a matter upon which opinions may properly, and in fact, do, differ. The only hope which may usefully — even if perhaps somewhat optimistically — be expressed is that, whatever solution Parliament in its wisdom may ultimately decide upon, it will give expression to its intention in clear and unambigous language which will at least enable all concerned to know where they stand.

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[42] This has been the position in England since 1949; see Patents Act, 1949, (12, 13 & 14 Geo. 6, c. 87), s. 41.

[43] Restrictive Trade Practices Commission, Report Concerning the Manufacture, Distribution and Sale of Drugs, Queen's Printer, 1963, pp. 516 — 524.

[44] *Ibid.* at p. 523.

[45] Royal Commission on Health Services, Queen's Printer, 1964, vol. 1, pp. 701 — 709.

[46] Recommendation 67, *ibid.* p. 42.

[47] Recommendation 69, *ibid.* p. 43.

[48] Recommendation 68, *ibid.* p. 43.