THE COMMISSIONER OF PATENTS ....APPELLANT;

AND

FARBWERKE HOECHST AKTIENGESELLSCHAFT VORMALS MEISTER LUCIUS & BRUNING ..... RESPONDENT.

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*Oct. 17, 18
Nov. 15

ON APPEAL FROM THE EXCHEQUER COURT OF CANADA

Patents—Patented chemical substance diluted by carrier—Composition claims rejected—Patent Act, R.S.C. 1952, c. 203, s. 41(1).

The respondent filed a parent and 9 divisional applications for the grant of Letters Patent all relating to different processes for producing an antidiabetic preparation, sulphonyl urea. These applications were made under s. 41(1) of the *Patent Act* and they claimed the substance as produced by the various processes. Letters Patent were subsequently granted pursuant to these applications. The respondent later filed an application for Letters Patent entitled "Anti-diabetic compositions containing sulphonyl ureas". This application contained 15 claims, all of which related to a medicine consisting of the sulphonyl urea diluted by a carrier. The Commissioner of Patents rejected these composition

*PRESENT: Fauteux, Abbott, Martland, Judson and Spence JJ.

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claims on two grounds: (1) that the applicant was entitled only to one patent for an invention and that the composition claims did not inventively distinguish from the product claims already granted, and (2) that the claims related to substances prepared by a chemical process and intended for medicine and were prohibited by s. 41(1) of the Act because they amounted to an attempt to protect the substance otherwise than by a patentable process by which it was produced. In allowing an appeal from the Commissioner's decision, the Exchequer Court held that although the mixture was intended for a medicine, it was a substance—a new substance not prepared or produced by a chemical process. It went on to hold that the antidiabetic composition was new and useful and therefore patentable. It also held that there was inventive ingenuity.

Held: The appeal should be allowed.

The respondent had a patent under s. 41 of the *Patent Act* for the invention of a medicine. It now wanted another patent for the medicine in a diluted form, that is, mixed with some inert substance, called "an orally ingestible pharmaceutically acceptable carrier", that would enable it to be put on the market for consumption. The addition of an inert carrier was nothing more than dilution and did not result in a further invention over and above that of the medicinal itself. If a patent subsisted for the new medicinal substance, a separate patent could not subsist for that substance merely diluted. If a legal impediment existed against a patent claim for the new medicinal substance, namely, s. 41(1) of the Act, that legal impediment was equally applicable to the diluted substance.

The mixing of a patented chemical with a carrier was not new and it was not the result of inventive ingenuity; it was still a substance identical in all respects except dilution with a substance produced by a chemical process and for which a patent had been granted under s. 41(1).

Commissioner of Patents v. Ciba Ltd., [1959] S.C.R. 378, discussed.

APPEAL from a judgment of the Exchequer Court of Canada[1], allowing an appeal from a decision of the Commissioner of Patents to reject an application for a patent. Appeal allowed.

Gordon F. Henderson, Q.C., and *D. Bowman*, for the appellant.

Christopher Robinson, Q.C., and *Russel S. Smart*, for the respondent.

The judgment of the Court was delivered by

JUDSON J.:—The Commissioner of Patent appeals from the judgment of the Exchequer Court[1], which allowed an appeal from his decision to reject an application for a patent.

[1] (1962), 22 Fox Pat. C. 141, 39 C.P.R. 105.

On June 5, 1956, the respondent filed a parent and 9 divisional applications all relating to different processes for producing an antidiabetic preparation, sulphonyl urea. These applications were made under s. 41(1) of the *Patent Act*, R.S.C. 1952, c. 203, and they claimed the substance as produced by the various processes. Letters Patent were subsequently granted pursuant to these applications.

On June 28, 1957, the respondent filed an application for Letters Patent entitled "Anti-diabetic compositions containing sulphonyl ureas". This application contains 15 claims, all of which are in issue in this appeal. These claims all relate to a medicine consisting of the sulphonyl urea diluted by a carrier.

On January 13, 1960, the Commissioner of Patents rejected these composition claims on two grounds. The first was that the applicant was entitled only to one patent for an invention and that the composition claims did not inventively distinguish from the product claims already granted. The inventive feature of the claimed composition was in the sulphonyl urea compound and not in the association of the compound with the carrier.

The second ground was that the claims related to substances prepared by a chemical process and intended for medicine and were prohibited by s. 41(1) of the Act because they amounted to an attempt to protect the substance otherwise than by a patentable process by which it was produced. By the time the Commissioner had rejected the application in question in this appeal, the respondent had already received, on September 1, 1959, the 10 Letters Patent for the substance and the processes pursuant to s. 41(1) of the *Patent Act*.

What the respondent is seeking can be put in very plain words. It has a patent under s. 41 for the invention of the medicine. It now wants another patent for the medicine in a diluted form, that is, mixed with some inert substance, called "an orally ingestible pharmaceutically acceptable carrier", that will enable it to be put on the market for consumption. Claim 1 in the application under consideration may be taken as an example. It reads as follows:

1. An antidiabetic preparation effective on oral administration to reduce the blood sugar level, said preparation comprising as the active blood sugar lowering ingredient a sulphonyl urea of the formula

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$R—SO_2—NH—CO—NR—R_1$ in which; R is a radical selected from the group consisting of phenyl, substituted phenyl having up to two substituents selected from the group consisting of alkyl; alkoxy and halogen, and aliphatic and cycloaliphatic hydrocarbon containing 3-8 carbon atoms; R_1 represents a radical selected from the group consisting of aliphatic and cycloaliphatic hydrocarbon containing 2-8 carbon atoms, or a salt thereof, and an orally ingestible pharmaceutically acceptable carrier therefor.

The only difference between this claim and the following claims is that each claims sulphonyl urea of a formula that is different in definition, together with the carrier.

The case was argued both in the Exchequer Court and here on an agreed statement of facts. I set out paragraphs 6, 13, 15 and 17:

> 6. In application No. 731,948, each of the claims is for an antidiabetic preparation comprising a sulphonyl urea or its salts and an orally ingestible pharmaceutically acceptable carrier therefor, and no process was claimed. Such preparation would consist of a sulphonyl urea mixed with a carrier, or diluted by a carrier, or enclosed or encapsulated by a carrier in the form of a capsule.
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> 13. The mixing, the diluting, the enclosing or encapsulating of a sulphonyl urea with an orally ingestible pharmaceutically acceptable carrier is not a chemical process.
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> 15. At the effective filing date of application No. 731,948, a person skilled in the art could, if so requested, have made a preparation of the sulphonyl ureas or their salts and an orally ingestible pharmaceutically acceptable carrier therefor without the exercise of any inventive ingenuity.
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> 17. The only utility disclosed in application No. 731,948 for the antidiabetic preparations claimed does not differ from the utility which is disclosed in the issued patents for the sulphonyl ureas and their salts, and upon which the grant of the said patents was predicated.

The Exchequer Court held that although the mixture was intended for a medicine, it was a substance—a new substance not prepared or produced by a chemical process. The fact that one of the ingredients in the substance was so prepared or produced did not make the substance as a whole one that was so prepared. This last assumption as it is applied to the facts of this case, which is merely one of dilution, is, of course, challenged by counsel for the Commissioner.

The Exchequer Court went on to hold that the antidiabetic composition was new and useful and therefore patentable. It also held that there was inventive ingenuity. It found this because the inventors had conceived the idea of mixing with a carrier the sulphonyl ureas, of whose unobvious utility they had knowledge so as to bring into being a new substance. But for their discovery of the un-

obvious utility of the substances, there would have been no reason for combining them with a carrier, for the utility of such a combination was not obvious. Thus, inventive ingenuity, one of the attributes of patentability, was in fact present.

The fallacy in the reasoning is in the finding of novelty and inventive ingenuity in this procedure of dilution. It is an unwarrantable extension of the ratio in the *Commissioner of Patents v. Ciba Ltd.*[1], where inventive ingenuity was found in the discovery of the valuable properties of the drug itself.

A person is entitled to a patent for a new, useful and inventive medicinal substance but to dilute that new substance once its medical uses are established does not result in further invention. The diluted and undiluted substance are but two aspects of exactly the same invention. In this case, the addition of an inert carrier, which is a common expedient to increase bulk, and so facilitate measurement and administration, is nothing more than dilution and does not result in a further invention over and above that of the medicinal itself. If a patent subsists for the new medicinal substance, a separate patent cannot subsist for that substance merely diluted. If a legal impediment exists against a patent claim for the new medicinal substance, namely, s. 41(1) of the *Patent Act*, that legal impediment is equally applicable to the diluted substance. The diluted medicinal is still a medicine and the essential step of the process for preparing the diluted medicinal is a chemical step. Therefore, s. 41(1) of the *Patent Act* applies. Further, the respondent has already received patent protection to the full extent allowed by the law. Invention may lie in a new, useful, and inventive process for producing a new medicinal substance, and the respondent has already obtained patents for such inventive processes and for the new product as produced by such processes. The process claims and process dependent product claims in these patents represent the full extent of the protection to which the respondent is entitled.

Therefore, the primary error in the judgment of the Exchequer Court is twofold. The mixing of a patented chemical substance with a carrier is not new and it is not

[1] [1959] S.C.R. 378, 19 Fox Pat. C. 18, 30 C.P.R. 135, 18 D.L.R. (2d) 375.

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the result of inventive ingenuity. It 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 and for which a patent has been granted under s. 41(1) of the *Patent Act*.

The decision under appeal is of extreme practical significance. It gives effect to form rather than substance. The claim to a pharmaceutical composition with which the present appeal is concerned is free from the limitations imposed by s. 41(1) and a person who obtained a patent in this way could assert such claims against anyone using the pharmaceutically active ingredient constituting the substance of the invention regardless of the process whereby it was produced. Further, it might affect compulsory licensing applications under s. 41(3).

I am therefore of the opinion that the rejection of the application by the Commissioner of Patents was well founded for the reasons stated by him in his letter of rejection, which I now set out in full:

> Applicant's letter of May 20, 1959, has been received and the application has been reviewed having regard to applicants' arguments.
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> However after careful consideration it has been decided that these arguments do not overcome the objections set forth in the last Office Action. The arguments will remain on record.
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> All of the applicants' claims (1 to 15 inclusive) are rejected, and this rejection is made final under the provisions of Rule 46.
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> The applicants are entitled to only one patent for their invention. The compositions defined in the claims fail to inventively distinguish from the product claims appearing in parent application number 708,643 now Patent number 582,621. The composition claims are obviously directed to the same invention as the product claims of Patent 582,621. The essential inventive feature of the claimed compositions resides in the medicinally active chemical compound, and not in the fact that this compound is associated with a carrier. It is general practice in the medicinal art to associate an active compound with a suitable diluting or carrying agent because, usually, such a compound cannot be used in the pure form. Furthermore the fact that the active compounds of the compositions have been allowed in the parent application in claims draughted along the requirements stated in Section 41 of the Patent Act constitutes evidence that said compounds are intended for medicine, and makes unnecessary and superfluous any claim to the mere use thereof. It is therefore clear that the composition claims of this application fail to reveal anything which is not taught or clearly implied by the allowed product claims of Patent 582,621.
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> In the Exchequer Court decision number 100035, Rohm and Haas Company vs The Commissioner of Patents, Cameron J. makes clear that claims such as the present composition claims are not patentable. He states: "I am of the opinion, however, that when a claim to a compound

has been allowed, a claim to a fungicidal composition merely having that compound as an active ingredient is not patentable". And further that: "The utility of the compounds as fungicides is fully set forth in the specification of the patent which has been allowed; to name the compound as a fungicidal composition is merely to recite one of its inherent qualities". When "medicinal" is substituted for "fungicidal" and, "medicines" for "fungicides", the above quotation applies squarely to applicants' claims.

The argument, made by the applicants, that by taking the already patented compounds of Patent 582,621 and merely mixing them with a carrier they have converted them into new products which are not governed by Section 41, cannot be accepted. The essential inventive feature of the composition claims is the new medically-active chemical compounds. The invention of these composition claims relates to substances prepared by chemical processes, and intended for medicine. Practically all new medicines must be diluted with some carrier or other ingredient, and cannot be used in the pure form. Such carriers obviously must be compatible with the active substance, and suitable for the way in which the medicine is to be administered. In this case there is no question of second invention involving the discovery of a new and particular carrier which imparts a special, new, and unexpected character to the compositions. To permit the claiming of a medicine mixed with a carrier in per se form, rather than in process-dependent form, would mean that all new medicines could be claimed free of the restrictions of Section 41 in the only practical form in which they may be used. This, of course, would defeat the whole purpose of the Section.

All the claims are rejected.

As the objections cannot be overcome by amendment, this action terminates the prosecution of the application before the examiner. Any request for review must be lodged within three months.

signed (G. Drouin)
Examiner—Group C-6

I have set out the reasons of the Commissioner in full because they show the kind of consideration he gave to this problem in his office and also because of a suggested limitation of his function in the reasons of the Exchequer Court. Following statements made in *R. v. Patents Appeal Tribunal, Ex p. Swift & Co.*[1], the Exchequer Court said that the Commissioner should not refuse to allow an application to proceed to the grant of a patent unless he is quite satisfied that the subject-matter of the application could not conceivably be patentable within the meaning of the *Patent Act*.

The Commissioner was well within even this definition of the scope of his duties but I think that the *obiter* of the Exchequer Court expresses the duty of the Commissioner too restrictively and fails to recognize the distinction between the United Kingdom and the Canadian Patent

[1] [1962] 1 All E.R. 610 at 616, 2 Q.B. 647.

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Acts. Under ss. 6, 7 and 8 of the United Kingdom *Patents Act, 1949,* the Examiner may examine only for anticipation. He may not and does not as a matter of practice examine as to inventiveness. This is left to the Court. Further, as pointed out in *Re Levy & West's Application*[1], no appeal lies from the Patent Appeal Tribunal, whereas in a subsequent action the validity of the patent may be impeached in the highest court in the land.

In contrast, in Canada the Patent Office, supervised by the Court, does examine as to inventiveness, and an applicant may appeal to the highest court. Moreover, in the particular class of case with which we are here concerned dealing with drugs and medicines, there is considerable public interest at stake, and the Commissioner should most carefully scrutinize the application to see if it merits the grant of monopoly privileges, and to determine the scope of the monopoly available.

I also wish to say something about the construction put upon the decision of this Court in *Commissioner of Patents v. Ciba Ltd., supra.* Although the learned President does find in this case that there was inventive ingenuity, erroneously in my respectful opinion, he also states categorically that the *Ciba* case held that novelty and utility are the only attributes of patentability that need to be present in order to constitute an invention. This, to me, is an erroneous interpretation of the effect of the *Ciba* case. With respect, the judgment of this Court did not proceed on the narrow ground that novelty and utility are the only two attributes of patentability. The judgment of this Court affirmed the judgment of the Exchequer Court for reasons common to both judgments, namely, an adoption of the principles stated by Jenkins J. in *Re May & Baker Ltd. and Ciba Ltd's. Letters Patent*[2], and as far as I can see, until the question was raised in the reasons delivered in the Exchequer Court no one ever doubted the principle that invention is an essential attribute of patentability. In any case, in this Court, as far as I know, wherever the question has been material the judgments have always so held.

The construction put upon s. 41(1) of the *Patent Act* in the reasons for judgment of the Exchequer Court

[1] (1945), 62 R.P.C. 97 at 104. [2] (1948), 65 R.P.C. 255.

requires comment. The section was held to be restrictive of the rights that an inventor would have except for the prohibitions of the section. Consequently, the Court should not find that a particular application came within its prohibitions unless the conditions for its application are clearly present. I can see no justification for this interpretation. There is no inherent common law right to a patent. An inventor gets his patent according to the terms of the *Patent Act,* no more and no less. If the patent for which he is applying comes within the provisions of s. 41(1) of the Act, then he must comply with that section.

I would allow the appeal with costs both here and in the Exchequer Court and declare that the fifteen claims of application, serial No. 731,948, be held to be unpatentable.

Appeal allowed with costs.

Solicitor for the appellant: G. W. Ainslie, Ottawa.

Solicitors for the respondent: Smart & Biggar, Ottawa.