PARKE, DAVIS & COMPANY ..... APPELLANT;

AND

FINE CHEMICALS OF CANADA, LIMITED ..... RESPONDENT.

1958
*Oct. 30, 31
1959
Jan. 27

ON APPEAL FROM THE EXCHEQUER COURT OF CANADA

Patents—Compulsory licence—Power of Commissioner of Patents to grant licence—Patent covering both process and substance—Product having therapeutic value— Product to be sold in bulk by licensee—Infringement—Market already served—Royalty—The Patent Act, R.S.C. 1952, c. 203, s. 41.

*PRESENT: Rand, Locke, Cartwright, Abbott and Martland JJ.

[1] [1958] Que. Q.B. 275.

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The appellant holds a patent covering both the process for manufacturing a chemical compound marketed under the trade name "Benadryl", which was described as being new and having therapeutic value, and also the product itself when produced by the patented process. The respondent manufactures chemical products in bulk, and was granted, by the Commissioner of Patents, a licence under s. 41(3) of the Patent Act to manufacture the product for sale. A royalty of 10 per cent. of its net selling price was to be paid by the licensee, whose stated intention was to sell in bulk form only. The order of the commissioner was affirmed by the Exchequer Court. The patentee appealed to this Court and contended that (1) the commissioner had no authority under s. 41(3) to grant the licence because the licensee would not be producing a medicine and because the licence covered both the process and the product, (2) the commissioner should have seen "good reason" not to grant the licence because the licensee had infringed the patent and because the market was already adequately served, and (3) the royalty was inadequate.

Held: The appeal should be allowed in respect of the adequacy of the royalty, which question should be referred back to the commissioner. In other respects, the appeal should be dismissed.

Per curiam: The evidence was quite inadequate to enable the commissioner to arrive at a royalty which would give due weight to all relevant considerations.

Per Rand and Abbott JJ.: Section 41(3) applied to a case where the patent covered both the process and the substance produced. The subsection was to be taken to include any new process for producing a new substance, and since the product depended on the process and as its invention involved the new process, a licence for the process necessarily involved the right to produce the substance: the process necessarily produced the product.

Per Locke, Cartwright and Martland JJ.: The word "medicine" as used in s. 41 should be interpreted broadly, and the product was a medicine within the meaning of the section, even when it was in bulk form.

Construing s. 41 as a whole, the commissioner had authority to grant the licence for the use of the invention. In terms, subs. (3) applied to "any patent" if such a patent is for "an invention intended for or capable of being used for the preparation or production of food or medicine".

The decision as to whether the commissioner should have seen "good reason to the contrary" was his to make, and it could not be said, on the evidence, that his decision was manifestly wrong.

APPEAL from a judgment of Thurlow J. of the Exchequer Court of Canada[1], affirming an order of the Commissioner of Patents granting a licence under s. 41(3) of the *Patent Act*. Appeal allowed in part.

J. J. Robinette, Q.C., and *J. Godfrey, Q.C.*, for the appellant.

[1] [1957] Ex. C.R. 300, 16 Fox Pat. C. 173, 27 C.P.R. 117.

G. H. Henderson, Q.C., and *D. Watson,* for the respondent.

The judgment of Rand and Abbott JJ. was delivered by

RAND J.:—The facts in this appeal are these. The appellant, to be called the "Company", holds a patent on both a process for making and the substance itself called Benadryl. The Company manufactures the chemical in the United States and ships it in bulk to a subsidiary in Canada by which it is prepared in dosage form with or without other ingredients for the treatment of allergies, colds or motion sickness. The respondent manufactures chemical products in bulk and applied for a license under s. 41(3) of the *Patent Act,* R.S.C. 1952, c. 203, as amended, to manufacture Benadryl for sale to manufactureres of pharmaceutical substances. The Commissioner of Patents granted the license and fixed the royalty at 10 per cent. of the net wholesale price of the licensee.

Section 41 is as follows:

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.

(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.

(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. . . .

Two questions are raised: first, does subs. (3) apply to a case where the patent covers both the process and the substance produced, and secondly, is the royalty allowed unreasonably small?

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The section is seen to deal with substances prepared or produced by chemical processes and intended for food or medicine and its provisions are exclusive in relation to their subject-matter. Their interpretation has been considered in this Court in two cases, *F. Hoffmann-LaRoche & Co. Ltd. v. Commissioner of Patents*[1] and *Commissioner of Patents v. Winthrop Chemical Company Incorporated*[2]. In the former the Exchequer Court was confirmed in holding that subs. (1) permitted the issue of a patent for a new substance only when it was associated with a new process at the same time patented. In the latter a claim for a new substance produced by an old process was held to be bad and the substance unpatentable. Mr. Robinette argues that the language of subs. (3) limits its application to the case of a patented process only and that where both the process and the product are within the monopoly, a licence under the section is not authorized. He stresses the words "for the purposes of the preparation or production of food or medicine" as being referable only to the active agency or process.

The legislative policy underlying the subsection to be gathered from its special terms and the section as a whole is obvious: all new substances, apart and as distinguished from processes, are, in the public interest, to be free from legalized monopoly, the conclusive evidence of which is the fact that no new substance may alone be patented; all unpatented processes are open to be used to produce the substance patented with its new process, with only the new process protected. Admittedly a licence can issue at once for the new process where the substance is old; but, on the argument made, where the substance is also new and patented both are to continue under monopoly unless, after three years, under s. 67, in case of an abuse of the exclusive right, a licence is granted. If, for example, the Salk vaccine and its process were patented, in the absence of another process the public would be denied the benefit of immediate licence and until s. 67 might become available; whereas a new, patented process for making the vaccine would be available for licence at once. This means that a new proc-

[1] [1955] S.C.R. 414, 15 Fox Pat. C. 99, 23 C.P.R. 1.
[2] [1948] S.C.R. 46, 7 Fox Pat. C. 183, 7 C.P.R. 58, 2 D.L.R. 561.

ess is to be held to be of more importance to the public than a new substance, however vital the latter may be for health. In this patent a number of new processes are included and the view advanced might defeat completely the purposes of the subsection through the possible exhaustion of efficient methods of production by the patent. Such a view contradicts the most significant fact that a new substance, however original and ingenious the idea behind it, cannot be patented alone. Subsection (3) is to be taken to include any new process for producing a new substance, and since the product is process dependent, and as its invention involves the new process, a licence for the latter necessarily involves the right to produce the former: the process necessarily produces the product. The case in which a licence is to be issued is "of any patent for an invention intended for or capable of being used for the preparation of production of food or medicine"; Benadryl is a substance of medicine and the patented process is intended for its production: *In re Glaxo*[1]. One consequence and an important one in extending the patent to the substance would be its pertinence to the ascertainment of a royalty.

The evidence before the commissioner on damages was quite inadequate to enable him intelligently to arrive at a royalty which would give due weight to all relevant considerations. Where the monopoly in such inventions is so considerably restricted in scope, we should be free from doubt that the royalty allowed is commensurate with the maintenance of research incentive and the importance of both process and substance. That does not appear to me to have been possible on the meagre evidence presented to the commissioner. The case should be referred back to the commissioner to enable further matter to be adduced. For that purpose it is not sufficient for the patentee to sit back and, if they only are available, keep important facts undisclosed as being private and confidential; once the commissioner decides the case to be one for licence, it lies with the patentee, by whatever means are open to him, to present substantial support for the royalty which he claims; in the absence of that he will be in a weak position to complain of any holding by the commissioner.

[1] (1941), 58 R.P.C. 12.

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Rand J.

I would, therefore, allow the appeal and refer back to the commissioner the matter of royalty; in other respects the appeal should be dismissed. In the circumstances there should be no costs to any party in this or the Exchequer Court.

The judgment of Locke, Cartwright and Martland JJ. was delivered by

MARTLAND J.:—This is an appeal from a judgment of Thurlow J. in the Exchequer Court[1], which dismissed the appellant's appeal from an order made by the Commissioner of Patents for the granting of a compulsory licence to the respondent with respect to the use of Canadian Patent 466,573, pursuant to subs. (3) of s. 41 of the *Patent Act*, R.S.C. 1952, c. 203, as amended.

The patent is entitled "Process for the Manufacture of Amino Ethers" and was issued on July 11, 1950, to the appellant as assignee of the inventor. It covers both the process for manufacturing a chemical known as diphenhydramine hydrochloride, also known as Benadryl, and also that product itself when produced by the patented process. The first sentence of the patent states: "The invention relates to a new class of chemical compounds of therapeutic value." The appellant manufactures this chemical in the United States of America and ships it in bulk to Parke, Davis & Company Limited, a Canadian company, which prepares the bulk chemical in dosage forms or combines it with other ingredients to produce preparations for allergies, for colds and for motion sickness.

The respondent is a Canadian company which manufactures pharmaceuticals and pharmaceutical chemicals. The licence granted to it by the Commissioner of Patents authorized it to manufacture, in its own establishment only, products according to the patented process with the consequent right to sell the products, subject to certain stated terms and conditions, including payment to the appellant of a royalty of 10 per cent. of its net selling price to others of the product. The stated intention of the respondent is to sell the product in bulk form only.

[1] [1957] Ex. C.R. 300, 16 Fox Pat. C. 173, 27 C.P.R. 117.

The provisions of the *Patent Act* requiring consideration in this appeal are subs. (1), (2) and (3) of s. 41, which provide as follows:

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.

(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.

(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.

Three contentions were raised by the appellant:

1. That the Commissioner of Patents was not authorized under subs. (3) to grant the licence because:

(*a*) the respondent would not be producing a medicine within the meaning of that subsection;

(*b*) a licence can be granted under that subsection only in respect of a patented process and not where a patent covers both the process and the product created by that process.

2. Even if the Commissioner of Patents had authority to issue a licence, he should have seen "good reason to the contrary" in considering this application because:

(*a*) it was alleged that there had been infringement of this patent by the respondent;

(*b*) the Canadian market was already adequately served by Parke, Davis & Company Limited.

3. In any event the royalty fixed by the Commissioner of Patents for the use of the invention was inadequate.

With respect to the first point, it was contended that the respondent would only be producing Benadryl in bulk form, and not bottled or labelled for sale for individual consumption, and that in bulk form it did not constitute a medicine.

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Reference has already been made to the first sentence in this patent, stating that it relates to a new class of chemical compounds of therapeutic value. Furthermore, the specifications also state:

> The compounds may be administered to humans as the hydrochloride or other salts or the free bases. They may be given orally, parenterally, rectally or as a vapour or mist. The more active compounds of the invention, such as Compound 1, are indicated for therapeutic use in humans for allergic conditions (asthma, urticaria, histamine cephalgia, anaphylactic shock), smooth muscle spasm (biliary spasm, dysmenorrhea).
>
> Compound 1 may be orally administered in dosage of 5 grains and given intravenously in amount of 150 mg.

It is also noted that the product claims in this patent are in the form specified in subs. (1) of s. 41 of the Act, which relates exclusively to inventions of substances prepared or produced by chemical processes and intended for food or medicine. From the evidence it appears that the product in question has no uses other than therapeutic uses.

I agree with Thurlow J. that the word "medicine", as used in s. 41 of the Act, should be interpreted broadly and I am of the opinion that the product Benadryl is a medicine within the meaning of that section, even when it is in bulk form.

It was also contended that the authority to grant a licence under subs. (3) of s. 41 was limited to a licence for the use of a patented process only and where there was no added claim for the product produced by that process. Reference was made to two decisions of this Court in respect of s. 41 of the Act; namely, *The Commissioner of Patents v. Winthrop Chemical Company Incorporated*[1] and *F. Hoffman-LaRoche & Co. Ltd. Co. v. The Commissioner of Patents*[2].

The earlier case decided that a claim cannot be entertained for a substance falling within subs. (1) of s. 41 unless a claim is also made in respect of the process by which it is produced. The latter case decided that the inventor of a new process for the manufacture of a product which is not new cannot obtain a patent for the product even on the basis of a process dependent product claim.

[1] [1948] S.C.R. 46, 7 Fox Pat. C. 183, 7 C.P.R. 58, 2 D.L.R. 561.
[2] [1955] S.C.R. 414, 15 Fox Pat. C. 99, 23 C.P.R. 1.

It was argued that, construing subs. (3) of s. 41 in the light of these decisions, it could only have been intended to relate to an invention of the process only and not to relate to a case where the product produced by the process had also been claimed. Emphasis was placed on the following words of the subsection: "a licence limited to the use of the invention for the purposes of the preparation or production of food or medicine but not otherwise". It was urged that such a licence could not permit the sale of the product, but only the use of the process. If the invention relates only to the process, then a sale of the product would not infringe the patent, but, if the product also is patented, then the sale would involve an infringement and the licence cannot, under the wording of the subsection, authorize such a sale. Therefore it was contended that the subsection was not intended to apply to such a patent.

In my opinion subs. (3) is not to be interpreted in this narrow manner. In terms it applies to "any patent" if such patent is for "an invention intended for or capable of being used for the preparation or production of food or medicine". The words of limitation of the licence appearing in the subsection, namely, "a licence limited to the use of the invention for the purposes of the preparation or production of food or medicine but not otherwise", are inserted because the subsection applies not only to inventions intended for the preparation or production of food or medicine, but also to inventions *capable* of being used for the preparation or production of food or medicine. There may be inventions capable of such use and also of other uses. The licence which may be granted under this subsection is limited to the use of the invention for the preparation or production of food or medicine.

It seems to me that s. 41 must be construed as a whole. Subsection (1) applies to inventions relating to substances prepared or produced by chemical processes and intended for food or medicine. Subsection (3) goes somewhat further and also applies to any patent for an invention capable of being used for the preparation or production of food or medicine. If subs. (3) were to be construed in the manner suggested by the appellant, it would eliminate from its

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operation inventions which fell within the operation of subs. (1). I do not think that such a meaning was intended and the wording of subs. (3) does not indicate that it must be so construed. The subsection relates to the use of any invention intended for or capable of being used for the preparation of food or medicine and the provisions as to royalty clearly contemplate the sale of the product produced by such use, for they refer to the making of the food or medicine available to the public at the lowest possible price consistent with giving to the inventor due reward for his research.

I am, therefore, of the opinion that the Commissioner of Patents had authority, under subs. (3) of s. 41 of the *Patent Act,* to grant a licence for the use of the invention in question.

As to whether he should have seen "good reason to the contrary" regarding the application for this licence, it would seem that this is a matter for the judgment of the Commissioner of Patents. The wording in question is "the Commissioner shall, unless he sees good reason to the contrary, grant to any person applying for the same . . ." In this case the commissioner did not see such good reason. The decision is his to make and it cannot be said, on the evidence, that his decision was manifestly wrong, bearing in mind that one of the main considerations before him is that of the public interest.

With respect to the matter of the adequacy of the royalty provided in the commissioner's order, I agree with my brother Rand that the evidence before the commissioner was inadequate to enable him intelligently to arrive at a royalty which would give due weight to all the relevant considerations. The monopoly in such inventions is considerably restricted in scope and the royalty allowed should be commensurate with the maintenance of research incentive and the importance of both process and substance. In the present case the respondent proposes to manufacture the product Benadryl in bulk form only. The provision in the commissioner's order as to royalty fixes the 10 per cent. royalty upon the net selling price to others of the product.

The royalty as fixed is, therefore, to be determined upon the wholesale price and has no relationship to the ultimate selling price of the medicines to the consumer.

I am, therefore, of the opinion that in respect of this matter only the appeal should succeed.

I would, therefore, allow the appeal in respect of the matter of the adequacy of the royalty and refer the matter back to the commissioner. In other respects the appeal should be dismissed. There should be no costs to either party in this or the Exchequer Court.

Appeal allowed in part.

Solicitors for the appellant: Arnoldi, Parry & Campbell, Toronto.

Solicitors for the respondent: Gowling, MacTavish, Osborne & Henderson, Ottawa.