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July 10

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

AND

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

Patents—Appeal from order of Commissioner of Patents granting a licence to use appellant's patented invention—The Patent Act, R.S.C. 1952, c. 203, ss. 2(d), 28, 35, 36, 41 and 46—Expression "Medicine" in s. 41(3)

of the Patent Act to be interpreted broadly—Right to market patented product is implied when produced under a licence—Infringement of patent prior to application for licence is a matter to be considered by the Commissioner of Patents on hearing application for licence—Order granting licence under s. 41(3) not wrong because applicant infringed patentee's invention.

The Patent Act, R.S.C. 1952, c. 203, s. 41 states:

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). .....

(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.

.....

Appellant is the patentee of Canadian Patent number 466573 for an invention relating to a class of chemical compounds alleged in the specification to be new and to have therapeutic value. One of the compounds is known as diphenhydramine hydrochloride and is marketed by appellant under the trade name "Benadryl". The Commissioner of Patents ordered that a licence should be granted to the respondent under the patent "for the ultimate purpose of the preparation or production of medicine only and for no other purpose". The respondent's purpose is to use the patented process to manufacture the product for sale in bulk, rather than to use it in the preparation or production of any other food or medicine, or to reduce it to capsules or tablets or any other dosage form, either with or without the admixture of other substances.

Appellant appealed from the decision of the Commissioner of Patents to this Court.

Held: That the expression "Medicine" in s. 41(1) of the Patent Act should be interpreted broadly and not restricted to opinions as to when a substance having medicinal values in small doses but noxious effects in larger doses, is medicine and when it is not, and the respondent in proposing to produce bulk diphenhydramine hydrochloride proposes to produce a medicine within the meaning of the word in s. 41(1) of the Patent Act.

2. That a right to market the patented product, when produced under a licence under s. 41(3) of the Patent Act to use the patented process, is to be implied from the wording of s. 41(3).

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APPEAL from an order of the Commissioner of Patents granting a licence under s. 41(3) of the Patent Act.

The appeal was heard before the Honourable Mr. Justice Thurlow at Ottawa.

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

Gordon Henderson, Q.C. and *David Watson* for respondent.

THURLOW J.:—This is an appeal by Parke, Davis & Co., the patentee of Canadian patent number 466573, from a decision of the Commissioner of Patents dated June 28, 1955, granting an application by Fine Chemicals of Canada, Ltd. for a licence to use the patented invention.

The application was made under s. 40 of the *Patent Act*, S. of C. 1935, c. 32, now s. 41 of the *Patent Act*, R.S.C. 1952, c. 203, which 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.

(4) Any decision of the Commissioner under this section is subject to appeal to the Exchequer Court.

(5) This section applies only to patents granted after the 13th day of June, 1923.

The patent in question was issued to the appellant on July 11, 1950 for an invention relating to a class of chemical compounds alleged in the specification to be new and to have therapeutic value. The specification describes the compounds and processes for their manufacture, as well as

methods for their administration to humans for the alleviation of certain disorders, and it ends with twenty-five claims, of which fourteen are for processes and the other eleven are for the compounds when produced by the claimed processes. One of the compounds is known as diphenhydramine hydrochloride and is marketed by the appellant under the trade name "Benadryl". It is this compound and some of the claimed processes by which it may be made in which the respondent is particularly interested.

On January 14, 1953 the respondent applied in writing to the Commissioner of Patents under s. 40, now s. 41, of the *Patent Act* for the grant of a licence under the patent "for the purpose of the preparation or production of the patented products." In the application, it is stated that the respondent is prepared to make the product for sale in Canada and is fully equipped to do so, and it appears from the evidence that the respondent's purpose is to use the patented process to manufacture the product for sale in bulk, rather than to use it in the preparation or production of any other food or medicine, or to reduce it to capsules or tablets or any other dosage form, either with or without the admixture of other substances. The appellant opposed the application and, after a hearing in which oral evidence was taken and argument heard, the Commissioner gave the decision from which this appeal was taken. The Commissioner's decision is based on his opinion that the patent affords protection for the processes alone, that the product itself is not protected by the patent, and that dealing with the product is free provided it has been produced legally. He concluded that a licence should be granted to the respondent under the patent "for the ultimate purpose of the preparation or production of medicine only and for no other purpose," and set a royalty to be paid by the respondent of ten per cent, based on the net selling price of the bulk product.

Notice of appeal from the Commissioner's decision was given on July 27, 1955. Subsequently, on January 19, 1956 a formal licence was issued which, after reciting the prior

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proceedings and the decision and that the form of the licence comes before the Commissioner to be settled pursuant to the decision, proceeds as follows:

> Now, THEREFORE, be it known that pursuant to the powers vested in me by the Patent Act and particularly by Sections 4 and 41 of said Act, I do order the grant to the applicant, Fine Chemicals of Canada, of a non-exclusive licence under Canadian Patent No. 466,573 for the unexpired term thereof, and under no other patent, to manufacture in its own establishment only, products according to the patented process with the consequent right to sell the products under the following terms and conditions:

Then follow ten paragraphs, setting out various terms, including provision for the payment of royalty as previously mentioned. The licence is included in the material making up the case on appeal, pursuant to an order of this Court made on June 28, 1956.

At the hearing in this Court, the appellant rested its appeal on four points. First, it was argued that diphenhydramine hydrochloride in bulk is not a medicine and, as the respondent is not a pharmaceutical manufacturer and proposes to make only the bulk product, the purpose for which the licence was asked was not within the provisions of s. 41(3). Secondly, the appellant argued that s. 41(3) is applicable only where the patent is one for a process alone and the subsection cannot be applied where the patent protects not only a process but a product as well, when produced by the process, that, as the patent in question is for both processes and products when produced by the processes, the Commissioner had no authority to grant a licence to use the processes where the result would be to authorize the manufacture of products protected by the patent, and that the Commissioner also exceeded his powers in purporting to license the sale of the products. Thirdly, it was argued that the Commissioner had not considered two matters which should have constituted good reason for refusing the application; that is to say, first, the fact that the Canadian market for diphenhydramine hydrochloride was already fully supplied and, secondly, the fact that the respondent had infringed the patent, both by making diphenhydramine hydrochloride by the patented process and by selling it prior to applying for the licence. Finally, it was argued that the royalty set by the Commissioner at ten per cent on the bulk sale price was inadequate.

At this point it will be convenient to refer to and set out several sections of the *Patent Act,* which bear on the problems raised.

Invention is defined as follows by s. 2(*d*):

(*d*) "invention" means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter;

Leaving out inapplicable expressions, an invention may thus consist of a process or of a composition of matter otherwise generally referred to as a substance. Section 28 provides that, within the limits therein mentioned and on compliance with the requirements of the Act, an inventor may obtain a patent granting to him an exclusive property in his invention. By s. 35 it is provided that an application for a patent shall be accompanied by a specification of the invention, and by s. 36 it is further provided as follows:

36. (1) The applicant shall in the specification correctly and fully describe the invention and its operation or use as contemplated by the inventor, and set forth clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it appertains, or with which it is mostly closely connected, to make, construct, compound or use it; in the case of a machine he shall explain the principle thereof and the best mode in which he has contemplated the application of that principle; in the case of a process he shall explain the necessary sequence, if any, of the various steps, so as to distinguish the invention from other inventions; he shall particularly indicate and distinctly claim the part, improvement or combination which he claims as his invention.

(2) The specification shall end with a claim or claims stating distinctly and in explicit terms the things or combinations that the applicant regards as new and in which he claims an exclusive property or privilege.

The limits of the exclusive property conferred by the patent on the inventor are found in s. 46, which is as follows:

46. Every patent granted under this Act shall contain the title or name of the invention, with a reference to the specification, and shall, subject to the conditions in this Act prescribed, grant to the patentee and his legal representatives for the term therein mentioned, from the granting of the same, the exclusive right, privilege and liberty of making, constructing, using and vending to others to be used the said invention, subject to adjudication in respect thereof before any court of competent jurisdiction.

But in the cases to which s. 41 applies such exclusive property is further limited by and subject to the provisions therein contained.

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In these proceedings, no question arises as to the validity of the patent. The respondent, when applying for a licence to use the invention, cannot be heard to challenge the patent in respect of the processes claimed, nor can a proceeding of this kind be used as a method of challenging the product claims. Consequently, the appeal must be determined on the basis of the patent being valid in its entirety and of the appellant being entitled to exclusive property in the whole of the invention as claimed; that is to say, for both the processes claimed and the products as claimed when produced by any of the claimed processes.

The first ground of appeal urged by the appellant may be put in two ways. The first is that the words "to any person applying for the same" in s. 41(3) refer to and are limited by the words "a licence limited to the use of the invention for the purposes of the preparation or production of food or medicine but not otherwise", that the product of the invention, bulk diphenhydramine hydrochloride, which the respondent proposed to produce is a chemical and not a medicine until certain further formulation processes have been carried out, and accordingly that the respondent's application for a licence to produce the patented product was not an application of the kind contemplated by s. 41(3). The other, and I think the stronger, way of putting the point is that since, under s. 41(3), the Commissioner can license the use of the invention only for the purpose of producing food or medicine, and since the respondent's declared intention is to use the invention to produce bulk diphenhydramine hydrochloride, which is neither food nor medicine, the Commissioner should have regarded it as established that the respondent did not propose to follow the terms of the only licence he could grant and accordingly should have refused the application. But, putting the argument in either way, it becomes necessary to determine whether the bulk diphenhydramine hydrochloride which the respondent proposed to produce could properly be regarded as medicine. It is not suggested that it could be a food.

There is opinion evidence given by Dr. R. Fleming that bulk diphenhydramine hydrochloride is not medicine until it is reduced to dosage form, because it is a dangerous substance if taken in too large a dose. The same witness also gave evidence that, in formulating the bulk chemical (which

may itself meet accepted standards for purity) into medicinals, change or adulteration is likely to occur, making the chemical no longer safe for medicinal use, and he expressed the view that diphenhydramine hydrochloride has therapeutic value when properly formulated but that, when produced in bulk form by the process of the patent, it cannot be used in medicine.

Notwithstanding this opinion, there is evidence that diphenhydramine hydrochloride is used in the treatment of allergies and is also useful in the treatment or the prevention of motion sickness, and it appears as well that the therapeutic value to be derived from its use rests in the diphenhydramine hydrochloride itself. While it may be desirable to use diphenhydramine hydrochloride along with other substances, the therapeutic benefits which it produces are its own and do not result from its reaction with the other substances.

The following is from the specification:

> The invention relates to a new class of chemical compounds of therapeutic value . . . .
>
> * * *
>
> 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.

In my opinion, the expression "medicine" in s. 41(1) should be interpreted broadly and not restricted by notions as to when a substance having a medicinal value in small doses, but noxious effects in larger doses, is medicine and when it is not. In the popular sense, medicine in bulk is none the less medicine merely because a person taking too much of it at one time or taking it in an undiluted form may expect to suffer from it rather than to be relieved. Nor does the probability that it may, under some conditions or because of certain things being done to it, deteriorate and become useless as a medicine make it any the less a medicine before such deterioration takes place. Moreover, I do not think the appellant can be heard to contradict the claims in its specification which clearly assert that the substance pro-

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duced by the processes described can be administered to humans for what are obviously medicinal purposes. It was not suggested that diphenhydramine hydrochloride has any utility except for such purposes. In my opinion the respondent, in proposing to produce bulk diphenhydramine hydrochloride, proposes to produce medicine, within the meaning of the word in s. 41(1), and the appellant's objection consequently fails.

The second ground of appeal urged by the appellant is that s. 41(3) is applicable only to patents for processes alone, that the Commissioner was without authority to license the use of the processes of the patent in question as the result is to authorize the manufacture of substances which are also protected by the patent, and that the Commissioner exceeded his powers in purporting to license the sale of the substances.

It may be noted that, while s. 41(1) is limited in its application to "inventions relating to substances prepared or produced by chemical processes and intended for food or medicine", the class to which s. 41(3) applies is different, being wider in some respects and narrower in others. Section 41(3) applies to inventions "intended for or capable of being used for the preparation or production of food or medicine." In my opinion, however, the invention in question falls within both classifications, and both ss. 41(1) and 41(3) are applicable.

The result of the applicability of s. 41(1) is that the appellant is entitled to the exclusive rights mentioned in s. 46 both in the processes claimed in the patent and in the substances when produced by such processes, but not in the substances when produced by any other process or processes. This situation is to be distinguished from one wherein the process is patented but the substance produced by it is not patented. In such a case, sale of the substance when produced by the patented process without the patentee's permission is unlawful and constitutes an infringement of the patent for the process. But while the protection so given for the process may in many cases be a *de facto* protection of the product as well, it is not protection for the product itself but protection for the process, which is the only thing patented. The right infringed by

such sale is the right in the process, not a right in the product. It was argued on behalf of the respondent that all that is protected in the present case is the process, but with this I cannot agree, for I think that in this case the substance, being new, is also protected when produced by the patented process. See the judgment of Rand J. in *Hoffman-LaRoche v. Commissioner of Patents* (1) at p. 418, where he says:

> . . . the section prohibits a claim for the new substance alone, but allows one for that substance as produced by the new process.

In such case the patentee has, in respect of the substance itself when so produced, the exclusive rights mentioned in s. 46.

Coming to s. 41(3), it may be doubted that the words "an invention intended for or capable of being used for the preparation or production of food or medicine" are apt to include both the processes claimed in the patent in question and the products or substances produced by the process as well, because the words quoted do not seem applicable to substances. But as this patent is one for an invention which includes a process of the kind referred to in s. 41(3) I can see no reason for holding the subsection inapplicable to it. It follows that, on a proper application, the Commissioner was authorized and, indeed, directed to grant a licence of the kind mentioned in the subsection.

The question of the extent of the licence which the Commissioner can grant is one of some nicety in this appeal, in view of the wording of the licence as above quoted. The words of s. 41(3) are:

> . . . shall grant a licence limited to the use of the invention for the purposes of preparation or production of medicine but not otherwise.

It is argued for the appellant that these words limit the power of the Commissioner to the granting of licences in cases where the patent is for a process alone, the product of which is not itself protected, and that the subsection cannot apply to patents for both process and product, as the Commissioner has no power to authorize sale of the product. Support for this view may be found in s. 46, where the right to sell the invention for use by others is expressly mentioned along with the right of using it, thus indicating that using the invention is not intended to include selling it.

(1) [1955] S.C.R. 414.

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But, whatever may be the limitations of the power of the Commissioner to authorize sale of a patented product, his power and his duty to license the use of the process in a proper case is clear. In purporting to license the sale of patented products, it may be that he would exceed the powers expressly granted to him by s. 41(3), but it does not follow that a right for the licensee of the process to sell the product of it would not exist. Such a right does exist in the case of a licence to use an invention covered by a bare process patent. And it would seem that the subsection has no application at all in the case of an invention of a substance alone. Such a case might occur in respect of a newly invented food or medicine not produced by chemical processes, and in such a case a patent could conceivably issue for the substance alone. But if, as I have held, s. 41(3) does apply to an invention for both process and product, and if the subsection contemplates in such cases the licensing of production only, without any expressed or implied right to sell the product, the policy of making food and medicine available to the public at low cost declared by the latter part of the subsection will obviously be frustrated in situations such as the present one and without any apparent reason why such a distinction should have been made.

Commenting on this subsection in *Commissioner of Patents v. Winthrop Chemical Co. Ltd.* (1), at p. 53 Kellock J., in delivering the judgment of himself and Taschereau J., said:

> Again when one turns to subsection 3, the same consideration appears. It provides that in the case of a patent for an invention intended for or capable of being used "for the preparation or production" of food or medicine, the Commissioner of Patents has power to grant a licence to an applicant therefor limited to the "use of the invention for the preparation or production" of food or medicine (*i.e.* the process) and it is declared that in settling the terms of the licence regard shall be had to the desirability of making the food or medicine (*i.e.* the substance) available to the public at a proper price. Under this provision it is the *invention* which is to be the subject of the licence and it is the *process* which is referred to by the subsection as the invention. If, therefore, subsection 1 is to be interpreted as applying to a substance produced by a process which need not be patentable, no licence could be obtained under subsection 3 for its production. In my opinion no such effect was intended by the legislation.

(1) [1948] S.C.R. 46.

Rand J. appears to carry the matter somewhat further, where he says at p. 56:

> Subsection (2) confirms the plain meaning of the words; it creates a procedural privilege or advantage to the holder of a patented process where the new substance is found produced by someone other than the patentee. The same confirmation arises from ss. (3) where authority to grant licenses to use the patented mode or process is conferred upon the Commissioner of Patents.
>
> I agree that ss. (2) could, as a matter of words, be construed to have only a partial application, limited to those cases in which the process itself is patented; but why, if under ss. (1) the process may be old, in the juxtaposition of the two subsections, the procedural benefit should not have been extended to the patentee of a substance restricted in production to an old process, has not been made apparent. I agree, also, that *under ss. (3) a license for the process may be deemed to imply a license for the substance itself where that likewise is the subject of patent;* but if the substance could be patented along with an old process, it would be a distortion of language to say that a license could issue for the substance alone and the declared purpose of the subsection would be defeated.

In speaking of an implied licence *for the substance itself, where that likewise is the subject of patent,* I think the reference is not to a licence merely to use the substance in any narrow sense but to deal with it in such a way as to accomplish the declared policy of making the food or medicine available to the public at the lowest possible price. Accordingly, I hold that a right to market the patented product, when produced under a licence under s. 41(3) to use the patented process, is to be implied from the wording of s. 41(3).

It follows that the licence granted in this case, in referring to the *consequent right* to sell the product and in fixing the royalty and other terms by reference thereto, does not purport to give to the licensee more than that to which it would be entitled had the wording of the licence followed exactly the wording of s. 41(3). It might have been preferable to follow the wording of the section, but so long as the licence purports to give no more than what the Commissioner is empowered to license I do not think it is open to objection. The objection taken by the appellant accordingly fails.

The third ground taken by the appellant is that the Commissioner did not consider two matters which ought to have afforded good reason for refusing the application; that is to say, first, the fact that the Canadian market for diphen-

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hydramine hydrochloride was already fully supplied and, secondly, the fact that the respondent had infringed the patent before applying for the licence.

In the Commissioner's decision, no mention is made of these two matters, and I think it must be assumed that if they were put forward at the hearing before him he considered them but did not see in them good reason for refusing the licence. Evidence was given indicating that the Canadian market is amply supplied, but it was not established that the product is available at the lowest possible price consistent with giving the inventor due reward for the research leading to the invention. Indeed, such evidence as was given as to the cost of production and the prices at which the products are sold indicates a wide spread between the two as to which no explanation was given. Consequently, I think the Commissioner properly rejected the mere availability of a supply as a ground for refusing a licence.

The other ground urged was that the respondent, having infringed the patent, should not have been granted a licence. An application under s. 41(3) is not a suit for an equitable remedy. It is a statutory proceeding to obtain a licence which the Commissioner is directed to grant in the public interest, unless he sees good reason to the contrary. The statute does not define what is to be regarded as good reason but leaves the matter to the judgment of the Commissioner. Obviously, reasons affecting the public interest would be proper ones to be taken into consideration, and it may be that in some cases conduct of the applicant in connection with the invention may have a bearing on whether or not it is in the public interest that a licence should be refused. But whether the infringement complained of could be regarded as good reason or not, the decision whether or not it should be so regarded in the circumstances of this particular case was one for the Commissioner to make and on what appears in the evidence I do not think it can be said that he was wrong in granting the licence, notwithstanding such infringement.

Finally, the appellant argued that the royalty set by the Commissioner is inadequate. No complaint is made of the use of the bulk sale price as a base on which to calculate the royalty, but it is argued that ten per cent on it is much too

low. The Commissioner gave no reasons for arriving at his figure, and I think it must stand unless it can be said that it is so high or so low that one is forced to the conclusion that it is based on some wrong principle or inadmissible material or on the omission to consider some matter which ought to have been taken into account. The only matter which the Commissioner is expressly directed to take into account is the desirability of making the 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. Mr. George Dyer, the secretary-treasurer of the respondent company, stated that five per cent on the bulk sales price would be a reasonable royalty. On the other hand, John Bradshaw, the assistant general attorney and assistant secretary of the appellant company, expressed the view based on his experience that five per cent on the bulk sales price would be exceedingly unfair, and he cited an example of an agreed licence whereon the royalty was set at thirty-five per cent of the bulk sales price. He also cited another example of a licence granted by the appellant in connection with its diphenhydramine patents, where the licensee was authorized to sell in bulk and whereon the agreed royalty was $7\frac{1}{2}$ per cent on the licensee's bulk sale price plus $3\frac{3}{4}$ per cent on the customer's selling price to the trade. Obviously, these rates total more than ten per cent on the bulk sales price, but how much more does not appear. The cost of the research leading to the invention is said to have been $185,000, but the record does not show the quantum of sales made or likely to be made during the continuance of the patent, either in Canada or any other country, or what profits can be expected from such sales. The evidence, as a whole, on the question of royalty is sketchy, and it is difficult to draw firm conclusions from it as to what would be a reasonable reward to the inventor from the Canadian market. On such evidence as does appear in the record, I am not satisfied that the royalty set is not ample, and in my opinion no sufficient ground has been shown for disturbing the Commissioner's finding.

The appeal will be dismissed with costs.

Judgment accordingly.