HOFFMAN-LA ROCHE LIMITED .....APPELLANT;

AND

BELL-CRAIG PHARMACEUTICALS DIVISION OF L. D. CRAIG LIMITED } RESPONDENT.

1965

*Dec. 13, 14, 15

1966

Jan. 25

ON APPEAL FROM THE EXCHEQUER COURT OF CANADA

Patents—Compulsory licence—Preparation or production of medicine—Exchequer Court affirmed granting of licence by Commissioner of Patents—Royalty as fixed by Commissioner changed by Exchequer Court—Patent Act, R.S.C. 1952, c. 203, s. 41(3).

Pursuant to s. 41(3) of the *Patent Act*, R.S.C. 1952, c. 203, the Commissioner of Patents granted to the respondent a licence to use for the purpose of the preparation or production of medicine an invention patented by the appellant and which related to a substance sold by it under the trade name Librium. The Commissioner of Patents fixed the royalty to be paid by the respondent at 15 per cent of respondent's net selling price of the bulk active material. The Exchequer Court affirmed the Commissioner's decision to grant the licence but changed the royalty fixed by the Commissioner to a royalty of 15 per cent of the respondent's net selling price of the patented drug in dosage form. The appellant appealed to this Court from that judgment and the respondent cross-appealed with regard to the amount of the royalty. At the conclusion of the argument on behalf of the appellant, the Court invited counsel for the respondent to argue only the cross-appeal asking that the royalty as fixed by the Commissioner should be restored.

Held: The appeal should be dismissed and the cross-appeal allowed; the royalty as fixed by the Commissioner should be restored.

The purpose of s. 41(3) of the *Patent Act* is clear. No absolute monopoly can be obtained in a process for the production of food or medicine. In the public interest there should be competition in the production and marketing of such products produced by a patented process in order that they might be "available to the public at the lowest possible price consistent with giving to the inventor due reward for the research leading to the invention". Since the royalty payable by a licensee for using a patented process is one of his costs of production, there is an obvious justification, in cases where a percentage royalty is decided upon, for using as a base, the sale price of the bulk material rather than a base which reflects a variety of packaging, distribution, promotion, sales and other like expenses. The Commissioner was entitled to use the base which he did in this case in establishing the royalty. The appellant has failed to discharge the burden which was upon it of establishing that the Commissioner acted on a wrong principle or that on the evidence his decision was manifestly wrong.

---

*PRESENT: Abbott, Judson, Ritchie, Hall and Spence JJ.

1966

HOFFMAN LAROCHE LTD. v. BELL-CRAIG PHARMACEUTICALS DIV. OF L.D. CRAIG LTD.

Brevets—Licence forcée—Préparation ou production de médicaments—La Cour de l'Échiquier confirmant la licence accordée par le Commissaire des Brevets—Redevance fixée par le Commissaire étant changée par la Cour de l'Échiquier—Loi sur les Brevets, S.R.C. 1952, c. 203, art. 41(3).

En vertu de l'art. 41(3) de la *Loi sur les Brevets*, S.R.C. 1952, c. 203, le Commissaire des Brevets a accordé à l'intimée une licence pour utiliser, pour les fins de la préparation ou production de médicaments, une invention brevetée par l'appelante et qui couvrait une substance vendue par elle sous la marque de commerce Librium. Le Commissaire des Brevets a fixé la redevance devant être payée par l'intimée à 15 pour-cent du prix net de vente par l'intimée de la substance en gros. La Cour de l'Échiquier a confirmé la décision du Commissaire d'accorder la licence mais a changé la redevance fixée par le Commissaire à une redevance de 15 pour-cent du prix net de vente par l'intimée de la drogue brevetée sous forme de dose. L'appellante en a appelé de ce jugement devant cette Cour et l'intimée a porté un contre-appel relativement au montant de la redevance. Lorsque l'appelante eut terminé sa plaidoirie, la Cour a invité l'avocat de l'intimée à ne faire porter son argument que sur le contre-appel par lequel elle demandait que la redevance telle que fixée par le Commissaire soit rétablie.

Arrêt: L'appel doit être rejeté et le contre-appel maintenu; la redevance telle que fixée par le Commissaire doit être rétablie.

Le but de l'art. 41(3) de la *Loi sur les Brevets* est clair. Aucun monopole absolu ne peut être obtenu pour des procédés visant à la production d'aliments ou de médicaments. Il est de l'intérêt public qu'il y ait une concurrence dans la production et le service commercial de ces produits provenant d'un procédé breveté afin qu'ils soient «accessibles au public au plus bas prix possible, tout en accordant à l'inventeur une juste rémunération pour les recherches qui ont conduit à l'invention». Puisque la redevance payable par un détenteur de licence pour utiliser un procédé breveté fait partie de ses frais de production, il y a une justification évidente, dans les cas où on se sert d'une redevance par pourcentage, d'utiliser comme base le prix de vente du matériel en gros plutôt qu'une base qui refléterait une variété de dépenses d'empaquetage, de distribution, de promotion, de vente et autres. Le Commissaire était justifié de se servir de la base dont il s'est servi dans ce cas pour établir la redevance. L'appelante n'a pas réussi à se libérer du fardeau qui lui incombait d'établir que le Commissaire avait agi selon un principe erroné ou que sa décision avait été manifestement erronée en regard de la preuve.

APPEL et CONTRE-APPEL d'un jugement du Président Jackett de la Cour de l'Échiquier du Canada[1], maintenant en partie une décision du Commissaire des Brevets. Appel rejeté et contre-appel maintenu.

APPEAL and CROSS-APPEAL from a judgment of Jackett P. of the Exchequer Court of Canada[1], allowing in part an appeal from a decision of the Commissioner of Patents. Appeal dismissed and cross-appeal allowed.

[1] [1965] 2 Ex. C.R. 266.

R. G. McClenahan and *C. R. Carson,* for the appellant.

I. Goldsmith, for the respondent.

The judgment of the Court was delivered by

ABBOTT J.:—This appeal is from a judgment of the President of the Exchequer Court[1] allowing in part an appeal by the present appellant from a decision of the Commissioner of Patents, pursuant to s. 41 (3) of the *Patent Act,* R.S.C. 1952, c. 203, as amended, which had granted to respondent a licence to use for the purpose of the preparation or production of medicine, the invention patented by Canadian Patent No. 612,497 held by appellant. This patent is entitled "1, 4 Benzodiazepine 4-Oxides and Process for the Manufacture Thereof". It relates to a substance, the chemical designation for which is 2-Methylamino-5-phenyl-7-chloro-3H-1, 4 benzo-diazepine 4-oxide, the generic name for which is Chlordiazepoxide, and which is sold by appellant under the registered trade name "Librium".

Section 41 (3) of the *Patent Act* provides:

> 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.

The President of the Exchequer Court affirmed the Commissioner's decision to grant the licence, but varied the terms as fixed by him and allowed the appeal with respect to the question of royalty, changing the royalty as fixed by the Commissioner at 15 per cent of respondent's net selling price of the bulk active material, to a royalty of 15 per cent of the respondent's net selling price of the patented drug in dosage form to persons with whom respondent is dealing at arm's length. Save as aforesaid the appeal was dismissed and appellant was ordered to pay to respondent 90 per cent of the costs of the appeal.

The appellant appealed to this Court from that judgment and respondent cross appealed with regard only to the amount of the royalty fixed by Jackett P.

[1] [1965] 2 Ex. C.R. 266.

1966

HOFFMAN-LAROCHE LTD. v. BELL-CRAIG PHARMACEUTICALS DIV. OF L.D. CRAIG LTD.

Abbott J.

It might be noted here in passing, that the patent in issue on this appeal is the same patent which was before this Court in *Hoffman-Laroche Ltd. v. Delmar Chemical Ltd.*[1] which dismissed an appeal by the present appellant from a judgment of the Exchequer Court which had confirmed a decision of the Commissioner granting, under s. 41 (3) to the respondent in that case, a licence to use the invention for the purposes of the preparation or production of medicine. The general principles to be followed by the Commissioner in deciding whether a licence should be granted under the said section, were dealt with by this Court in the *Delmar* case and in an earlier decision, *Parke, Davis & Company v. Fine Chemicals of Canada Limited*[2].

Before both the Exchequer Court and this Court, appellant asked for an order declaring the licence granted to the respondent by the Commissioner of Patents to be null and void. In the alternative appellant asked that the cross-appeal on the question of royalty be dismissed and that the royalty to be paid by respondent be fixed at the sum of $3,528.37 per kilogram of chlordiazepoxide made and sold by respondent.

At the conclusion of the argument on behalf of appellant, counsel for respondent was informed that the Court did not need to hear him on the main appeal either as to the finding that a licence should issue or as to the adequacy of the royalty. He was invited therefore to argue only the cross-appeal asking that the royalty as fixed by the Commissioner should be restored.

Under s. 41 (3), the decision both as to whether a licence should issue, and if so the royalty to be paid, was one for the Commissioner to make. While an appeal lies from that decision, in order to succeed it is for the appellant to show that the Commissioner acted on a wrong principle or that, on the evidence, the decision was manifestly wrong. *Parke, Davis & Company v. Fine Chemicals Limited* and *Hoffman-Laroche Ltd. v. Delmar Chemical Ltd., supra,* and *The King v. Irving Air Chute Inc.*[3]. It was not suggested before this Court that the evidence before the Commissioner in this case was inadequate to enable him intelli-

[1] [1965] S.C.R. 575, 50 D.L.R. (2d) 607.

[2] [1959] S.C.R. 219, 18 Fox Pat. C. 125, 30 C.P.R. 59, 17 D.L.R. (2d) 153.

[3] [1949] S.C.R. 613 at 621, 9 Fox Pat. C. 10, 10 C.P.R. 1.

gently to arrive at a royalty which would give due weight to all the relevant considerations.

The Commissioner in his reasons dealt with the question of royalty as follows:

> The next question to be determined is that of royalty. The patentee brought, as a witness to the hearing, a Chartered Accountant who has an extensive experience in business practices and who has a thorough knowledge of the pharmaceutical industry. He gave us a detailed explanation of the way the pharmaceutical industry figures out what part of each sales dollar goes to the different items of expenditure that have to be accounted for before profits can be determined.
>
> The purpose was to arrive at a royalty figure. However, the royalty arrived at through his method would amount to the fantastic sum of three thousand five hundred and twenty-eight dollars per kilo of bulk active material which costs approximately one hundred and fifty dollars to make. Of course that was based on the cost of the complete and sustained research program undertaken by the patentee company, the overhead, return on capital invested, depreciation, sponsoring, advertising, and keeping the physicians' interest in the drug, all figured out on the sales of the product when capsuled, sealed and labelled, ready for patient's consumption.
>
> In all these considerations the patentee forgets that I am dealing with a patent covering a process. He has no exclusive right to the bulk active material per se, except when made by the particular process of the patent. Anyone is free to make and sell the product if he can develop a different process or somehow obtain it legally. I am therefore concerned with the process only. Much less has he any exclusivity on the finished material in dosage form, packaged and labelled. This is outside the scope of the patent and it is immaterial to me. Reference can be made to the case of *Fine Chemicals Limited v. Parke, Davis & Co.* where I followed the same reasoning, (1957, Vol. 16 Fox Patent cases p. 38). The Commissioner's decision was affirmed in the Exchequer Court, (1957, Vol. 16, Fox Patent cases p. 173) and in the Supreme Court (1959, Vol. 18 Fox Patent cases p. 125). The principle I have established of fixing the royalty on the sale price of the bulk material has not been disturbed by the courts. In the Supreme Court, Mr. Justice Martland said at page 134 (Fox) "The Royalty as fixed is, therefore, to be determined upon the wholesale price and has no relationship to the ultimate selling price of the medicine to the consumer." He went on to question the adequacy of the royalty but not the principle.

I pause here, in the recital of those reasons to emphasize that the passage quoted from the reasons for judgment of Martland J. in the case cited by the Commissioner was merely a description of the method in fact adopted by the Commissioner for the determination of the royalty in that case. The Commissioner is however correct in stating that this Court did not disapprove of the method as constituting an improper means of the determination of royalty. Such a basis of determination is certainly a permissible basis but it was not necessarily the only one open to the Commissioner,

1966

HOFFMAN-LAROCHE LTD. v. BELL-CRAIG PHARMACEUTICALS DIV. OF L.D. CRAIG LTD.

Abbott J.

and on this point I adopt the following statement of Rand J. in the *Irving Air Chute* case, *supra*, at p. 625:

> I am unable to follow either the Commissioner or the President of the Exchequer Court in the preliminary ascertainment of a rate or percentage as something in some degree absolute which will thereafter be applied to a subsequently ascertained base money value. What the inventor is to receive is a sum of money related to the invention used; and the base value, whether cost or selling price of either the whole or part of the apparatus embodying the invention, is obviously bound up with the rate or percentage to be used. Base values as in practice adopted are limited in number and can be accurately ascertained; and being fixed upon, the important question, to which the evidential matters are relevant, becomes that of the highly variable percentage.

I resume the quotation from the Commissioner's reasons:

> Although the product per se is not actually patented the royalty payments have to be calculated on the amount of product made by the process, because it would be next to impossible to assess the value of a process except on the basis of the extent of its use to make a product which in turn can be evaluated in terms of dollars and cents.
>
> In the case at hand the patentee has arrived in his calculations at a royalty of $3,528.37 per kilo but this figure includes all the irrelevant factors that I have in the past refused to consider and which are not part of what is covered by the patent.
>
> * * *
>
> On the basis of past experience and upon considering the wide acceptance of the product, I will fix the royalty at 15% of the net selling price of the bulk active material made by the licensee and sold to others, or should the licensee process all of its production for sale as finished medicine ready for patients consumption, the royalty payments should be based on what would be a fair selling price of the bulk material to others.

The learned President after summarising the arguments of counsel for appellant with reference to royalty said this:

> In this case, the only attack on the Commissioner's decision with reference to royalty is that it is too low. It has not been suggested that it is higher than it should be. As I see the problem, therefore, the only question is whether the royalty fixed is commensurate with the maintenance of research incentive and the importance of both process and substance.

After discussing various considerations to be taken into consideration in fixing a royalty, the President made this finding:

> I have come to the conclusion that the Commissioner fell into error in thinking that "the finished material in dosage form, packaged and labelled" was "outside the scope of the patent" and "immaterial" to him. On the contrary, the drug in the dosage form, if it was made in accordance with the patented process, is just as much the subject matter of the patentee's monopoly as it is when it is sold in bulk. It is precisely the same product as it is when it is in bulk except that it has been packaged so as to be in the form in which it has value as a merchantable commodity.

He then proceeded to fix the royalty payable at 15 per cent of the licensee's selling price when it sells the patented drug in dosage form. The President in the passage just quoted was referring of course to the statement made by the Commissioner in his reasons that:

> In all these considerations the patentee forgets that I am dealing with a patent covering a process. He has no exclusive right to the bulk active material per se, except when made by the particular process of the patent. Anyone is free to make and sell the product if he can develop a different process or somehow obtain it legally. I am therefore concerned with the process only. Much less has he any exclusivity on the finished material in dosage form, packaged and labelled. This is outside the scope of the patent and it is immaterial to me.

With respect I am unable to agree with the conclusion reached by the learned President.

As Martland J. pointed out in the *Parke, Davis* case, *supra,* at p. 228, the monopoly in a process patent for the production or preparation of food or medicine 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. Such royalty should also be commensurate with the desirability of making food or medicine available to the public at the lowest possible price consistent with giving to *the inventor*—not the patentee—reward for the research leading to the invention.

In my view the purpose of s. 41 (3) is clear. Shortly stated it is this. No absolute monopoly can be obtained in a process for the production of food or medicine. On the contrary Parliament intended that, in the public interest, there should be competition in the production and marketing of such products produced by a patented process, in order that as the section states, they may be "available to the public at the lowest possible price consistent with giving to the inventor due reward for the research leading to the invention".

The royalty payable by a licensee for using a patented process is one of his costs of production. That being so there is an obvious justification, in cases where a percentage royalty is decided upon, for using as a base, the sale price of the bulk material produced by the patented process, rather than a base which reflects a variety of packaging, distribution, promotional, sales and other like

1966

HOFFMAN-LAROCHE LTD. v. BELL-CRAIG PHARMACEUTICALS DIV. OF L.D. CRAIG LTD.

Abbott J.

expenses. In my opinion on the evidence before him, the Commissioner was entitled to use the base which he did in establishing the royalty.

As I have already stated, it is well established that the appellant could succeed on its appeal only if it were able to establish that the Commissioner acted on a wrong principle, or that on the evidence his decision was manifestly wrong. In my opinion, the appellant failed to discharge that burden, and the royalty as fixed by the Commissioner should not have been interfered with.

I would dismiss the appeal with costs here and below, allow the cross-appeal with costs, restore the royalty as fixed by the Commissioner of Patents and order that the licence be amended accordingly.

Appeal dismissed and cross-appeal allowed with costs.

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

Solicitors for the respondent: Duncan, Goldsmith & Caswell, Toronto.