HOFFMAN-LA ROCHE LIMITED APPELLANT:

T; 1965

AND

*Mar. 15, 16 Apr. 9

DELMAR CHEMICAL LIMITEDRESPONDENT.

ON APPEAL FROM THE EXCHEQUER COURT OF CANADA

Patents—Compulsory licence—Patentee requesting oral hearing or cross-examination upon affidavits before Commissioner—Whether refusal by Commissioner a denial of justice—Public safety—Patent Act, R.S.C. 1952, c. 203, s. 41(3).

The Commissioner of Patents granted to the respondent a licence under s. 41(3) of the *Patent Act*, R.S.C. 1952, c. 203, to use, for the purpose of the preparation or production of medicine, an invention patented by the appellant. The Commissioner had refused the patentee's request that it be allowed an oral hearing or to cross-examine the licensee on the supporting affidavits filed with the application. The Exchequer Court found that the Commissioner's refusal was not a denial of justice as contended by the patentee. The latter appealed to this Court.

Held: The appeal should be dismissed.

The Commissioner was correct when he said that, there being no regulations governing the practice under s. 41(3), he was entitled to set the procedures and was not bound to hold a hearing on demand by one of the parties. It was for the Commissioner to decide whether or not the circumstances required an oral hearing, cross-examination upon affidavits, or oral submissions. His decision not to require any of these things could not be considered to be a denial of natural justice. Furthermore, the patentee had failed to establish any valid ground for disturbing the Commissioner's decision. The patentee had submitted what it contended were good reasons not to grant the licence. These were considered by the Commissioner and rejected. The patentee has not established that the Commissioner had acted on a wrong principle or that, on the evidence, his decision was manifestly wrong.

^{*}PRESENT: Taschereau C.J. and Abbott, Martland, Ritchie and Hall JJ.

HOFFMAN-LA ROCHE LTD. v. DELMAR CHEMICAL LTD. Brevets—Licence forcée—Requête du titulaire du brevet pour une audition ou un contre-interrogatoire sur affidavit devant la Commissaire—Le refus du Commissaire n'est pas un déni de justice—Sécurité du public—Loi sur les Brevets, S.R.C. 1952, c. 203, art. 41(3).

Le Commissaire des Brevets a émis en faveur de l'intimé une licence en vertu de l'art. 41(3) de la Loi sur les Brevets, S.R.C. 1952, c. 203, pour utiliser, pour les fins de la préparation ou production de médicaments, une invention brevetée par l'appelant. Le Commissaire avait refusé au titulaire du brevet de lui accorder une audition ou de lui permettre de contre-interroger le porteur de la licence sur les affidavits produits au soutien de la demande. La Cour de l'Échiquier a jugé que le refus du Commissaire n'était pas un déni de justice tel que le prétendait le titulaire du brevet. Ce dernier en appela devant cette Cour.

Arrêt: L'appel doit être rejeté.

Le Commissaire avait raison lorsqu'il a dit que, puisqu'il n'existait aucun règlement régissant la procédure sous l'art. 41(3), il avait droit d'établir la procédure et n'était pas obligé de tenir une audition sur la demande d'une des parties. Il appartenait au Commissaire de décider si les circonstances requéraient une audition, un contre-interrogatoire sur affidavits, ou des soumissions orales. Sa décision de ne requérir aucune de ces choses ne pouvait pas être considérée comme étant un déni de la justice naturelle. Bien plus, le titulaire du brevet n'a pas réussi à établir aucun motif valide pour faire changer le décision du Commissaire. Le titulaire du brevet avait soumis ce qu'il prétendait être des bonnes raisons pour que la licence ne soit pas accordée. Ces raisons furent considérées par le Commissaire et rejetées. Le titulaire du brevet n'a pas réussi à établir que le Commissaire avait agi en vertu d'un mauvais principe ou que, en se basant sur la preuve, sa décision avait été manifestement erronée.

APPEL d'un jugement du Juge Thurlow de la Cour de l'Echiquier du Canada¹, maintenant en partie une décision du Commissaire des Brevets. Appel rejeté.

APPEAL from a judgment of Thurlow J. of the Exchequer Court of Canada¹, maintaining in part a decision of the Commissioner of Patents. Appeal dismissed.

Gordon F. Henderson, Q.C., and R. G. McClenahan, for the appellant.

D. J. Wright and W. L. Hayhurst, for the respondent.

The judgment of the Court was delivered by

Martland J.:—This is an appeal from the Exchequer Court of Canada¹ against the judgment of Thurlow J., who dismissed, in part, an appeal by the present appellant from a decision made by the Commissioner of Patents which,

pursuant to s. 41(3) of the Patent Act, R.S.C. 1952, c. 203, had granted to the respondent a licence to use, for the purpose of the preparation or production of medicine, the invention patented by Canadian Patent No. 612,497, dated January 10, 1961, held by the appellant. The Commissioner settled the royalty to be payable by the respondent to the appellant. The learned trial judge directed that that issue Martland J. be referred back to the Commissioner for reconsideration and there is no appeal from that direction. The sole issue before us is as to whether the granting of the licence by the Commissioner was a valid exercise of his powers under s. 41(3).

The respondent's application for a licence under s. 41(3) was dated March 20, 1962. It was supported by the affidavit of its president. The patent in question is described in that application as follows:

Patent No. 612,497 is governed by section 41(3) since the invention claimed is intended for and capable of being used for the preparation and production of 1, 4-benzodiazepine 4-oxides and acid addition salts thereof, and these products are medicines within the meaning of the section, being useful as sedatives and tranquilizers for humans. Generic names of the products are methaminodiazepoxide and chlordiazepoxide. The patentee sells the products under the trade mark LIBRIUM.

The respondent described its own capacities in the application as follows:

The applicant and its predecessor Delmar Chemical Company have, since, 1941, been engaged in the synthesis and manufacture of many pharmaceutical fine chemicals, most of them organic synthetics, used as medicines within the meaning of section 41(3). The applicant is a substantial and reputable company with the facilities and technical knowhow for manufacturing the product claimed in Patent No. 612,497 by the process claimed therein and is ready, willing and able to manufacture it by such process in its own premises in Canada and with its own equipment and personnel.

On April 2 the Commissioner wrote to the appellant advising of the application and that the respondent had been requested to serve on the appellant a copy of the application and affidavit. The letter went on to say:

You will have sixty days within which to file with me your counterstatement supported by affidavit and serve a true copy on the representative of the applicant Ridout & Maybee, 111 Richmond Street, West, Toronto 1, Canada.

The applicant will have thirty days to file a reply with me and serve a copy thereof upon you.

On the same date the Commissioner wrote to the respondent advising as to the steps to be taken regarding notice of

1965 HOFFMAN-LA ROCHE LTD. DELMAR CHEMICAL LTD.

578

v. DELMAR CHEMICAL LTD.

its application, by way of advertising and notice to the appellant, and the times fixed for filing the appellant's counterstatement and the respondent's reply.

On May 25 appellant's solicitors wrote to the Commissioner requesting additional time for filing the counterstatement, because most of the technical information required to Martland J. formulate it would have to be obtained from the office of the appellant's parent company in Switzerland. The Commissioner granted an extension of two months, until August 8.

> The counterstatement was dated July 25 and supported by the affidavit of a vice-president of the appellant. It described the invention as belonging to a new class of compound not theretofore employed in medical therapeutics. It described the advantageous purposes of "Librium" and stated that the manufacturing process involved the use of highly volatile solids, dangerous to inhale. It stated that the respondent's described production facilities were not adequate to cope with the manufacture of Librium. It pointed out that if the licence were granted the quality of manufacturing, storage and capsulating treatment accorded the drug would no longer be subject to control, and urged that public interest would not be served by making the drug open and available to the public free from control.

> Along with the counterstatement the appellant's solicitors filed a "demand for hearing" in respect of the application.

> On August 8 the Commissioner wrote to the appellant's solicitors pointing out that there were no regulations governing the practice under s. 41(3), that he was entitled to set the procedure and that he was not bound to hold a hearing on demand by one of the parties. He pointed out that the respondent had thirty days to file a reply and that after that time he would decide whether a hearing was warranted or not.

A reply, dated August 13, was filed by the respondent.

On September 7 solicitors for the appellant wrote to the Commissioner in support of a request for a hearing, or, alternatively, a request to cross-examine the president of the respondent on his affidavits supporting the respondent's application and reply. The letter contended that issues of public safety and matters of public concern were involved in the application.

With respect to the matter of public safety, stress was laid upon risks involved in connection with the manufacture of the product. The appellant also urged that the manufacture of a product of inferior quality could destroy the reputation of Librium and have a detrimental effect upon the reputation of the appellant. It was suggested that the Commissioner inspect the respective plants of the appellant and the Martland J. respondent.

1965 HOFFMAN-La Roche LTD. DELMAR CHEMICAL Ltd.

On September 14 respondent's solicitors wrote a letter to the Commissioner in reply to this letter.

On November 19 the Commissioner wrote to the appellant's solicitors advising that he need not inspect the plants, and that he would decide, within a few weeks, whether a hearing would be held.

On November 23 appellant's solicitors again wrote to the Commissioner, stating that the respondent was not considered competent to produce a safe product and that improper control in the manufacture and handling of the product would create dangers to those handling it and to the consumers. A further demand for a hearing was made.

On February 6, 1963, the Commissioner made his decision. After reciting the provisions of s. 41 (3) of the Patent Act he went on to say:

The Commissioner has no choice but to grant a licence, unless he sees good reason to the contrary. There being no regulations governing his inquiry, he is at liberty to use his judgment in any individual case in order to arrive at a just and fair conclusion.

In the present case the patentee has forcefully objected to the grant of a licence mainly on the grounds that the process is one which involves a great deal of care on account of some volatile and unstable substances used therein or obtained therefrom.

On the other hand the applicant claims that he was aware of the process having verified experimentally, on an adequate scale, that he can produce the products economically. Again in his reply to the counterstatement which stresses the dangers contingent with the process and the instability of some of the products involved the applicant reaffirms his awareness of the difficulties. He then goes on to name some of the hazardous substances and unstable chemical compounds which he handles.

I have no reason to believe that the applicant has not the ability to make the compound. He is a well known manufacturer of synthetic organic compounds.

I therefore decide that no hearing is necessary in this case and that the petition should be granted.

I have recited the various steps which occurred prior to the Commissioner's decision in some detail because the

1965 Hoffman-

580

LA ROCHE LTD. 1). DELMAR CHEMICAL LTD.

appellant contends that there was, in this case, a denial of natural justice.

The appellant's appeal from the Commissioner's decision to the Exchequer Court was dismissed, and the appellant now appeals to this Court.

The relevant provision of the Patent Act, s. 41(3), pro-Martland J. vides as follows:

> (3) In the case of any patent for an invention intended for or capable of being used for the preparation or production of food or medicine, the Commissioner shall, unless he sees good reason to the contrary, grant to any person applying for the same, a licence limited to the use of the invention for the purposes of the preparation or production of food or medicine but not otherwise; and, in settling the terms of such licence and fixing the amount of royalty or other consideration payable the Commissioner shall have regard to the desirability of making the food or medicine available to the public at the lowest possible price consistent with giving to the inventor due reward for the research leading to the invention.

> This subsection does not lay down any procedure to be followed by the Commissioner before reaching his decision and, in this respect, differs materially from proceedings under ss. 67 to 72 of the Act in respect of allegations of an abuse of patent rights. Under s. 71(2) any of the parties in such proceedings may demand a hearing.

> In my opinion the Commissioner was correct when he said in the present case, in his letter to the appellant's solicitors, dated August 8, 1962, that, there being no regulations governing the practice under s. 41(3), he was entitled to set the procedures and was not bound to hold a hearing on demand by one of the parties.

> Counsel for the appellant did not contend that a party to a proceeding under s. 41(3) could demand a hearing, but he did urge that the failure of the Commissioner to permit cross-examination upon the affidavits filed by the respondent to support its application and its reply and to permit oral argument was a denial of justice in the circumstances of the present case.

> Various authorities were cited by the appellant regarding the subject of natural justice, including the decision of the House of Lords in Ridge v. Baldwin¹. It is, however, unnecessary to embark on a discussion of the principles laid down in that and other similar cases because, in the circumstances of this case, whether he was obligated to do so or

1965

La Roche

LTD.

v. DELMAR

CHEMICAL LTD.

not, the Commissioner did cause the respondent to serve the appellant with a copy of the application and affidavit; he Hoffmandid furnish to the appellant ample opportunity to present its case in writing, and the appellant did make written submissions to the Commissioner.

I have already referred to the substantial difference which exists between an application under s. 41(3) and one made Martland J. under s. 67 or 68 in respect of the procedural requirements. As the Commissioner correctly pointed out in this case, he was entitled to set the procedures, and he did so. It was for him to decide whether or not the circumstances required an oral hearing, cross-examination upon affidavits, or oral submissions. In my opinion, his decision not to require any of these things cannot be considered to be a denial of natural justice to the appellant.

I am also of the opinion that the appellant has failed to establish any valid ground for disturbing the decision which the Commissioner has reached. Section 41(3) required him to grant to the respondent the licence applied for by it, unless he saw good reason to the contrary. The appellant submitted to him what it contended were good reasons to the contrary and these were considered by him. As was pointed out in Parke, Davis & Company v. Fine Chemicals of Canada, Limited¹, the decision was his to make. While an appeal lies from that decision, in order to succeed it is for the appellant to show that he acted on a wrong principle or that, on the evidence, the decision was manifestly wrong. In my opinion the appellant has not established either of these things in the present case.

I would, therefore, dismiss the appeal with costs.

Appeal dismissed with costs.

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

Solicitors for the respondent: Ridout & Maybee, Toronto.

¹ [1959] S.C.R. 219 at 228, 18 Fox Pat. C. 125, 30 C.P.R. 59, 17 D.L.R. (2d)153.