
BETWEEN:

HOFFMANN-LA ROCHE LIMITED .....APPELLANT;

AND

DELMAR CHEMICALS LIMITED .....RESPONDENT.

1963
Apr. 4-6

1964
July 23

Patents—Patent Act, R.S.C. 1952, c. 203, s. 41—Compulsory licence—S. 41(3) aims at freeing new process from absolute control of patentee—Applicant for licence required by Patent Act to prove competence to produce food or medicine in question—Good reason for refusing licence—Limits to discretion of Commissioner of Patents under s 41(3)—Public interest and interests of patentee—Patentee not to challenge the adequacy of the teaching of his specification—No duty on Commissioner to investigate questions of public safety—Procedure on applications under s 41(3) to be established by Commissioner—Commissioner not required to hold oral hearing or hear oral argument—Amount of royalty.

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The appellant appealed from a decision of the Commissioner of Patents granting to the respondent a licence under s. 41(3) of the *Patent Act* to use for the preparation or production of certain sedative drugs an invention patented by the appellant. The royalty to be paid by the respondent was fixed by the Commissioner at 12½ per cent of the net selling price of the crude product before processing for patients' consumption. The grounds of appeal were that the Commissioner's decision was made without proper investigation of the relevant facts and without granting the appellant's demands for an opportunity to cross-examine a deponent whose affidavits accompanied the respondent's application and reply and for a hearing at which oral evidence might be offered and oral argument presented. The appellant alleged that the respondent was not capable of using the invention and manufacturing the product safely and of producing a medicine that was safe for the public.

Held: That the problem posed for the Commissioner when dealing with an application under s. 41(3) of the *Patent Act* is whether the public interest in having the food or medicine available at the lowest possible price consistent with due reward to the inventor and the public interest in affording to interested persons the opportunity to devise improvements in the patented process and to use them immediately will be better served by refusing the licence than by granting it.

2. That apart from the question of the public interest, the interest of the patentee is a proper matter to be taken into account in the sense that the Commissioner may think that the patentee should be entitled to assurance that the royalty or other consideration for the licence will be paid and where the circumstances indicate the need for it, the unwillingness of the applicant to secure the payment may also be good reason for refusing an application.

3. That in this case the patentee's counterstatement contained nothing which the Commissioner was under any necessity to regard as good reason for instituting an inquiry or for refusing a licence.

4. That the substantial requirements of justice have not been violated by the Commissioner's refusal in the circumstances to accede to the appellant's demand for an oral hearing and that the appellant's submission that in the circumstances it was incumbent on the Commissioner in the public interest to grant the appellant's demand for an oral hearing or for an opportunity to cross-examine on the applicant's affidavit is unfounded.

5. That there was no legal necessity for the Commissioner to satisfy himself of the immediate competence of the applicant to manufacture and store the product and the capability of the applicant to do at once everything necessary to meet such standards as the patentee may wish to see observed in the use of its invention is beside the point, such matters being governed not by the patentee but by the law of the land including the provisions of s. 41 of the *Patent Act*.

6. That as there is nothing in the record upon which to base or justify a finding as to the amount of royalty to be paid by the licensee, this matter will be referred back to the Commissioner.

APPEAL from a decision of the Commissioner of Patents.

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

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

W. L. Hayhurst for respondent.

The facts and questions of law raised are stated in the reasons for judgment.

THURLOW J. now (July 23, 1964) delivered the following judgment:

This is an appeal from a decision under s. 41(3) of the *Patent Act* R.S.C. 1952, c. 203. by which the Commissioner of Patents granted to the respondent a licence to use for the purpose of the preparation or production of medicine the invention patented by Canadian patent number 612497 dated January 10, 1961, and settled the royalty payable therefor by the respondent at 12½ per cent of the selling price of the bulk product. The basis of the appeal is the complaint by the appellant that the Commissioner's decision was made without a proper investigation of the relevant facts, and without granting the appellant's demands for an opportunity to cross-examine a deponent whose affidavits accompanied the respondent's application and reply or for a hearing at which oral evidence might be offered and oral argument presented. Had such a hearing been held and had such cross-examination been allowed the appellant would, in its submission, have been able to show that the process described in the patent by which a drug sold by the appellant under the trade name Librium is made, involved dangers to the persons employed in making it and in the vicinity and that unless properly prepared and used involved dangers to the persons using it as well, that the respondent was not capable of exercising the necessary care in making and taking care of the drug and that if allowed to prepare and sell it in bulk the appellant's control over the use of the drug would be lost with consequent danger of its reputation being destroyed. These it was submitted were matters which the appellant ought to have been permitted to establish by an oral hearing and by cross-examination of the respondent's deponent, and which ought to have persuaded the Commissioner to refuse the application.

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Before outlining the facts a few comments on s. 41(3) may be in order. The subsection reads 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 provision represents a limitation on the exclusive rights which an inventor may obtain in an invention of the kind to which the subsection applies. Generally speaking, under the provisions of the *Patent Act* the inventor of any new and useful art, process machine, manufacture or composition of matter or of any new and useful improvement therein is entitled, subject to the provisions of the Act and on complying with the requirements thereof, to obtain a patent granting to him for 17 years the exclusive right to make, construct and use his invention and to sell it to others to be used. The rights obtainable under the statute are, however, not absolute but are limited by the provisions against abuse contained in ss. 66 to 73, by s. 67(3) of which it is declared that in considering whether there has been abuse as defined in the Act it shall be taken that patents for new inventions are granted not only to encourage inventions but to secure that new inventions shall so far as possible be worked on a commercial scale in Canada without undue delay. In the case of inventions to which s. 41(1) applies, that is to say, inventions relating to substances prepared or produced by chemical processes and intended for food or medicine the scope of the rights obtainable is also restricted as therein provided to exclusive rights in a new process and in a new product when made by a new process, *vide Hoffman-La Roche & Co. v. Commissioner of Patents*[1], *Commissioner of Patents v. Winthrop Chemical Company Incorporated*[2], and Rand J. in *Parke, Davis & Co. v. Fine Chemicals of Canada Ltd.*[3]. In cases to which s.

[1] [1955] S C.R. 414. [2] [1948] S C.R. 46.
[3] [1959] S.C.R. 219.

41(3) applies the rights of the patentee are subject as well to the authority thereby conferred on the Commissioner to grant licences to others to use the invention. Apart from the rights obtainable under the statute, which are granted in consideration of the disclosure by the inventor of the invention to the public, it is the right of any member of the public to make, use and sell the invention, subject only to such restrictions or controls if any on the use and sale thereof as may be provided by the law.

With respect to the purpose of s. 41(3) Rand J. in *Parke, Davis & Co. v. Fine Chemicals of Canada Ltd.* said at p. 222:

> 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.

I would carry the matter a stage further and say that the subsection also aims at freeing the new process from the absolute control of the patentee by denying him both the exclusive right to refuse licences and thus to prevent the use of the process by others, (except where in a particular case the Commissioner sees good reason for refusing a licence) and the right to dictate the terms of a licence.

In requiring the Commissioner "unless he sees good reason to the contrary" to grant a licence "to any person applying for the same" Parliament has imposed no qualification of any kind on the person to whom a licence is to be granted save that of being a "person applying for the same", and there is no statutory requirement that an applicant prove anything to entitle him *prima facie* to the licence for which he applies. In particular there is no statutory requirement that he prove that he is competent to produce the food or medicine or that he is possessed of the equipment, know-how and resources to do so, though the Commissioner may consider it of some importance, depending on the facts of the case, to be informed of the applicant's qualifications and if he thinks necessary to inquire into them. Nor has Parliament defined what sort of consideration ought to be regarded by the Commissioner as

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"good reason" why a licence should not be granted. However, by providing in s. 41(4) for an appeal to this Court from the Commissioner's decision Parliament while leaving the matter generally to the discretion of the Commissioner has imposed the limitation that his decision is not to be made capriciously but upon grounds which an appellate court would regard as sufficient to justify his conclusion. Thus in the *Parke Davis* case to which I have already referred, where the licence had been granted and on appeal certain matters which had been rejected by the Commissioner as reasons for refusing the licence, were put forward Martland J. said at p. 228:

> 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.

The authority of the Court to determine whether the judgment of the Commissioner is "manifestly wrong" in my opinion necessarily involves authority to determine when necessary what sort of reason may or may not be treated as good reason within the meaning of the statute, but as Parliament has seen fit to leave the Commissioner's discretion unfettered it would not in my opinion be desirable for this Court on an appeal to lay down principles for its exercise beyond what is necessary for the particular case. The purpose of the section, however, is of prime importance in every case and the problem which it appears to me to pose for the Commissioner is whether the public interest in having the food or medicine available at the lowest possible price consistent with due reward to the inventor and the public interest in affording to interested persons the opportunity to devise improvements in the patented process and to use them immediately will be better served by refusing the licence than by granting it. If, for example, the Commissioner is satisfied that the granting of an application will make the product more expensive to the public or that it will cause a reduction rather than an increase in research being carried on the Commissioner may, depending on all the circumstances of the case, reach the

conclusion that good reason for refusing the licence appears. Moreover, apart from the question of the public interest, the interest of the patentee is a proper matter to be taken into account in the sense that the Commissioner may think that the patentee should be entitled to assurance that the royalty or other consideration for the licence will be paid and where the circumstances indicate the need for it the unwillingness of the applicant to secure the payment may also be good reason for refusing an application. But, as I read the section, neither the ability of the particular applicant to produce the food or medicine safely nor his ability to produce a safe food or medicine is a matter which the Commissioner is concerned to ensure. These are matters for the authorities to whom the administration of the provisions of the law respecting the manufacture and distribution of foods and drugs, applicable whether there is a patent or not, is committed. The licence which the Commissioner may grant under s. 41(3) is plainly not an authority to do anything contrary to law. It operates only to authorize the applicant's use of the patented invention which the patentee would otherwise be in a position to prevent. Moreover, since the grant of the patent is conditional upon and in consideration of the disclosure by the inventor of the invention to the public in such terms as will enable those skilled in the art to make use of it after the patent has expired it is not open to the patentee on an application of this kind to contend that a person possessed of the knowledge common to the art by following the directions of the specification will not be able either to use the invention safely or to use it to produce a safe product for in either case he attacks the validity of the rights which his patent purports to give him.

When the ability of the applicant to manufacture a new food or medicine is put forward, in support of an application under s. 41(3) and is not disputed, it may no doubt influence the Commissioner more readily to grant a licence to the particular applicant but it is at most a collateral fact and is relevant only in the sense that the Commissioner might regard it as of some importance in determining whether good reason for refusing the licence existed if it were shown that the applicant had not the qualifications of a workman of ordinary skill and competence in the art.

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But whether the ability of the applicant as one skilled in the art is raised or not the question for the Commissioner is still the same and is to be resolved by reference to the interests which I have mentioned, bearing in mind that the statute directs that the matter be determined in favour of granting the licence unless good reason appears for thinking that these interests will be better served by refusing it.

It is also worthy of note at this stage, because of the directions given by the Commissioner to which I shall refer later in these reasons, that no procedure for dealing with applications for licences under s. 41(3) is prescribed either by the statute itself or by the regulations made pursuant to it. This is in marked contrast with the provisions of ss. 67 to 73 relating to abuse of patent rights where the procedure to be followed is prescribed in ss. 70 and 71 and in the Rules made under the Act, with some particularity. That procedure involves *inter alia* a written application setting out the applicant's interest and the facts upon which his case is based, verified by statutory declaration, notice thereof to the patentee and advertisement in the Canada Gazette and the Canadian Patent Office Record, a counter-statement by the patentee, if he opposes, verified by statutory declaration fully setting out the grounds of opposition and a hearing if any party demands it or the Commissioner himself so appoints. In contrast with the situation on an application under s. 41(3) in proceedings under the abuse provisions the onus of proving abuse rests on the applicant and the procedure prescribed apart from being less suited to an application under s. 41(3) is not applicable thereunder in the absence of a direction by the Commissioner that it be followed in a particular case. With respect to the requirements of procedure under s. 41(3) Cameron J. in *Parke, Davis & Company v. Fine Chemicals of Canada Limited*[1] after quoting from the judgment of Lord Selborne in *Spackman v. Plumstead Board of Works*[2] held at p. 484:

> In the instant case, Parliament has conferred on the Commissioner power to decide the question, but his decision is of a very limited nature. He is required to grant the licence "unless he sees good reason to the contrary". In the absence of any requirement or direction as to how he should proceed "the law will imply no more than that the substantial requirements of justice shall not be violated."

[1] [1959] Ex. C.R. 478. [2] (1885) 10 A.C. 229.

I turn now to the facts, all of which appear from the Patent Office file. The respondent filed its application on or about March 24, 1962, and in it alleged *inter alia* that the patent was one to which s. 41(3) applied since the invention claimed was intended for and capable of being used for the production of certain sedative drugs which were medicines within the meaning of the subsection, that to the best of the applicant's knowledge and belief the process claimed in the patent was not being carried on in Canada, that the applicant wished to use the process for the preparation or production in Canada of the substances referred to in the patent and had applied to the patentee for a licence to do so but had been informed that a decision could not be expected for some months, that the applicant and its predecessor company had since 1941 been engaged in the synthesis and manufacture of many pharmaceutical fine chemicals most of them organic synthetics used as medicines, that the applicant was a substantial and reputable company with facilities and know-how for carrying out the process and was ready, willing and able to carry on manufacture of the products in its own plant in Canada using its own equipment and personnel, that it employed some thirty people including a number of technicians, three chemists engaged in research and development work and one in analytical control work, that it had certain production facilities in its plant and had verified experimentally on an adequate scale that it could produce the products economically in commercial quantities, that its estimates indicated that it could sell the products at between $350 and $450 per kilo and that it therefore applied for a non-exclusive licence under the patent, limited to the use of the invention for the purpose of the preparation or production of medicine but not otherwise with the consequent right to use and sell the products and submitted that there was no good reason for refusing the licence. This was accompanied by an affidavit of Geza S. Delmar, the president of the appellant company, stating that he had personal knowledge of the facts set forth in the application and that such facts were true to the best of his knowledge and belief.

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On April 2, 1962, the Commissioner wrote to the applicant's solicitors acknowledging receipt of the application and saying:

> As there are no rules governing the prosecution of an application under the provisions of section 41 subsection 3 of the Patent Act, I direct that the following procedure be adopted:
>
> 1. You are to advertise the application in the Patent Office Record and in the Canada Gazette. The advertisement should be in the form accompanying this letter.
>
>   A five dollar ($5.00) fee is required for advertisement in the Patent Office Record.
>
>   You should advise me of the date at which the advertisement has appeared in the Canada Gazette.
>
> 2. Within sixty days from the date of this letter you must serve the patentee, Hoffmann-La Roche Limited, 1956 Bourdon Street, Ville St. Laurent, Montreal 9, Quebec, with a copy of the application and affidavit.
>
> 3. The patentee will have sixty days within which to file a counter-statement with me and serve a copy thereof upon you.
>
> 4. You will have thirty days to file a reply with me and serve a copy thereof on the patentee's representative.

This, it will be observed, so far as it went, was similar to the procedure prescribed under ss. 70 and 71 of the Act. By another letter written the same day the Commissioner also advised the appellant of the filing of the application, that the applicant had been requested to serve the appellant within 60 days with a copy of the application and of the supporting affidavit that the appellant would have 60 days within which to file and serve its counter-statement supported by affidavit and that the applicant would have 30 days to file and serve a reply, but he does not appear to have advised the appellant of his directions to the applicant to advertise the application.

On August 2, 1962 the appellant, having in the meantime obtained a two month extension of time, filed a counter-statement which read as follows:

> 1. Hoffmann-La Roche Limited, the owner of Canadian Patent 612497 opposes the application made under Section 41(3) of the Patent Act by Delmar Chemicals Limited for a licence under the said patent.
>
> 2. Librium, the trade name under which Hoffmann-La Roche Limited sells the invention of the said patent, belongs to a new class of compound which has not, heretofore, been employed in medical therapeutics.

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3. It is the first specific medication for the symptoms of anxiety and tension and has accordingly been subject to use by the medical profession, both as specific or adjunctive therapy in treating medical, surgical or psychiatric disorders.
4. Previously available medications would relieve the symptoms of anxiety and tension, but either to a lesser extent than Librium, or by also producing undesirable side effects, such as habituation or addiction.
5. The librium manufacturing process involves the use of highly volatile solids dangerous to inhale, the use of numerous chemicals which can cause skin afflictions and the use of highly explosive solvent systems. Applicant's described production facilities are not adequate to cope with the manufacture of librium.
6. Librium substance is light sensitive and will break down into its derivatives if not properly controlled. Some of these derivatives are more potent than the parent compound and would cause an overdosage which produces undesirable side effects such as drowsiness and ataxia (muscle incoordination). Some of the derivatives are less potent which would render the substance ineffective and others are definitely toxic.
7. Delmar Chemicals Limited, in its application, states that it has verified, experimentally, on an adequate scale, that it can produce the patented products. Making a drug in the laboratory and manufacturing it on a commercial scale are two vastly different propositions. Commercial production requires great care and the use of specialized equipment and facilities for both manufacturing and storing which are not possessed by the applicant. Cutting corners in the manufacture of the drug would involve great danger both during manufacture and to the ultimate consumer.
8. The fact that Delmar Chemicals Limited has been found to be qualified to manufacture certain products in other instances does not mean that it is qualified to manufacture the drug involved in this application.
9. Librium substance has been used in substitution for barbiturates and is therefore subject to abuse. It is under consideration for classification for restricted distribution as a controlled drug under Schedule G of The Food & Drug Act.
10. If Delmar Chemicals Limited obtains the licence it seeks, it can then sell librium substance to any other drug manufacturer or retailer in Canada and the quality of the manufacturing, storage and capsulating treatment accorded the drug will no longer be subject to control. A licence to one to manufacture the bulk substance is, in effect, a licence to all to sell it, and, with a drug such as that involved in this instance, the public interest would not be served by making the drug open and available to the public free from control.
11. If, contrary to the submissions herein, a licence is granted, the royalty payable thereunder should be commensurate with the maintenance of research incentive and with the importance of both the process and the substance involved.
12. A "demand for hearing" will be made by Hoffmann-La Roche Limited.

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This was accompanied by a statutory declaration by John S. Frolick, the vice-president of the appellant company, stating only that he had read the counter-statement and on the basis of the knowledge which he had by virtue of his position of vice-president, he found that the facts stated in the counter-statement were true to the best of his knowledge and belief. On the same day a notice demanding a hearing in respect of the application and requesting that a date for such hearing be fixed was served on the Commissioner who appears to have endorsed on it the notation "No provision for hearing under s. 41(3) Commissioner's discretion for rules of procedures. J.W.T.M. 2.8.62."

On August 8 the Commissioner wrote to the appellant's solicitors acknowledging receipt of the counter-statement and demand for a hearing and saying:

> In answer I must say that there being no regulations governing the practice under section 41 subsection 3 of the Patent Act, the Commissioner is entitled to set the procedures. Under the circumstances the Commissioner is not bound to hold a hearing on demand by one of the parties.
>
> The applicant has according to my instructions a period of thirty days to file a reply if he wishes. After that time I shall study the application and decide whether a hearing is warranted or not.

The respondent's reply was filed on August 18. In it considerable portions of what was set out in the counter-statement were admitted including paragraphs 1 to 4, the first sentence of paragraph 5 and the statements in paragraph 6 as to the stability of the products but the other statements were met with either denials or argumentative explanations or both. In particular it stated that insofar as the respondent's facilities might turn out to be inadequate it was prepared to acquire any necessary facilities. The reply ended with a paragraph submitting that there was no need for a hearing and that the counter-statement showed no good reason why a licence should be refused and requesting that a licence be granted. This was accompanied by a further affidavit of Geza S. Delmar stating that he had personal knowledge of the facts set forth in the reply and that they were true to the best of his knowledge and belief.

Thereafter, though not invited to do so by the Commissioner, the applicant's solicitors on September 7 wrote a three page letter to him submitting that issues of public safety were raised in the counter-statement which required full investigation, that the magnitude of the danger could

not be appreciated without such an investigation and that the applicant itself was not fully aware of such danger, that the problems of safety were not associated with the carrying out of the patented process but were collateral problems relating to risks involved in safely dissipating noxious fumes, production and disposal of toxic by-products and the use of appropriate apparatus and equipment that an examination of the appellant's and respondent's plants should be made for the purpose of comparing them and that oral evidence to be adduced at a hearing and cross-examination of the respondent's witnesses would establish the inability of the respondent to produce the product safely. The letter then proceeded to request a hearing or in the alternative that the appellant should be given at least an opportunity to cross-examine Mr. Delmar, and that the Commissioner visit the respective plants and it concluded with a suggestion that because of the public safety factors involved in the case it was in the public interest that the Commissioner be satisfied that the respondent is capable of making the product.

The respondent thereupon replied to the arguments so made by a letter in which among other things its solicitor objected to the Commissioner visiting the plants as suggested and on November 19, 1962, the Commissioner wrote to the appellant's solicitors stating that he had considered the petition in the light of their letter and had come to the conclusion that he need not visit the plants as suggested adding that a careful study of the patent and of patents covering closely related compounds had not revealed that there was anything unusual and that he would decide in a few weeks whether or not a hearing would be held.

The appellant's solicitors thereupon sent another letter to the Commissioner this time emphasizing its view that the respondent was not competent to produce a safe product and properly test it and the consequences which might ensue from an unsafe product being put on the market, and inviting the Commissioner to check with the Food and Drug Directorate with respect to the accuracy of certain statements in the respondent's reply and again demanding a hearing.

Shortly afterwards the respondent's solicitors replied to the submission so made and concluded by submitting that the appellant by its correspondence had argued its case and

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shown no good reason for a hearing to argue it over again and that none of the points raised by the patentee furnished any justification for refusal of a licence to the respondent.

Some two months later the Commissioner wrote to the appellant's solicitors enclosing a copy of his decision on the application and saying:

> This is a case which presents no difficulty and I have therefore made my ruling without a hearing considering that in my opinion no good reason to the contrary had been advanced.

In his formal decision the Commissioner after quoting s. 41(3) stated that he had no choice but to grant a licence unless he saw good reason to the contrary and that as there were no regulations governing his inquiry he was at liberty to use his judgment in any individual case in order to arrive at a just and fair conclusion. Then after very briefly reviewing some of the arguments and statements made by the parties he found that he had no reason to believe that the applicant had not the ability to make the compound, adding that the respondent was a well known manufacturer of synthetic organic compounds and therefore he decided that no hearing was necessary in the case and that the petition should be granted. In a further paragraph he also set a royalty to be paid by the respondent of 12½% of the net selling price of the crude product before processing for patients' consumption. The present appeal was then taken.

The appellant's main submission, as I understand it, is that its counter-statement raised questions of public interest and of public safety which it thereupon became the duty of the Commissioner on behalf of the public to investigate fully before deciding to grant a licence, that in denying the appellant's request for an oral hearing and for an opportunity to cross-examine Mr. Delmar the Commissioner had deprived the appellant of its right to show him the several dangers to public safety involved in licencing the respondent to use the patented process to produce the drug and the magnitude of such dangers, that the Commissioner had reached a conclusion as to the extent of dangers incident to the manufacture of the drug on information obtained from other patents the identity of which was not made known to the appellant and that the appellant therefore had not had the fair hearing to which, as a party

whose property was affected by the decision, the appellant was entitled.

In my opinion there is no duty cast upon the Commissioner by the statute, to investigate on behalf of the public, questions of public safety. His concern is not with public safety but with the effects of the monopoly rights of the patentee on the freedom of others to use the invention to promote the public interest in obtaining the new medicine as cheaply as possible and in enabling others to devise and use improvements in the patented process. When the Commissioner grants a patent he is not concerned with what dangers to the public may be involved in the lawful practice of it and neither is this his field of concern when application is made for a licence to practice what but for such licence would be infringement of the monopoly and but for the monopoly the applicant could practice without it. Moreover, even if in the special features of a particular case the dangers involved in practicing an invention could be regarded as affording a reason for refusing a licence the extent to which the Commissioner would for such purpose initiate inquiries for the purpose of ascertaining on behalf of the public the extent to which such dangers exist would be for him to decide rather than for the patentee to dictate, as, in my view, it seeks here to do. Having required the publication of a notice of the application in the Canada Gazette calling upon all parties wishing to oppose the application to show cause if they had any, why the licence should not be granted, by filing a counter-statement and having received only the patentee's counter-statement, in which no case of any special features requiring exceptional safeguards in the public interest was stated, I think it was plainly open to the Commissioner to reach the conclusion that so far as public safety was concerned no further inquiry was required or even indicated. The statements in the counter-statement with such admissions as were contained in the reply comprised the whole of the material properly before the Commissioner for consideration on this point under the procedure which he had directed and if matters thought to be of importance for his consideration were not stated in the counter-statement the appellant in my opinion cannot at this stage be heard to complain. None of the paragraphs of the counter-statement appears to me

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to state anything which the Commissioner was under any necessity to regard as good reason for instituting an inquiry or for refusing a licence. In effect instead of stating and establishing reasons why a licence should not be granted the appellant in its counter-statement has done nothing but suggest a number of areas where if the Commissioner searches hard enough he may conjure up reasons, and at the same time has demanded the right to present its case at an oral hearing rather than by the procedure which the Commissioner has directed. While the appellant in demanding an oral hearing may have hoped for an opportunity to amplify the presentation of the matters stated in the counter-statement it could scarcely have been unaware that the invitation to file a counter-statement verified by affidavit was its opportunity to present its case and that no further opportunity would necessarily be afforded to it. The reference by the Commissioner in his letter of April 2, 1962 to a counter-statement, rather than simply to a statement of reasons if any, to be supported by affidavit, may have been ill advised as being suggestive of the procedure under ss. 70 and 71, in which a right to a hearing in some instances arises, but I do not think the appellant or its solicitors could have been under misapprehension of the true position on this account or that anyone would on that account have been justified in concluding without inquiry that a hearing would necessarily be held on demand of either party. It is also of significance that no request was made for an oral argument on the material filed. I am therefore of the opinion that the substantial requirements of justice have not been violated by the Commissioner's refusal in the circumstances to accede to the appellant's demand for an oral hearing and that the appellant's submission that in the circumstances it was incumbent on the Commissioner in the public interest to grant the appellant's demand for an oral hearing or for an opportunity to cross-examine Geza S. Delmar on his affidavits is unfounded. Moreover, as the allegation of public danger was not squarely stated in the counter-statement but was first raised in the letter written by the appellant's solicitors in support of its request for an oral hearing and was not verified even by the glib declaration which accompanied the counter-statement the fact that the Commissioner may have satis-

fied himself that there was nothing to the point by reference to other patents rather than by ignoring the suggestion and rejecting the invitation to visit the appellant's plant out of hand is in my view immaterial.

There remains the question of whether the appellant had an adequate hearing in respect of the issue raised in the counter-statement as to the competence of the respondent to manufacture the drug in question. The possession by the respondent of the equipment required for production of the drug was asserted by the respondent in its application and was challenged by the appellant in the counter-statement, whereupon the respondent in its reply stated that insofar as its facilities might turn out to be inadequate it was prepared to acquire any necessary facilities. Attention was directed to this as indicating that the respondent did not know what was required for commercial production and distribution of the drug and was therefore not competent to manufacture and distribute it and it was submitted that an oral hearing on this question should have been held with an opportunity for the appellant to adduce evidence on the point or that at the least cross-examination of Mr. Delmar on his affidavit should have been allowed. In his formal decision the Commissioner took into account statements contained in the respondent's reply and found that he had no reason to believe that the respondent had not the ability to make the compound, thus in a negative way resolving the issue against the appellant.

If the adequacy of the respondent's existing facilities and its immediate competence to manufacture the drug were of critical importance to the authority of the Commissioner to grant a licence I doubt if a decision based on a finding of such ability could in the circumstances be allowed to stand but there was no legal necessity that the Commissioner be satisfied of the immediate competence of the respondent to manufacture and store the product, and the issue though raised in the statement that its facilities were inadequate, in my opinion, was but a side issue at best. Nowhere is the fact of the respondent being a manufacturer of pharmaceutical fine chemicals with a substantial background of experience in that field and with a considerable establishment of its own as alleged in its application, put in

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issue. Beyond that the capability of the respondent to do at once everything necessary to meet such standards as the patentee might wish to see observed in the use of its invention is in my opinion beside the point. Such matters are governed not by the patentee but by the law of the land including the provisions of s. 41 of the *Patent Act* and if the inventor properly disclosed his invention and the best means known to him of putting it into operation no further qualification beyond those which have not been disputed should be required. Nor can the patentee be heard to challenge on an application of this kind the adequacy of the teaching of his specification. On the application and counter-statement coupled with the admissions of the reply there were in my view no material matters in dispute and there was nothing to indicate any good reason within the meaning of the statute why the licence should be refused. I am therefore of the opinion that the Commissioner was correct in finding as stated in the letter accompanying the decision that no good reason had been advanced for refusing the licence and that his decision to deny a further hearing and to grant the licence should be affirmed.

On the question of royalty, however, as there is nothing in the record upon which to base or justify a finding the case is in my view indistinguishable from that of *Parke Davis & Co. v. Fine Chemicals of Canada Limited*[1] and *Aktiebolaget Astra, Apotekarnes Kemiska Fabriker v. Novocol Chemical Manufacturing Company of Canada Limited*[2], and I shall therefore follow the course adopted in those cases and refer the matter back to the Commissioner. In that respect alone the appeal will be allowed.

As success is divided there will be no costs of the appeal to either party.

Judgment accordingly.

[1] [1959] S.C.R. 219.

[2] [1964] Ex. C.R. 955.