
1965
Feb. 8-12
Mar. 8

BETWEEN:

HOFFMANN-LA ROCHE LIMITED ....APPELLANT;

AND

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

Patents—Compulsory licence—Hearing before Commissioner of Patents—Good reason not to grant compulsory licence—Duty of Commissioner on application for compulsory licence—Objective of compulsory licence provision of Patent Act—Commissioner having regard to own knowledge when considering effect and weight of technical or professional evidence—Determination of amount of royalty payable under compulsory licence—Royalty commensurate with maintenance of research incentive and importance of both process and substance—Patent Act, R.S.C. 1952, c. 203, s. 41(3).

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This is an appeal by the owner by assignment of the Canadian patent in respect of an invention for the preparation of the drug, chlordiazepoxide or chlordiazepoxide hydrochloride, sold by it under the trade name Librium, from an order of the Commissioner of Patents made pursuant to s. 41(3) of the *Patent Act*, granting to the respondent a licence to use the invention.

Prior to the making of the order by the Commissioner of Patents both parties filed affidavit evidence with the Commissioner and a hearing was held before him at which both parties adduced *viva voce* and documentary evidence and submitted argument.

The appellant now appeals against the granting of the licence to the respondent, against the royalty fixed by the Commissioner and against other terms of the licence granted by the Commissioner.

Held: That even if a reason put forward by the appellant on this appeal were one which, as a matter of law, is a "good reason" why the Commissioner should not have granted the licence, the Commissioner was not manifestly wrong in failing to see it as a good reason when the appellant did not, when it was before the Commissioner, present that reason to the Commissioner for consideration.

2. That the Commissioner cannot be regarded as having been manifestly wrong in not having seen a "good reason" which was not sufficiently obvious to prompt the appellant to raise it before the Commissioner.

3. That evidence that was adduced in the proceedings before the Commissioner with regard to one issue cannot be regarded as having established a fact to which neither the Commissioner nor the parties addressed their minds at the time of the hearing.

4. That the objective of s. 41(3) of the *Patent Act* is to bring about competition.

5. That there is no duty imposed upon the Commissioner by s 41(3) of the *Patent Act*, when he is considering whether there is "good reason" to reject an application for a compulsory licence, to conduct an investigation as to whether the prices at which the patentee has been selling the patented product are in fact "reasonable".

6. That the Commissioner is entitled, in considering the effect and weight of technical or professional evidence, to take advantage of his general knowledge of the particular subject matter acquired throughout the years of his experience as Commissioner and also, indeed, to have regard to his own professional knowledge as a chemical engineer.

7. That the statutory rule set out in s. 41(3) of the *Patent Act* to be applied in determining the amount of royalty will result in a royalty less than it otherwise would be if the only rule to be applied were the rule in s. 19 of the *Patent Act*. The general tendency of the rule must be to require that the Commissioner have regard to the desirability of making the royalty or other consideration less than market price but he must not make it so low that it is not consistent with giving to the inventor due reward for the research leading to the invention.

8. That on the one hand there is a ceiling on the royalty or other consideration to be determined by reference to the theoretical market place and, on the other hand, there is a floor, beneath which it must not be reduced from that ceiling, in that it is not to be reduced from market value to an amount that is not "commensuate with the maintenance of research incentive the importance of both process and substance".

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9. That s. 41(3) of the *Patent Act* does not contemplate or require that the patentee is entitled through payment of royalty by the licensee, in effect, to that proportion of its wholesale selling price of the sales that it will lose by virtue of the compulsory licence that medical information costs and research costs are of the total sale price of all its sales of patented drugs.

10. That in fixing the royalty or other consideration under s. 41(3) it is not right to attribute, with some show of mathematical precision, a part of research cost, or of other costs, to each part of the product manufactured pursuant to a particular invention and to conclude that, as a matter of law, that is the royalty that must be awarded.

12. That the Commissioner erred in thinking, when considering the amount of royalty to be paid under the licence, that the finished material in dosage form, packaged and labelled, was outside the scope of the patent and immaterial to him because it is precisely the same product as it is when in bulk except that it has been packaged so as to be in the form in which it has value as a merchantable commodity.

13. That the appeal is dismissed with the exception of a change in the method of calculation of the royalty to be paid.

14. That the appellant will pay to the respondent 90 per cent of its costs of the appeal.

APPEAL from an order of the Commissioner of Patents.

The appeal was heard by the Honourable Mr. Justice Jackett, President of the Court, at Ottawa.

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

I. Goldsmith for respondent.

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

JACKETT P. now (March 8, 1965) delivered the following judgment:

This is an appeal from an order of the Commissioner of Patents, made pursuant to subsection (3) of section 41 of the *Patent Act*, R. S. C. 1952, chapter 203, granting to the respondent a licence for the use of an invention for the preparation of a drug, chlordiazepoxide or chlordiazepoxide hydrochloride, which is used as a tranquillizer and is sold by the appellant under the trade name Librium.

The appellant is a company that carries on business in Canada selling drugs and vitamins. A substantial part of its drug business consists in the sale of Librium, which it imports in bulk, capsulates, packages and sells in Canada.

The appellant is one of a group of related companies, hereinafter referred to as the "La Roche group". The other members of the La Roche group carry on business in other countries. Some of the other companies in the group carry on research activities in the United States of America, the United Kingdom and Switzerland. Librium is manufactured by members of the group in the United States and Switzerland and is distributed throughout the world. The appellant purchases it from members of the group who so manufacture it. As far as the evidence shows, each member of the group carries on business on its own behalf.

The appellant is the owner of a patent (No. 612,497) under the *Patent Act*, R. S. C. 1952, chapter 203, in respect of the invention in question, apparently being the assignee of the Canadian patent rights from the inventor, Leo H. Sternbach, of Upper Montclair, New Jersey, U.S.A.

The relevant portion of section 41 of the *Patent Act* 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.
>
> (4) Any decision of the Commissioner under this section is subject to appeal to the Exchequer Court.

The first branch of the appellant's appeal is against the granting of the licence to the respondent. The second branch of the appeal is against the royalty fixed by the Commissioner. The third branch relates to other terms of the licence granted by the Commissioner.

I had occasion recently, in *Aktiebolaget Astra, Apotekarnes Kemiska Fabriker v. Novocol Chemical Manufacturing Company of Canada Limited*[1], to consider the Court's function on such an appeal and I do not propose to repeat here what I said in that case.

A proper appreciation of the submissions of the parties on the first branch of the appeal requires a consideration of

[1] [1964] Ex. C.R. 955.

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the proceedings leading up to the Commissioner's decision and it is necessary, therefore, to review such proceedings in some detail. My review of those proceedings as is follows:

(1) APPLICATION BY RESPONDENT FOR COMPULSORY LICENCE:

On August 17, 1962, the respondent filed an application with the Commissioner of Patents for a compulsory licence for the use of the invention disclosed by Patent No. 612,497 for the purpose of the preparation or production of medicinal and pharmaceutical products containing or incorporating chlordiazepoxide. The application states that the respondent was established in 1945, since which time it had carried on the business of a manufacturer and distributor throughout Canada of ethical pharmaceutical products. It gives information concerning the respondent's premises and its staff and states that it had ample facilities for the manufacture of pharmaceutical products. The application states that the respondent at all times maintained strict controls and high standards of purity fully complying with the *Food and Drug Act* and that the respondent's premises and facilities are periodically inspected by officials of the National Health and Welfare Department. The application states that the respondent's average turnover during the previous five years had been $345,000 and that its average profits for that period before taxes had amounted to $28,300 annually. After giving certain information concerning the patented product and process, the application states that the respondent company had a guaranteed source of supply of the "starting material" necessary for the manufacture of the patented product and that the respondent intended to manufacture the patented product at its premises by the method of manufacture described in the patent. The application gives certain information concerning the process of manufacture as set out in the patent and states that the steps referred to are standard procedures well within the capacity and ability of the respondent's facilities and personnel.

The application states that the respondent expected to be able to manufacture chlordiazepoxide at a cost of $85 per kilo and to market the substance in tablets or similar form to be sold to the public at prices specified in the application, for example, 10 mg. capsules or tablets

at $7.75 per hundred. The application states that, to the best of the respondent's information and belief, the appellant is the only supplier of chlordiazepoxide in Canada, that the appellant sells such compounds under the trade name Librium at specified prices, for example, 10 mg. capsules at $12 per hundred and that, accordingly, if a licence were granted to the respondent, the latter would be in a position to make chlordiazepoxide available to the Canadian public at prices substantially lower than those at which it was then being sold.

(2) COUNTERSTATEMENT FILED BY APPELLANT:

On January 25, 1963, the appellant filed with the Commissioner of Patents, a document entitled "Counterstatement".

By paragraph 2 of the Counterstatement the appellant asserted that "The public interest would not be served by granting the licence for which the Applicant has applied". Paragraphs 3 to 14, inclusive, state in detail the position of the appellant as stated in general terms in paragraph 2.

Paragraph 3 states that Librium is the first specific medication for the symptoms of anxiety and tension and that 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. It states that Librium is light sensitive and will readily break down into derivatives if not properly controlled, that some of the derivatives are more potent than the parent compound and would cause an overdosage producing undesirable side effects, that some of the derivatives are less potent which would render the substance ineffective, and that others are "definitely toxic".

Paragraph 4 states that the applicant is not qualified to manufacture chlordiazepoxide and has neither the competence nor the facilities to reproduce the process of the patent "safely". The paragraph states that it is apparent, from the application, that the respondent did not comprehend the magnitude of the process and did not appreciate the facilities, equipment and personnel required and the hazards and risks that are involved. Paragraphs 5 to 10, inclusive, elaborate in some detail

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the appellant's reasons for alleging that the respondent is not qualified to manufacture chlordiazepoxide safely or to manufacture a product which it would be safe to put on the market from the point of view of the user.

Paragraph 11 of the Counterstatement alleges that the respondent's statements in its application concerning the prices at which the appellant sells Librium are incorrect, the suggestion concerning the prices at which chlordiazepoxide manufactured by the respondent could be marketed is misleading and that "Quality is a more important criterion of public interest than is the price of a drug".

Paragraph 12 of the Counterstatement says that, in addition to the issues of "competence, facilities, public interest and public safety" there is a further issue involving the reputation of a most beneficial product. It states that if a product of inferior quality is produced by the respondent, the reputation of "Librium" could be destroyed and, by virtue of a loss of reputation, a very valuable drug may be denied to the public and that, in addition, the reputation of the appellant is in issue in that "Librium" is now associated in the public mind with the appellant and any inferior product would have a detrimental effect upon the reputation of the appellant.

In paragraph 13, the appellant comes back to the question of the respondent's ability to manufacture a product which it is safe to market. In this paragraph, the appellant says in effect that the appellant makes its own starting material and therefore is in a position to be sure that its ultimate product will be satisfactory and suggests that the respondent cannot be sure, if it uses a starting material acquired from someone else, that there will not be impurities in it which "may react with other ingredients of the process causing other toxic by-products in the final substance".

Paragraph 14 of the Counterstatement refers to paragraph 17 of the application where the respondent states that it expected to be able to manufacture chlordiazepoxide at a cost of $85 per kilo and states that the appellant, from its own knowledge, knows that the manufacture of the starting material alone will cost in the neighbourhood of $85 per kilo if properly made.

(3) REPLY:

On March 26, 1963, the respondent filed a document entitled "Reply", which contains the respondent's answers to some of the allegations in the Counterstatement. There is no need to review such answers for the purposes of this appeal. The Counterstatement contains, in addition, a statement that the respondent had, then, for the first time, obtained a firm quotation for the starting material and that, based on that quotation, its cost of manufacturing chlordiazepoxide should not exceed $150 per kilo. (It will be remembered that the costs were estimated in the application at $85 per kilo.)

(4) HEARING:

On August 21, 1963, the Commissioner of Patents gave to each of the parties an opportunity of adducing evidence and of presenting argument. The respective parties were represented before the Commissioner by the counsel who represented them on the hearing of the appeal in this Court. The parties adduced evidence by way of sworn testimony and by way of documentary exhibits. I have reviewed the transcript of the hearing before the Commissioner and it seems clear that each of the parties restricted its proof and argument to supporting the contentions in the material it had previously filed and attacking the contentions in the material previously filed by its opponent. I have been able to find no indication that either of the parties asked the Commissioner to consider any submission not set out in the documents filed before the hearing. In particular, I have not been able to see that the appellant, at any time, asked the Commissioner to make any finding on the question of "good reason" to refuse the licence other than those contemplated by the Counterstatement. I am confirmed in this view by a review of the transcript of the argument made by counsel for the appellant before the Commissioner. At pages 53-4 of the transcript of the argument, counsel for the appellant summed up the submissions he had made to that point as follows:

> In relation, then, to this particular prescription drug, I submit:
> (1) The applicant is not technically qualified:
> (*a*) He has not had experience in the manufacture of chemicals.
> (*b*) In particular, he has not had experience in the manufacture

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of chemicals having the type of reaction which is entailed here, involving the type of material which must be handled: on the contrary, he has shown a lack of understanding of this material and a lack of competence to deal with it.

(c) He has shown that he does not have the personnel, he is not himself equipped, and he intimates that he must send his engineer over to learn—over somewhere. And, as I have said, he has no contract which would give rise to an assurance that something is going to be obtained.

In view of all this, I submit that this country ought not to be delivered to the vagaries of the Italian will. In short, he has no know-how, he has no experience, he has no personnel. I say he is not qualified.

(2) The applicant is not qualified from the point of view of facilities.

His present building is a menace to the community and I say this—and I repeat it—in Mr. Craig's presence. If he carries out this process he does it at his risk in those premises, and one can only say: Be it on his own head. I say that to carry out an explosive type of reaction such as he proposes to carry out in premises of this kind, with the volatile materials he proposes to use, and in a residential neighbourhood, is a real risk—and I am speaking in terms of the product he is seeking to produce and under the conditions contemplated.

I have no knowledge of what he is producing now. I am not criticizing what he is doing now, I repeat, because I have no knowledge of what he is doing now; I am speaking in the context of what he is asking you to allow him to do in the premises he has now, and in that context I say he would be operating not only [sic] but at his neighbour's risk as well.

Counsel then dealt with the contention that the respondent's premises and equipment were not suitable for the manufacture of the drug and, commencing at page 58, he developed his contention that the obligation to make the substance available to the public at a reasonable price must be considered in the light of the fact that the drug is a prescription drug which must be considered "in terms of risks in use". At page 59, counsel made the submission that "private rights are not to be ignored" and that if the product should lose its reputation in the market then the long term benefits from the drug may be lost and, on page 60, he submitted that, as the drug was still in the formative stage, this worked "in favour of control from a single source". On pages 60-1, he justified the appellant's refusal to make public its "controls", and on pages 62-3, he came back to the adequacy of the respondent's organization and qualifications. At page 63, he turned to the question of royalty.

On July 6, 1964, the Commissioner delivered his decision. He dealt with the question as to whether or not a compulsory licence should be granted to the respondent in that part of his decision which reads as follows:

The application has been opposed by the patentee on the grounds that the applicant is not technically qualified, that he does not have the proper facilities in the way of housing and equipment and that the use of the invention involves the handling of extremely dangerous materials.

I have heard many such cases before and it is always a common ground of attack by the patentee to dwell on the lack of competency of the applicant and it is my duty to analyze the facts very carefully in order to arrive at a decision which is in conformity with the true intent of the legislation.

In this case it has been argued that many volatile, explosive and corrosive substances are involved and that a great many things concerning the process are known by the patentee which are not known by the applicant.

That the patentee, who has had several years of experience in dealing with the process, knows a great deal more about it than any applicant for licence, is obvious. It cannot normally be otherwise; however, if an applicant has to know nearly as much as the patentee concerning a patent, the purpose of the licencing provisions would be defeated.

Section 36 of the Patent Act requires that an applicant shall fully describe his invention in such full clear, concise and exact terms as to enable any person skilled in the art to which it appertains, or to which it is most closely connected, to make, construct, compound or use it. I must take it for granted that the patentee has fulfilled the requirements of the Act in describing his invention and he cannot at this time come and say, Oh no! with the specification alone you cannot do it. It may be true that the patentee has since learned much about the process, but what he has learned can also be learned by others. Reference could appropriately be made here to the statement of Thorson, P. in the Exchequer Court in the case of *Minerals Separation North American Corporation v. Noranda Mines Limited,* [1947] Ex. C.R. 306 at pages 316 and 317:

> Two things must be described in the disclosures of a specification, one being the invention, and the other the operation or use of the invention as contemplated by the inventor, and with respect to each the description must be correct and full. The purpose underlying this requirement is that when the period of monopoly has expired the public will be able, having only the specification, to make the same successful use of the invention as the inventor could at the time of his application. The description must be correct; this means that it must be both clear and accurate. It must be free from avoidable obscurity or ambiguity and be as simple and distinct as the difficulty of description permits. It must not contain erroneous or misleading statements calculated to deceive or mislead the persons to whom the specification is addressed and render it difficult for them without trial and experiment to comprehend in what manner the invention is to be performed. It must not, for example, direct the use of alternative methods of putting it into effect if only one is practicable, even if persons skilled in the art would be likely to choose the practicable method. The description of the invention must also be full; this means that its ambit must be defined, for nothing that has not been described may be validly claimed. The description must also give all information that

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is necessary for successful operation or use of the invention, without leaving such result to the chance of successful experiment, and if warnings are required in order to avert failure such warnings must be given. Moreover, the inventor must act uberrima fide and give all information known to him that will enable the invention to be carried out to its best effect as contemplated by him.

I have studied the specification very closely and I have not detected any particular difficulties in carrying out the process of the claims. The reaction is not carried out at any high temperatures or high pressures. It is a heterogeneous reaction which, I admit, may present some problems, but nothing in the specification points out to any unknown necessary procedure of control. The patentee has stressed the dangers involved in the handling of the chemical substances which are used in the process. Out of eight such substances said to be so dangerous I say that seven of them are used in a great many synthetic organic reactions as reactants, solvents, agents of precipitation or crystallizing media and are found in mostly all research laboratories and manufacturing plants of organic chemicals. Most organic chemists are thoroughly familiar with such common substances as methanol, ethanol, acetone, ether, petroleum ether, methylene chloride and methyl amine. Dealing with quinazoline, I have not found in the chemical literature any warning concerning such severe skin irritating properties as ascribed to it by the patentee. Considering the statements made by a witness for the patentee concerning the dangers of the other substances mentioned above and the careful way the statements were made, while in essence they were true, they would lead a person who is not conversant with chemistry to a very distorted impression of the behavior of such substances. In the case of quinazoline, the irritating properties, which I do not deny, may also have been slightly overstressed. A great many organic chemical substances are fluffy and dusty and can produce irritation of the skin or of the mucous membranes when people come in contact with them or inhale them. I believe that any chemist with a reasonable knowledge of organic chemistry and observing the rules of safety is qualified to work the process of the claims. There may be a considerable amount of know-how to be learned, but this can be acquired by a newcomer, the same as it was acquired by the patentee.

The applicant has in his employ one chemical engineer one pharmacist, three chemists and one bacteriologist. With such a staff, I have no doubt that the process described in the patent can be well understood and that the necessary precautions can be taken particularly in view of the severe warnings given by the patentee during these proceedings.

Objection has also been taken to the fact that the applicant does not have the proper plant and equipment. Here again, it is not fair to expect an applicant to spend considerable sums of money before he knows whether he is going to have a licence or not.

In view of the above considerations I find that a licence should be granted to the applicant.

The Commissioner then dealt with the question of royalty in a part of his reasons to which I will refer at a later stage of these reasons.

By notice of appeal dated July 21, 1964, supplemented by a further notice of appeal dated October 15, 1964, the appellant appealed from the Commissioner's decison.

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On August 11, 1964, an application was made to this Court to stay proceedings in relation to the Commissioner's decision, the purpose of the application being to obtain from this Court an order postponing the effective date of the compulsory licence pending disposition of the appeal. I dismissed that application[1] and gave the following reasons for so doing:

> The only ground, of those that have been urged upon me, upon which I would consider granting a stay, if I have authority to grant a stay, is that the Court might conclude, upon the disposition of the appeal, that the Commissioner of Patents erred in *not* forming the opinion that the risk of danger to the public inherent in permitting the respondent to manufacture the patented substance was good reason for refusing the licence.
>
> In that connection, I refer to a statement by Thurlow J. in *Hoffman-La Roche Limited v. Delmar Chemicals Limited* (27 Fox P.C. 178; [1965] 1 Ex. C.R. 611), concerning the duty of the Commissioner in dealing with an application under ss. (3) of s. 41, as follows:
>
> > 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.
>
> Having regard to that statement, with which I agree, I cannot conclude that there is a probability that this Court will dispose of this appeal upon the ground that the Commissioner erred in not forming the opinion that the risk of danger to the public inherent in permitting the respondent to manufacure the patented substance was good reason for refusing the licence.
>
> Furthermore, I am not satisfied that this Court, in an appeal under ss. (3) of s. 41, has any authority to affect the operation of the Commissioner's order prior to disposition of the appeal.

The appellant applied to a judge of the Supreme Court of Canada for leave to appeal from that decision, but such leave was refused.

On the argument of the branch of the appeal having to do with the Commissioner's decision to grant the licence, counsel for the appellant indicated that the appellant was not abandoning the public safety point but, in view of the opinion so expressed on August 11, he would not make submissions in this Court with regard to that point.

On the branch of the appeal having to do with the Commissioner's decision to grant a licence, while it was put in various ways from time to time during the course of a long argument, the appellant, in effect, based the major portion of its attack on one principal ground. There was in addition one relatively minor ground for the attack that was quite separate from that principal ground.

[1] [1965] 1 Ex. C.R. 179

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The principal ground can, I think, be summarized as follows:

(*a*) it is admitted that section 41(3) requires the Commissioner to grant the licence applied for by the respondent "unless he sees good reason to the contrary",

(*b*) the purpose of the provision is to ensure that the medicine is made available to the public at the lowest "possible" price,

(*c*) the lowest possible price at which the medicine can be made available to the public is a price that is reasonable having regard to all the necessary costs of discovering, producing and making available to the public, drugs of this particular kind,

(*d*) the appellant did, by its evidence before the Commissioner, establish that the drug was already being made available to the public at such a reasonable price, which is therefore "the lowest possible price"[1], and there was no evidence upon which the Commissioner could have found that there was a likelihood that the respondent would be able to make the drug available to the public at a lower price,

(*e*) it having been established that the drug is already being made available to the public at the lowest possible price, it follows that the grant of a compulsory licence will serve no useful purpose in this particular case,

(*f*) the grant of a licence to a person such as the respondent to manufacture and distribute the drug in question will be contrary to the public interest

[1] It was accepted for purposes of the hearing before the Commissioner that the respondent could produce chlordiazepoxide in bulk (variously referred to as the "crude", "basic" or "active" material) for $150 per kilo and that there would be an additional cost of $250 per kilo for capsulating and of $60 per kilo for bottling and packaging, making a total cost for putting the material in usable dosage form of $460 per kilo. It was also common ground that, at the price of $7.75 per 100 of the 10 mg. dosage size, at which the respondent claimed it could enable the product to be supplied to the public, the respondent would net about $3,500 per kilo after allowing for retailer's margin, wholesaler's margin and taxes At the appellant's suggested list price to the public of $12 per 100 of the same size, making the same allowances, the appellant netted about $5,405 per kilo but its average price per kilo was $4,600. The difference between the cost of $460 per kilo and the appellant's realization of $4,600 per kilo appeared, on the evidence, if it could be taken to give a complete and balanced picture, to be no more than adequate to cover costs of research and medical information, other necessary overhead expenses and a modest profit.

(i) because it will deprive the appellant of the monopoly rights essential to its recovering the costs of discovering such new and useful drugs and making them available to the public and will thus tend to deprive the public of the possibility of similar discoveries of new and useful drugs in the future, and

(ii) because it will deprive the public of the advantages which flow from the appellant's programme of gathering and distributing medical information with reference to the drug, which is still in a formative stage, which programme can only be carried on with real advantage to the public if the appellant is the sole manufacturer of the drug so that it can ensure that all of the drug distributed to the public is maintained in accordance with a constant standard of purity;

(*g*) the Commissioner should have seen that the facts outlined above constituted good reason for not granting the licence pursuant to the appellant's application and he was manifestly wrong in not seeing it.

Put slightly differently, but amounting to the same thing, the appellant contended that

(*a*) on the one hand, the purpose of providing for a compulsory licence is to ensure that the particular drug is sold at a reasonable price and this reason for granting the licence was negatived once it was shown that the appellant sold the drug at a reasonable price, and

(*b*) on the other hand, it is in the public interest that these new drugs—referred to in the business as "winners"—be discovered and, therefore, that the essential research and medical information be paid for, and it is also in the public interest that the full potentialities of the drug be developed and placed at the service of the public and these objectives can only be achieved by leaving to the patentee the full scope of his monopoly so that he may recover such essential costs and have the required conditions of guaranteed standards of purity of the drug for its development by the medical information services:

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and the Commissioner was manifestly wrong in not having recognized such obvious facts and conclusions as being "good reason" for not granting the licence.

There are many possible answers to the appellant's complex submission, which I have endeavoured to summarize as fairly as I can. It will be sufficient for my purpose to indicate three of them, each of which I am satisfied is an adequate answer, and to indicate that I am not to be taken otherwise to have accepted any part of the submission.

The first answer to this submission, in my view, is that, even if the reason put forward now were one which, as a matter of law, is a "good reason", the Commissioner was not manifestly wrong in failing to see it as a good reason when the appellant did not, when it was before the Commissioner, present that reason to the Commissioner for consideration[1]. It has to be recognized that all the propositions outlined in the paragraphs I have lettered (*b*) to (*f*) above have to be taken together to constitute a single "good reason" which, in the appellant's submission, the Commissioner should have seen. The appellant contended, but without too much assurance, that it had presented this to the Commissioner as a "good reason". Alternatively, it contended that, whether or not a submission had been made to the Commissioner with regard thereto, the Commissioner was manifestly wrong in not having seen it himself because it was to be gleaned from an examination of the evidence presented to the Commissioner. In my view, the Commissioner cannot be regarded as having been manifestly wrong in not having seen a "good reason" which was not sufficiently obvious to prompt the appellant to raise it before the Commissioner.

My second reason for rejecting this submission on behalf of the appellant is that I am not satisfied that the facts which, according to the submission, were clearly established by the evidence were, in fact, so clearly established or, indeed, established at all. For example, no issue was raised by the respondent's Application or the appellant's Counter-statement as to whether the appellant's prices were reasonable and the evidence adduced before the Commissioner was not therefore adduced with regard to such an issue. I cannot

[1] There is some doubt in my mind whether a situation could ever arise where the Commissioner would be wrong in law in not seeing a particular reason as a "good reason" providing he has complied with the rules of natural justice.

agree that evidence that was adduced with regard to some other issue can be regarded as having established a fact to which, as far as I can ascertain, neither the Commissioner nor the parties addressed their minds at the time of the hearing. If such evidence had been given for the expressed purpose of establishing the facts upon which the appellant now relies, it might have been supplemented or qualified by cross-examination or by other evidence. Furthermore, there are many attacks that could be made upon the evidence as it stands from the point of view of whether it establishes that the price at which the appellant sells its product in Canada is the "lowest possible price" and, therefore, a reasonable price. The very fact that, according to the evidence, the drug appears to have been sold by the La Roche group at different prices in different countries and, indeed, at different prices in Canada, and that no evidence was adduced as to actual prices, but only as to averages, raises some question as to whether it is being sold in Canada at the "lowest possible price". As suggested by the respondent, it would have been interesting to know the group's prices in countries where it has no patent for the drug and to have been able to compare such prices with prices in Canada. The more fundamental difficulty with the evidence, as I understand the case that the appellant now tries to make out, is the assumption that, in respect of certain matters, the world costs of the La Roche group should be spread evenly over all the patented drugs sold by all the companies forming that group for the purpose of determining what is a "reasonable" price at which to sell in Canada and that other costs incurred by the appellant company itself in Canada should be spread evenly over the drugs sold by the appellant in Canada for the same purpose. Even where a tribunal is set up to regulate the prices of a statutory monopoly, such as a transportation company, it is not usual, and certainly not legally necessary, to determine "reasonable" prices in such an arithmetical way. I am not satisfied that, as a matter of law, such a formula must be applied to determine "reasonable" prices for the sale of goods under a monopoly conferred by a patent and this, in effect, is what the appellant contends. In fact, of course, the appellant does not recover its research and medical information costs evenly from all its sales. It sells the drug in the dosage form at prices that

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vary as widely as from $3,450 per kilo, at which price it sells to hospitals, to $5,405 per kilo, which appears to have been its ordinary wholesale price in Canada.

My third reason for rejecting the appellant's main submission in support of its appeal against the granting of the licence is that, in my view, it is based upon a fundamental misconception as to the legislative intention embodied in section 41(3). The appellant's contention, as I understood it, is that the fundamental, if not the sole, objective of section 41(3) is to ensure that the particular product is sold at a reasonable price or, "at the lowest possible price" which, according to his interpretation, is the reasonable price having regard to the costs of the patentee. He deduces from this that it is the Commissioner's duty under the section to determine whether or not the patentee's prices are reasonable because that must, as a matter of law, be a very important factor in determining whether there is "good reason" for rejecting the application for a licence. In my view, the objective of the provision is to bring about competition. On balance, in most fields, competition is regarded by Parliament as being in the public interest because competition regulates prices in the public interest and also because competition tends to bring about greater efficiency, better service, and further research. The monopoly granted to an inventor is an exception to this general principle in our law. Section 41(3) was passed because, in the field to which it applies, "the specific public interest in free competition" was deemed to be more important than the maintenance of the patentee's monopoly rights. Compare *Howard Smith Paper Mills, Limited v. The Queen*[1]. Just as it has been consistently held that it is no answer to a charge of a breach of the Canadian laws against combines to show that, in a particular case, the prices at which the goods have been sold have been "reasonable" so, in my view, there is no duty imposed upon the Commissioner by subsection (3) of section 41 of the *Patent Act*, when he is considering whether there is "good reason" to reject an application for a compulsory licence, to conduct an investigation as to whether the prices at which the patentee has been selling the patented product are in fact "reasonable".

For the above reasons, I reject what I have referred to as the appellant's "principal" attack on the Commissioner's decision to grant a licence.

[1] [1957] S.C.R. 403.

The other ground upon which the appellant attacks the Commissioner's decision to grant a licence is that the Commissioner, in considering the submissions that were made to him by the appellant with regard to the ability of the respondent to make the drug in question, went outside the evidence that was before him and relied upon material which the appellant was given no opportunity to answer[1]. To appreciate the weight that should be given to this submission, reference should be made to the whole of the passage in the Commissioner's reasons in which is found the particular statement upon which the appellant founds its objection. That passage reads as follows:

> I have studied the specification very closely and I have not detected any particular difficulties in carrying out the process of the claims. The reaction is not carried out at any high temperatures or high pressures. It is a heterogeneous reaction which, I admit, may present some problems, but nothing in the specification points out to any unknown necessary procedure of control. The patentee has stressed the dangers involved in the handling of the chemical substances which are used in the process. Out of eight such substances said to be so dangerous I say that seven of them are used in a great many synthetic organic reactions as reactants, solvents, agents of precipitation or crystallizing media and are found in mostly all research laboratories and manufacturing plants of organic chemicals. Most organic chemists are thoroughly familiar with such common substances as methanol, ethanol, acetone, ether, petroleum ether, methylene chloride and methyl amine. *Dealing with quinazoline, I have not found in the chemical literature any warning concerning such severe skin irritating properties as ascribed to it by the patentee.* Considering the statements made by a witness for the patentee concerning the dangers of the other substances mentioned above and the careful way the statements were made, while in essence they were true, they would lead a person who is not conversant with chemistry to a very distorted impression of the behaviour of such substances. In the case of quinazoline, the irritating properties, which I do not deny, may also have been slightly overstressed. A great many organic chemical substances are fluffy and dusty and can produce irritation of the skin or of the mucous membranes when people come in contact with them or inhale them. I believe that any chemist with a reasonable knowledge of organic chemistry and observing the rules of safety is qualified to work the process of the claims. (The emphasis is mine.)

The appellant's objection to the Commissioner's treatment of this subject is related particularly to the words "Dealing with quinazoline, I have not found in the chemical literature any warning concerning such severe skin irritating

[1] As this attack relates to the portion of the Commissioner's reasons where he was dealing with the "public safety" point, concerning which the appellant made no submission in this Court, I would be bound to reject it, even if it were otherwise sound, because, in my view, the Commissioner should have, and would have, rejected "public safety" as a "good reason" regardless of his finding on the facts.

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properties as ascribed to it by the patentee". In support of his objection to the fact that the Commissioner resorted to chemical literature, the appellant relied upon *Hughes v. Lancaster's Steam Coal Collieries*[1] per Tucker, L. J. at page 558. In that case, a compensation board had rejected evidence of an expert nature concerning the characteristics of hernia by reason of evidence received by the board in other cases and Tucker, L. J. said that "The Judge clearly went wrong, as he is not entitled to reject the uncontradicted evidence before him by reason of his preference for evidence that had been given by other witnesses in other cases . . ." This, in my view, is not the same sort of case. In this case, the Commissioner was appraising the weight to be given to the evidence which he was discussing and was not rejecting the evidence in favour of evidence which he had found outside the record. His conclusion was that "In the case of quinazoline, the irritating properties . . . may also have been slightly overstressed". There can, in my opinion, be no doubt that the Commissioner was entitled, in considering the effect and weight of technical or professional evidence, to take advantage of his general knowledge of the particular subject matter acquired throughout the years of his experience as Commissioner and also, indeed, to have regard to his own professional knowledge as a chemical engineer, which, I understand, is his profession. This is supported, in my view, by the balance of the sentence in Tucker, L. J.'s judgment, from which I have already quoted. That sentence concludes ". . . although, no doubt, he is perfectly entitled to use the knowledge that he has acquired in this class of case in order to understand and test the evidence of the witnesses who are called before him".

The appellant also attacked the Commissioner's reference to chemical literature as constituting a failure to observe the principle of natural justice which was applied by the House of Lords in *Ridge v. Baldwin*[2]. Possibly, the most favourable statement of the rule in question, from the point of view of the appellant, is the statement of Lord Parmoor in *De Verteuil v. Knaggs*[3], where he said that the person who there had the duty of making a decision had ". . . a duty of giving to any person against whom the complaint is made a fair opportunity to make any relevant statement which he may

[1] [1947] 2 All E.R. 556.

[2] [1963] 2 All E.R. 66.

[3] [1918] A.C. 557.

desire to bring forward and a fair opportunity to correct or controvert any relevant statement brought forward to his prejudice". I doubt very much that this rule operates in any way in this case in favour of the appellant. In the first place, the issue in this case was whether there was "good reason" why a licence should not be granted to the respondent and the appellant was in the position of making allegations with regard thereto to the prejudice of the respondent[1]. In the second place, I have not been able to find any case in which the rule has been applied so as to require that the person making a complaint against someone else, or indeed the person against whom a complaint has been made, be given an opportunity of seeing and commenting on all the material ultimately placed before the officer having to make the decision. (In *De Verteuil v. Knaggs, supra,* the rule was held to have been observed by reason of the fact that the person against whom the complaint was made had been informed of the substantive allegations made against him and was given an opportunity of answering them.) In any event, in my view, the rule does not detract from the right of the tribunal to "understand and test" the evidence of the witnesses having regard to the general body of knowledge available to the tribunal concerning the technical subject to which the evidence relates.

The second branch of the appeal against the Commissioner's decision has to do with the amount of the royalty.

The sole reference to royalty in the appellant's Counter-statement was paragraph 15 which reads as follows:

> If, contrary to the submission herein, a licence is granted to the applicant, the royalty paid thereon should be commensurate with the maintenance of research incentive and with the importance of both the process and the substance involved.

At the hearing before the Commissioner, the appellant put in a large volume of evidence concerning the cost of the research operations carried on by the La Roche group and relating such costs to the total volume of sales of patented drugs by those companies. Evidence was also given designed to show that this group of companies did not make unreasonable profits on its sales of patented drugs. There was also evidence establishing the importance of the drug

[1] It would seem that, having formed a tentative appraisal of the appellant's evidence, the Commissioner turned to the textbooks to make sure that there was nothing there to invalidate his conclusion. This process does not involve an "allegation" to the prejudice of either party.

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Librium to the general public. No evidence was offered as to the amount of royalty for which a licence would be granted by a willing patentee to a person willing to enter into a contract for such a licence. It appears, from the evidence that it is improbable that any meaningful evidence could have been found on that point.

Evidence was put in that was designed to show that the annual research costs of the La Roche group amounted to 17.8 per cent of annual sales by those companies of patented drugs and that a reasonable return on the capital invested in those research activities amounted to 7.12 per cent of such annual sales of patented drugs. Evidence was further put in designed to show that the medical information operations of the Canadian company (i.e., the appellant) amounted to 39 per cent of the appellant's sales of patented drugs and that a reasonable return on its investment of capital in medical information services would amount to 12.5 per cent of such sales. The total of these four items is 76.4 per cent. Evidence was also put in to show that the appellant's average selling price of the drug in Canada was $4,600 per kilo. The appellant contended before the Commissioner, on the basis of this evidence, that the royalty should be 76.4 per cent of $4,600 per kilo, or $3,528.37 per kilo.

The Commissioner dealt with the question of royalty in that part of his reasons reading 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. 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.

My understanding of the argument of counsel for the appellant in this Court with reference to royalty, while it was put in various ways at different times during the course of argument, may be summarized as follows:

(*a*) the La Roche group, like other groups of companies in the same class of business, carry on continuously a very expensive research programme and the general experience is that it is only once in ten to twenty years that such a research programme results in a discovery of a new drug which is of sufficient general importance in the world to enable the companies to recoup research expenses—such a drug is known as a "winner";

(*b*) if such a group of companies is going to be able to continue the sort of research programme that is calculated to produce new important drug discoveries in the future, they must be able to sell a winner at a high enough price to enable them to recoup the research expenses of their whole research operation;

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(c) mere discovery of a new and important drug is not sufficient to give to the public the advantage of its therapeutic value—as long as such a drug is in a state of development, it is essential to provide medical information services by means of which

(i) doctors throughout the world are supplied with information concerning the drug so that they can appreciate its value as a new drug and know how to use it for the benefit of their patients, and

(ii) a continuing service is provided of gathering information from all the doctors in the world who are using the drug, co-relating the information and making available to the doctors of the world the conclusions drawn therefrom;

(d) before the La Roche group can obtain any reimbursement of its research costs out of the price for which it sells its winners, it must first recover the cost of the aforesaid medical information services, and of course, before it can recover the cost of the medical information services, it must recover the actual cost of producing, packaging and distributing the drug,

(e) out of each dollar of sales of the drug, the company must therefore first recover an appropriate amount in respect of its costs of medical information and have left over 24.92 per cent. to apply in respect of its research costs,

(f) as the demand for the drug is inelastic the appellant, for all practical purposes, will lose sales in Canada substantially equal to those made by the respondent after it gets into production and starts to distribute the drug,

(g) as it is by virtue of the compulsory licence that the appellant will lose that volume of sales and consequently the ability to obtain recoupment of its medical information costs and research costs, the royalty paid in respect of the compulsory licence should be equal to the amount of such costs that the appellant will not be able to recover by the sales so lost to it, or in other words, 76.4 per cent. of the appellant's selling price in Canada of $4,600 per kilo[1].

[1] While I do not return to the accuracy or cogency of the individual statements and arguments in this review of the appellant's position concerning royalty, I must not be taken as having accepted their accuracy or cogency.

The appellant takes the position in effect that, if it is not allowed a royalty of 76.4 per cent. on its wholesale price of $4,600 per kilo, it will not have a royalty "commensurate with the maintenance of research incentive" as is required by the decision of the Supreme Court of Canada in *Park, Davis & Co. Ltd. v. Fine Chemicals of Canada, Ltd.*[1]

The statutory rule which has to be applied is that part of subsection (3) of section 41 of the *Patent Act* which reads as follows:

> . . . In settling . . . the amount of royalty or other consideration payable the Commissioner shall have regard to 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.[2]

Where, under section 19 of the *Patent Act*, the Government has a statutory right to use a patented invention and the Commissioner's duty is to fix "a reasonable compensation for the use thereof", such reasonable compensation is to be determined by what, under normal conditions in the market, would be paid to a willing licensor by a willing licensee bargaining on equal terms. See *The King v. Irving Air Chute Inc.*[3] Presumably, the same rule would apply in determining royalty or other consideration under subsection (3) of section 41 if the portion of that subsection that I have just quoted did not require the Commissioner to "have regard" to "the desirability" of making the medicine available at the lowest possible price "consistent with . . . due reward for the research . . ." The general purport of this rule is, in my view, that the royalty or other consideration is to be less than it otherwise would be if the only rule to be applied were the rule in the *Irving Air Chute* case. Only

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

[2] Counsel for the appellant rested much of his argument regarding the royalty that should have been fixed upon *J. R. Geigy S.A.'s Patent* [1964] 141 R P.C. 391. Whether or not the decision in that case determines how a direction to fix terms so as to make a patented medicine available to the public at the lowest prices consistent with the "patentees'" deriving "a reasonable advantage from their patent rights" must be applied on facts such as those in this case, I cannot agree that it determines how royalty or other consideration must be fixed when the direction is to have regard to the desirability of making the patented drug available to the public at the lowest possible price consistent with giving to the "inventor" due "reward for the research leading to the invention". In any event, there does not appear to have been any controversy in the *Geigy* case as to the method to be followed or any adjudication with regard thereto. The parties differed as to certain details in the application of the method followed by each of them and the adjudication concerned such details.

[3] [1949] S C.R 613.

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by making the royalty less than it otherwise would be could the Commissioner be said to have regard to the desirability of making the medicine available to the public at the lowest possible price. The general tendency of the rule must, therefore, be to require that the Commissioner have regard to the desirability of making the royalty or other consideration less than market price. However, there is a qualification upon this direction that, in having regard to the desirability of making the price as low as possible, the Commissioner must not make the royalty or other consideration so low that it is not consistent with giving to the inventor due reward for the research leading to the invention. The result of the statutory direction, for practical purposes, as interpreted by the Supreme Court of Canada in *Parke, Davis & Co. v. Fine Chemicals of Canada, Ltd.*, *supra,* is that the royalty is to be "commensurate with the maintenance of research incentive and the importance of both process and substance".

On the one hand, as I see it, there is a ceiling on the royalty or other consideration to be determined by reference to the theoretical market place and, on the other hand, there is a floor, beneath which it must not be reduced from that ceiling, in that it is not to be reduced from market value to an amount that is not "commensurate with the maintenance of research incentive and the importance of both process and substance".

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. I cannot accept the appellant's proposition that the appellant is entitled, in effect, to that proportion of its wholesale selling price of the sales that it will lose by virtue of the compulsory licence that medical information costs and research costs are of the total sale price of all its sales of patented drugs. As I read section 41(3) of the *Patent Act,* it does not contemplate or require any such result. What the statute says is that the Commissioner shall "have regard" to "the desirability" of a certain result and this has been interpreted by the Supreme Court of Canada to mean that the Commissioner shall fix a royalty "commensurate

with the maintenance of research incentive and the importance of both process and substance." In my view, this is not something that can be determined by applying some arithmetical rule to ascertainable facts. Relevant facts must be taken into account but, when they are ascertained as well as they can be, there is a necessity for the exercise of judgment just as there is whenever any person or authority has a responsibility of laying down a general rule for the future designed to accomplish a certain result. The problem is not unlike the problem facing Parliament or some branch of the executive when it has to fix remuneration for persons in the service of the state, such as cabinet ministers, members of Parliament, judges, soldiers or civil servants. In fixing such remuneration, regard must be had to the necessity of making the offices or positions attractive to persons of the requisite ability and experience and to the importance of the duties to be performed by the respective officers or functionaries. It is important, in making such a decision, to know what it costs a person to accept such an office or position (i.e., what alternative earnings in private industry he will probably forgo by accepting the offer) and it is necessary to make an evaluation of the importance of the particular office or position to the state. When, however, such facts have been evaluated as well as may be, and ordinarily this can only be done in a very general way, the person or authority responsible for making the decision must, of necessity, make a more or less arbitrary decision which, while it takes the relevant facts into account, must reflect his judgment as to what amount will meet the requirements of the situation. Similarly, in fixing the royalty or other consideration under section 41(3), it is not right to attribute, with some show of mathematical precision, a part of research cost, or of other costs, to each part of the product manufactured pursuant to a particular invention, and to conclude that, as a matter of law, that is the royalty that must be awarded. On the other hand, information as to what research in the particular field costs is a relevant factor to be taken into consideration just as is information as to the importance of the particular invention. Having those factors in mind, however, the Commissioner is nevertheless faced with the task of making a more or less arbitrary decision reflecting his judgment as to what amount of royalty or other consideration is "commensurate with the

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maintenance of research incentive and the importance of both process and substance".

I therefore reject the appellant's argument that the royalties should be $3,528.37 per kilo and I also reject his argument as to the manner in which the royalties must, as a matter of law, be computed. (If I accepted his argument that the royalties must, as a matter of law, be computed in that manner, I would refer the matter back to the Commissioner for a new hearing during which the Commissioner and the parties would be directing their minds to the issues of fact raised by that method.)

Having regard to the decision of the Supreme Court of Canada in *Parke, Davis & Co. Ltd. v. Fine Chemicals of Canada, Ltd. supra,* I must nevertheless consider whether the evidence before the Commissioner was adequate to enable him intelligently to arrive at a royalty which would give due weight to all the relevant considerations, for, if it was not, it would appear that the matter must be referred back to the Commissioner for reconsideration.

In this case, it is to be noted, that the appellant gave much consideration and thought to the preparation of a case, which it placed before the Commissioner, concerning the amount of the royalty and, while I have rejected the appellant's submissions as to the conclusions to be drawn from that evidence, nevertheless that evidence was calculated to give the Commissioner a very clear idea as to the general burden of research costs on the drug industry and, particularly, on the La Roche group.[1] That evidence was also calculated to give the Commissioner a clear idea as to the value and importance of the drug which is the subject matter of the patent and made it clear that it is practically impossible to segregate out the costs of the "research leading to the invention" of this particular drug. Having regard to the fact that there is no question of the royalty as fixed by the Commissioner being too high, I find it very difficult to envisage what further evidence the parties could place before the Commissioner if the matter were referred back to him for further consideration. As the appellant made no submission in this Court that the evidence before the Commissioner was inadequate to enable

[1] I am relieved, by a concession made by the respondent on the facts of this case, from having to decide whether such costs are relevant when it appears clear that neither the patentee (the appellant) nor the inventor bore any part of the costs "leading to the invention".

him to determine the compensation or royalty and as I cannot conceive of any other class or type of evidence that might have been placed before the Commissioner, I do not think that I am justified in referring the matter back to the Commissioner for a further hearing as to the quantum of royalty or other consideration. In this connection, I also have in mind that portion of Mr. Justice Rand's judgment in *Parke, Davis & Co. Ltd. v. Fine Chemicals of Canada, Ltd. supra,* at page 223, where he said:

> . . . Once the Commissioner decides the case to be one for licence, it lies with the patentee, by whatever means are open to him, to present substantial support for the royalty which he claims; in the absence of that he will be in a weak position to complain of any holding by the Commissioner.

The appellant here did not have an opportunity to establish the amount of the royalty *after* the Commissioner had decided that the case was one for a licence. However, the appellant was prepared to put in his case before the Commissioner on the question of royalty at the same time as it put in its case on its opposition to the grant of a licence and it was, at that time, afforded full opportunity to do so. That being so, I am of opinion that, to use Mr. Justice Rand's words, the appellant is "in a weak position" to complain of the royalty fixed by the Commissioner on the ground of the adequacy of the material before the Commissioner.

That, however, does not complete my task concerning the question of royalty. Throughout the consideration of this appeal, I had difficulty with that part of the Commissioner's reasons where he speaks of "the principle I have established of fixing the royalty on the sale price of the bulk material" as not having been disturbed by the Courts. I do not understand the intrinsic merit of a principle that requires that the royalty be fixed on the sale price of the bulk material. The royalty should be so fixed that it complies with the rule in the last half of section 41(3). To achieve that result, presumably, a lower percentage rate would have to be chosen if a formula were adopted that called for application of a percentage rate to the wholesale price of the product in dosage form than that which would have to be chosen if a formula were adopted that called for application of a percentage rate to the sale price of the bulk material. I should have thought that there is nothing intrinsically right or wrong with either type of

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formula[1] and I do not understand that Mr. Justice Martland in the case of *Parke, Davis & Co. Ltd. v. Fine Chemicals Ltd.* gave approval to any such "principle" as that suggested by the Commissioner. On the contrary, there is, in my view, a strong indication in that judgment that, on facts such as were present in that case and are present in this case, the real monetary indication of the value of the patented medicine is in the price at which it sells in dosage form. As I understand the facts, the medicine is distributed to the public in dosage form and not in the bulk form, which, so far as its use as a medicine is concerned, is merely an intermediate stage in the creation of a merchantable form of the product.[2] 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.[3]

Rather than send the matter back to the Commissioner and put the parties to the expense of a further hearing, I have come to the conclusion that I should allow the appeal and change the royalty as fixed by the Commissioner to a royalty of 15 per cent. of the licensee's selling price when is sells the patented drug in dosage form to persons with whom it is dealing at arm's length. I do this, not only because I have the impression that the Commissioner would have so fixed the royalty himself if he had not thought that he was constrained by principle to choose the lower base but, more particularly, because, giving the matter the best consideration I can, and having regard to my understanding of the correct approach as set out above, it is my judgment of a consideration that is "commensurate

[1] cf. *The King v. Irving Air Chute Inc.* [1949] S.C.R. 613 at pages 625, 629 and 635.

[2] It will be recalled that the application stated that the respondent expected to market the substance "in tablets or similar form".

[3] cf *Colonial Fastener Co. Ltd. v. Lightning Fastener Co. Ltd.* [1937] S.C.R. 36 at pages 40-1.

with the maintenance of research incentive and the importance of both process and substance" having regard to the evidence. (In reaching this conclusion, I have in mind that this allows a much larger incentive for research than the appellant company, which does no research, is required to contribute to the other members of the La Roche group that do the research. It buys bulk material that has a cost of production of from $50 to $100 per kilo for $294.87 per kilo. This means a contribution of not more than $150 per kilo for research although income tax considerations, I should have thought, would keep the inter-company price reasonably realistic.)

In making this change in the royalty formula as fixed by the Commissioner, I have no reason to think that it is a very substantial change. There is no evidence as to the price for which the material would sell in bulk but we do know that it would probably be sold by the respondent in dosage form for $3,500 per kilo and that the cost of converting from bulk form to dosage form is only $310 per kilo. There is no reason to think that the respondent would sell in bulk form at a price very much less than it could get for it after converting it to dosage form at such a relatively minor cost.[1]

The third branch of the appeal relates to the terms of the various provisions in the licence as settled by the Commissioner.

It was apparent to both parties that the paragraph numbered 1 in the licence requires some change in wording in order to carry out the obvious intention of the Commissioner. That paragraph reads as follows:

> The Licensee shall pay to Hoffmann-La Roche Limited a royalty of fifteen percent (15%) on its net selling price to others of the active product in its crude form, prepared or produced pursuant to this licence and sold by it.
>
> The term "net selling price" employed herein shall mean the price actually received by the Licensee from the sale of the product prepared or produced by it pursuant to this licence, less any allowances for returns and any sales tax or other tax forming part of the sale of such product and required to be remitted by the Licensee to any taxation authority.

As so framed, paragraph 1 is deficient in that it only provides for payment of royalty on the product when

[1] It may be that the respondent will sell some in crude form to other drug companies who sell to retail druggists. In such case, it might sell at a difference in price that would reflect not only the cost of capsulating, packaging, etc., but also the cost of selling to retailers as opposed to merely selling to wholesalers.

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actually sold in the crude form (i.e., in bulk) and also because it contemplates computation of the royalty by reference to the price at which it is sold in the crude form even when it is sold to a person with whom the licensee does not deal at arm's length.

I may say that the Commissioner invited the parties to endeavour to agree on the terms of the licence and the appellant took the position that it was not prepared to attempt to reach any agreement with the respondent concerning such terms. Similarly, I invited the parties to endeavour to agree on the terms of a revision of paragraph 1 on the assumption that the royalty award would be unchanged. In the absence of any agreement by counsel for the parties, I have, tentatively, come to the conclusion that the paragraph might be revised to read somewhat as follows:

1. (*a*) The licensee shall pay to Hoffmann-La Roche Limited, in respect of the patented product that is prepared or produced pursuant to this licence and sold by it in the pharmaceutical dosage form to a person or persons with whom it was dealing at arm's length, fifteen per cent. (15%) on the net selling price at which it was so sold.

(*b*) The term "net selling price" employed in this paragraph means the price actually received by the licensee from the sale of the product prepared or produced by it pursuant to this licence, less any allowances for returns and any sales tax or other tax forming part of the sale of such product and required to be remitted by the licensee to any taxation authority.

(*c*) The licensee shall pay to Hoffmann-La Roche Limited, in respect of the patented product that is prepared or produced pursuant to this licence to which subparagraph (*a*) does not apply fifteen per cent. (15%) of what would be the net selling price if the product had been sold in the pharmaceutical dosage form by the licensee to a person with whom it was dealing at arm's length.

If this revision of paragraph 1 is not acceptable to either or both of the parties, the matter may be spoken to before the minutes of judgment are settled.

With reference to the other terms of the licence, the appellant made a number of submissions as to changes which should be made therein but, in each case, the submission amounted to a request that I interfere with the substantive terms as settled by the Commissioner for no good reason other than that the interests of the appellant would be better served if the change were made and I have not been able to detect any good reason why I should interfere with the terms as settled by the Commissioner. However, counsel for the respondent did indicate that the

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respondent was prepared to have a term added to the licence by which the licensee would be required, upon request by the appellant, to advise the patentee promptly whether or not it had sold the licensed product to a named purchaser and if so the date and quantity of such sale. If the appellant elects to have such a term added to the licence, a term may be included in the minutes of judgment amending the licence accordingly.

The appeal will be allowed to the extent of making the indicated changes in the licence as granted by the Commissioner. Subject thereto the appeal is dismissed. As the appellant has been completely unsuccessful on the first branch of the appeal, has been unsuccessful in the main portion of its appeal as to royalty (only being successful to the extent of a relatively small increase based on quite a different principle from that which it advocated) and has not obtained anything on the third branch of the appeal that it would not have been able to obtain had it accepted the Commissioner's invitation to cooperate in setting the terms of the licence, the appellant will pay to the respondent 90 per cent, of its costs of the appeal.

Judgment accordingly.