

BETWEEN:

HOFFMANN-LA ROCHE LIMITED APPELLANT;

AND

DELMAR CHEMICALS LIMITED RESPONDENT.

Ottawa
1967
May 2-4
May 16

Patents—Compulsory licence—Production of medicine—Confirmation of licence on appeal—Referral back of royalty—New scale of royalty fixed by Commissioner—Appeal—Whether rate manifestly wrong—Effect of prior appeal—Patent Act, s. 41(3).

On March 26th 1963 the Commissioner of Patents settled and issued to respondent a licence for the compulsory use of appellant's patented process in the production of the medicine chlordiazepoxide at a royalty of 12½% on the sales price of the bulk product effective from February 8th 1963, on which date he had made his written decision to grant a licence on specified terms. On an appeal from the Commissioner's decision this Court on July 23rd 1964 confirmed the licence but referred the royalty back to the Commissioner ([1965] 1 Ex. C.R. 611). On June 20th 1966 the Commissioner again fixed the royalty at the 12½% rate from February 8th 1963 to December 31st 1965 and thereafter at 15%.

Held, an appeal from the Commissioner's decision must be dismissed.

1. As the 15% rate fixed by the Commissioner from January 1st 1966 was the same rate and calculated on the same basis as the rate fixed by him and affirmed by the Supreme Court of Canada in the *Bell-Craig* case in respect of the same invention ([1966] S.C.R. 313) it could not be said on the material before this court (which in the main paralleled that in the *Bell-Craig* case) that such royalty was manifestly wrong. It is desirable that the same royalty be fixed for all licensees under the same patent. Nor did anything in the material before the court or in the nature of the case indicate that the royalty of 12½% for the earlier period was manifestly wrong. The appropriate royalty could not be determined with mathematical nicety; the Commissioner must have set the lower rate for the earlier period as an incentive to effective competition.
2. On the facts the licence was effective from February 8th 1963 and the judgment of this court of July 23rd 1964 confirming the licence but referring the royalty back to the Commissioner did not render the licence void *ab initio*; it remained valid subject to the payment of such royalty as might later be fixed by the Commissioner. *Hoffmann-*

1967
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 HOFFMANN-
 LA ROCHE
 LTD.
 v.
 DELMAR
 CHEMICALS
 LTD.

La Roche & Co. and Geigy v. Inter-Continental Pharmaceuticals [1965] R.P.C. 226; *Geigy S.A.'s Patent* [1966] R.P.C. 250; *Hoffmann-La Roche v. Delmar Chemicals* [1966] Ex. C.R. 713, distinguished.

APPEAL from Commissioner of Patents.

R. G. McClenahan for appellant.

Donald J. Wright, Q.C. for respondent.

THURLOW J.:—This is an appeal from a decision of the Commissioner of Patents made on June 20, 1966 by which he fixed the royalty payable by the respondent under a licence granted under s. 41(3) of the *Patent Act*¹. The licence authorizes the respondent to use the invention of Canadian Patent No. 612,497, which relates to a substance known as chlordiazepoxide, for the purpose of the preparation or production of medicine but not otherwise and to sell the resulting product. The document as settled is dated March 26, 1963 but purports to require the payment of royalty on sales of the product made after February 6, 1963, the date of a written decision by the Commissioner to grant a licence with effect from that date. The royalty payable by the respondent was originally set at 12½ per cent on the respondent's net selling price to others of the active product in its crude form but on July 23, 1964 this Court, while confirming the decision of the Commissioner to grant the licence, allowed the appellant's appeal in respect of the royalty to be paid by the respondent and referred that question back to the Commissioner for consideration². A further appeal from the decision to grant the licence was dismissed by the Supreme Court of Canada on April 9, 1965³.

Proceedings to have royalty reconsidered began in August 1965 when the appellant's solicitors forwarded to the Commissioner and to the respondent's solicitors copies of a lengthy affidavit by Robert Hunter, a chartered accountant, which was represented in a letter which accompanied it as comprising the appellant's written royalty statement. At the same time the appellant requested an "opportunity of replying to the licensee's statement and of presenting oral evidence and/or oral argument at a hearing or at least the opportunity of cross-examining the licensee on the royalty issue". Some correspondence ensued which indicates that

¹ R.S.C. 1952, c. 203.

² [1965] 1 Ex. C.R. 611.

³ [1965] S.C.R. 575.

the Commissioner decided to defer dealing with the matter pending the judgment of the Supreme Court of Canada in the *Bell-Craig*⁴ appeal, which also related to a licence under the same patent, and ultimately on January 27, 1966 the respondent's solicitors forwarded to the Commissioner a copy of the reasons for judgment of the Supreme Court in that case and a letter which set out their submissions as to what the royalty should be in this case and in the case of a licence under another patent held by the appellant relating to an intermediate substance used in making chlor-diazepoxide and suggested that it would be helpful if the Commissioner could promptly deal with the matter. Thereafter without holding any hearing or obtaining any further written information or argument from either party the Commissioner on June 20, 1966 amended the licence so as in effect to confirm the royalty at 12½ per cent on the sale price of the bulk product from the time of the granting of the licence to the end of the year 1965 and to set a royalty of 15 per cent on the sale price of the bulk product thereafter. No reasons were given for this decision.

The present appeal was thereupon brought.

The grounds for the appeal as stated in the notice are that the Commissioner proceeded on a wrong principle or was manifestly wrong on the evidence in that:

1. he erred in directing that the new rate of royalty take effect with the half-yearly report due thirty days after June 30, 1966, thereby applying the new royalty as and from January 1, 1966;
2. he erred in providing that "previous half-yearly computations" and "previous payments shall not be affected" thereby implying
 - (a) that the original royalty as fixed by the Commissioner of Patents and as set aside by this Court remained in effect from July 23, 1964 until December 31, 1965; and
 - (b) that the licence granted to the Respondent dated March 26, 1963 remained in effect from July 23, 1964 until June 20, 1966;
3. he erred in fixing a royalty which on the evidence before him, is manifestly low.

1967
 HOFFMANN-
 LA ROCHE
 LTD.
 v.
 DELMAR
 CHEMICALS
 LTD.
 Thurlow J.

⁴ *Hoffmann-La Roche Limited v. Bell-Craig Pharmaceuticals Division of L. D. Craig Limited* [1966] S.C.R. 313.

1967

HOFFMANN-
LA ROCHE
LTD.
v.
DELMAR
CHEMICALS
LTD.

Thurlow J.
—

In the course of the hearing it was agreed by counsel that the material before the Court on this appeal should consist of the material in the record as certified and any additional material contained in the Commissioner's file or in the case on appeal to the Supreme Court.

It will be convenient to deal first with the submission that the royalty as fixed is manifestly low. It should be noted, at this point, that no complaint was put forward in the notice of appeal that the material before the Commissioner was inadequate to enable him intelligently to arrive at a royalty which would give due weight to all relevant considerations, and that, while counsel for the appellant pointed out that the respondent had adduced no evidence—as had been done in the *Bell-Craig* case, which, in his submission, differentiated that case from this—he also stated that from the point of view of the appellant, (on whom the duty rested of adducing material to support the royalty demanded—*vide* Rand J. in *Parke, Davis & Company v. Fine Chemicals*⁵ at page 223) the material before the Commissioner was sufficient to arrive at a correct royalty. He contended, however, that the royalty as set by the Commissioner was manifestly too low since, on the basis of Mr. Hunter's affidavit, even without taking the costs of gaining and maintaining medical acceptance of the drug into account there would be no incentive to research if the appellant received less than \$740 per kilo of the substance, and that a royalty of \$2,958.67 per kilo was required to maintain research incentive which included the promotion and maintenance of such medical acceptance of the drug, whereas on the basis of 15 per cent of the respondent's selling price of about \$450 per kilo for the crude material the royalty amounts to only about \$67.50 per kilo. It was also said that it could be deduced from the sales figures in evidence that the Canadian market for the drug amounted to about 450 kilos per year, which suggests that if the licensee captured the whole market the total annual royalties would be in the vicinity of \$30,000. This, however, would be an annual amount and would be for the Canadian market alone which it was suggested would amount to about 3 per cent of the world market open to the patentee and the other La Roche companies with which it is affli-

⁵ [1959] S.C.R. 219.

ated. Projecting this over a seventeen year period indicates the possibility of royalties of about \$500,000 from the Canadian market and suggests that on the same royalty basis the whole market might conceivably produce the not inconsiderable total of about \$17,000,000 over the same seventeen year period.

1967
 HOFFMANN-
 LA ROCHE
 LTD.
 v.
 DELMAR
 CHEMICALS
 LTD.

Thurflow J.
 ———

Insofar as it does not consist of opinions and argumentation the information in the Hunter affidavit appears in the main to parallel that which Mr. Hunter gave orally in the *Bell-Craig* case⁶. Among other things it is stated that the annual research costs of the La Roche Companies for the preceding ten year period amounted to 16.30 per cent of annual sales by those companies of patented drugs, that a reasonable return (30 per cent before income taxes) on the capital employed in those research activities amounted to 9.78 per cent of annual sales, that the costs of promoting, establishing and maintaining acceptance of the drug by prescribing physicians amounted to 31.50 per cent of annual sales and that a similar reasonable return on the capital used for this purpose amounted to 7.56 per cent of annual sales. The total of these four items is 65.14 per cent which, on being applied to \$4,542, which was said to be the La Roche average selling price per kilo of the drug in capsulated form, yields the figure of \$2,958.67 per kilo already mentioned as the royalty required to maintain research incentive. It was also stated that the appellant's promotional efforts had brought about a widespread acceptance of the substance and that but for such efforts and expenditure chlordiazepoxide would have been and remained a laboratory curiosity. There was no evidence of what the research leading to the particular invention amounted to but a number of paragraphs of the affidavit were devoted to explaining the impracticability of endeavouring to make such a calculation and that such a calculation if made would be unrealistic and unreliable.

In reaching his conclusion the Commissioner also had before him the decision of the Supreme Court in the *Bell-Craig* case in which his own reasoning and finding had been preferred to that of this Court. In that case, as I read his decision, the Commissioner had rejected the appellant's

⁶ See the description of the evidence put before the Commissioner in that case in [1965] 2 Ex. C.R. at pp. 285-286.

1967
 HOFFMANN-
 LA ROCHE
 LTD.
 v.
 DELMAR
 CHEMICALS
 LTD.
 Thurlow J.

calculation of royalty at \$3,528.37 per kilo as being "based on the cost of the complete and sustained research programme 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 capsulated, sealed and labelled ready for patients consumption" which factors and calculations he regarded as irrelevant. He then proceeded:

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.

This in my view expressed his decision and the basis for it.

In the Supreme Court after reviewing the Commissioner's reasons and those of the President of this Court Abbott J., for the Court said at page 319:

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

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

The royalty payable by a licensee for using a patented process is one of his costs of production. That being so there is an obvious justification, in cases where a percentage royalty is decided upon, for using as a base, the sale price of the bulk material produced by the patented process, rather than a base which reflects a variety of packaging, distribution, promotional, sales and other like expenses. In my opinion on the evidence before him, the Commissioner was entitled to use the base which he did in establishing the royalty.

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

In the present case though the Commissioner gave no reasons for his finding I think it is apparent that he again rejected the research and promotional calculations offered by Mr. Hunter in his affidavit. To my mind it is not surprising that he should have done so as these calculations were not based on the cost of the research leading to the particular invention or on the cost of production of the substance plus a reasonable profit thereon. It is clear, moreover, that the effect of requiring payment of the royalty so calculated would be to stifle any effective competition by the respondent since the affidavit goes on to state that other producers such as the respondent and others who had applied for licences could not produce the substance as economically as the La Roche companies. It also seems clear that, since the invention of the process, which alone is the subject of the licencing, was complete when the usefulness and potentiality of the substance had been discovered, expenditures subsequently incurred in the promotion of the drug could not be regarded as part of the research leading to the invention. I would, moreover, infer that the Commissioner fixed the royalty on the basis of his experience and the wide acceptance of the product as he had done in the *Bell-Craig* case. Whether this can be said to have been his reasoning or not, it is a train of reasoning that, as I see it, was open to him on the basis of the judgment of the Supreme Court in the *Bell-Craig* case and as both the basis of calculation and the 15 per cent rate which he fixed for the period from January 1, 1966 are the same and are in respect of the same invention as in the *Bell-Craig* case it seems to me to follow that on the material before the Court the royalty so set cannot be said to be manifestly wrong. I may add that I should have thought anyway that in general it is desirable and proper in the interest of even competition for the Commissioner to award the same royalty in the case of all licensees under the same patent. Insofar as the Commissioner set the royalty at 15 per cent, therefore, I can see no valid reason for disturbing his finding.

The point is, however, taken that there was no basis in the evidence for making any distinction between the time prior to January 1, 1966 and that subsequent thereto and that the 12½ per cent royalty which the Commissioner confirmed in respect of the earlier period could not be justified.

1967

HOFFMANN-
LA ROCHE
LTD.v.
DELMAR
CHEMICALS
LTD.

Thurlow J.

1967
 HOFFMANN-
 LA ROCHE
 LTD.
 v.
 DELMAR
 CHEMICALS
 LTD.
 Thurlow J.

As I see it, however, the problem of setting a royalty in a situation such as this is not one that can be solved with mathematical nicety but must inevitably be determined to a great extent by the application of the principle of the "broad axe". As the Commissioner in fixing the royalty at 15 per cent on June 20, 1966, made that rate retroactive to January 1, 1966, but confirmed it at 12½ per cent for the earlier period, it is apparent that he must have addressed his mind to the question of what amount of royalty would be appropriate for that earlier period and he must have thought that for the first three years or thereabouts of the respondent's use of the invention a royalty of 12½ per cent would be adequate. In my opinion, there is nothing in the material before the Court or in the nature of the case which would require the royalty to be set at exactly the same rate throughout the duration of the licence, and it is not inconceivable that the Commissioner may have regarded it as desirable for the purpose of maintaining the respondent's interest in operating under the licence and providing effective competition that it should enjoy the lower rate for the earlier period, which was a starting up period and had already passed. In my view therefore it has not been shown that the Commissioner's estimate of 12½ per cent as an adequate royalty for the period prior to January 1, 1966, was manifestly wrong.

The other two grounds stated in the notice of appeal may be dealt with together since a single submission was made with respect to both. The point taken was that the effect of the judgment of this Court allowing the earlier appeal on the question of royalty was to set aside the Commissioner's decision thereon, that the effect of this in turn was to nullify the licence as well until the royalty was again fixed by the Commissioner on June 20, 1966, and that his setting of a royalty with respect to any period prior to that date was retrospective and therefore invalid.

In support of his contention that the effect of the judgment allowing the appeal was to set aside the Commissioner's original determination of the royalty counsel cited *Powley v. Whitehead*⁷, *Sherk v. Evans*⁸ and *Boal v. Weir*⁹

⁷ (1859) 16 U.C.Q.B. 589.

⁸ (1895) 22 O.A.R. 242.

⁹ (1922) 22 O.W.N. 129.

but I do not find in any of these assistance in determining the effect of the judgment in question. Nor have I been able to find any case that does afford assistance on the point. The judgment as settled adjudged that the decision of the Commissioner to grant the licence should be affirmed and that on the question of royalty the appeal should be allowed and that that question should be referred back to the Commissioner for consideration. Nowhere did the order expressly purport to amend or set aside the licence or any provision of it. Nor was it determined that the royalty as fixed in the licence was wrong. In these circumstances I am inclined to view the effect of the judgment as being a confirmation of the licence as granted but subject to a direction to the Commissioner to reconsider the question of royalty and to make such changes therein as might be indicated after considering any material the parties might see fit to put before him. Any other interpretation would involve holding either that the licence itself to use the invention became invalid in spite of the affirmance of the decision to grant it or that it remained in effect with no requirement that the licensee pay anything therefor until the royalty was later settled. On the other hand the interpretation which I am inclined to adopt would maintain the efficacy of the licence to use the invention and require payment of royalty as well pending the review and reconsideration of the royalty directed by the Court. However, as this point is not free from doubt I shall also express my view of the effect of the judgment on the licence itself on the assumption that the judgment should be treated as having set aside the Commissioner's original fixation of the royalty.

On this basis the appellant's contention was that when the royalty became unsettled by the order of this Court the licence itself became void *ab initio* since there could be no licence until so fundamental a provision had been determined and fixed. On this point counsel cited *Hoffmann-La Roche & Co. and Geigy v. Inter-Continental Pharmaceuticals*¹⁰, *Geigy S.A.'s Patent*¹¹ and *Hoffmann-La Roche v. Delmar Chemicals*¹² and he also relied on analogy to cases in which transactions purporting to be leases or contracts have been held to be incomplete and therefore not binding

1967
 HOFFMANN-
 LA ROCHE
 LTD.
 v.
 DELMAR
 CHEMICALS
 LTD.
 Thurlow J.

¹⁰ [1965] R.P.C. 226.

¹¹ [1966] R.P.C. 250.

¹² [1966] Ex. C.R. 713.

1967

HOFFMANN-
LA ROCHE
LTD.

v.

DELMAR
CHEMICALS
LTD.

Thurlow J.

on the parties because some material term remained unsettled and incapable of being settled save by agreement of the parties.

In my opinion neither of the two English cases which I have mentioned is in point. The relevant point decided in the earlier of these cases was that under the English provision comparable to section 41(3) the Comptroller had no power to grant a licence with retrospective effect. That may I think be taken to be the law under section 41(3) as well. In the later English case it was held on the basis of wording in the English section, which is not in section 41(3), that a licence under the English section is not effective until the Comptroller grants it "on such terms as he thinks fit" and that accordingly where material terms have never been settled the grant is not complete. This principle is not necessarily applicable in determining when a licence becomes effective under s. 41(3), where the language used is different, but in any event the question here is not when a licence came into effect but what effect an order of this Court, which unsettled a material term, had upon a licence which had been complete and in effect at an earlier stage. The case of *Hoffmann-La Roche v. Delmar Chemicals*¹³ in this Court is also inapplicable for the same reason since there the problem was simply one of whether the stage had been reached when a decision to grant a licence had been made from which there was a right of appeal. I do not think, moreover, that the analogy to incomplete contracts or leases assists the appellant. On the contrary it seems to me that the present situation is more closely, though not by any means perfectly, analogous to one where parties have made a contract but in it have left a particular term to be settled by some third party or by some procedure by which the term can be rendered certain¹⁴. The analogy to this kind of case appears to me to lend support to the view that the licence to use the invention remained in effect but upon terms requiring payment of such royalty as the Commissioner should thereafter fix.

It may be well to recall at this point that the proceeding in which the judgment in question was rendered was an

¹³ [1966] Ex. C.R. 713.

¹⁴ *Vide Calvin Consolidated Oil & Gas Ltd. v. Manning* [1959] S.C.R. 253.

appeal under section 41(4) of the *Patent Act* from a decision of the Commissioner made on February 6, 1963 and that this proceeding was begun by a notice of appeal dated February 15, 1963 more than a month before the formal document dated March 23, 1963 and referred to as a licence was executed. The concluding paragraphs of the decision so appealed from read as follows:

1967
 HOFFMANN-
 LA ROCHE
 LTD.
 v.
 DELMAR
 CHEMICALS
 LTD.
 Thurlow J.

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

The applicant will have a non-exclusive licence to carry out the patented process in Canada and sell the resulting product for the sole purpose of the preparation or production of medicine but not otherwise. The licence is to be effective as of the date of this decision. The royalty shall be set at 12½% of the net selling price of the crude product before processing for patients consumption.

The parties will have sixty days within which to submit to me an agreed draft of the licence for approval. If the parties fail to do so within the time set, I shall draft the licence upon my own terms.

In my view this on the face of it had all the elements of and constituted the grant of "a licence containing appropriate terms and providing for royalty or other consideration" as referred to by the President of this Court in *Hoffmann-La Roche v. Delmar Chemicals*¹⁵. It contemplates that a formal document evidencing the licence will be settled, leaves it to the parties to submit an agreed draft for approval and indicates that if they fail to do so the Commissioner himself will draft the licence upon his own terms, which presumably means that he will draft in his own language the terms which he has already expressed, that is to say, that the licence is not exclusive, that it is for the sole purpose of the preparation or production of medicine but not otherwise; that it is to be effective from February 6, 1963 and that the royalty is to be 12½ per cent of the net selling price of the crude product before processing for patients consumption¹⁶. As I see it nothing more was re-

¹⁵ [1966] Ex. C.R. 713 at p. 716. See also the judgment of the Lord Chief Justice Parker in *Geigy S.A.'s Patent* [1966] R.P.C. 250 at p. 264, lines 6-38.

¹⁶ In fact, the formal document when subsequently settled contained a number of additional terms but how they came to be incorporated therein and what the rights of the parties are with respect to them are matters which are not before me in this appeal. For this reason as well as because two other proceedings purporting to be appeals from such terms or some of them are still pending, it would not be appropriate for me to comment on them.

1967
HOFFMANN-
LA ROCHE
LTD.
v.
DELMAR
CHEMICALS
LTD.
Thurlow J.

quired to authorize the use by the respondent of the invention from that date. Moreover, the appellant having appealed from this decision both to this Court and later to the Supreme Court of Canada is in my view in no position to challenge that a licence was in existence from February 6, 1963 and the respondent having failed on a motion to quash the appeal to this Court on the ground that it was premature is I think also precluded from taking such a position. This case therefore as I see it falls to be determined on the basis that there was a licence in existence from February 6, 1963 which remains operative to this day except insofar as it may have been arrested as a result of the appeal proceedings.

It would seem to follow from what I have said that the licence must have remained effective to authorize the respondent's use of the invention and to render such use lawful at least until the date of the judgment of this Court and that even the setting aside of the royalty or of the licence itself would not have rendered unlawful what had been done pursuant to the licence in the meantime. Had the Court adjudged that the royalty should be increased it might, however, have required the payment of royalty at the higher rate from February 6, 1963. By the same token had the Court adjudged that the royalty was too high, it might have required repayment to the licensee of the difference in respect of the period from February 6, 1963. In neither of these cases would the efficacy of the licence in the meantime have been open to serious challenge. Instead, however, of following either of these courses or of hearing evidence and then determining the matter, the course adopted by the Court—in view of the absence of evidentiary material in the record before it—was to refer the matter to the Commissioner to receive such material as might be offered by the parties and to redetermine what royalty would be appropriate. In my opinion this direction applied to the whole period both past and future during which the licence had been and would be in effect.

Moreover even assuming that the effect of allowing the appeal on the question of royalty and referring that matter back to the Commissioner for consideration was to set aside the Commissioner's determination of the royalty, in my opinion it is not to be presumed that the Court intended

more than its order states and the affirmance of the decision to grant the licence appears to me to be an indication that the licence itself to make use of the invention was not being interfered with but that it was to continue pending the consideration by the Commissioner and determination by him of a royalty that would meet the needs of the situation from the time when the licence was granted. I shall, therefore, hold that even if the effect of the judgment allowing the appeal on the question of royalty was to set aside the original fixation of royalty the licence itself to make use of the invention from February 6, 1963 was not affected but continued in effect at such royalty as the Commissioner might thereafter on consideration determine. Having reached this conclusion, I do not think there can be any serious challenge to the authority of the Commissioner after consideration either to confirm the original royalty with effect from February 6, 1963 to December 21, 1965 or to make the new rate at 15 per cent effective from January 1, 1966.

The appeal therefore fails and it will be dismissed with costs.

1967
 HOFFMANN-
 LA ROCHE
 LTD.
 v.
 DELMAR
 CHEMICALS
 LTD.
 Thurlow J.