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CASE NO. 612/87
/CCC

IN THE SUPREME COURT OF SOUTH AFRICA

(APPELLATE DIVISION)

In the matter between:

SOUTH AFRICAN DRUGGISTS LIMITED — APPELLANT

and

PFIZER INC — RESPONDENT

CORAM: CORBETT, CJ, HOEXTER, NESTADT, KUMLEBEN JJA et NICHOLAS, AJA

DATE HEARD: 9 MARCH 1989

DATE DELIVERED: 26 MAY 1989

J U D G M E N T

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NESTADT, JA

Respondent, a United States corporation, is engaged inter alia in the pharmaceutical industry. It is an internationally active company with subsidiaries in various parts of the world. It is the patentee of South African Patent 69/5760 entitled "Process For Preparing Benzothiazine Dioxides". One of the compounds covered by the patent is known generically as piroxicam. It is an anti-inflammatory agent with analgesic properties. Its main use is in the treatment of rheumatoid arthritis and similar conditions. In South Africa piroxicam has been marketed under the trade name of "Feldene" by respondent's wholly owned subsidiary company here, Pfizer Laboratories (Pty) Limited. However, this has taken place only since January 1981. This was some eleven years after the commencement of the term of the patent on 12 August 1969 and about four and a half years before its expiration on 12 August

1985. Before January 1981, no remuneration was earned from the patent.

It was in these circumstances that respondent, in terms of section 39(1)(a) of the Patents Act, 37 of 1952, ("the Act") read with section 3(1)(d) of the Patents Act, 57 of 1978, timeously applied for an extension of the term of the patent for a period of five years on the ground that, due to no fault on its part, it had not derived adequate remuneration from the patent. The application (I refer to it as the main application) was opposed by appellant. It is a South African company which trades in competition with respondent. Shortly before the hearing, appellant gave notice by way of an interlocutory application of its intention to seek an order in terms of Supreme Court Rule 6(5)(g) that, in limine, certain persons who had deposed to affidavits in support of the main application appear personally to be cross-examined as witnesses. The Commissioner of Patents

STEGMANN J), despite respondent's opposition, granted the relief sought by appellant. (The judgment is reported in 1985-1986 BP 170.) Respondent appealed to the Transvaal Provincial Division. The appeal was struck off the roll on the ground that the order in question was not appealable. (The judgment is reported: see Pfizer Inc vs South African Druggists Ltd 1987(1) S A 259(T).) Thereafter the main application, which had previously been postponed, was re-enrolled for hearing. It came before ELOFF DJP. At the instance of respondent, he departed from the order of STEGMANN J which referred the matter to oral evidence. It was directed that the issues be resolved on the papers as they stood. The learned Commissioner then proceeded to hear argument on the merits of the main application which he granted by ordering an extension of the patent for five years. Appellant was directed to pay the costs of the interlocutory application (which had been reserved), as also the costs of respondent's

application to vary STEGMANN J's order. (The judgment is reported in 1985-1986 BP 713.) Appellant unsuccessfully appealed to the Transvaal Provincial Division against the order of ELOFF DJP. The present judgment is concerned with a further appeal to this Court.

Lengthy affidavits were filed on behalf of both parties. In due course it will be necessary to canvass their contents in some detail when separately considering the various issues that arise for determination. This must be done with the meaning and requirements of section 39(1)(a) in mind. The relevant part of the section provides:

> "39.(1) A patentee ... may ... apply ... for an extension of the term of the relevant patent on the ground that -
> (a) he has not derived adequate remuneration from that patent."

This Court has interpreted section 39 in a number of cases and

in particular in South African Railways and Harbours vs Standard Car Truck Co. 1982(1) S A 806(A) especially at 818 G - 821 G. I understand the governing principles, in so far as they are presently relevant, to be the following. The first function of the Commissioner is to determine whether the patentee has been adequately remunerated. In order to do this, the Commissioner is required to make a comparison. The comparison is between the remuneration (i) in fact derived from the patent (the actual remuneration) and (ii) that which the patentee could and would have derived from it, but for some reason did not (the potential remuneration). Obviously (ii) must be shown to be more than (i). In some cases, this will be proved by the production of actual comparative figures. In this event, there will be direct evidence of inadequate remuneration. But there may be circumstantial evidence of inadequate remuneration rendering it unnecessary to quantify it. This occurs where there is

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proof that for part of the term of the patent, usually commencing at the beginning of the term, the invention did not earn remuneration. This is the lost time situation. It may give rise to the prima facie inference that had the patentee exploited his patent over its full term, he would have derived more remuneration than he actually did and that he accordingly earned inadequate remuneration. But there are two instances where the inference has been said (though not in so many words) to be negated. One is where the patentee, whilst the patent was being exploited, so fixed the price of his product as to recoup the prior loss of remuneration (i e sustained in the sterile period). Whether this is still to be regarded as correct is dealt with later. The other is where the lost time was due to some inherent weakness or shortcoming in the invention (as opposed to an extraneous factor or circumstance) so that it was, in any event, not capable of earning remuneration. The reasoning here is that the patentee's remuneration is only to be regarded as

inadequate if the lost time was due to circumstances extraneous to the invention. Only then should he be afforded more time to earn remuneration (by way of an extension). If, however, there are other factors which cause or simultaneously contribute to the delay in exploiting the invention, viz, intrinsic defects in it, the patentee cannot, in respect of the period during which the invention was so defective, complain about inadequate remuneration. For then it cannot be said that the failure to earn remuneration was due to circumstances dehors the invention. Finally, in regard to the second main function of the Commissioner, viz, to determine, subjectively, in the exercise of his discretion, whether an extension should be granted, and if so the period thereof, a relevant consideration is whether the failure of the applicant to derive adequate remuneration was ascribable to his fault.

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Appellant's contentions on appeal, in support of a general submission that respondent had failed to show that it derived inadequate remuneration were, in summary, the following: (i) the decision of ELOFF DJP not to allow respondent's witnesses to be cross-examined was wrong; (ii) respondent failed to show that during the period after January 1981 it did not, by increasing its prices, recoup its prior loss of remuneration; (iii) respondent failed to sufficiently particularise its actual remuneration; (iv) the invention suffered from an inherent weakness so that it was, in any event, incapable of earning any remuneration until about December 1978 at the earliest; and between then and January 1981 when sales of Feldene commenced there was a culpable delay in marketing the product and thus earning remuneration; accordingly, the time lost does not avail respondent.

Because the evidence relevant to the issue raised by (iv) relates to a period of time prior to that which bears on (i), (ii) and (iii), I propose to deal with it first. It involves an enquiry into the reasons for the lost time. This is fully explained in respondent's founding affidavits. The position that emerges is, in outline, the following. Piroxicam was first synthesised in respondent's laboratories in America in November 1967. It was patented there in August 1968. However, although it was already known through pharmaceutical testing that it possessed substantial anti-inflammatory properties, many years were to elapse before piroxicam could be marketed. Respondent's policy was to patent its inventions at the earliest possible date lest competitors anticipate it. Such patenting will normally be "well before the development work necessary to commercialise a pharmaceutical product can be completed". What such development work consisted of, in the case of piroxicam, was, broadly

speaking, the following:

(a) To begin with, exhaustive tests, first on animals and them on humans, had to be carried out. Their purpose was to demonstrate that piroxicam was safe to use and efficacious. Initially, these tests were carried out on a closely-related compound called sudoxicam. However, problems relating to elevated enzyme levels were encountered and further testing of sudoxicam was halted. Piroxicam, which until then had been regarded as a "back-up" compound, then came to the fore. This was in March 1972. Toxicological studies of piroxicam then commenced and continued through to 1977 and beyond. This involved a series of experiments on a variety of animals. Their principal purpose was to ascertain whether any harmful side-effects

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resulted from the administration of piroxicam and thus to avoid them in human subjects upon which clinical testing would follow. Early in 1973 a start was made with such clinical testing of piroxicam. It consisted of three phases, stretching over a number of years. The trials, which involved careful planning and preparation, were conducted in the United States and Western Europe. A total of about 1 000 patients participated in them. By the beginning of 1977 respondent's experts were convinced that piroxicam was efficacious and safe for use as an anti-inflammatory agent and that its commercial development and marketing could be proceeded with.

(b) During the course of the clinical trials certain problems regarding the bulk manufacture and

formulation of piroxicam arose. As to the former, it is stated that whilst "small batches of a particular compound made in a laboratory may prove effective and safe, the production of the compound in a large plant may result in a commercial product which is less effective and/or more toxic unless very careful quality control is exercised". Thus, as regards piroxicam, there had to be a large expenditure of time and manpower to achieve an acceptable product which could be manufactured on a commercial scale. Simultaneously, problems of formulation or dosage form were being dealt with. By this is meant "the total physical mixture of non-active excipients (inert substances which constitute the vehicle by which the active ingredient is carried into the ... body) and the

active ingredient. Formulations can take numerous forms such as capsules, tablets, solutions or suppositories..." Which of these formulation is adopted is important because each may differently affect the rate and level of absorption of the drug into the body, as also the product's stability and thus its shelf-life. Initially, a capsule formulation was used. Because of problems arising from the incidence of what is called polymorphism, bulk lots of piroxicam were then (by May 1975) prepared in tablet form. However, respondent's scientists soon determined (early in 1976) that the tablet form gave rise to undesirable side-effects, whereupon they decided to return to the capsule formulation. By March-April 1976, bulk lots of capsules had been prepared. This change-over

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caused the clinical trials to be delayed by about six months. But problems continued to be encountered. The capsule was affecting the dissolution rate of the drug. It thus became necessary to modify the capsule. Samples of the modified capsule were prepared in the first half of 1977. It would seem that even these showed poor dissolution properties. It was only in August 1979 that respondent was finally able to commercially produce capsules having acceptable dissolution characteristics.

(c) The successful results of the clinical trials led to it being decided to submit what is termed a New Drug Application to the United States Food and Drug Administration. Its approval was necessary before piroxicam could be marketed in that country. The

compilation of the necessary information for this purpose took many months so that it was not before March 1978 that the application could be lodged. Only then was respondent in a position to make a similar application to the relevant authority in South Africa. It is called the Medicine Control Council (MCC). The application for registration of piroxicam with the MCC was made in December 1978. The application could not reasonably have been done earlier. In June 1979 the MCC requested substantial additional information. This was furnished two months later. However, registration was only obtained in September 1980 when respondent was for the first time enabled to market its product. It was too late to do this before the new year, ie January 1981, when, as I have said, sales commenced.

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The question is whether this catalogue of events and circumstances was such as to frustrate respondent's reliance on lost time. ELOFF DJP did not think so. And I think he was right. As has been indicated, there are two aspects to be considered. One is whether due to some inherent weakness or shortcoming in the invention it was not capable of earning remuneration; the other is whether respondent's loss of remuneration was caused by its fault. I deal firstly with the latter. It is, I think, clear that the various procedures undertaken were necessary. Respondent's deponents are at pains to point out that at each of the development stages referred to, every effort was made to complete the work as expeditiously as possible and that what delays did occur were not due to any remissness on its part. There is no effective denial of this in appellant's papers. There is an assertion in the affidavit of

Anthony Karis, its deputy managing director, that respondent's selection of sudoxicam for tests whilst "virtually ignoring" piroxicam was "unreasonable, unscientific (and) unbusinesslike" and caused a delay of about three years. In my opinion, it is not justified. Respondent has explained what the rationale was behind the decision to initially proceed with the development of sudoxicam and it seems to me to be a perfectly reasonable and acceptable one. Generally, it must be borne in mind that "(t)he decision to commence production and marketing of a particular drug is an extremely serious and important step. Not only does Pfizer have an immense moral responsibility not to market a drug of dubious safety, but the legal consequences of such a step could be momentous." (I have quoted from the affidavit of respondent's Senior Vice-President, Medical, a Dr Jefferis.) It is obvious that respondent had to proceed with care and caution. The only other point that need be mentioned concerning respondent's alleged fault is Mr Plewman's submission, on behalf

of appellant, that between July 1979 (when, he said, piroxicam was for the first time capable of earning a remuneration) and January 1981, there was no good reason why marketing should not have taken place. I disagree. The delay in obtaining MCC approval cannot be laid at respondent's door. This, as I have said, was only given in September 1980. And appellant has not shown that the decision to wait until January 1981 before launching Feldene was unreasonable.

I turn to the other aspect of (iv) above, viz, whether the invention was incapable of earning remuneration because of some inherent weakness or shortcoming in it. Appellant contends for an affirmative answer. Now, it cannot be gainsaid that piroxicam could in fact not be generally sold until about 1979. Indeed, as appears from what has already been said, this was the basis on which respondent's claim that it received inadquate remuneration was founded. And its deponents

acknowledge as much. Thus it is said: "in the drug industry, therefore, there is inevitably a lapse of time between the date upon which an invention is patented and the date upon which actual commercial exploitation commences"; "by the end of 1968, I was convinced that both sudoxicam and piroxicam had the potential for development into successful commercial non-steroidal anti-inflammatory agents of substantial benefit to mankind provided, of course, that they successfully completed the extensive toxicological and clinical trials necessary to establish safety and efficacy in humans and to obtain approval for product marketing from regulatory authorities"; "the development of a marketable pharmaceutical compound is an ongoing process"; "it will be apparent ... that a number of years passed before completion of clinical trials sufficient to enable Pfizer to consider the marketing of piroxicam". But it does not follow that respondent cannot rely on the sterile period to

support an allegation of inadequate remuneration. An inability to exploit the invention commercially does not per se show a weakness or shortcoming in the invention. The enquiry that has to be made is whether the lack of commercial viability was not due to some extraneous factor or circumstance. In Lennon Ltd and Another vs Hoechst Aktiengesellschaft 1981(1) S A 1066(A) at 1084 B - C, the expression used is "some unconnected, extraneous factor or circumstance". But I think the omission of the word "unconnected" would be more in keeping with what the learned judge meant in the light of the facts he was dealing with and the sort of problem that arises in this type of case.

In contending that piroxicam lacked commercial viability because of an inherent weakness or shortcoming, Mr Plewman, consistently with what had been alleged in appellant's answering affidavits, confined his submissions to those founded on the factors referred to in (a) and (c). The

argument was, in other words, that the failure to earn remuneration was caused by the need to first establish the safety and efficacy of piroxicam and then to obtain its registration; and these, so he said, were inherent shortcomings and weaknesses in the invention. There is no merit in the point. These are the classic, extraneous factors usually relied on (with success) by patentees applying for an extension of inter alia a pharmaceutical patent under section 39(1)(a). (See eg, at least as far as (a) is concerned, Lennon's case at 1084 E.)

The remaining set of circumstances (referred to in (b)) can also be briefly dealt with. As I say, appellant did not contend that they evidenced an inherent weakness or shortcoming in piroxicam. They were, however, debated with Mr Puckrin, who appeared for respondent, during argument. Suffice it to say that I do not think that problems of production and formulation, in the circumstances of this case (unlike those in

South African Druggists Limited vs Bayer Aktiengesellschaft, case number 623/87, a judgment of this Court delivered on 26 May 1989) were or arose out of any weakness or shortcoming in the invention itself. As respondent's experts point out, piroxicam was, ab initio, an effective, anti-inflammatory agent (as subsequent events demonstrated); no further discovery or development of the compound itself was required to render it capable of earning remuneration. The position is, in principle, the same as in the Lennon case where one of the problems that contributed to the delay in marketing the drug there in issue was "having to produce furosemide with a sufficient degree of stability and purity for testing purposes and the loss of some three million tablets, made for the initial marketing of the product, through deterioration caused by an unforeseen phenomenon - the effect of light on sugar-coated tablets packed in non-coloured bottles" (see at 1074 E - F). Though this point does not appear to have been

specifically dealt with subsequently in the judgment, it is obvious that the problems referred to were not regarded by WESSELS JA as a weakness or shortcoming in the invention.

The issues raised by the arguments (i), (ii) and (iii) earlier referred to really all bear on respondent's actual remuneration and in particular whether it was sufficiently proved and how it was calculated. They may therefore largely be dealt with together. In its affidavits, respondent alleged the following. Its remuneration, in the form of profits from the sale of Feldene in South Africa is derived from two sources: (i) the profits which accrue from the sale to Pfizer Laboratories of piroxicam in bulk, powder form by a subsidiary of respondent in Eire (where it is manufactured); and (ii) the profit which Pfizer Laboratories makes from the sale of Feldene in South Africa (consequent upon it preparing the material for sale in the form of capsules). Neither the price (called the transfer

price) nor the profits which it produces are, in relation to (i), disclosed. It is said by Maurice Roche, the executive vice-president of the holding company of respondent, that it, for reasons which are set out but which need not be detailed, "does not wish" and has been advised that it is not necessary to disclose what such profit is; but it is prepared to have the whole of the income derived from the sale of bulk piroxicam to Pfizer Laboratories treated as profit and, therefore, as remuneration. The profits accruing to the latter company from the sale of Feldene up until the expiry of the patent are, to a limited extent, disclosed. Annual turnover figures are given. So, too, are the company's expenses, with the important exception of the "considerable" cost to it of piroxicam. The total amount of sales up to the expiry of the normal term of the patent amounted to R19.9 million and the "profit" to R10 million. (I have given both in fairly round figures.) The last-mentioned

figure, in the words of David Rosenberg, the company's financial controller, "represents the absolute maximum remuneration which could possibly be held to have accrued to (respondent) as a result of the exploitation of piroxicam in South Africa". Obviously, however, seeing that the transfer price has not been deducted, that figure is greater than the actual profit earned.

It is necessary to deal in more detail with what is said about the prices at which Feldene has been sold and how they were calculated. In substance, it amounts to the following: the prices were "reasonable"; they were dictated by market factors such as the price of competitor's products (particulars whereof are given); all the prices were more or less on a par with each other. The question whether there was an increase or "loading" of prices (to make up for lost time) is specifically raised and answered in the negative. Thus Dennis Chambers, the chief executive of Pfizer Laboratories says: "I

emphasise that the fact that the applicant has lost more than 11 years during the life of the normal term of Patent No. 69/5760 has not influenced the price at which Feldene has been sold in South Africa".

In his answering affidavit on behalf of appellant, Karis, relying mainly on a statement by Chambers that respondent's large research costs have to be financed by its few successful products "during the period which is invariably somewhat less than the full term of the patent", "disputes" Chambers's assertion that respondent's prices were reasonable and that the lost time did not influence the prices at which Feldene was sold. In a supporting affidavit a Mr MacIntosh, a chartered accountant, alleges both in relation to the price of Feldene and the transfer price that market considerations (ie the prices of competing products), though a factor, are not dominant. He argues that respondent must have realised that "it has less than the full patent term to exploit a product free of competition and

must take this factor into account in fixing its transfer prices. In so doing the company compensates itself for the loss of remuneration during the early unproductive development years". He, too, "disputes" the correctness of Chambers' evidence that there was no loading of Feldene's prices.

Respondent's replying affidavits reiterate and amplify its original stance. Chambers states, for example, that "(t)he simple fact is that the applicant would not have charged any more or any less for Feldene (piroxicam) whatever the effective term of the patent had been". In particular a document dated 20 August 1979 evidencing respondent's pricing policy applicable to its operations in the Republic was produced. Such policy is stated to be that Feldene "should be priced directly competitive with the market leader" of certain named "major competitive products" save that "wherever possible, a premium of at least 15% should be obtained". Such policy, it is said by a Mr Price, the manager of the pricing division of a

subsidiary of respondent, was carried out; and the extent of the premium referred to was directly related to market forces; respondent cannot fix a price which "the market is unable to bear"; the transfer price, too, was dependent on the price of competitor's products; it is always determined so as to allow the subsidiary company (Pfizer Laboratories) to make a reasonable profit. Price also pertinently denies that lost time was taken into account in determining prices for piroxicam in South Africa.

This, then, was the background against which appellant brought the interlocutory application. It was widely framed. A dispute of fact was alleged in relation to a number of issues. STEGMANN J, however, in granting an order, confined the issue to be resolved to the following: "whether or not the patentee priced its product piroxicam or Feldene in such a manner as to compensate itself wholly or in part for the fact that it was unable to derive any remuneration therefrom for a number of

years". (I refer to it as the "recoupment reasoning" or "recoupment argument".) The deponents who, in accordance with his direction, were to give viva voce evidence were Chambers, Roche, Rosenberg, Price and another. ELOFF DJP, in refusing to follow this order, held, on the basis of what WESSELS JA said in the Lennon case at 1082 C - H, that the criterion to be applied in considering whether there had been recoupment for lost time, was whether respondent's prices of Feldene were competitive; such prices, so he accepted, were competitive; (by implication therefore) there was no dispute of fact warranting the order that had been made by STEGMANN J; and, on the merits, respondent had established that its prices of Feldene had not been increased to compensate it for the lack of remuneration in the lost time period.

In my opinion, the submission that ELOFF DJP should have given effect to the interlocutory order must be rejected. As a matter of principle, the recoupment reasoning,

on which it is based, is no longer available as a valid answer to an application for extension based on inadequate remuneration caused by lost time. This is the effect of the judgment in South African Druggists Ltd vs Bayer, supra, in which NICHOLAS AJA, in dealing with the lost time principle, examined the validity generally of the recoupment reasoning. The learned judge refers to the fact of its incorporation in paragraph 8(b) of the principles set out in the SAR case where, at 820 D, it is said:

> "(8) If lost time is proved, its cogency in establishing that there has been inadequate remuneration from the patent depends on all the facts and circumstances. Relevant considerations in this regard would include ...
> (b) whether or not the royalties demanded by the patentee or the prices fixed for its product have been calculated and fixed in such a way as to compensate the patentee for the lost time or allow him to recoup loss of remuneration sustained during the period of lost time (see Lennon's case supra at 1082 C - H)"

In a fresh approach to the problem, NICHOLAS AJA nevertheless finds that this is not a principle of law but simply an argument;

that he was therefore free to reconsider it; and that it was fallacious. At pp 28(d) - 31 of the typed judgment (which was concurred in by the majority of the members of the court) the following is said:

> "The proposition on which an applicant relies who adopts the lost time approach is that, however large or substantial the remuneration which he in fact derived from the patent, it was nevertheless inadequate within the meaning of s 39(1)(a), since, during the lost years, he derived no remuneration from the patent. (See the Lennon case at 1079H.) On such an approach there can be no talk of 'compensation' or 'recoupment' - it just does not enter into the matter. If the patentee, in calculating and fixing the price of his product, subjectively makes provision for compensation or recoupment in respect of lost years, he deludes himself: he does not compensate for lost years by subjectively attributing remuneration received to compensation for remuneration not earned, any more than a man enriches himself by transferring his money from one pocket to another...
>
> Moreover, the contention flies in the face of economic realities. A patentee is in general at liberty to fix whatever price he may wish to charge for his product, using the data and techniques he considers to be appropriate for that purpose. In practice, the lower price limit is set by his production costs - unless a product can be priced to yield an attractive margin

> above the production costs, he will not offer it at all. The upper limit is set by what the buyer will pay for the product... There is, therefore, a limited range within which the prices of a product must be fixed. It can be assumed that a manufacturer's object is to maximize his profits... The manufacturer will therefore seek to calculate and fix the 'optimum' price for his product, that is, the price which will yield the greatest profit. To fix too low a price would be self-denial - which is not a virtue to be attributed to economic man; and to fix it too high would be self-defeating, because then he would price himself out of the market. Emptor emit quam minimo potest, venditor vendit quam maximo potest... It follows that when the manufacturer has calcuclated the 'optimum' price, there is no room for adding on something 'to compensate for a reduced monopoly period.' "

On this basis alone, the recoupment argument fails. But in any event, I am satisfied, despite Mr Plewman's strong argument to the contrary, that ELOFF DJP correctly found that on the facts there had been no loading of Feldene's prices. The issue that had to be decided was whether appellant had made out a sufficient case for viva voce evidence under rule 6(5)(g) (or, one may add, under section 76(1)(f) of the Act which empowers the Commission to allow any witness to be cross-examined

on his affidavit). Rule 6(5)(g) provides:

> "Where an application cannot properly be decided on affidavit the court may dismiss the application or make such order as to it seems meet with a view to ensuring a just and expeditious decision. In particular, but without affecting the generality of the aforegoing, it may direct that oral evidence be heard on specified issues with a view to resolving any dispute of fact..."

Many cases over the years have dealt with its meaning (and the broadly similar, previously existing rule 9 of the Transvaal Rules of Court). A useful explanation in this regard is that of KUMLEBEN J in Moosa Bros. and Sons (Pty) Ltd vs Rajah 1975(4) S A 87(D). The learned judge finds that as a matter of interpretation there is nothing in the language of rule 6(5)(g) which restricts the discretionary power of the Court to order the cross-examination of a deponent to cases in which a dispute of fact is shown to exist. Without attempting to lay down any principle which may have the effect of limiting the wide discretion implicit in the rule, he expresses the opinion that

oral evidence should be allowed if there are reasonable grounds for doubting the correctness of the allegations concerned. He adds that in reaching a decision, it is necessary to carefully scrutinise facts peculiarly within the knowledge of an applicant and which, for that reason, cannot be directly contradicted or refuted by the opposite party. (See at 93 F - H.)

In applying these principles to the present matter, it must, of course, be remembered that the prescribed procedure for obtaining an extension of the term of a patent is by application. Furthermore, a reference to oral evidence would inevitably cause a delay in finalising the matter. This is a result which in the public interest should if possible be avoided (see the remarks of STEYN CJ in Firestone South Africa (Pty) Ltd and Others vs Gentiruco A.G. 1968(1) S A 611(A) at 631 A - B, although they were made in a different context). These considerations must, naturally, not be allowed to improperly restrict appellant's rights under rule 6(5)(g). Nevertheless,

they can, I think, legitimately be taken into account by the Commissioner in deciding how to exercise his discretion under the rule. And they serve to underline the difficulty that an objector, who raises the issue of loading, has in successfully invoking the rule. This is particularly so where the invention is being exploited in a competitive situation. Perhaps that accounts for this being the first case, so far as I am aware, where in the context of an application under section 39(1)(a), resort to rule 6(5)(g) has been attempted. The attempt must fail. Respondent's prices would have had to be inflated to an appreciable extent to compensate it, over a period of about four and a half years, for it not earning any remuneration for more than eleven years. Far from that being the case, respondent's affidavits show, as I have said, that the price of Feldene has been much the same as that of its rivals. The evidence on this point was not, as was suggested, hearsay. As appears from the Lennon case, at 1082 G, the inference, in these circumstances, is

that there was no loading. The reason for this obviously is that where a price is competitive, it is likely to be one that the patentee would have charged whether or not there was lost time.

To what extent do appellant's affidavits detract from this? They go no further than vague, unsubstantiated, argumentative denials of respondent's allegations. No facts are presented to counter respondent's evidence that Feldene's price is competitive. There is no particularity as to what appellant contends a reasonable or competitive price is or should be or in what amount Feldene's price is excessive. Appellant should have been able to give this information. In the result, and despite making due allowance for respondent's pricing being a matter peculiarly within its own knowledge, I do not think appellant succeeded in raising a real dispute of fact. Nor did it show that there were reasonable grounds for doubting the correctness of respondent's allegations that it did not increase its price for Feldene so as

to recoup what it did not earn in the sterile period. The interlocutory application was therefore not well-founded and ELOFF DJP correctly departed from the order made pursuant thereto. This he was entitled to do (Bell vs Bell 1908 TS 887).

This brings me to appellant's complaint that respondent did not sufficiently particularise its actual remuneration. Appellant's argument centred upon the transfer price. It was said that it and in particular respondent's expenses in producing piroxicam (such as its research, development, manufacturing, packaging, distribution and administrative costs) should have been disclosed. This would have revealed respondent's true remuneration in the form of its profit on the transfer price and thus (taking into account Pfizer Laboratory's profit) on the patent as a whole. It was vital to know this. Only then could the worth of the invention and the adequacy of remuneration be assessed. This, rather than whether respondent had earned the maximum, was what had to be determined.

As matters stood, the figure of R10 million (being Pfizer Laboratory's deemed profit, referred to earlier) was meaningless.

The argument is fallacious and must be rejected. It seeks to resurrect the requirement of section 51(1) of the old Patents Act, 9 of 1916, viz, that the court, in considering its decision (whether to grant an extension) had to have regard to inter alia "the profits made by the patentee". Section 39(1) of the Act is differently worded. Nor, on its proper interpretation, and unlike English law (on which Mr Plewman relied) does the patent or the benefits conferred on the public have to be valued. As has been indicated, a comparison has to be made between the actual and potential remuneration; and where there has been lost time you may not need to know their amounts in order to do this. For, if the invention has merit and is commercially successful in the years in which it is actually exploited, this will sustain the inference that no

matter how substantial the remuneration then earned, appreciably more would have been derived had there been no lost time (see the SAR case at 820 B - C).

This is the position here. It is clear on the papers that the invention has great merit. This is dealt with in some detail and was not disputed by appellant. It was established that from 1 January 1981 Feldene was sold at a profit. That sufficed. It was not necessary for respondent to disclose the exact amount thereof. Even in the absence of this information, the most probable inference in the circumstances was that had respondent been able to trade during the lost time period, profits would have been made then as well. It would follow that had the patent been exploited over the full term, respondent's remuneration would have been greater; and that it accordingly derived inadequate remuneration. I ought to stress, however, that it is not to be assumed that in every case of lost time a more precise quantification of the patentee's actual

remuneration and therefore of his loss of remuneration may be dispensed with. Where the invention is not of great merit and the period of lost time is relatively short, the position may be different. But on the facts of this case, I am satisfied that what was essentially an evidential problem was correctly resolved in respondent's favour.

This conclusion disposes of the matter. It was submitted in appellant's heads of argument that the Commissioner should not, in the exercise of his discretion, have granted an extension for any period, alternatively for the maximum permissible period of five years. However, apart from the contention that respondent was at fault in relation to part of the period of lost time (a matter already dealt with) no reasons were advanced in support of the submission. In my opinion, no fault can be found with the manner in which ELOFF DJP exercised his discretion.

The appeal is dismissed with costs. Such costs are to include the fees of two counsel.

NESTADT JA

CORBETT, CJ)
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HOEXTER, JA) CONCUR
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KUMLEBEN, JA)
)
NICHOLAS, AJA)