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NvH

SOUTH AFRICAN DRUGGISTS LIMITED

and

BEECHAM GROUP p.l.c.

SMALBERGER, JA -

IN THE SUPREME COURT OF SOUTH AFRICA(APPELLATE DIVISION)

In the matter between:

SOUTH AFRICAN DRUGGISTS LIMITED

Appellant

and

BEECHAM GROUP p.l.c.

Respondent

CORAM:

CORBETT, HOEXTER, SMALBERGER, NESTADT,

JJA, et NICHOLAS, AJA

HEARD:

3 MARCH 1988

DELIVERED:

22 March 1988

J U D G M E N T

SMALBERGER, JA :-

The respondent is a company incorporated in the

United Kingdom where it manufactures and markets, inter alia,

pharmaceutical /

pharmaceutical preparations. It was the registered proprietor of South African patent No 69/6021 ("the 1969 patent"), entitled "Penicillins", which was granted under the provisions of the Patents Act 37 of 1952 ("the Act"). The effective date of the 1969 patent was 22 August 1969. It was due to expire, in terms of section 28(1) of the Act, on 22 August 1985. On 22 February 1985 the respondent lodged an application, in terms of section 39(1)(a) of the Act, for the extension of the term of the 1969 patent, or the issue of a new patent, for a period of three years from the date of whatever order was made.

The ground for the application was that the respondent had not derived adequate remuneration from the patent. Notwithstanding the repeal of the Act by the Patents Act 57 of 1978,

the /

the provisions of section 39 of the Act were still applicable -
see section 3(1)(d) of the 1978 Act.

The application was opposed by the appellant, the holding company of a group of companies active throughout the Republic in the manufacture and marketing of pharmaceutical products, as well as by Vita Pharmaceuticals (Pty) Limited.

After having heard argument, the Commissioner of Patents,

VAN ZYL, J, found for the respondent and issued a new patent

for a term of three years from 15 April 1986 (the date of his

judgment), together with an appropriate order as to costs.

The appellant noted an appeal to the Full Bench of the Transvaal

Provincial Division. No appeal was noted by Vita Pharmaceu=

ticals (Pty) Limited. The Full Bench (GOLDSTONE, KIRK-COHEN,

JJ and /

JJ and MELAMET, AJ) dismissed the appeal, with costs, but

amended the Commissioner's order to reflect the term of

the new patent as three years and 236 days from 22 August

1985. The 236 days represents the period from 22 August

1985 to the date of the Commissioner's judgment, the Full

Bench being of the view that the term of the new patent

should commence from the date of expiry of the old patent.

The present appeal is directed against the judgment and

order of the Full Bench. The judgments of the Commissioner

and the Full Bench are reported in 1986 BP 335 and 1986 BP

691 respectively.

The background /

The background to the respondent's application is set out clearly and succinctly in the following passage from the judgment of the Commissioner:-

"The applicant has been engaged in research in the field of penicillins for a considerable time. Prior to 1957 only two penicillins were commercially available and clinically used, namely penicillin G and penicillin V, which had varying effectiveness in combating certain bacteria. After the applicant had succeeded in isolating the nucleus of the penicillin molecule, known as '6-APA' (an abbreviation of '6-aminopenicillanic acid'), it was established that, by coupling the nucleus with carboxylic acids, an almost infinite variety of new

penicillins /

penicillins, known as semi-synthetic penicillins, could be produced. This resulted in the applicant's obtaining a 'master patent' covering these numerous semi-synthetic penicillins, the South African patent being obtained under the number 59/3827 and being referred to as the '1959 Patent'. Further research led to the discovery of ampicillin, which was highly successful and justified a patent in addition to the 1959 patent, namely, in South Africa, patent no. 61/2128 (the '1961 patent'). Both the 1959 and 1961 patents expired in September 1975. The next significant step in the research programme was the discovery of a group of compounds (numbering 9 or 6, depending on whether certain mixtures of compounds should be regarded as separate or not) which were particularly active against certain bacteria, known as Gram negative bacteria. These compounds, described as the hydroxy derivatives of ampicillin, were subsequently protected by a further patent, registered in South Africa under no. 63/4795 (hereinafter referred to as the '1963 patent').

One of the compounds covered by the 1963 patent was amoxycillin, but the pharmaceutical world failed to realise its advantages over ampicillin

from /

from the teaching contained in such patent. It was left to further research to disclose, in April 1968, that the vital advantage of amoxycillin was its extensive quality of absorption from the human alimentary tract resulting in high blood levels within a short period of time. This gave rise to the application for the 1969 patent, presently under consideration, the gist of its claims being for 'a pharmaceutical composition adapted for oral administration to human beings'.

Although the 1963 patent did not specify the particular invention relating to amoxycillin, it did, in fact, embrace it, so that an attempt by a competitor to introduce amoxycillin onto the South African market during 1975-1976 was successfully interdicted by virtue of the provisions of the 1963 patent. At that stage an infringement action in respect of the 1969 patent was not possible since the patent had not yet been granted."

The infringement proceedings referred to culminated in the judgment of this Court reported as B-M Group (Pty) Ltd v Beecham Group Ltd 1980(4) SA 536 (A). Additional facts

relevant /

relevant to the present appeal are the following. The application for the 1969 patent was opposed by the B-M Group (Pty) Limited. This opposition delayed the grant of the 1969 patent for many years. It was eventually granted on 13 September 1982 when the B-M Group withdrew its opposition.

Amoxycillin, under its trade name "Amoxil", was introduced onto the market in the Republic for the first time on 11 October 1972 i.e. more than three years after the effective date of the 1969 patent. The failure to exploit amoxycillin commercially sooner was not attributable to any fault on the part of the respondent, nor to any inherent weakness or shortcoming in the invention. The delay was caused by the need to conduct exhaustive pharmacological and clinical tests in order

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to enable the respondent to satisfy, not only itself, but also the regulatory authorities in the United Kingdom and the Republic, that amoxycillin was both effective and safe, and to obtain the necessary registration thereof. Amoxycillin is a product of undoubted utility and merit, and has been a resounding commercial success ever since its introduction onto the market. Its sales have generated substantial profits. In April 1979 the respondent applied for an extension of the term of the 1963 patent on the ground that it had derived inadequate remuneration therefrom. The need to do so arose from the fact that the grant of the 1969 patent was still being opposed, and the respondent was unable to assume that it would be granted. This application (i.e. for the extension of the /

the 1963 patent) was also opposed by the B-M Group. The upshot of the application was that the Commissioner (ELOFF, J) granted a new patent for a period of three years from 21 August 1980, but limited the monopoly afforded by such new patent to amoxycillin. The judgment is reported sub nom Beecham Group Limited v Bristol-Myers Company and The B-M Group (Proprietary) Limited 1980 B P 508. The facts set out above are either common cause or not in dispute for the purposes of the present appeal. There was no extension of the terms of either the 1963 or the 1969 patents : both were re-issued as new patents. Nevertheless it will be convenient to refer to the re-issue of each as the extension thereof.

One must not lose sight of the fact that the 1963 and 1969 patents were separate and distinct patents. While

the /

the 1963 patent embraced amoxycillin, it did so as one of a number of compounds active against Gram negative bacteria.

This was a different disclosure from that made in the complete specification of the 1969 patent, which stressed the high blood absorption properties of amoxycillin adapted for oral administration. It must be accepted that the disclosure in the 1969

patent constituted a step forward, and was sufficiently new and inventive to justify the grant of such patent. A registered

patent is prima facie valid i.e. it is valid until the

person asserting the contrary proves otherwise - see Par

Excellence Colour Printing (Pty) Ltd v Ronnie Cox Graphic

Supplies (Pty) Ltd 1983(1) SA 295 (A) at 308 C. The appellant

did not seek to challenge the validity of the 1969 patent in

either its notice of opposition or the affidavits filed on

its /

its behalf. The validity thereof is accordingly not open to attack on appeal. While the 1969 patent, despite the opposition thereto, enjoyed provisional protection under section 20(1) of the Act from the date of application therefor, the respondent was not entitled, in terms of section 20(2) of the Act, to found infringement proceedings on it until it was granted. -- Hence the need to rely on the 1963 patent to interdict the B-M Group in December 1975 from manufacturing and selling amoxycillin. But for the unjustified opposition to the 1969 patent which delayed its grant until 1982, the remedy of an interdict would have been available to the respondent under the 1969 patent.

The principles governing an application to extend the normal term of a patent on the ground that adequate remuneration /

ration has not been derived therefrom have been authoritatively
spelt out in South African Railways and Harbours v Standard

Car Truck Co 1982(1) SA 806 (A) at 818 G - 821 G. As appears

from the judgment, the Commissioner's function in determining

the respondent's application was a twofold one. Firstly,

he had to decide objectively on the facts whether the respondent

had not derived adequate remuneration from the 1969 patent.

This involved a comparison between the actual remuneration

derived by the respondent from the exploitation of the 1969

patent and the remuneration which, objectively determined, the

respondent could and would have derived from it, but for some

reason did not (the potential remuneration). This was the essential enquiry

in the application, and the onus of proof in respect thereof rested on the

respondent /

respondent. Secondly, having objectively determined that the respondent had not derived adequate remuneration from the 1969 patent the Commissioner was called upon to determine subjectively in the exercise of his discretion whether, having due regard to all the relevant facts and circumstances, an extension of the 1969 patent was justified and if so, for what period and on what terms and conditions. In the result the Commissioner exercised his discretion in favour of the respondent.

Mr Plewman, for the appellant, contended that the measure of the difference between the actual remuneration derived by the respondent from the 1969 patent, and the potential remuneration, was not the sole criterion for determining the inadequacy or otherwise of the respondent's remuneration.

He sought to import a further consideration, viz., whether the respondent had been sufficiently compensated for the benefits conferred on the public by the 1969 patent. In doing so he placed reliance on a passage in the judgment of STEYN, CJ, in Anglo-American Corporation of S A Ltd v Vereinigte Österreichische Eisen - Und Stahlwerke Aktiengesellschaft 1967(4) SA 322 (A) at 330 H - 331 A to the effect that:

"Adequacy of remuneration implies a comparison of the remuneration in fact derived from a patent and the remuneration which would be a sufficient compensation for the benefits conferred on others than the patentee or exclusive licensee. Such benefits cannot be divorced from the utility of the patent"

In developing this argument Mr Plewman, as I understood him, contended that the public had derived the full benefit of

amoxycillin /

amoxycillin under the 1963 patent and the extension thereof.

No additional benefit was conferred on the public under the 1969 patent. The benefit on which the respondent relied to justify the grant of an extension of the 1969 patent was the same as that on which it relied when it sought, and was granted, an extension of the 1963 patent. The public had already paid for the utility of amoxycillin and should not have to pay for it again; conversely the respondent should not be compensated twice in respect of a single benefit. This amounted to double patenting, and could not be permitted. The respondent had derived adequate remuneration from its invention of amoxycillin under the 1963 patent and the extension thereof.

The respondent was therefore not entitled to an extension of the 1969 patent - such an extension would in effect amount to

a duplication of the earlier extension granted in respect of the 1963 patent.

This argument is ill-conceived. It loses sight of the fact that the 1963 and 1969 patents are separate and distinct patents. The benefit to the public under the 1963 patent was amoxycillin as one of a number of compounds; that under the 1969 patent was amoxycillin alone and as adapted for oral administration. Implicit in the granting of the 1969 patent was that it conferred a benefit on the public over and above that conferred by the 1963 patent. Separate monopolies were therefore constituted by the 1963 and 1969 patents respectively. By disputing that the 1969 patent conferred a separate benefit the appellant is in effect attacking its validity on the ground of lack /

of lack of novelty. It is not open to the appellant to do so in the present proceedings. Furthermore, the reliance upon the dictum of STEYN, CJ, in the Anglo-American case, (supra) is misplaced. The test enunciated therein was departed from in Lennon Ltd and Another v Hoechst Aktiengesellschaft 1981(1) SA 1066 (A) at 1077 B, where it was first laid down that the proper test to determine inadequacy of remuneration lies in a comparison between actual and potential remuneration. This was followed in the Standard Car Truck Co case, (supra) at 819 B, and must be taken to reflect correctly the law on the point. The extent to which the public has benefitted is therefore not per se relevant to whether a patentee has been sufficiently compensated. It does not follow that the merit and utility of an invention are totally irrelevant considerations

in a /

in a matter such as the present. They may be relevant in

assessing the patentee's potential remuneration from the

patent (see Lennon's case, (supra) at 1077 E). Regard

may also properly be had to them by the Commissioner in the

exercise of his discretion to extend the term of a patent.

Thus the inability to exploit a patent for a period during

its normal term may, applying the actual versus potential

remuneration test, lead to the conclusion that the patentee

has not derived adequate remuneration from the patent, but

the merit, utility and commercial success of the patent may

be so insubstantial as to justify the Commissioner exercising

his discretion against the patentee.

The /

The respondent's claim that it has derived inadequate remuneration from the 1969 patent is based on its inability to exploit the 1969 patent and earn remuneration from it over the period 22 August 1969 to 11 October 1972, when amoxycillin for oral use could first be commercially exploited - the so called "lost time" in the exploitation of the patent. The criterion of lost time to determine inadequacy of remuneration is now firmly established. As previously mentioned, this lost time was not due to any fault on the part of the respondent, or any inherent weakness or shortcoming in the invention. The underlying theory of the patent system is to encourage disclosure of inventions by granting a monopoly to an inventor to ensure that he will be

adequately /

adequately compensated for disclosing his invention to the public, see Lewis Berger and Sons Ltd v Svenska Ojeslageri Aktiebolaget 1959(3) SA 604 (T) at 612 A - C). The statutory period of the monopoly provided by a patent in terms of section 28(1) of the Act is sixteen years, after which the invention passes into the public domain, unless the term of the patent is extended. The respondent was accordingly entitled to enjoy a monopoly under the 1969 patent for sixteen years from 22 August 1969 to 22 August 1985. It in fact only benefited from such monopoly from 11 October 1972 to 22 August 1985 - more than three years less than the statutory period. The period over which it was able to derive remuneration was reduced pro tanto. The period of extension of the 1963 patent fell wholly within the normal term of the 1969 patent.

Neither the 1963 patent nor its extension afforded the respondent any remuneration to which it would not in any event have been entitled under the normal term of the 1969 patent. The lost time under the 1969 patent was accordingly not redressed by the extension of the 1963 patent. The fact that the 1963 patent afforded the respondent the benefit of interdict protection at a time when such protection was not available under the 1969 patent is irrelevant. Inadequacy of remuneration is measured in money terms. It is concerned with pecuniary loss. The benefit of interdict protection under the 1963 patent does not bear on the issue whether the respondent received adequate remuneration from the 1969 patent. As amoxycillin adapted for oral administration was undoubtedly an invention of great utility and merit, and was a resounding commercial /

commercial success during the period it was exploited, the inference is irresistible that if the respondent could have exploited amoxycillin during the lost time it would have derived appreciably more remuneration from sales of amoxycillin over the full term of the 1969 patent than it actually did derive, even though the latter remuneration was very substantial - see Standard Car Truck Co case, (supra) at 820 B - C. It was never suggested that the respondent had so structured the price of amoxycillin that it was able to recoup loss of remuneration sustained during the period of lost time.

In the result the respondent succeeded in discharging the onus of proving that it had not derived adequate

remuneration /

remuneration from the 1969 patent. Mr Plewman's alternative submission that absence of public benefit should have been taken into account by the Commissioner in the exercise of his discretion must be rejected as, for the reasons given, not only did the 1969 patent confer benefits on the public, but it in any event was not open to the appellant to attack the validity of the 1969 patent. It was not seriously contended that the Commissioner failed in any other way to exercise his discretion properly in extending the term of the 1969 patent. Any such contention would have been without substance as the Commissioner clearly did not apply any wrong principle or overlook any relevant consideration in the exercise of such discretion.

The appeal /

The appeal is dismissed, with costs, such
costs to include the costs of two counsel.

J W SMALBERGER
JUDGE OF APPEAL

CORBETT, JA)
HOEXTER, JA)
NESTADT, JA)
NICHOLAS, AJA)

CONCUR