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IN THE COURT OF APPEAL OF NEW ZEALAND

C.A. 14/91

BETWEEN

ALLEN & HANBURYS LIMITED
a company incorporated in
England having its
registered office at
Horsenden House, Oldfield
Lane North, Greenford,
Middlesex, UB6 0HB,
England

First Appellant

AND

GLAXO GROUP LIMITED a
company incorporated in
England having its
registered office at
Clarges House, 6-12
Clarges Street, London,
W1Y 8DH, England,
Pharmaceutical Company

Second Appellant

A N D

THE COMMISSIONER OF
PATENTS

First Respondent

AND

PACIFIC PHARMACEUTICALS
LIMITED a company
incorporated in New
Zealand having its
registered office at 76
Leonard Road, Mt
Wellington, Auckland,
Pharmaceutical Company

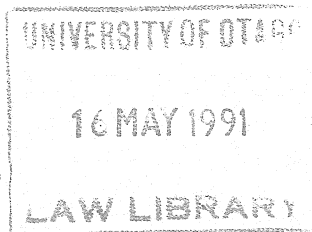
Second Respondent

Coram: Cooke P.
Hardie Boys J.
Thorp J

Hearing: 22 and 23 April 1991

Counsel: B.W.F. Brown and T.F. Arthur for Appellants
Solicitor-General J.J. McGrath Q.C. and
C.B. Littlewood for First Respondent
J.E. Hodder for Second Respondent

Judgment: 23 April 1991



JUDGMENT OF THE COURT DELIVERED BY COOKE P.

Background

The appellants ('Glaxo') are the respective patentees in New Zealand under letters patent numbers 184759 and 198522 relating to the antipeptic ulcerant ranitidine, marketed in New Zealand by Glaxo New Zealand Limited under the trade mark Zantac. They appeal from a judgment of Ellis J. delivered on 17 December 1990 dismissing applications made by them for judicial review of a decision by the Commissioner of Patents under s.52(2) of the Patents Act 1953 that Pacific Pharmaceuticals Limited had made out a prima facie case for orders for the grant of compulsory licences under those patents.

The Commissioner's decision is, according to the correspondence, embodied in the following minute:

I find a prima facie case on the above four applns. under S.51. I direct pursuant to Reg 119(3) that they proceed to advertisement, and that the applicant serve copies of the docs. on the patentees, and the Director General of Health.

(Signature) H. BURTON
20/7/90

As required by the statute the Commissioner advertised the applications, after thus finding a prima facie case, in the Patent Office Journal. The

advertisement appeared in the issue of 28 August 1990. It allowed two months for filing notice of opposition, but instead of or in advance of opposing the applications on the merits the patentees have brought judicial review proceedings challenging the finding of a prima facie case. In the normal course the patents will expire during 1993 and 1997 respectively. As to the possibility of extension, see Douglas Pharmaceuticals Ltd v. Ciba-Geigy AG [1990] 2 N.Z.L.R. 46 and Merck & Co. Inc. v. Pacific Pharmaceuticals Ltd [1990] 2 N.Z.L.R. 55.

The basis of the challenge is pleaded in various ways in the statements of claim, but in all versions it turns on the point that in the applications made on or about 22 June 1990 and the supporting affidavits by Mr J.W. Kemp, the managing director of Pacific, it was said that Pacific intended to sell ranitidine in New Zealand at \$57.33 per unit and that the price charged by the originator was \$63.70 per unit. In truth it emerges that as from 12 June 1990 Glaxo had reduced its price to wholesalers from \$63.64 to \$53.53. The reduction was consequent upon a review by the Department of Health reducing to that level the reimbursement price or subsidy to be paid by the Department. Glaxo challenged this reduction by High Court proceedings in 1990, but without material success and the reduction in the wholesale price followed.

Mr Kemp's affidavits of 22 June 1990 included the following paragraphs, their numbering being that in the first of the two affidavits reproduced in the case on appeal:

Pricing

27. My belief that my company will be able to supply RANITIDINE in New Zealand pursuant to a compulsory licence at prices lower than the prices presently being charged by the patentee, is based on the following:

28. Pacific has a strong history of providing "generic products" in New Zealand at prices lower than those of the original patentee's product with which my company's generic products compete. In general Pacific has been able to provide generic products to the wholesaler/retailer at least 10% (ten percent) lower in price than that supplied by the patentee or the patentee's subsidiary. The presence of a generic product on the market operates to prevent the patentee from raising its prices.

29. In my experience the introduction by the generic manufacturer of a generic product in competition with the original branded product has consistently resulted in reductions in wholesale prices and controls on price increases. The prescription pricing schedule produced by the Department of Health lists the price which it will pay to a pharmacist for a particular pharmaceutical. If two companies supply the same medicine containing the same active ingredient and one of them is prepared to sell it at a lower wholesale price than the other, the Health Department will set a price based on the lower cost to be charged for the medicine. If the manufacturer or distributor of the higher priced brand does not reduce its price to meet that lower cost, a "part charge" is set on that brand, which is paid by the patient on receiving the dispensed prescription. The facts of competition and the disincentive provided by the part charge consistently operate, in my experience, to lower prices and certainly to inhibit regular price increases when a generic medicine enters the market.

30. I have annexed hereto and marked with the letters "JWK-5" a table I have prepared showing the difference in price of a number of pharmaceuticals between February 1980 and February 1990 showing in each case how the introduction of a competitive generic product has maintained or even reduced the price over a 10 year period of high annual inflation.

31. My company intends to provide RANITIDINE in the following formulations and at the following wholesale prices in comparison to the patentee's New Zealand subsidiary:

	<u>Pacific</u>	<u>Patentee</u>
150 mg x 60	\$57.33	\$63.70
300 mg x 30	\$57.33	\$63.70

In subsequent affidavits he has explained that at the time of his original affidavits he did not know of the reduction in the Glaxo price brought about by the Department of Health. An affidavit sworn by him on 19 October 1990 includes the following paragraph:

8. In my Affidavit sworn on 22 June 1990, I indicated that my Company could sell Ranitidine at a price lower than that sold by Glaxo. Now that I am aware of the lower price of Ranitidine sold by Glaxo, namely at a price of \$53.53 for both the 60 x 150 mg packs and the 30 x 300 mg tablet packs, I can say that my Company will be able to sell Ranitidine in New Zealand at that price and most probably at a more economical price, although any lower price will depend upon the the terms of the compulsory licence when granted.

Sections 51 and 52 of the New Zealand Patents Act 1953, in terms copied from ss.41 and 43 of the United Kingdom Patents Act 1949 (which Act now applies to old patents only), read as follows:

51. Inventions relating to food or medicine, etc. -
 (1) Without prejudice to the foregoing provisions of this Act, where a patent is in force in respect of -

- (a) A substance capable of being used as food or medicine or in the production of food or medicine; or
 - (b) A process for producing such a substance as aforesaid; or
 - (c) Any invention capable of being used as or part of a surgical or curative device, -
- the Commissioner shall, on application made to him by any person interested, order the grant to the applicant of a licence under the patent on such terms as he thinks fit, unless it appears to him that there are good reasons for refusing the application.

(2) In settling the terms of licences under this section the Commissioner shall endeavour to secure that food, medicines, and surgical and curative devices shall be available to the public at the lowest prices consistent with the patentees' deriving a reasonable advantage from their patent rights.

(3) A licence granted under this section shall entitle the licensee to make, use, exercise, and vend the invention as a food or medicine, or for the purposes of production of food or medicine or as part of a surgical or curative device, but for no other purposes.

(4) A licence granted under this section may permit the licensee to import the patented article.

52. Procedure on application under sections 46 to 51 - (1) Every application under sections 46 to 51 of this Act shall specify the nature of the order sought by the applicant and shall contain a statement (to be verified in such manner as may be prescribed) setting out the nature of the applicant's interest (if any) and the facts upon which the application is based.

(2) Where the Commissioner is satisfied, upon consideration of any application, that a prima facie case has been made out for the making of an order, he shall direct the applicant to serve copies of the application upon the patentee and any other persons appearing from the register of patents to be interested in the patent in respect of which the application is made, and shall advertise the application in the Journal.

(3) The patentee or any other person desiring to oppose the application may, within such time as may be prescribed or within such further time as the Commissioner may on application (made either before or after the expiration of the prescribed time) allow, give to the Commissioner notice of opposition.

(4) Any such notice of opposition shall contain a statement (to be verified in such manner as may be prescribed) setting out the grounds on which the application is opposed.

(5) Where any such notice of opposition is duly given, the Commissioner shall notify the applicant, and shall, subject to the provisions of section 53 of this Act with respect of arbitration, give to the applicant and the opponent an opportunity to be heard before deciding the case.

The Purpose of Compulsory Licences for Inventions
relating to Food or Medicine

These appeals are concerned only with what is required to show, to the satisfaction of the Commissioner, a prima facie case on an application under s.51 of the Patents Act 1953. They are not concerned with applications coming within ss.46 to 50, nor with what is required to make out a prima facie case for an order under any of those sections. Sections 46 to 50 are directed to abuse of patent rights, failure to work the invention, and like matters; whereas s.51 is not dependent on any failure or conduct on the part of the patentee. Obviously what is required for a prima facie case will vary according to the section under which application is made.

Section 51 operates as a limit on the rights of patentees of inventions relating to foods or medicines or

surgical or curative devices. The philosophy reflected in it is plainly that it is desirable to restrict or relax the monopoly rights granted by such patents. Section 51(1) makes it mandatory for the Commissioner to grant a licence to an applicant who is a person interested (an expression of wide scope in this context), unless it appears to the Commissioner that there are good reasons for refusing. The presumption is in favour of a grant,

Section 51(2) states the object which the Commissioner must endeavour to secure in settling the terms of the licences, namely that the medicines etc. shall be available to the public at the lowest prices consistent with the patentees' deriving a reasonable advantage from their patent rights. The latter words afford protection for patentees and, it may be expected, ample scope for argument. The former words are wide enough to include a tendency to or a likelihood of the lowering of prices or of the holding of prices. Price factors must be important for the purposes of the section but they are not the only relevant factors. Quality of the product, wider availability, speedier distribution are examples (not necessarily exhaustive) of other advantages that could flow from competition in particular cases. As the Solicitor-General put it in argument in this Court, the section is concerned to create a climate of competition. In enacting the section the legislature has assumed that competition is likely to be

beneficial to the public. The section casts no onus on an applicant to show precisely how public benefit will result from a compulsory licence.

Section 51 does not specify what may be good reasons for refusing an application. The Court should not attempt to limit these. An example would be inability of the applicant to work the licence effectively. If the Commissioner were satisfied that the applicant lacked the necessary technical skill or resources or was not a reputable and reliable licensee, those would doubtless be proper reasons for refusal. There appears to be no suggestion of any such reasons in this case.

In theory, and not necessarily in this case, there could be other good reasons. Conceivably, on the facts of a particular case, the Commissioner might ultimately be affirmatively satisfied that no public benefit in respect of price or in any other respect would be likely to be produced by a compulsory licence. That, though, would be a strong conclusion to which the Commissioner (or the Court on appeal under s.53) would be slow to come in the face of the manifest philosophy of the section. And, as to the stage covered by s.52(2), only in an exceptionally clear situation, we think, would the Commissioner be justified in deciding that the applicant had not made out a prima facie case on the ground that no public benefit was likely to result from competition. Because of the structure of s.51

the threshold for a prima facie case on an application under it cannot be high.

The foregoing observations are to much the same effect as those of Ellis J. in the judgment under appeal. He cited and applied the judgment of the Canadian Federal Court of Appeal delivered by Heald J. in American Home Products Corporation v. ICN Canada Ltd (1985) 5 C.P.R. (3d) 1, 6, that the Canadian section there interpreted did not require a commitment from the licensee to market at the lowest possible price as a condition precedent to the grant of a licence: that the Commissioner's role was not to determine the actual market price resulting from competition: that the scope of the licence was not limited to the price structure proposed.

In this Court Mr Brown for the appellants contended that the Canadian section is distinguishable. There are some differences, but we agree with Mr Hodder that the general purpose and structure were similar to those of our s.51. We accept Heald J.'s observations as in point and helpful.

A finding by the Commissioner of a prima facie case exposes a patentee to a contest which, to adapt some words of Lord Wilberforce in Wiseman v. Borneman [1971] A.C. 297, 317, may come to be fought expensively through a chain of tribunals. Like counsel for the respondents, we accept that such a finding is open to judicial review. If it were shown

to be based on a mistake or misconception of fact, the Court would no doubt be able to grant a remedy: compare Daganayasi v. Minister of Immigration [1980] 2 N.Z.L.R. 30. But, when ss.51 and 52 are approached in the way already outlined, it becomes apparent that it would not be easy to satisfy the Court that some mistake in the evidence presented to the Commissioner has been the basis of his decision. Only a mistake sufficiently material to be described as the basis or the probable basis of the Commissioner's decision could, as it seems to us, warrant the Court in putting a stop to proceedings at the preliminary stage, thus compelling the applicant, if still willing, to start afresh.

In the instant case the details of the comparative prices set out by the applicant could properly be seen as unimportant at the preliminary stage and perhaps even at the ultimate stage. On the other hand, the general effect of competition between patentees and 'generic' drug suppliers, deposed to in paragraphs 28, 29 and 30 of Mr Kemp's affidavit as previously quoted, are certainly important. Mr Brown makes the point that, in the examples alluded to by Mr Kemp, the generic manufacturer has not had to pay royalties to the patentee. The amount and the likely effect of a royalty, however, is the kind of question best investigated at the stage of opposition.

In those quoted paragraphs there was ample before the Commissioner to justify a finding that there was a prima facie case for an order. Ellis J. went further, saying that, on the basis of the correct information now placed before the Court, the Commissioner would have been obliged to find a prima facie case, as there was no suggestion of any other 'good reasons' (apart from pricing) for refusing the application. The 'correct information' to which the Judge referred includes, as we understand him, the statement in Mr Kemp's affidavit of 19 October 1990 to the effect that Pacific will be able to sell at prices equalling and, dependent on the terms of the licence, most probably less than Glaxo's present reduced price. We agree with the Judge: for, in the light of that evidence and in the absence of any other apparent good reason for refusing the application, the policy reflected in the Act would point to the granting of the application, and a fortiori a prima facie case is shown. Moreover it has not been shown that the incorrect details of the price structure were the basis of the Commissioner's decision. On the contrary it is probable that he was not primarily concerned about the particular price structure at that stage, but was more concerned, assuming that he applied himself to the statute correctly, with the likely general tendency of competition.

That is enough to dispose of the appeals, but it should be added that, subject to possible statutory changes, New Zealand may now be moving into an era of patent law in

which applications for compulsory licences for drug patents become more common. On behalf of the Commissioner the Solicitor-General, while refraining from making submissions on the merits of the present case, drew attention to the danger that the prospect of prolonged litigation may discourage potential applicants under s.51. The very limited use of the section in the past suggests that there may be something in this apprehension.

The point is illustrated by some of the history of this case. An interim order, in effect by way of injunction, was granted by the Judge on 23 October 1990; his judgment now under appeal was directed not to be sealed before 31 January 1991; on 25 January 1991 he granted a stay on terms. We are not now called upon to consider whether any of those orders was appropriate. There may well have been justification for them in the particular circumstances of this pioneering case. In future cases the Commissioner and the Courts cannot be expected to accede at all readily to applications having the effect of delaying the ultimate issue of any licence.

For these reasons we dismiss the appeals.

In this Court the appellants will pay the second respondent for the cost of the appeals \$3000. There will be no order for costs in the High Court.

R. B. C. v. P.

Solicitors:

A.J. Park & Son, Wellington, for Appellants
Crown Law Office, Wellington, for First Respondent
P.T. McCabe, Wellington, for Second Respondent