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IN THE HIGH COURT OF NEW ZEALAND
AUCKLAND REGISTRY

A 906/83

493

BETWEEN ELI LILLY & COMPANY

Plaintiff

A N D DOUGLAS PHARMACEUTICALS LIMITED

Defendant

Hearing: 1 and 2 May 1984

Counsel: Mr Gault and Mr D J Jones for Plaintiff
Mr A H Brown and Mr D S Johnston for Defendant

Judgment: 2 May 1984

ORAL JUDGMENT OF HILLYER J

This is a motion for an interim injunction. The principles upon which interim injunctions are granted are too well known for it to be necessary for me to set them out in detail. They originated in the House of Lords' case of American Cyanamid Co v Ethicon Ltd [1975] RPC 513; were discussed in Fellowes & Son v Fisher [1975] 2 All ER 829; approved by the Privy Council in Eng Mee Yong v Letchumanan [1979] 3 WLR 373; and approved by our Court of Appeal, particularly in Consolidated Traders Ltd v Downes [1981] 2 NZLR 247.

I therefore proceed to consider immediately the first of the matters that are of importance in motions for interim injunctions and that is whether there is a serious question to be tried.

It has been conceded by the defendant that there is a serious question to be tried. Nevertheless affidavits have

been filed on behalf of the defendant setting out experiments which have been conducted by a Professor Ferrier, who holds the Chair of Organic Chemistry at Victoria University of Wellington and for whose opinion, of course, I have the greatest respect, and a Professor Freeman who considered by X-ray crystallography the product of Professor Ferrier's experiments. These have in turn have been commented on by Dr Pfeiffer on behalf of the plaintiff. A substantial amount of argument has been addressed to me by both parties designed on the part of the defendant to establish that there is a serious doubt as to whether the patent held by the plaintiff is a valid one and contrariwise, on the part of the plaintiff to establish that not only is that patent valid, subsisting and sound, but that Professor Ferrier has misunderstood the teaching of the specification.

The parties have gone to these lengths in spite of the concession made by the defendant for two reasons; the defendant says, first, it wishes to demonstrate that it has a serious and genuine defence and is not merely playing for time so as to get a further opportunity of infringing the plaintiff's patent; secondly, under the balance of convenience factors a consideration of the merits of the case may be an important factor where other factors are evenly balanced.

The basis of the plaintiff's case is a patent for one of the cephalosporins, an antibiotic, which I have always been delighted to learn was found in a Sardinian sewer. This antibiotic is a broad spectrum antibiotic and in one of its applications is in a semi-synthetic form, that is to say, a form which is produced by taking the naturally occurring substance and modifying it. It is known as "cephalexin". This variety of cephalosporin is effective against both gram positive and gram negative bacteria and is effective when taken orally. Indeed, it does have the extraordinary property of being absorbed essentially one hundred per cent from the gastrointestinal tract when taken orally and is excreted essentially completely and without alteration in the urine. For that reason it has achieved a strong position in the market place throughout the world.

When produced by the ordinary method of crystallisation from an aqueous solution however, it has the disadvantage that it comes in a form which is so bulky that a 250 mg dose will not fit into a single capsule of acceptable size for taking orally and of course, where 500 mg doses are required that is even less feasible. This required, therefore, the taking of multiple doses or the swallowing of several tablets at a time and in some circumstances that was a real difficulty.

The plaintiff had a patent in New Zealand for "cephalexin" and related cephalosporins but that patent expired in March 1983. There subsists however a further patent for what is called a "New Crystalline Cephalosporin and Processes for Preparing Same". This is patent number 159749 and it does not expire until April 1986. It has thus just under two years still to run and it is for the protection of this patent for that remaining period that this interim injunction is sought.

The discovery protected by this patent is the discovery that broadly speaking, if cephalexin prepared by any of the recognised methods is purified by suspending the antibiotic or a salt thereof, in an aqueous solution, adding a strong acid in a significant quantity to dissolve the suspended antibiotic, raising the temperature of the solution to above about 58^{o}C and then precipitating the anti-biotic therefrom by the addition of a base, a crystal is formed which is dense, stable and non-hygroscopic. The problem with the crystals that are precipitated at temperatures below 58^{o}C is that they are the fluffy, bulky type crystals that I have mentioned, they absorb water which causes them to change weight and make accurate weighing difficult and they repel one another and tend to be "fly-away" when being weighed and filled into capsules.

After the crystals have been precipitated, of course, it is still necessary to recover them from the solution in which they have been precipitated and if this is done in a solution which is kept above 58^{o}C then the crystals

precipitate in the form of a monohydrate cephalexin whereas when they are recovered from the solution below the 58°C they appear to be converted into a cephalexin dihydrate. Both the cephalexin monohydrate recovered at the higher temperature and the cephalexin dihydrate recovered at the lower temperature however appear to retain the dense non-hygroscopic form and the stability that I have mentioned as being the advantage claimed for the invention. This, it is said, is the basis on which Professor Ferrier fell into error in that he carried out normal laboratory techniques and following the teaching of Example 1 in the specification, finished up with a cephalexin dihydrate because, as he put it, the normal procedure would not have been to heat the solution in which the crystals had been precipitated, or more accurately perhaps, to keep that solution heated. He permitted it to cool and therefore recovered the dihydrate.

It is to be noted however that whether the dihydrate or monohydrate was recovered it was still recovered in the dense form of crystal that I have mentioned, thus retaining the advantage of the patent.

Experiments conducted by Professor Pfeiffer indicate that what Professor Ferrier found was quite understandable but that the substance as precipitated was the monohydrate and changed into the dihydrate when the solution cooled and in the recovery from the cooled solution. This ability of the cephalosporin monohydrate, as Mr Gault put it, to "flip flop" backwards and forwards between monohydrate and dihydrate is demonstrated by the fact that the dihydrate, on exposure to air for a period, does, on occasions, revert to the monohydrate and this appears to have something to do with the ambient humidity.

Professor Ferrier indicated that in his view, based on meteorological reports in Wellington, ambient humidity in his laboratory would be of the order of seventy per cent and it may be that Professor Pheiffer was conducting his experiments in an air-conditioned laboratory or a laboratory in which the

humidity was not as high. Be that as it may, the explanation that was given by Professor Pfeiffer of the experiments conducted by Professor Ferrier does not in my view justify the allegations that have been made by the defendant that they have a very strong attack on the validity of the patent.

It is not necessary, nor of course would it be proper for me to try to determine at this hearing questions of the validity of the patent. Suffice it to say that there is undoubtedly a serious question to be tried as to whether the defendant, by importing and distributing cephalexin monohydrate, would be infringing the patent. Equally, of course, if the substance that it is distributing is cephalexin dihydrate, which has been produced by a process which first produced cephalexin monohydrate, which then converts into the dihydrate in the recovering process, still there would be an infringement of the patent or at least there would be a serious question as to whether the patent was infringed.

For the sake of completeness I should mention that the standard method of determining the nature of a crystal is by X-ray diffraction. X-ray diffraction figures have been given in Professor Pfeiffer's affidavit for both the monohydrate and the dihydrate and it is on the basis of those figures that Professor Ferrier and Dr Freeman arrive at the conclusion that the substance that they obtained was the dihydrate. But that is not the essential point of the patent. What the patent is concerned with is producing a crystal which is dense, non-hygroscopic and stable and those terms, of course, must be read in the light of the disclosure of the specification.

It is frequently said that the writer of the specification provides his own dictionary for the claims made in the patent. Therefore, when one is endeavouring to read the patent one must look at the teaching of the specification to see what is meant by the terms "dense" and "non-hygroscopic". The important point, however, is that whether the substance

exhibits X-ray diffraction pattern of the monohydrate or the different diffraction pattern of the dihydrate, in each case a preferred type of crystal may be obtained, that is to say, the dense non-hygroscopic one as opposed to the fluffy one that will not fit into the small type of capsule.

I turn therefore to the question of the balance of convenience and again the principles here have been clearly identified in the case of Fellowes & Son v Fisher, where Browne LJ at page 840 said (quoting Lord Diplock):

> " If damages ... would be adequate remedy and the defendant would be in a financial position to pay them, no interlocutory injunction should normally be granted, however strong the plaintiff's claim appeared to be at that stage. "

It has been conceded by the plaintiff that the defendant would be in a position to pay whatever damages might be awarded if an interlocutory injunction was refused and it turned out when the matter came to trial that the injunction should have been granted and that the defendant therefore must pay damages.

This is a question of some difficulty but I start with the principle that the plaintiff at present is servicing a market which it has said is growing and which has the potential for tremendous growth if, as is suggested is possible, the drug is given a drug tariff listing. The situation in New Zealand, as I understand it, is that if a drug is given a drug tariff listing then it is supplied free of charge to the patient from pharmacists. When it is not listed, or if it has a restricted listing, then the patient will have to pay the whole or part of the cost. Doctors therefore are reluctant, unless it is necessary, to prescribe a drug which is not on the list, thereby requiring their patients to incur further expense. If an antibiotic, for example, which would do the same job as cephalexin monohydrate, was available and that drug was on the drug tariff list, doctors would be likely to prescribe it in preference to cephalexin monohydrate. Effectively therefore

this restricts the sale of pharmaceuticals, all of which of course, must obtain the approval of the authorities before they can be used in this country to our hospital pharmacy. It is in that field only that until now cephalexin monohydrate has been distributed. If however listing is even now obtained then in the remaining period a three fold increase in the use of the drug could take place. Whether the entry of a competitor into the market, selling at a lower price, might result in the drug listing being obtained, is of course a matter for speculation. All one can say is that there is the possibility of an increase in the market. It is not a static one.

The other factor that appears to me to be of particular importance is that a patent monopoly not only enables the patentee to sell the patented substance without competition during the period of his monopoly but it also enables him to approach or to enter on the period after the monopoly ceases in a very strong position in the market place. This was recognised in the American Cyanamid case by Lord Diplock at page 543. He said:

> " It is notorious that new pharmaceutical products used exclusively by doctors or available only on prescription take a long time to become established in the market, that much of the benefit of the monopoly granted by the patent derives from the fact that the patented product is given the opportunity of becoming established and this benefit continues to be reaped after the patent has expired. "

That is what Mr Gault referred to as the "bridgehead" and it is clear that if at this stage the defendant were permitted to continue its sales or indeed, as seems likely, to mount a much more aggressive marketing campaign than it has done in the past, it would enter into the period of unrestricted sales with a very substantial advantage. I do not know how that could be valued or the basis on which damages for that period could be assessed.

Mr Brown for the defendant has said with some force that any sales made by the defendant during the period of the monopoly could be ascertained and if it turned out that the injunction should have been granted, either a royalty paid on those sales of an account of profits granted for them. But it is one thing for a defendant at this stage to say that is the basis on which damages or royalties could be assessed and another for that to be said when a claim for damages is being assessed. The defendant certainly cannot be bound by such statements. It may well be that when the time came to calculate damages, if damages were to be calculated, allegations may be made that some of the sales were due to there being a demand in the market place for the substance because of the aggressive skilled marketing techniques employed by the defendant. It may be said these had the effect not of taking sales away from the plaintiff but of taking sales away from vendors of comparable antibiotics such as ampicillin or amoxycillin

The defendant is further suggesting, with a proposition that a trust fund of one-fifteenth of its sales should be established, that in effect it should be given a compulsory licence with the possibility that it could avoid payment of licence fees if it was established that the patent is invalid. In that way it would get the best of both worlds because in normal circumstances a licensee is not permitted to challenge his licensor's title.

It is clear in my view that if this case were to come to trial before the expiration of the patent monopoly period, it would be an extraordinary example of diligence and good luck on the part of counsel on both sides. I would think that the likelihood would be that it would not come to trial until well after the patent monopoly had expired so that the "bridgehead" that Mr Gault has referred to would not be able to be re-established before the competition had to be faced.

There were a number of other factors put forward by the plaintiff to demonstrate that damages would not be an

adequate remedy. Without any disrespect, I am of the view that some of them are of less significance than others and in particular, the ones I have mentioned but I was intrigued by what was described as the "hawks on the telephone line" principle, or perhaps more accurately ornithologically, the "hawks on the tree branch". I do not think hawks sit on telephone wires. The principle here was that if one infringer gets in effect a licence to operate until the monopoly expires, other would-be infringers would swoop down and it would be difficult to prevent their obtaining a similar concession.

In answer to this Mr Brown said that it had taken his client years to get to the position he was now in and he thought it extremely unlikely that others would be able to come on to the market before the expiration of the patent period. But I have no evidence as to what other competitors, if I may mix the metaphors, may be "lurking in the wings" and the extent to which they might be ready to burst on to the stage. Undoubtedly, if any other infringer were to come on to the market it would be difficult to obtain an interim injunction against him if one were refused against this defendant and it would be equally difficult then to determine against whom damages should be awarded and the extent of those damages.

It was indeed for the reason that there was more than one infringer that the interim injunction was refused in the case of Catnic Components v Stressline Ltd [1976] FSR 157. I conclude therefore that damages would not be an adequate remedy for the plaintiff because of the difficulty of assessing them in the light of the uncertainties I have outlined and in the light of the difficulty of valuing the "bridgehead".

I turn therefore to determine whether, if an injunction is granted and it is determined that an injunction should not have been granted, the defendant can be adequately compensated by damages. In this regard the first enquiry would be whether the plaintiff has the ability to pay damages. Of course it is an overseas company of substantial value but the action is brought by the overseas company and not by its New

Zealand subsidiary. I am advised from the Bar however that if an injunction is granted there would be an undertaking on behalf of the plaintiff and on behalf of its New Zealand subsidiary, that suitable arrangements would be made by way of guarantee to pay any damages that may be awarded. If the parties were not able to agree then the matter could be further determined by the Court.

I turn therefore to consider whether the defendant would be adequately compensated by damages and again it is a matter of considerable difficulty. I note, however, that in the period that the defendant has been selling the drug on the New Zealand market, a period of ten months, total sales have amounted only to the sum of $6069.26. It has on hand total stock amounting to $18,038.54. Clearly if called on to assess damages a court would be reluctant to say, if that value of the drug had been lost because of its limited shelf life, that the fault was the defendant's because it had failed to take adequate steps either to send them back to the manufacturer or to do something else with them. In that regard Mr Gault indicated that of course there would be no complaint by his client that the defendant was dealing with the patented product if it forwarded the drugs out of this country and I could hardly imagine there would be much sympathy for such an allegation.

In effect what the defendant will suffer is the loss of the opportunity of competing for a period of 23 months. I cannot accept that the efforts it has made to date in approaching the Nelson and other hospital boards could not be quantified and compensation given for that. The Courts continually have to assess damages and without wishing in any way to minimise the efforts that have been made, it is clear that to date, in my view, the effort that has been expended by the defendant in approaching different hospital boards is not such as would present substantial difficulty to a court in assessing adequate compensation for it.

I do, however, acknowledge that there would be some difficulty and I therefore go on to consider other factors. In particular the allegations made on behalf of the defendant that it will suffer significant hardship. It is alleged on behalf of the defendant that this was not a case in which the defendant went into the conduct complained of with its eyes open and cannot therefore plead the hardship which it is likely to suffer if an injunction was granted. These principles have been mentioned in The New Zealand Farmers' Co-Operative Association of Canterbury Ltd v The Farmers Trading Co Ltd & Anor (Christchurch A496/78 judgment of Chilwell J delivered 15 February 1977); Probe Publications Ltd v Profile Communications Ltd & Ors (Auckland A 318/81 judgment of Chilwell J delivered 27 May 1981); Keg Restaurants Ltd & Anor v Brandy's Bar Ltd & Ors (Auckland A 1042/83 judgment of Tompkins J delivered 16 November 1983).

Mr Gault commented that it was hardly a case of the defendant going into this matter with his eyes open. He said that for a company involved in pharmaceutical trading, which regularly sells pharmaceutical drugs after patents have expired, the system of checking on patents set out by the defendant was "naive and hardly credible".

The defendant's managing director said that his practice was to look in the Merck Index. He said that this was the Bible for the pharmaceutical industry and listed products and all relevant patents. He said that the entry in the ninth edition, 1976 for cephalexin base referred to two patents, both sealed in 1976, one in South Africa and one in Belgium, and that they were both in favour of the plaintiff. He said that under the entry for cephalexin monohydrate there was no reference to any patent being sealed. He said that when there is a reference to a United Kingdom or United States patent he always does one of two things; either arrange a patent search by his patent attorney, Messrs Baldwin Son & Carey, or he would go back to his principal to ask about any relevant patent. On this occasion, he said, because there were no patents shown in

the Merck Index for cephalexin monohydrate he considered there would be no patent in New Zealand . He said the considerable number of trade names published in the Merck Index for both cephalexin base and cephalexin monohydrate indicated to him that it was most unlikely that there would be a valid international patent.

I do not know what a valid international patent is but it is clear that this was a most inadequate way of checking on the existence of a patent for cephalexin monohydrate. I note that even though the previous cephalexin patent did not expire until March 1983, the defendant sold to the Thames Hospital Board in November 1982 and to the Marlborough and Timaru Hospital Boards in February 1983 its form of cephalexin. This does not indicate any particularity or care on the part of the defendant to avoid infringement of patents. It should, in my view, have been obvious to the defendant that a substance as important as cephalexin or indeed, cephalexin monohydrate, would be likely to be the subject of a patent in New Zealand and a simply request to his patent attorneys would have ascertain the position without difficulty.

Mr Gault indicated that he did not think it was a matter so much of the defendant going into the matter with its eyes open, it was more a matter of a Nelsonian approach. I must say that I consider there was some justification for that comment.

In that regard also I note the submission made on behalf of the defendant that the plaintiff's delay in seeking injunctive relief is one of the critical factors in determining the balance of convenience in this case. Mr Brown submitted it is well established law that "interlocutory relief is granted only in matters of urgency so that a plaintiff who delays thereby demonstrates the absence of any urgency requiring prompt relief (Snell's Principles of Equity (28th ed) p 644).

Mr Brown points to the fact that the Minister's consent to distribution of cephalexin monohydrate in New

Zealand was published in the New Zealand Gazette on 7 April 1982 and that the authority to import was published on 21 October 1982. In reply Mr Gault points to the evidence of Miss Berkahn, the pharmaceutical marketing manager of the New Zealand subsidiary of the plaintiff, who says that until March 1983 she had no knowledge that the defendant was proposing to market the substance in New Zealand; that she then learned that an approach had been made to the Auckland Hospital Board; that by a reduction in price she secured the order from the Auckland Hospital Board for her company and thought that that had sufficiently dealt with the matter. When she did ascertain that the defendant intended to continue marketing in New Zealand she had the company's patent attorneys, Messrs A J Park and Son, write to the defendant and that was done in July 1983. Following that no substantial delay took place in the issue of a writ.

I do not consider that the delay that took place in commencing this action is such as would justify the refusal of an injunction to the plaintiff, if all other factors were equal. The commencement of an action of this nature is a matter which involves considerable effort and expense and if a company believes, as the plaintiff was entitled to do, that the application for consent to distribute was a preliminary step, not necessarily involving immediate intention to distribute, it would be justified in refraining from taking any further steps until the position was clear.

On this basis therefore I am of the view that an injunction should issue. The plaintiff has demonstrated, and it has been accepted, that there is a serious question to be tried. I hold that damages will not adequately compensate the plaintiff if an injunction is refused and it is subsequently ascertained that an injunction should have been granted. Although there would be difficulty in ascertaining the damages payable to the defendant if it appears subsequently that an injunction should not have been granted, those difficulties are not as great as the difficulties that there would be in ascertaining the damages due to the plaintiff

For the sake of completeness I do mention the question of the status quo. I have been referred to the decision in Garden Cottage Foods Limited v Milk Marketing Board [1983] 2 All ER 770. It is in my view a matter of considerable difficulty to determine what is the status quo which should be preserved. I have difficulty in believing that where an infringer, without the knowledge of the patentee, had indulged in some infringing activities, the fact that those alleged infringing activities had taken place would be justification for permitting them to continue. The problem further is that where there is a marketing situation, with further importation and further sales, with a fresh infringement each time the product is dealt with, it would not be possible to preserve the status quo by holding the level of sales, for example, at the level that existed immediately prior to the issue of the writ. The only satisfactory way of preventing an increase in that activity, in the case of a marketing operation of this nature, would be to prevent sales entirely.

The matter is one of considerable difficulty and I am relieved that I do not have to decide it. The choices are between preserving the situation prior to the commencement of the conduct complained of or preserving the situation immediately preceding the issue of the writ, with some modification if there had been an reasonable delay in bringing on the motion, or some situation between those two.

There will therefore be an injunction in the terms of the notice of motion, that is to say, restraining the defendant, its servants or agents from importing, offering for sale, selling or otherwise disposing of the chemical product cephalexin in the monohydrate form, until the trial or earlier expiry of the patent. That injunction will not restrain the defendant, if it is able to do so, from sending back to its principal the stocks of cephalexin monohydrate it is now holding. Arrangements are to be made as mentioned regarding possible damages payable by the plaintiff.

In accordance with normal principles I will reserve the question of costs on the motion for interim injunction pending the hearing of the main action but I give leave if there is any delay in bringing the motion on for a hearing to either party to come back on the question of costs. That is not to be taken as an indication that I am considering awarding costs to the defendant on this application.

On the motion for security for costs, by consent there will be an order that security be given by an undertaking to the Court in writing, made by the local subsidiary of the plaintiff, to pay any costs that may be awarded in the action up to the amount of $10,000.

D Mallon J

Solicitors
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