

Freeze-dried generics frozen in their tracks

Pharmacia Italia S.p.A v Mayne Pharma Pty Ltd [2005] FCA 1078 (5 August 2005, Crennan J)
Pharmacia Italia S.p.A. v Interpharma Pty Ltd [2005] FCA 1675 (23 November 2005, Sundberg J)

In two separate Federal Court decisions relating to the same patent owned by Pharmacia Italia S.p.A. (**Pharmacia**) Federal Court Judges have found infringement by Mayne Pharma Pty Ltd (**Mayne**) and granted an injunction against Interpharma Pty Ltd (**Interpharma**).

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The *Mayne Pharma* decision is notable for finding infringement in circumstances where the literal wording of the claims was avoided. The *Interpharma* decision is interesting because the interlocutory injunction was granted despite validity being put in issue. It stands in contrast to the unsuccessful attempt by Roche to obtain an injunction against Hexal which we reported in September 2005. In the *Interpharma* decision the Judge also considered the definition of *exclusive licensee* under the *Patents Act* and the nature of exclusivity required to provide a licensee with standing to bring infringement proceedings.

1. BACKGROUND – THE PATENT

Australian Patent No. 589197 (*Patent*) relates to injectable ready-to-use solutions containing an anti-tumor anthracycline glycoside. The priority date of the Patent is 2 April 1985. Pharmacia is the proprietor of, and Pfizer (Perth) Pty Limited (*Pfizer*) a licensee of, the Patent. Both proceedings were brought jointly by Pharmacia and Pfizer (*Applicants*).

In each proceeding, the alleged infringing product was a ready-to-use solution of the anthracycline glycoside, epirubicin hydrochloride. The matter before the Court depended on the Court's interpretation of claim 1.

This is set out below in a manner highlighting the six essential integers identified by the Court:

- (1) a sterile
- (2) pyrogen-free
- (3) anthracycline glycoside solution
- (4) which comprises
 - (i) a physiologically acceptable salt of an anthracycline glycoside
 - (ii) dissolved
 - (a) in a physiologically acceptable aqueous solvent therefor
 - (b) at an anthracycline glycoside concentration of from 0.1 to 50 mg/ml
- (5) *which has not been reconstituted from a lyophilizate*
- (6) and the pH of which
 - (i) has been adjusted from 2.5 to 5.0
 - (ii) *solely* with a physiologically acceptable acid.

The italicised text highlights the terms which raised issues of construction relevant to the *Mayne Pharma* proceedings. Integer 5 was also relevant to the *Interpharma* proceedings.

2. MAYNE PHARMA PROCEEDINGS

By consent the Court considered the issue of infringement separately from all other issues.



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Whether the Mayne Pharma product infringed claim 1 turned on whether the Mayne Pharma product included the integers presented in bolded language in paragraphs (5) & (6).

(a) **“which has not been reconstituted from a lyophilizate”**

In an early stage of the manufacturing process, bulk lyophilizate was dissolved. Mayne Pharma (unsuccessfully) argued that its product did not infringe the Patent because the solution had been reconstituted from a lyophilizate.

The Applicants argued that the words in claim 1 “which has not been reconstituted from a lyophilizate” should be construed in such a way as to exclude solutions of a type known at the priority date which were made up shortly before administration to a patient. On that basis, the words would not exclude the dissolution of a lyophilizate at an early stage in manufacture, such as in the method used by Mayne Pharma.

Numerous experts gave evidence about the meaning of the term “reconstituted”. Mayne Pharma’s experts did not disagree that the word had a meaning when used in pharmaceutical science of “reconstitution of a lyophilized product prior to administration to a patient”. However, it argued that in claim 1 the word had its ordinary meaning as the term was plain and unambiguous.

Crennan J held that the word “reconstituted” was “not a term of art used to refer to the dissolution of a lyophilized product so as to produce a solution suitable for intravenous injection shortly thereafter”. It was clear however that both the word “reconstituted” and the expression of which it forms a part in claim 1 were used in a special sense in the specification.

Crennan J further held that if the word was capable of more than one meaning it lacked

clarity so it was permissible to have resort to the body of the specification. The body of the specification showed the expression “which has not been reconstituted from a lyophilizate” in claim 1 disclaims preparations known in the prior art. References in the body of the specification to lyophilized preparations known as at the priority date were references to lyophilized preparations in a vial.

Accordingly, the claim for infringement by reference to integer (5) of claim 1 was made out.

(b) **“solely with a physiologically acceptable acid”**
Mayne Pharma admitted that, in the processing of their product after August 2004, the pH had been adjusted to be within the range stated by use of a physiologically acceptable acid (hydrochloric acid). A similar step had occurred in an original process used before August 2004. The Court found that each of these batches constituted a textual infringement of claim 1.

Mayne Pharma also prepared a further (third) batch of an alleged infringing product where hydrochloric acid was used to adjust the pH of the solution to be within the claimed range of 2.5 - 5.0 (adjusted to 2.7 (or 2.8)), and then a minor amount of sodium hydroxide was added to further adjust the pH to 2.9. Accordingly, this product did not represent textual infringement of claim 1.

However, Crennan J considered that the question of infringement of a combination patent is whether the essence or substance of an invention underlying its form has been taken, such that in substance and effect an infringement has occurred.

Crennan J cited the following comment of Dixon J in *Radiation Ltd v Galliers & Klaerr Pty Ltd* (1938) 60 CLR 36 eschewing literalism as an approach to assessing whether an alleged infringement fell



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within the language of the claim:

But, on a question of infringement, the issue is not whether the words of the claim can be applied with verbal accuracy or felicity to the article or device alleged to infringe. It is whether the substantial idea disclosed by the specification and made the subject of a definite claim has been taken and embodied in the infringing thing.

Crennan J also referred to *Commonwealth Industrial Gases Ltd v MWA Holdings Pty Ltd* (1990) 180 CLR 160, where Menzies J found against the defendant who consciously attempted to avoid infringement of a combination patent by making slight modifications in manufacture to a particular part of a piece of equipment:

Patent rights are not to be set at naught by such a subterfuge which ... added nothing to the equipment and was made merely in an attempt to take full advantage of the invention while avoiding infringement of the plaintiff's letters patent by a modification so small as to be insignificant.

Crennan J found that the addition of minor amounts of sodium hydroxide in order to avoid textual infringement is a modification so small as to be insignificant. In substance the invention was still taken. Accordingly, the respondents infringed claim 1.

The decision is to be contrasted with recent decisions of the Federal Court (reported in our September 2005 issue of Case Notes) which emphasised the importance of the claim language in assessing infringement.

3. INTERPHARMA PROCEEDINGS

In these interlocutory proceedings, the Applicants obtained an injunction preventing Interpharma from importing or offering to

import its doxorubicin hydrochloride and epirubicin hydrochloride injection formulations until the hearing and determination of the main proceeding.

Interpharma had obtained approval from the Therapeutic Goods Administration and listing under the Pharmaceutical Benefits Scheme (*PBS*) for the products. In the course of obtaining PBS listing, it had also provided the requisite assurance that stock would be available for supply on the date of PBS listing. However, it had not, at the date of hearing, imported any stock.

The Applicants sued for infringement.

Interpharma filed a cross-claim seeking revocation of the Patent on the grounds that it:

- lacked novelty;
- lacked an inventive step;
- did not involve a manner of manufacture;
- did not comply with s 40 of the *Patents Act 1990* (Cth); and
- was obtained by false suggestion.

The parties agreed to the proceedings being heard together. Pending the resolution of the combined proceedings, the Applicants sought an interlocutory injunction, which required it to establish that:

- (a) there is a serious question to be tried (in that if the evidence remained the same, there is a probability at the final trial that it would be entitled to final relief);
- (b) if relief is not granted it will suffer irreparable harm for which damages will not be an appropriate remedy; and
- (c) the balance of convenience favours the relief.

Sundberg J found for the Applicants on each of these factors.



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(a) Serious question to be tried

(i) Pfizer's standing

Interpharma alleged that Pfizer lacked standing on the ground that it was not an exclusive licensee under the *Patents Act*. In other words it was argued that Pfizer was not:

a licensee under a licence granted by the patentee and conferring on the licensee, or on the licensee and persons authorised by the licensee, the right to exploit the patented invention throughout the patent area to the exclusion of the patentee and all other persons

where

exploit, in relation to an invention, includes, where the invention is a product make, hire, sell or otherwise dispose of the product, offer to make, hire, sell or otherwise dispose of it, use or import it, or keep it for the purpose of doing any of those things.

Pfizer was in fact a sub-licensee (Pharmacia Italia (*PI*) itself having granted a licence to Pharmacia Cork Limited (*PC*), who in turn granted a licence to Pfizer). Sundberg J held that, at least for the purposes of the motion, the licensee/sub-licensee relationships by themselves were of no consequence. It remains to be seen whether this issue is relevant to Pfizer's standing in the substantive proceedings and if so, how the Court chooses to address it. For example, it is arguable whether a sub-licensee can meet the requirements of "a licensee under a licence granted by the patentee".

A predecessor of PI had granted a non-exclusive licence to David Bull Laboratories (*DBL*) (ironically a company related to Mayne Pharma) "for the purposes of **DBL manufacturing, using and selling**" the product. Under the licence from PC, Pfizer was granted "(subject only to the rights, if

any, subsisting from time to time, under the [DBL licence])" an exclusive, royalty-free sub-licence to exploit the invention the subject of the Patent throughout Australia to the exclusion of PC and all other persons.

In assessing whether Pfizer was an exclusive licensee, Sundberg J considered a 1963 High Court decision under the 1952 *Patents Act* and a 2003 decision under the 1990 *Patents Act*. The High Court observed that the definition of "exclusive licensee" under the 1952 Act specifically required the licence to grant to the licensee the exclusive right to "make, use, exercise and vend" the patented invention. It followed that any licence that did not grant all of these rights could not be an exclusive licence. By contrast, in *Grant v Australian Temporary Fencing Pty Ltd* (2003) 59 IPR 170, Holmes J found that under the 1990 Act the definition of "exploit" was non-exhaustive and the various acts set out in that definition were listed in "an inclusive and distributive way". Holmes J found that it was possible to grant exclusive licences to each of the acts listed in that definition.

Sundberg J distinguished the High Court decision. While His Honour also found that the present case was not "on all fours" with the Grant decision, he also found that, since the DBL licence did not include the right to **import**, such right would have been included in the rights licensed to Pfizer. Since the right to import was the right Interpharma would infringe, Sundberg J found that Pfizer had at least an arguable case of standing as exclusive licensee.

(ii) Infringement

Interpharma argued that in the course of manufacture of the solutions it proposed to import, the solutions were reconstituted from a lyophilizate. Accordingly, the solutions did not fall within integer (5) of claim 1.



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Pfizer presented information the manufacturer of the imported solutions had provided to the TGA suggesting that the solutions were manufactured from a crystalline powder rather than a lyophilizate. This evidence contradicted evidence of Interpharma's managing director that the manufacturing process involved reconstitution in the form of a lyophilizate. Sundberg J preferred Pfizer's evidence and found that there was a serious question to be tried on the issue of infringement.

(iii) Validity

Sundberg J was dismissive of Interpharma's attack on the Patent for lack of novelty and inventive step. The novelty evidence included an opinion of a patent attorney in which none of the prior art documents cited clearly disclosed all of the integers. The other novelty evidence was "hearsay upon (apparent) hearsay about events that took place 20 years ago" and comprised "precisely the prior art that Crennan J held in [the] *Mayne Pharma* [proceedings] was excluded by integer [5]". On inventive step the patent attorney's opinion failed to consider whether the six documents relied upon formed part of the common general knowledge.

Interpharma conceded that the attack on section 40 grounds was a matter for the trial and Sundberg J was also quite dismissive of Interpharma's attack on the grounds of manner of manufacture and false suggestion.

Sundberg J found that Interpharma failed to establish that there is a serious question as to the alleged invalidity of the Patent.

(b) Irreparable harm

The evidence established that Pfizer supplied the patented solutions to a related company, Pfizer Australia Pty Ltd (*PA*) which actually sold and

distributed the solutions. The evidence in support of irreparable harm related to the sales *PA* would forgo. Interpharma argued that *PA*'s losses were not relevant to the question, as *PA* was not a party. Pfizer argued that it was the sole supplier of these solutions to *PA* and that *PA*'s lost sales would flow directly through to Pfizer as corresponding lost sales. Whilst there was no evidence as to the price at which Pfizer sold the solutions to *PA*, Sundberg J concluded that Pfizer's losses would be substantial.

Sundberg J also found that Interpharma had only a modest capacity to meet any significant award of damages. It was a very young company and its capacity depended on it importing the allegedly infringing solutions, from which activity it projected a certain level of profit. Profit was not assured and Interpharma had not offered to quarantine any part of that profit. In contrast, there was no dispute as to Pfizer's capacity to pay damages pursuant to the usual undertaking.

Sundberg J found that damages payable by Interpharma would not be adequate compensation to Pfizer.

(c) Balance of convenience

Sundberg J found in favour of Pfizer here, stating that "Interpharma entered its chosen market with 'its eyes wide open' to the possible consequences...It cannot avoid being enjoined simply because of those possible consequences. Further, it is an invader yet to establish itself in its chosen market. It had not, as at 9 November 2005, imported the imported solutions."

The strength of these closing comments should provide patentees seeking to obtain interlocutory injunctions with some renewed hope following some recent decisions where interlocutory injunctions have been denied.



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It is also interesting to note that the injunction was granted despite Interpharma's commitment to the PBS, and with no apparent consideration of the consequences of Interpharma being unable to honour this commitment.

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