

Australian Case Report

Sigma Pharmaceuticals (Australia) v Wyeth



In the recent Australian Federal Court decision of *Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth* [2009] FCA 595, Wyeth were successful in preventing Sigma's launch of a generic version of EFEXOR-XR™ (venlafaxine hydrochloride), the leading antidepressant in Australia in terms of units sold and value of sales.

The decision of Justice Sundberg granted Wyeth an interlocutory (pre-trial) injunction restraining Sigma from continuing its launch of its generic version of EFEXOR-XR™, pending final determination of infringement/revocation proceedings in respect of Wyeth's method of treatment patent claims.

Despite Sigma establishing a *prima facie* case of invalidity for lack of inventive step (obviousness) and not meeting the threshold requirement of an "invention"¹, as well as Sigma's preparedness to undertake that it would not apply for PBS listing, maintain full and complete accounts and sales records, retain all sales proceeds apart from disbursements in a separate account and would not discount or provide material benefit to purchasers by "bundling" EFEXOR-XR with other pharmaceuticals, Justice Sundberg found that the balance of convenience favoured the grant of interlocutory relief to Wyeth pending final determination at trial.

Notably, Wyeth argued that if Sigma's product entered the market and Wyeth later

succeeded at trial it may lead to a reduction in the beneficial effect of the medication as changes in the appearance of the medication may cause confusion and, as a result, missed doses or discontinuance.

Justice Sundberg appeared to accept this argument (at [65]):

"It is not in the public interest that vulnerable people, those with mental health issues, including depression, and elderly patients with a variety of medications, be subjected to confusion as a result of the refusal of interlocutory relief."

With this latest decision, patentees of pharmaceutical inventions have had a 75% success rate² in obtaining interlocutory injunctions in the Federal Court of Australia since 2006.

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¹ Specifically, that the claimed methods of treatment amounted to no more than a new use of a known substance for which its known properties make it useful. It should also be noted that claims to methods of medical treatment are patentable subject-matter in Australia.

² *Merck & Co Inc v GenRX Pty Ltd* (2006) 70 IPR 286 – granted (FOSAMAX™); *Roche Therapeutics Inc v GenRX Pty Ltd* (2007) 71 IPR 456 – refused with undertakings (DILATREND™ and KREDEX™); *Interpharma Pty Ltd v Commissioner of Patents* (2008) 79 IPR 261 – granted (EBEGEMCIT™); *Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth* [2009] FCA 595 (3 June 2009) – granted (EFEXOR-XR™). Not including matters resolved by the giving of undertakings and consent orders.



John McCann

Principal

john.mccann@sprusons.com.au

The recent case of *LED Technologies Pty Ltd v Elecspe Pty Ltd* [2008] FCA 1941 is one of only a few design infringement cases decided under the (relatively new) *Designs Act 2003*. This decision covers a wide range of issues under the new design laws including authorship, quality of representations (drawings), validity, infringement and damages.

Authorship

The plaintiff was the registered proprietor of a number of design registrations for LED lamp assemblies for motor vehicles. Authorship of the design was challenged by alleging that specifics of the final products marketed by the plaintiff were designed by their manufacturer in China, and thus, the authors named in the registration were in error. However, the Court found that the author was the "person whose mind conceives the relevant shape, configuration, patent or ornamentation applicable to the article in question and reduces it to visible form". The Court also found that the original drawings provided by the (named) author to the Chinese manufacturer were sufficient to establish authorship of the design.

Drawing Quality

Whilst the applications were filed with line drawings of reasonable quality, those drawings were subsequently replaced during the application phase by photographic representations of arguably poorer quality. Interestingly, the Court found that each design was "reasonably clear and succinct... and (whilst the) drawings are not perfect or that they could be better or clearer... each design does appear with reasonable clarity, and without necessity for unreasonably prolonged or complicated series of deductions." The Court also found that representations contained in the electronic records of IP Australia were able to be magnified to illustrate details that would not ordinarily be visible, and further that the official record includes the file records of IP Australia which may not be reproduced on the electronic records (in this case the original informal drawings).

Well Designed

Federal Court supports designs registered under the Australian Designs Act



Validity

The validity of the designs was questioned on the basis of prior art. Design registrability requires a test of both newness and distinctiveness. Newness is a simple test of fact of whether there is an identical design somewhere in the prior art. No prior publication was identified. The Court held though that distinctiveness is assessed by comparing the design individually to each relevant piece of prior art, and not by comparing the design in question to the prior art base as a whole. This appears (under the provisions of the 2003 Act) to be in contrast to the decision of *Control v. Meco McCallum* [1996] FCA 475 where the defendant in design infringement proceedings was able to form a mosaic of the prior art to teach each and every feature of the registered design under the, now superseded, *Designs Act 1906*.

The Court also discussed the standard of a “informed user” and said that such a person:

1. is reasonably informed, not an expert but more informed than an average consumer;
2. is of an average standard however expert evidence may still be adduced in Court to

assist the Court in applying the informed user concept; and

3. focuses on visual features and is not concerned with internal features or features that are not visible to the naked eye.

Infringement

In considering the issue of infringement, the Court had the benefit of a statement of newness and distinctiveness associated with the design registrations. For each registration, the same statement was used and stated as follows:

“separate clip-in lenses, base to take a variety of 2, 3 or 4 combination lenses, tail and indicator, reverse LED lenses, no visible screws”.

The Court acknowledged that the alleged infringement contained two visible screws but even though the design emphasised “no visible screws”, the Court held that the presence of the screws “does not create a different visual appeal. The screws are the same colour as the flat strip or landing between each lens and sit low in the socket. They are not “visual” screws as one would describe the screws in some prior art...where the screws are chrome in

colour and protruding.” The Court found that the alleged infringement was “substantially similar in overall impression” and a witness in the proceedings acknowledged that the alleged infringements were closer to the registered designs than they were to the prior art. Infringement was therefore found. The decision also included clarification as to what is primary and secondary infringement.

Conclusion

The 2003 Act was touted as being one that would provide better scope for designers to enforce their intellectual property rights. This appears to have been well supported by the Court in this instance. In the author’s opinion, the registered proprietor was fortunate that the Court accepted the quality of the representations as registered, and even further that the Court sought to consider the representations as originally filed, which arguably were not on the “Register”. Also, the Court disregarded the apparent express limitation of “no visible screws” in the Statement of Newness and Distinctiveness whilst at the same time acknowledging the presence of visible (albeit almost hidden) screws in the alleged infringement.

Nevertheless, the decision is most encouraging for prospective design registrants.



Lee Pippard

Principal

lee.pippard@sprusons.com.au