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Interlocutory injunction granted in a pharmaceutical patent infringement case

The latest pharmaceutical patents to come under attack in court in Australia are two patents for Lilly's Gemzar oncology drug. The active agent in Gemzar is gemcitabine hydrochloride. Gemzar is protected, in Australia, by two patents - one for the compound (the compound patent) and one for a process relating to the manufacture of gemcitabine hydrochloride (the process patent).

THE PROCEEDINGS

The Australian generic pharmaceutical company Interpharma Pty Ltd commenced proceedings against the patentee, Lilly, seeking revocation of the compound patent and challenging the decision to extend the term of that patent. A cross-claim was subsequently commenced by Lilly alleging infringement of the compound patent. That cross-claim was subsequently amended to add an allegation of infringement of the process patent.

Through enquiries with the Australian Department of Health and Ageing, Lilly became aware that on 1 September 2008 an application had been made by Interpharma to list a gemcitabine hydrochloride product on the Australian Pharmaceutical Benefits Scheme (PBS) with effect from 1 December 2008. Lilly brought an application in the Federal Court seeking urgent interlocutory relief, effectively preventing Interpharma from launching a gemcitabine hydrochloride product in Australia on 1 December 2008 as it intended to do.

THE COURT'S APPROACH TO INTERLOCUTORY RELIEF

The Court applied the conventional approach on interlocutory injunction applications namely:

- ◆ Whether there is a serious question to be tried or has the patentee made out a prima face case in the sense that, if the evidence remains the same, there is a probability that at trial they will be entitled to relief for patent infringement.
- ◆ Whether the patentee will suffer irreparable harm, for which damages will not be adequate compensation unless an injunction is granted; and
- ◆ Whether the balance of convenience favours the granting of an injunction.

SERIOUS QUESTION - THE GENERAL APPROACH

The Court held that the requisite degree of seriousness of the question depended on the nature of the rights that the patentee asserts, and the practical consequences likely to flow from the orders sought.

The issue whether there is a serious question should not be considered in isolation from the issue of the balance of convenience. But what is the situation when there is an allegation that the patent or patents relied upon are invalid? The Court held that the onus was on the respondent to show that invalidity is a triable question. But even where this is established, unless the case for invalidity is sufficiently strong to qualify the conclusion that the patentee has a serious question - or a probability of success - in relation to infringement, the Court should move on to consider the adequacy of damages, the balance of convenience and other discretionary matters.

Was there a serious question on infringement of the compound patent?

The issue of substance on infringement was whether a compound consisting of a particular anomer infringes a patent which specifies the racemate. On the authority of *Ranbaxy Australia Pty Ltd v Warner Lambert Company LLC* [2008] FCA FC82 and *Alphapharm Pty Ltd v H Lundbeck A/S* [2008] FCA 559, Interpharma argued that a compound which consists of one enantiomer only does not infringe a patent that is not concerned with anomeric forms.

Lilly, relying implicitly on the decision in *Apotex Pty Ltd v Sanofi-Aventis* [2008] FCA 194 argued, not surprisingly, that the compound patent recognised the existence of different stereochemical forms of the compound claimed, and that the patent should be construed as extending not merely to the racemate, but also to the different anomers as elements thereof.

The Court, on an interlocutory application, was not prepared to resolve the issue of the construction of the patent - that was a matter for the trial judge. Justice Jessup observed, however, that: "By reference to the authorities, particularly *Ranbaxy* and *Apotex*, [Interpharma's] point is of some apparent force. It is not so self evidently likely to succeed, however, as to compel the conclusion that [the Lilly parties] do not have a serious question to be tried."

Was there a serious question on invalidity of the compound patent?

Interpharma also challenged the validity of the compound patent on the ground that it was not useful. Utility gives rise to the question of whether the invention as claimed attains the result promised by the patentee. Despite the fact that gemcitabine is used as an anti-tumour agent, the compound patent stated that the compounds claimed are effective for the treatment of viral infections in general and, most particularly, in the treatment of infections caused by viruses of the herpes genus. Evidence was led by Interpharma that gemcitabine was not therapeutically useful in the treatment of viral infections due to its toxicity. Lilly argued that, properly understood, the patent made no promise with respect to antiviral efficacy in a human clinical context. Rather, the only promise was that a compound made in accordance with the patent would have an antiviral effect or that it would be an antiviral agent.

Justice Jessup again held that the resolution of this issue was a matter of the construction of the patent. The question was what did the specification promise? The judge was attracted by the argument that the specification of the compound patent at least implied that the claimed compound could be used in a human context. Accordingly, he was inclined to think that there was a persuasive prima face case that the compound patent might be held at trial to be invalid on the ground of lack of utility. Notwithstanding that observation, Justice Jessup took the view that the inutility argument was not so manifestly destined to succeed as to require the conclusion that there was no prima face case of infringement of the compound patent.

The serious question - infringement of the process patent

The judge also found that there was a prima face case of infringement of the process patent. Interpharma's process for the manufacture of gemcitabine hydrochloride was confidential and there is little meaningful consideration in the case about this issue.

The serious question - invalidity of the process patent

Interpharma also challenged the validity of the process patent, this time on the ground of obviousness. After considering the evidence led by Interpharma on that issue, Justice Jessup held that invalidity was for Interpharma to prove. He observed that the material upon which it relied in this regard left considerable scope for argument. Accordingly, he held: "To the extent that I am otherwise of the view that [the Lilly parties] have established a prima face case of infringement with respect of the process patent, I am not prepared to qualify that view by reason of the prospect that that patent might be invalid for want of an inventive step."

ADEQUACY OF DAMAGES AS A REMEDY

Evidence was presented by the patentee that the introduction of Interpharma's generic version of Gemzar would lead to an immediate price reduction of 12.5 per cent in the price received by Lilly for Gemzar, and then annual reductions for three consecutive years of two per cent in that price. This followed as a result of the recent reforms to the PBS in Australia introducing Formulary 1 and 2.

Lilly also argued that if no injunction was granted there would be other manufacturers of generic alternatives to Gemzar that would enter the market, making it more difficult for them to quantify the extent of any loss which might flow because of Interpharma's entry.

Interpharma countered that a simple comparison of the "before and after" listing of Interpharma's generic version of Gemzar would show the extent of the patentee's losses. The patentee argued that this was not so, claiming that its loss was not limited to the loss and damage that it might suffer in the period between the listing of the generic version of the product and judgement at trial. Rather, it was submitted that it would be also necessary to estimate future losses that may be very difficult to calculate.

The Court took into account the lack of clarity in the position (even assuming there were no other generic entrants into the market in the meantime) about whether the Department of Health and Ageing might restore the PBS price reductions that would have been implemented in the meantime. The Court also held that the mere fact of competition in the market may well lead to quite substantial changes in the prescribing practices of medical practitioners, which would be unquantifiable. Some emphasis was also given to the Court about the commercial advantage of being the only supplier of the gemcitabine product - the effects of which were said to be both subtle and powerful.

Justice Jessup was much attracted by the approach taken by the Court in *GenRx Pty Ltd v Sanofi-Aventis* that temporary disturbance of the status quo was not justified.

The judge did, however, draw a distinction between the compound patent and the process patent in considering whether damages would be an adequate remedy. The compound patent was due to expire in March 2009. Given the period in which Interpharma would be found to have been in infringement of the compound patent would be relatively short (if that were to occur at trial), there would be very little likelihood of any other supplier in the market with a gemcitabine product, thereby giving rise to a relatively simple calculation of the patentee's loss. However, the process patent did not expire until 2013 and those factors therefore did not apply in relation to that patent.

On balance, Justice Jessup was of the view that damages are much more likely to be an adequate remedy should it be found that Interpharma was in breach of the compound patent than in the case of the process patent.

THE BALANCE OF CONVENIENCE

Lilly relied upon the proposition that the status quo should be retained - Lilly had the benefit of the patents for a long time and Interpharma was now proposing to enter the market. The judge held that there was merit in requiring the parties to hold their present position until the rights and wrongs of the matter could be established at trial.

Interpharma argued that retaining the status quo would unfairly act to its detriment. Interpharma's whole commercial focus was upon pharmaceuticals valuable in oncology and that if it were not able to supply gemcitabine hydrochloride to the market, this would have a negative impact on its marketing campaign. It also had supply contracts in place that would come into effect from 1 December 2008.

The Court was not attracted by these arguments and observed that Interpharma had gone into the situation with its "eyes wide open". It had undertaken all its commercial preparations in the knowledge of one or both of the patents and had been "less than assiduous" in its enquires as to whether the marketing of a generic product by it may constitute an infringement of those patents.

Justice Jessup concluded by stating that the patentee had the better of the argument on the question of infringement of the process patent and it showed enough to entitle it to an interlocutory injunction with respect to that patent. However, he was not persuaded to grant interlocutory relief in relation to the compound patent on the basis that the patentee had not established that it had the stronger case on the issue of infringement, and that damages in relation to the compound patent would be relatively straightforward to calculate.

CONCLUSION

This is yet another example of the line of recent cases that suggest the Australian Federal Court is more likely to grant interlocutory injunction applications in pharmaceutical patent cases than not grant them. This, in turn, makes it even more important that generic pharmaceutical companies wishing to gain early market entry into Australia take prompt steps to clear the path of any patent obstacles they have to negotiate.

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