

WHAT'S THE DAMAGE? - THE FEDERAL COURT'S DECISION IN SIGMA V WYETH

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Legal Briefings - By **Emma Iles and Nicola Gollan**

Justice Jagot's recent decision (of more than 400 pages) in *Sigma v Wyeth*¹ is an Australian first. The judgment considers the damages payable pursuant to an undertaking given for the grant of an interlocutory injunction in a pharmaceutical patent case.

It therefore provides unprecedented insight into enforcement of such undertakings. The decision also contains findings of relevance to the way in which an interlocutory injunction application should be framed and supported. As such, it is likely to be an important judgment for those engaged at the front-end of the interlocutory injunction process. In the pharmaceutical context, generics will likely rely on this case to support their balance of convenience arguments, as it provides an example of the complexity involved in calculating generic losses in the event of an interlocutory injunction.

The judgment is extensive, and addresses in great detail many issues which are highly fact specific. This article summarises some of the more general principles which emerge.

SUMMARY OF PRACTICAL LESSONS

While each interlocutory injunction application or claim for compensation under an undertaking as to damages will depend on its facts, there are a couple of general lessons which parties can take from the decision in *Sigma v Wyeth*, including:

1. **Enforcing an undertaking as to damages:**

- In assessing the loss arising from an interlocutory injunction, where this is done many years after the fact, the Court places significant weight on contemporaneous records to determine what position the parties would have been in had the injunction not been granted. This underscores the need to keep and maintain such records.
- The forensic decisions a party makes during the course of the primary proceedings will bind it in defending a claim for compensation under an undertaking. The result being that a party will not be able to raise a defence based on legal rights it did not assert in the primary proceedings.

2. Applying for an interlocutory injunction:

- In the pharmaceutical area, this case will likely be relied on by generics in balance of convenience arguments to support a proposition that the calculation of their losses is complex. Patentees on the other hand are likely to seek to distinguish themselves from Wyeth's position in this case on relevant facts.
- Parties should be aware that evidence led in support of an interlocutory injunction regarding potential market share, or loss thereof, will also be relevant to the quantification of a later claim made on an undertaking as to damages.

FACTS

The key facts of the case can be summarised as follows:

1. Wyeth was the patentee of a number of patents related to an anti-depressant called venlafaxine, including a method patent for an extended release formulation. Wyeth was also the sponsor of an extended release formulation of venlafaxine known as Efexor-XR in 37.5 mg, 75 mg and 150 mg doses, each of which were listed on the PBS. Efexor-XR was the leading anti-depressant brand in Australia, with annual sales of \$114 million.

2. Sigma, Alphapharm and Generic Health (collectively, the **generics**) were sponsors of registrations on the ARTG of generic versions of Efexor-XR. In 2009, the generics each commenced separate proceedings in the Federal Court of Australia challenging the validity of Wyeth's method patent. In each case, Wyeth cross-claimed for infringement and sought an interlocutory injunction to restrain generic launch.
3. The Court granted these interlocutory injunctions in 2009 and in turn, Wyeth provided an undertaking as to damages in the usual terms.
4. On 8 November 2010, Jagot J dismissed the challenges to validity of Wyeth's method patent, and made final orders restraining the generics from infringing the patent. The interlocutory injunctions were also discharged, and Wyeth was released from each of the undertakings. However, on 28 October 2011, the Full Court overturned the first instance decision, instead finding that the method patent was invalid. An application for special leave was refused by the High Court in May 2012.
5. The current proceedings involved claims by the generics, as well as Alembic and Pharmathen (who manufactured and supplied generic venlafaxine products to Generic Health and Alphapharm), for compensation pursuant to the undertakings given by Wyeth. Each party claimed it had been adversely affected by the operation of the interlocutory injunctions. The Commonwealth also made a claim under the undertakings, but settled this claim prior to judgment.
6. Ultimately, Jagot J held that Wyeth should pay compensation to each of the claimants for the adverse effect of the interlocutory injunctions.

KEY FINDINGS

ENFORCING AN UNDERTAKING AS TO DAMAGES

Causation - the focus is on what happened because of the interlocutory injunction, rather than what would have happened but for the interlocutory injunction: Jagot J emphasised that it is "the operation of the interlocutory order which is the focus of the undertaking", rather than events leading up to or following the making of the undertaking. On this basis, in determining whether the generics had proved that they had actually suffered loss as a result of the interlocutory injunctions, Jagot J held that there would not be a loss of a valuable opportunity only if a generic established that, but for the injunction, they "would have" obtained a PBS listing and supplied under the PBS and/or the private market. However, such a loss would exist if the generic proved on the balance of probabilities that because of the interlocutory injunction they were prevented from exercising the supply rights they already had because of their ARTG registration. Jagot J held that the value of this opportunity lost was then to be "determined as a matter of the probabilities and possibilities". This included an assessment of the likelihood that the generics would have obtained a PBS listing and supplied under the PBS and/or the private market.

This approach was also reflected in:

- Jagot J's determination regarding the manufacturers' claims. Her Honour held that Generic Health and Pharmathen's claims for loss of an opportunity to supply other generics under "potential contracts which did not exist at the time the interlocutory injunctions were granted" and depended on future negotiations were too remote to be recoverable. However, Jagot J held that the manufacturers could claim losses, where an existing contract was in place and they proved that the generics "would have ordered additional products" from them.
- Jagot J's rejection of Alphapharm and Generic Health's argument that they should be compensated for losses suffered from modifying their conduct in anticipation of an interlocutory injunction (Alphapharm and Generic Health having been enjoined after Sigma). Jagot J held that "action taken in mere anticipation of an interlocutory injunction" does not "engage the undertaking" as "[a]n order cannot operate before it is made".

The window of loss arising from an interlocutory injunction ends when final relief is granted at first instance: The generics argued that the window of time for relevant loss should extend beyond the date on which final orders were made at first instance (on 8 November 2010). They argued that it should instead run until the Full Court overturned this decision, or until the High Court dismissed the special leave application. However, Jagot J held that it would be wrong for the generics to be able to claim against Wyeth the losses they suffered after the final orders were made at first instance. Such losses were not the result of the interlocutory injunctions, but rather arose because the final orders were wrongly granted (as was established on appeal). Jagot J held that losses arising from final orders being "overturned on appeal are part of the exigencies of litigation", which are not compensable (except for costs).

The starting assumption of the counter-factual used to determine the loss should be that the injunction was not sought, not that the injunction was refused: A 'counter-factual' is an analytical exercise engaged in by the Court to assess causation, in which the Court effectively asks what position the claimant would be in but for the injunction. In developing the counter-factual in *Sigma v Wyeth*, Jagot J held that all the events leading up to the date on which the application for the interlocutory injunction was heard should be taken to have occurred. However, importantly, Jagot J found that the counter-factual should not be premised on the assumption that the interlocutory injunction was refused (especially on the grounds which the Full Court later found, being that the method patent invalid). Her Honour held that this would result in the generics being compensated for the loss they suffered as a result of the existence of the method patent and the litigation, rather than loss arising from the interlocutory injunctions (to which the undertaking is directed). Instead, Jagot J held that the counter-factual should proceed on the assumption that Wyeth chose not to prosecute its interlocutory injunction applications on the date they were to be heard, for reasons that the generics would not have known. This is an important distinction and one that will need to be borne in mind in evidence preparation in future cases.

In this context, for example, a generic would not have the benefit of an interlocutory injunction decision in their favour when making decisions about PBS-listing and product launch. This is quite a different 'risk matrix' for a generic from the situation where decisions are made with the benefit of a favourable interlocutory decision. In that situation a generic's decisions might be influenced by enhanced confidence about the likelihood of ultimate success in the proceedings.

The counter-factual cannot be based on a party hypothetically exercising legal rights which it had previously decided not to exercise during the course of the proceedings: As part of its proposed counter-factual Wyeth advanced a two-pronged argument based on copyright infringement of its Efexor-XR PI and CMI documents. First, Wyeth argued that if the interlocutory injunctions had not been granted, it would have sought interlocutory and final relief based on the generics' infringement of its copyright in these documents. Second, Wyeth argued that all the generics' hypothetical profits now payable under the undertaking were tainted by illegality, such that it would not be just to compensate the generics because those profits would have been the result of copyright infringement.

Jagot J strongly rejected both these arguments, instead determining that Wyeth could not now assert copyright infringement for any purpose. Jagot J found that to allow Wyeth to do so could amount to an abuse of process in circumstances where Wyeth had made a forensic decision during the primary proceedings (i.e. during the trial, Full Court appeal and special leave application) not to assert copyright infringement. Jagot J went as far to say that "[t]o permit this course would make a mockery of principles essential to the administration of justice including the finality of litigation".

While Wyeth's arguments based on copyright infringement may be considered to be at the extreme end of the spectrum, this does demonstrate that while the counter-factual is necessarily hypothetical in nature, it does not extend to other legal rights which a party might have exercised, but chose not to, in the course of the proceedings. By analogy, it would follow that if an interlocutory injunction was obtained based on alleged infringement of one patent, and that patent was ultimately found to be invalid or not infringed, the party could not then raise in defence of paying damages on the undertaking, the hypothetical assertion of another patent.

Contemporaneous records will be given more weight by the Court than affidavit evidence adduced many years after the event: Jagot J considered in detail the evidence led by each of the generics to determine what each would have done had Wyeth not prosecuted the interlocutory injunctions in 2009. While Jagot J's consideration of the evidence led in *Sigma v Wyeth* is highly fact specific, it still has relevance because of the emphasis placed on contemporaneous records, as opposed to subsequent oral or affidavit evidence. Throughout the judgment, Jagot J emphasised that oral and affidavit evidence adduced many years after the fact is likely to be inherently more unreliable due to the inevitable effect of hindsight and, in some cases, the glare of self-interest. Indeed, on numerous occasions, Jagot J dismissed this 'after the fact' evidence altogether. This underscores the importance of producing and maintaining contemporaneous records of business decisions and plans, particularly in circumstances where an interlocutory injunction is anticipated.

APPLYING FOR AN INTERLOCUTORY INJUNCTION

The balance of convenience for generics and patentees: Patentees often argue that the balance of convenience is in their favour in circumstances where a generic is threatening to seek PBS listing, as the mandatory price drop triggered by the listing of a second brand on the PBS is (in the words of Sigma following a discussion with its lawyers) often considered to be “irrevocable and not considered by the courts to be remedied by undertakings or guarantees”. However, significantly, in her concluding remarks in *Sigma v Wyeth*, Jagot J states:

It is difficult to imagine that when Sundberg J and then I granted the interlocutory injunctions in 2009 we anticipated that if those injunctions turned out to be wrongly granted, the resulting exercise would bear any resemblance to this one. Hindsight makes one thing certain. Knowing what has occurred, it could never have been concluded, for example, that insofar as relevant to the balance of convenience it would be easier for the generics to prove their loss if the interlocutory injunctions were wrongly granted than for Wyeth to prove its loss if the interlocutory injunctions were withheld and the method patent was valid.

These comments, and the complicated nature of the analysis that Jagot J had to undertake, are likely to have ramifications for parties applying for interlocutory injunctions in the future. For the balance of convenience, generics will no doubt rely on this case to argue that the calculation of their losses is complex. However, patentees will likely seek to distinguish their position from the facts of this case.

Evidence led during the interlocutory injunction application is considered relevant to assessing loss for the purposes of the undertaking: In calculating the losses suffered by the generics, Jagot J placed significant weight on the evidence which Wyeth had led in support of its interlocutory injunction applications, regarding the potential market share the generics would have gained had they not been enjoined in 2009. Jagot J held that this evidence should be considered when determining the compensation payable under the undertakings, including because:

...it was evidence Wyeth called in 2009 to persuade the Court to grant the interlocutory injunctions. The equitable context of both Wyeth’s applications for the interlocutory injunctions and the claimant’s applications pursuant to the undertakings and the maxim that the party which sought and obtained equity (Wyeth) must do equity indicates that Wyeth should not be allowed to suggest that its own evidence in 2009 about the market shares the generics might have achieved if unrestrained is unreliable.

This emphasises the importance of parties carefully considering the evidence they lead in support of an interlocutory injunction. While emphasising the magnitude of potential losses may be an important part of seeking an injunction, this may prove very costly in the event that a claim for compensation is later made on the undertaking as to damages.

ENDNOTES

1. [\[2018\] FCA 1556](#).

KEY CONTACTS

If you have any questions, or would like to know how this might affect your business, phone, or email these key contacts.



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