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# WHERE IS THE BALANCE NOW? PRELIMINARY INJUNCTIONS IN PHARMACEUTICAL PATENT PROCEEDINGS IN 2020 AND BEYOND

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Legal Briefings – By **Rebekah Gay, Aaron Hayward, Emma Iles and Henry Simpson**

Recent decisions of the Federal Court of Australia have significantly changed the way in which parties to pharmaceutical patent litigation should analyse and approach preliminary injunction applications.

While previously a patentee could generally expect to obtain a preliminary injunction if their product was facing a mandatory price drop as a result of generic or biosimilar launch, a series of decisions over the last 18 months or so have altered the lens through which preliminary injunction applications are assessed.

In this article, we provide an overview of how the Court's approach has shifted through these decisions, and discuss the likely impact on future applications.

## KEY TAKEAWAYS

- Preliminary injunctions are still an important remedy for patentees in Australia. However, patentees will no longer be able to rely on a single factor, like a mandatory price drop, to

tip the balance of convenience in their favour. Rather, a more nuanced consideration of all factors will be required.

- The first instance decision of *Commonwealth of Australia v Sanofi (No 5)*[1] demonstrates the difficulties the Australian Government faces in obtaining compensation from patentees pursuant to the undertaking given when a preliminary injunction is granted, although it confirms that, in principle, the Government can make a claim for such compensation.

- Proposed changes to the disclosure regime of the Therapeutic Goods Administration may, if implemented, allow for early instigation and resolution of proceedings before generic or biosimilar launch, providing an alternative to preliminary injunctions for patentees in Australia.

# BACKGROUND

## PRELIMINARY INJUNCTIONS AND THE USUAL UNDERTAKING AS TO DAMAGES

At the request of a patentee in infringement proceedings, an Australian Court may grant a preliminary injunction (**PI**) to restrain the launch of a generic or biosimilar pharmaceutical product until the final determination of the proceedings.

In determining whether or not to grant the injunction, the Court will consider whether the patentee has a *prima facie* case of infringement. If so, it will then weigh the 'balance of convenience' by comparing the harm that the patentee will suffer if the injunction is not granted to the harm that the alleged infringer will suffer if the injunction is granted.

Where a patentee is granted a PI, the Court will invariably require the patentee to give the 'usual undertaking as to damages', by which the patentee undertakes to compensate the alleged infringer, and any other person adversely affected by the PI, for any loss suffered as a result of the injunction if it is ultimately determined that the patent is not infringed or is invalid.

## THE BALANCE OF CONVENIENCE BEFORE *SIGMA*

The 2018 decision of *Sigma v Wyeth*,[2] was the first time an Australian court had determined liability of a patentee to pay damages to generics under the usual undertaking. Before that decision, it is fair to say that the Courts, in assessing the balance of convenience, placed significant emphasis on the mandatory price reduction that would result from first listing of a new brand of a pharmaceutical substance on Australia's Pharmaceutical Benefits Scheme (**PBS**). The significant losses to the patentee from this price reduction, together with the unpredictable impact of future generic competition (which would further impact price),[3] and the difficulty in quantifying these losses, meant that the balance of convenience typically weighed strongly in favour of granting the injunction.[4] This was despite recognition that a complex calculation of damages could occur where an injunction was granted and the generic was ultimately successful. [5]

# A TIME OF CHANGE: *SIGMA* AND SUBSEQUENT CASES

Beginning with the decision in *Sigma* in late 2018, a number of key decisions have marked a significant shift in the way the Federal Court has approached PIs in pharmaceutical patent litigation. In *Sigma,* the patentee was ordered to pay compensation to several generic companies and manufacturers for damages they suffered by reason of a PI, after Sigma's patent was found invalid.

The decision in *Sigma* was extensive, running to more than 400 pages (read our analysis of the key takeaways from the decision here), and the complexities in the generics' claims caused Jagot J to remark:

> 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.[6]

Shortly following *Sigma*, the Court refused PIs in two pharmaceutical patent cases.

In *Sanofi v Alphapharm*[7] Burley J refused an application for a PI even though the launch of Alphapharm's generic product would result in a mandatory 25% price drop for several Sanofi products. In reaching that decision, his Honour referred to Jagot J's comments in *Sigma*, and considered that calculating Alphapharm's loss if the injunction were granted was likely to be "*highly speculative*", and more difficult than calculating Sanofi's loss if the injunction were not granted.[8] Sanofi's position was also impacted by a "*significant complicating factor*" in that Sanofi was proposing to launch a second generation product, which may have meant that the market for the generic "*could diminish or even disappear before any interlocutory injunction is lifted.*"[9]

Burley J's decision was subsequently upheld on appeal,[10] although the Full Federal Court emphasised that "*the weighing of the balance of convenience in this case was affected by the specific circumstance*" of Sanofi's proposed new product launch. It also emphasised that Burley J was not "*expressing some principle of general application about the relative difficulty of assessing damages as between an innovator and generic drug company*".[11]

In *Mylan Health Pty Ltd v Sun Pharma ANZ Pty Ltd (No 2)*[12] Yates J dismissed an application for an interim injunction pending appeal proceedings, with the relevant claims of Mylan's patent having been found invalid at first instance. Citing *Sigma*, Yates J stated that the *"most compelling reason*" for this determination was "*the difficulty, complexity and uncertainty involved in assessing the compensation under an undertaking as to damages"*.[13]

Most recently, the decision in *Commonwealth v Sanofi*[14] was handed down. As we discussed previously, that decision, also an Australian first, considered the Commonwealth's ability to seek compensation under a patentee's usual undertaking. Nicholas J accepted in principle the Government's ability to be compensated, but rejected the particular claim, concluding:

- the Government's loss was not a direct result of the injunction given the terms of the injunction did not prevent the generic from applying for PBS listing;[15] and
- there was an *"evidentiary deficiency"* in establishing that the generic would have launched its product and obtained PBS listing, had the PI been refused.[16]

The decision is now the subject of an appeal to the Full Court of the Federal Court. However, it (and the reasoning in any appeal judgment) is likely to be relevant to future PI applications in a number of ways:

- Several decisions have acknowledged that difficulties in calculating the compensation payable to the Government may be relevant to the balance of convenience. In *Sanofi* Burley J observed that the potential difficulty of quantifying the Government's damages was a factor weighing against the granting of the injunction, albeit one "*on the low end of the spectrum*".[17] Additionally, Yates J in *Mylan v Sun* weighed the likelihood of a Government claim for compensation, along with its complexity, against the granting of an injunction.[18]
- As we noted previously, it may be that in response to this decision, the Commonwealth seeks to take an active interest in the terms of any such injunctions at the time when they are awarded.
- In reaching his decision, Nicholas J considered (in the context of one counterfactual scenario) that it was more likely than not that the PBS price drop would have been reversed had the generic been removed from the market after a decision at first instance (had a PI not been granted initially). Although constrained to the facts of that specific counterfactual situation, this is an instructive finding of the Court, as even as recently as *Sanofi* there was significant scepticism from the Court that a PBS price drop would ever be reversed,[19] which increased the perceived difficulty of quantifying a patentee's loss.

## WHERE TO NOW?

## CAN PATENTEES EVER OBTAIN INTERLOCUTORY INJUNCTIONS?

While recent decisions may suggest that patentees will face hurdles in obtaining a PI, it is our view that PIs can still be obtained in Australia. The reasoning in *Sanofi* was specific to the particular circumstances being considered, as confirmed by the Full Court on appeal. *Mylan v Sun* was also an unusual case, in that an injunction was being sought after the patentee was unsuccessful at first instance.

We therefore think that, in many cases, the complexity of calculating each party's loss will be a "neutral factor", and pointing to a single factor, like the mandatory price drop, is unlikely to shift the balance in favour of the patentee as it once seemed to do. Instead, as Burley J noted in *Sanofi*, *"as often is the case in such matters, the balance of convenience is quite evenly balanced"*.[20] Patentees must therefore carefully consider the specific circumstances of their case and whether they can demonstrate that the loss they will suffer is likely to be greater, and less easy to be compensated for, than that of the generic.

Factors that will likely be a focus in future cases include:

1. **The strength of a patentee's *prima facie* case**

   An assessment of the strength of both the infringement case and any cross-claim for invalidity, is required in assessing the balance of convenience.[21] For example, the existence of a serious *prima facie* case for invalidity appears to have been a significant factor in the Court refusing a PI in both *Hexal Australia Pty Ltd v Roche Therapeutics Inc* (where there was a "serious question" that the asserted claims lacked fair basis)[22] and *Sanofi* (where there was a "sufficiently strong" prospect at least two pieces of prior art anticipated the asserted claim).[23]

   Patentees should therefore give thought to which claims are best to assert, not only from an infringement perspective but also in relation to potential validity challenges. The result is that the broadest claim may not always be the best option. Considering those matters well in advance of potential generic competition is advisable so that, if claim amendments might assist, they can be sought and granted before the PI is sought.[24]

2. **The product in question and its particular market**

As illustrated in *Sanofi*, it is essential to consider whether there are specific features of the particular market that mean the loss to one party is likely to be more significant, or less readily compensable, than the other. Those features might include:

- **the nature of the product and market**, including where and how a product is distributed and any barriers to entry by a generic, and how these might impact the rate at which the generic gains market share. For example, in *Sanofi*, the Court noted that the prescribing route of the product in question meant that the generic was likely to establish market share quickly;[25]
- **industry developments**, in particular if the relevant market is likely to change substantially during the course of litigation regardless of generic entry (for example due to a second generation product, as was the case in *Sanofi*), or is likely to remain relatively stable;
- **the number of competing originator and generic products**, as readily substitutable alternative medicines, or multiple potential generic entrants, may mean that generic entry would result in unpredictable market changes; and
- **the market position of the generic**, including any "first mover advantage" that the generic would lose if the injunction was granted (as was recognised in both *Mylan v Sun* and *Sanofi*).

3. **The impact on the patentee's business**

The Court has recognised as a relevant factor the potentially non-compensable impacts that a decision not to grant an injunction may have on the business of the patentee. This may include reductions in expenditure for the affected areas of the patentee's business,[26] cuts to education and awareness programs[27] or patient support programs, reduction in staff,[28] and the fact that these outcomes may negatively impact the reputation of the patentee.[29]

4. **The impact on third parties**

Finally, the impact on third parties will also influence the balance of convenience.[30] These impacts can both favour, or work against, the granting of an injunction. For example, the difficulty of the Commonwealth obtaining compensation, the public interest in the price reduction of the product in question,[31] and the desirability of consumers being able to choose between different treatment options[32] have been recognised as factors weighing against granting the injunction. On the other hand, the Court has acknowledged the negative impact not granting an injunction may have, for example, on programs for patients or health care professionals,[33] and on a related corporate body of the patentee that is neither patentee or exclusive licensee.[34]

# ANOTHER PATH?

In March 2020, the Therapeutic Goods Administration announced an outline of proposed changes to the disclosure regime of the TGA, which, if implemented, will require early notification of generic medicine applications to the patentee.

Currently, patentees will almost always find out about the entry of a generic or biosimilar competitor into the market only once the generic has obtained listing on the Australian Register of Therapeutic Goods (ARTG). The proposed changes, however, would require the sponsor of a generic medicine meeting certain requirements to notify the patentee after the generic or biosimilar application has passed preliminary assessment, but before the evaluation phase. Implementation of the proposed changes is planned to occur from early 2021.

These foreshadowed changes have the potential to provide an alternative to preliminary injunctions. Earlier notification of a potential ARTG listing of a generic or biosimilar will provide a patentee with more time in which to assess whether its patent is infringed. Depending on the precise timing of the notice and time to completion of TGA evaluation of the generic or biosimilar, a patentee may be able to seek expedited proceedings in which a final judgment is delivered prior to the generic or biosimilar listing and launch, bypassing the need for interlocutory relief altogether. In other cases it may at least reduce the length of any delay to the generic or biosimilar entry caused by the PI, which could significantly alter the balance of convenience (and any compensation payable under the usual undertaking as to damages if the patentee's claim is ultimately unsuccessful).

1. *Commonwealth of Australia v Sanofi (No 5)* [2020] FCA 543 (***Commonwealth v Sanofi***).
2. *Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth* [2018] FCA 1556 (***Sigma***).
3. See, for example, *Sanofi v Alphapharm* (below fn 7),[148].
4. See, for example, *F-Hoffman-La Roche AG* [sic] *v Sandoz Pty Ltd* [2018] FCA 874 (***Roche v Sandoz***), [212]-[216]; *Otsuka Pharmaceutical Co., Ltd v Generic Health Pty Ltd* [2012]

FCA 239 (***Otsuka v Generic Health***), [155] and [170].

5. *Roche v Sandoz*, [223], [228]; *Janssen Sciences Ireland UC v Alphapharm Pty Ltd* [2017] FCA 1399, [162], [168] and [170]; *Otsuka v Generic Health*, [182].

6. *Sigma,* [1336].

7. *Sanofi-Aventis Deutschland GmbH v Alphapharm Pty Ltd (No 3)* [2018] FCA 2060 (***Sanofi***).

8. *Sanofi*, [163].

9. Ibid, [170] - [174].

10. *Sanofi-Aventis Deutschland GmbH v Alphapharm Pty Ltd* [2019] FCAFC 28.

11. *Sanofi-Aventis Deutschland GmbH v Alphapharm Pty Ltd* [2019] FCAFC 28, [46].

12. *Mylan Health Pty Ltd v Sun Pharma ANZ Pty Ltd (No 2)* [2019] FCA 505 (***Mylan v Sun***).

13. Ibid, [137].

14. *Commonwealth of Australia v Sanofi (No 5)* [2020] FCA 543.

15. Ibid, [445] – [446].

16. Ibid, [349].

17. *Sanofi*, [179].

18. *Mylan v Sun*, [138].

19. *Sanofi,* [129].

20. *Sanofi-Aventis Deutschland GmbH v Alphapharm Pty Ltd (No 3)* [2018] FCA 2060, [118].

21. See e.g. *Samsung Electronics Co. Limited v Apple Inc* [2011] FCAFC 156 (***Samsung v Apple***), [67]; *Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth* (2009) 81 IPR 339, [15].

22. *Hexal Australia Pty Ltd v Roche Therapeutics Inc* [2005] FCA 1218, [78].

23. Ibid, [90] and [119].

24. As noted in *Sanofi* at [185], an application for an interlocutory injunction is to be determined based on the form of the claims as they presently exist, and not as they might be amended.

25. Ibid, [157].

26. *Mylan v Sun*, [96].

27. *F. Hoffman-La Roche AG v Sandoz Pty Ltd* [sic] [2018] FCA 874, [213].

28. *Mylan v Sun*, [96].

29. See *Castlemaine Tooheys v South Australia* (1986) 161 CLR 148, [15]; *Samsung v Apple*, [66].

30. Ibid, [127].

31. *GlaxoSmithKline Australia Pty Ltd v Reckitt Benckiser Healthcare (UK) Limited* [2013] FCAFC 102, [84].

32. *Mylan v Sun*, [96].

33. *Janssen Sciences Ireland UC v Alphapharm Pty Ltd* [2017] FCA 1399, [169].

# 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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