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COMMONWEALTH FAILS IN ITS CLAIM FOR COMPENSATION FOR PBS EXPENDITURE

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

THE FEDERAL COURT'S DECISION IN *COMMONWEALTH V SANOFI*

Justice Nicholas' long-awaited decision in *Commonwealth v Sanofi* is an Australian first.[1] Of the 4 cases in Australia in which the Commonwealth has sought compensation for losses arising from an interlocutory injunction restraining the launch of a generic drug, it is the only one to have reached judgment.[2]

The decision therefore provides novel insight into the Commonwealth's ability to claim compensation for the savings it would have derived in PBS expenditure from generic competition. In dismissing the Commonwealth's claim, the decision highlights the difficulties that the Commonwealth faces in establishing that it has suffered compensable loss as a result of an interlocutory injunction, which will be of some relief to originators seeking to prevent the launch of a generic or biosimilar.

However the case also highlights how potentially valuable such claims can be to the Commonwealth, which suggests that the Commonwealth will be carefully considering its options for appeal, as well as for future claims.

KEY TAKEAWAYS

- Each interlocutory injunction application and claim for compensation pursuant to an undertaking as to damages will ultimately turn on its particular facts. The failure of the Commonwealth to obtain damages in this case does not mean that it will not succeed in the future.

- However, the decision underscores the difficulties the Commonwealth will face in making any such claim, including establishing that the Commonwealth's loss is a direct result of an interlocutory injunction, where such injunctions do not typically, in terms, prevent the generic from applying for PBS listing.

- More generally, the failure of the Commonwealth to establish that Apotex would have launched "at risk", and the evidentiary deficiencies in its case, illustrate that it is likely to be difficult to establish as a matter of fact that it has suffered relevant loss. Doing so will likely require considerable cooperation on the part of the generics involved.

- While not determinative to the decision, the judge also found that that it was likely that the mandatory 12.5% statutory price drop that would have occurred on PBS-listing of the first generic, would have been reversed. This, together with the fact that direct harm to a third party such as the Commonwealth could not be established, is likely to be relevant in future interlocutory injunction applications.

BACKGROUND

THE USUAL UNDERTAKING AS TO DAMAGES

When a patentee seeks an interlocutory injunction to restrain a generic from launching its product ahead of the final determination of proceedings, the patentee will usually be required to provide the 'usual undertaking as to damages'. This is an undertaking to compensate any person adversely affected by the injunction, should the Court ultimately determine the patent to be invalid or that it was not infringed. The terms of the injunction will typically prevent 'exploitation' of the patent in question (ie the injunction prohibits acts of infringement).

The Commonwealth's claim in such cases is based on the statutory price drop that is triggered by the listing of a first generic alternative on the Pharmaceutical Benefits Scheme (PBS) and subsequent price reductions that could be expected to occur through PBS price disclosure mechanisms as a consequence of generic competition and discounting practices. Because the injunction delays the listing of the generic, the Commonwealth pays a price that, but for the injunction, would have been discounted. Its claim for compensation seeks to recover this price differential from the originator.

FACTS OF THIS CASE

This case has an extensive history, beginning over a decade ago. In brief, in 2007, Sanofi obtained an interlocutory injunction against Apotex, restraining Apotex's launch of a generic version of clopidogrel. That interlocutory injunction was replaced by a final injunction in 2008, when Gyles J found that relevant claims of Sanofi's patent were valid and infringed. Both the interlocutory injunction and the final injunction (pending an appeal by Apotex) were supported by the usual undertaking as to damages from Sanofi.

In 2009, Apotex's appeal against Gyles J's decision was successful, and Sanofi's application for special leave to appeal to the High Court was refused in 2010. Apotex made a claim for compensation under the undertaking given by Sanofi, which was resolved by agreement in 2014. However, in 2013, the Commonwealth made a separate claim for compensation under the same undertaking.

Judgment had been reserved on the Commonwealth's claim since 29 September 2017. The total amount of compensation claimed by the Commonwealth was approximately $325 million (excluding interest and costs), including $50.7 million in respect of mandatory statutory price reductions that would have occurred on 1 April 2008 and 1 August 2009, and more than $215 million in respect of price reductions following subsequent price disclosures.[3]

THE DECISION

Justice Nicholas dismissed the Commonwealth's claim for compensation in its entirety. In doing so, his Honour made several key findings:

- His Honour accepted that, in principle, the Commonwealth was entitled to make a claim for compensation under an undertaking as to damages given by a patentee. However, such a claim must be limited to loss that flows directly from the interlocutory injunction and is of a kind that could have been foreseen at the time it was granted.[4] While his Honour accepted that the Commonwealth's loss was a foreseeable result of the injunction, he held that it was not a direct result. This is because the injunction did not prevent Apotex from seeking listing of generic clopidogrel on the PBS, even if it prevented Apotex from supplying that product.[5] Moreover, Apotex had separately undertaken not to seek PBS listing, but that undertaking was not supported by an undertaking as to damages.[6]

- Further, his Honour held that the Commonwealth's case suffered from an "*evidentiary deficiency*" such that he could not be satisfied that Apotex would have launched its generic clopidogrel product "at risk" had Sanofi failed to obtain an interlocutory injunction. The primary reasons for this were:

    - Although the Commonwealth relied on a number of internal communications from within Apotex concerning its launch plans, a number of these documents were privileged and produced in redacted form, including documents that were directly relevant to Apotex's plans. As such, his Honour could not be satisfied that those documents conveyed an accurate or complete picture of the author's state of mind.[7]

    - Although the Commonwealth also relied on affidavit evidence from Apotex's Australian Managing Director, his Honour found that "final approval" would have been required from Apotex's CEO, Dr Sherman, whom the Commonwealth had not called to give evidence.[8] While some internal communications suggested Dr Sherman also had a desire to launch "at risk", these pre-dated a number of procedural developments including the scheduling of the final hearing to commence in the same month as the earliest date on which Apotex could obtain PBS listing. In the absence of evidence from Dr Sherman, Nicholas J was not persuaded that he would have authorised a launch at risk in those circumstances.[9]

- His Honour considered that this was also the case in relation to the period after the determination at first instance when a final injunction was in place, since, even if it were assumed that there had been no injunction, it still must be assumed that the Court had issued a judgment finding that Apotex's products infringed a valid patent.[10] His Honour was again unwilling to infer that Dr Sherman would have authorised continued supply in those circumstances.[11]

- Moreover, his Honour found that, even if Apotex had launched "at risk", in a counterfactual scenario where Apotex ceased to supply its products following the judgment at first instance, it was more likely than not that the Commonwealth would have reversed the statutory 12.5% price reduction that would have occurred when Apotex's product obtained PBS listing.[12] As such, the Commonwealth had suffered no ongoing loss in this period. Again central to this finding was a failure by the Commonwealth to call a relevant witness in Ms MacDonell, who was the relevant decision-maker within the Pharmaceutical Evaluation Branch of the Department of Health at the time the decision in relation to reversing the price reduction would have been made.[13]

- Sanofi also argued that various discretionary factors weighed against the grant of compensation to the Commonwealth, including that the Commonwealth had delayed in bringing its claim, that public interest considerations should prevent the claim and that Sanofi argued that manufacture of Apotex's products in Canada would have infringed Sanofi's Canadian patents. His Honour did not consider that these factors weighed against an award of compensation.

IMPACTS

The decision is likely to have significant impacts on the approach taken by the Commonwealth to compensation claims such as these.

In particular, the finding that the Commonwealth's loss was not a direct result of the injunction would seem to prevent any claim for damages made by the Commonwealth succeeding where an interlocutory injunction does not specifically prevent an application for PBS listing. As a result, parties to an interlocutory injunction application need to carefully consider the wording of that injunction, and any associated undertakings as to damages, as to the potential effect it may have on third parties. It may also be that the Commonwealth looks for ways to take an active interest in the terms of any such injunctions at the time when they are awarded and not only when seeking compensation after the substantive litigation has concluded.

Moreover, the evidentiary challenges faced by the Commonwealth in this case emphasise the practical difficulties the Commonwealth will face in establishing any claim for compensation. As a result, unless the Commonwealth receives considerable assistance from the generics involved, it may be forced to undertake a more extensive fact finding exercise, including potentially by way of subpoenas and discovery, in relation to any such clams.

These factors, together with other findings in the judgment (in particular regarding the ability and likelihood PBS price reductions being reversed) are also likely to have repercussions on the assessment of the balance of convenience in future interlocutory injunction applications.

ENDNOTES

1. *Commonwealth of Australia v Sanofi (No 5)* [2020] FCA 543.
2. The others being *Sigma v Wyeth* [2018] FCA 1556 and *AstraZeneca v Apotex* [2015] HCA 30, in which the Commonwealth settled with both originators before judgment; and *Otsuka v Generic Health* [2015] FCA 848, which is still under way.
3. [24].
4. [196].
5. [445]; see *Warner-Lambert Company LLC v Apotex Pty Ltd* [2017] FCAFC 58.
6. [446].
7. [175]-[176].
8. [251].

9. [349].
10. [540].
11. [547].
12. [528].
13. [522].

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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