CONSIDERATIONS WHEN PROVIDING THE 'USUAL UNDERTAKING'

KEY POINTS FROM *COMMONWEALTH v SANOFI*

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WHAT IS THE "USUAL UNDERTAKING"?

The form of the usual undertaking is prescribed by a Federal Court practice note as follows (our emphasis):

> *(a) to submit to such order (if any) as the Court may consider to be just for the payment of compensation, (to be assessed by the Court or as it may direct),* ***to any person, (whether or not that person is a party), affected by the operation of the order or undertaking*** *or any continuation (with or without variation) of the order or undertaking; and*
>
> *(b) to pay the compensation referred to in (a) to the person affected by the operation of the order or undertaking.*

The usual undertaking is required to be given in patent infringement proceedings in support of an application for a preliminary injunction.

IMPORTANCE IN THE PHARMA CONTEXT

- For a PBS listed product on the F1 formulary, when a generic brand of the same active ingredient becomes PBS listed, the product shifts to the F2 formulary, triggering an immediate reimbursement reduction (currently 25%). The drug will later be subject to price-disclosure based price cuts, further driving down the reimbursement price.
- If a generic supplier is restrained from launching and PBS listing its generic product because a PI is granted, and the relevant patent is later found to be invalid, persons affected by the operation of the order or undertaking will claim compensation under the "usual undertaking"
- In such a scenario (as arose in the Sanofi Case) the Commonwealth may argue that:

  (a) Save for the PI, the generic would have launched, thereby triggering the reductions; and

  (b) It is entitled to damages based on the difference between the higher reimbursement amount it paid in fact during the relevant period, and the lower reimbursement it should have paid during that period.

IMPORTANCE IN THE PHARMA CONTEXT (CONT.)

- The lack of visibility in relation to the PBS listing process puts Innovators in the position where they must act quickly to protect their market, often by seeking a PI to maintain the status quo until the dispute can be resolved.
- The possibility that the Commonwealth may seek damages pursuant to the usual undertaking is a relevant consideration in relation to seeking and obtaining a PI to prevent generic launch.
- This is to be contrasted against the Commonwealth's position in relation to reversing the reimbursement reduction in circumstances where a PI is not sought by the Innovator, but a final injunction is awarded and the generic is forced to withdraw from the market. While it is in theory possible to reverse the reimbursement reduction, it is not commonly done.

COMMONWEALTH V SANOFI

- On 28 April 2020, Justice Nicholas handed down his decision in the case of *Commonwealth of Australia v Sanofi (formerly Sanofi-Aventis) (No 5)* [2020] FCA 543.
- It is the first Federal Court decision in which the Commonwealth's claim for compensation under the "usual undertaking as to damages" was considered and determined.
- Justice Nicholas held that the Commonwealth had suffered a compensable loss, but rejected the Commonwealth of Australia's claim for $325 million in damage, finding that the loss did not "flow directly" from the preliminary injunction.
- The case turns on its facts, but nevertheless gives guidance regarding the court's approach to such claims for compensation by the Commonwealth.
- The Commonwealth has filed an appeal, and Sanofi has filed a Notice of Contention – the appeal will likely be heard later this year or early next year.

SANOFI: KEY ISSUES FOR CONSIDERATION

Nicholas J identified the following three issues as being determinative:

1. **Causation**: Would the relevant loss have been sustained ***but for*** the grant of the PI?
    a) Would Apotex have launched at risk? (No)
    b) Would Apotex's PBS application have been accepted with ongoing litigation? (Yes)
2. **Remoteness**: Did such loss ***flow directly*** from the PI? (No)
3. **Reasonable foreseeability**: Could loss of the kind sustained have been ***foreseen*** at the time the PI was granted? (Yes)

BACKGROUND FACTS

- 2007 - Apotex commenced revocation proceedings in relation to Sanofi's Patent for clopidogrel (Plavix).
- 25 September 2007 – Having cross-claimed for infringement, Sanofi obtained a preliminary injunction (**PI**) against Apotex. The terms of those orders relevantly included:

  (a) An order prohibiting Apotex making an offer of supply (the usual undertaking by Sanofi applied); and

  (b) An undertaking by Apotex that it would not apply to list its clopidogrel products on the PBS until the determination of the proceeding or further order (to which the usual undertaking by Sanofi did not apply);

- The fact that Sanofi did not give any undertaking as to damages in return for the Apotex undertaking, underpins a key aspect of his Honour's reasoning.
- April 2008 - The patent validity/infringement trial commenced.
- August 2008 - the Court found that the Patent was valid and granted Sanofi a final injunction restraining Apotex from infringing the Patent. Apotex appealed.

BACKGROUND FACTS (CONT.)

- September 2009 - Apotex's appeal was allowed. The Patent was revoked and the final injunction set aside.
- March 2010 - High Court application was heard and refused.
- 1 May 2010 - Apotex's generic products were listed on the PBS.
- 4 May 2010 - Apotex filed an application seeking damages against Sanofi and BMS pursuant to the various undertakings given to the Court in support of the PI and other undertakings that Sanofi subsequently gave to the Court. Apotex and Sanofi later settled this claim in November 2014 on confidential terms.
- 1 April 2018 - The Commonwealth commenced its claim for damages, seeking orders requiring Sanofi and BMS to pay to it compensation for the loss it asserted it suffered as a result of Apotex having been prevented from supplying its generic products in Australia and obtaining a PBS listing of such products.
- Relevant to the Commonwealth's evidentiary burden, it commenced its proceedings some 4 years after the matter had been settled by the parties and was required to prove that Apotex would have come to market in the face of a "very substantial" potential liability.

ISSUE 1: CAUSATION

- The Court considered detailed records of internal Apotex communications and strategy discussions, with a focus on evidence from Roger Millichamp, Apotex's Australian MD at the time. His Honour found the evidence indicated:
  - that the risk facing Apotex if it was to launch its generic products and lose the Patent proceeding was "very substantial"; and
  - that Apotex had an "intention to use the undertaking as to damages as a means of having Sanofi underwrite the decision not to launch."
- Further, the Commonwealth did not call Dr Sherman, the Chairman of Apotex at the time, and an adverse inference was drawn
- The Court therefore was not persuaded, on the balance of probabilities, that Apotex would have sought and obtained a PBS listing of its generic products from 1 April 2008 at "very substantial" risk, even if the PI had not been granted.
- Demonstrating that the Generic would have launched in the face of the potential damages liability remains a key evidentiary hurdle for the Commonwealth to overcome in cases of this nature.

ISSUE 2: DID THE LOSS "FLOW DIRECTLY" FROM THE PI

- Since *Warner-Lambert (No 3)*, the Court will not order that a Generic be precluded from seeking PBS listing *per se*.
- It is now common to seek an injunction in the following example terms, with subparagraph (x) being the aspect of the undertaking that directly prevents PBS listing. Guarantee of supply is an essential element of PBS listing. After the injunction is provided, the parties inform the PBS that there is no Guarantee of Supply. The PBS then stops the Generic product being listed on the PBS, which in turn avoids the 25% reimbursement reduction.

  Subject to [Generic] providing or arranging security for any claim on the undertaking as to damages in an amount acceptable to [Generic] or, failing that, the Court, until the hearing and determination of this proceeding or further order, the [Generic], by itself, its directors, officers, servants, agents or howsoever otherwise, be restrained from engaging or threatening to engage in the following acts within the patent area (as that term is defined in the Act) without the licence or authority of the [Patentee], during the term of the [relevant patent]:

  (x) providing or continuing to provide any assurance of supply in relation to Generic's Products for the purpose of obtaining listing pursuant to the PBS;

ISSUE 2: DID THE LOSS "FLOW DIRECTLY" FROM THE PI

The "practical effect" of the PI

- His Honour found at 428:

  Because the interlocutory injunction prevented Apotex Australia from supplying its clopidogrel products, it would have made it impossible for Apotex Australia to give an assurance of supply or to comply with its supply obligations during the guaranteed period for so long as it remained in force. I therefore accept that the interlocutory injunction had the practical effect of preventing Apotex Australia from applying for a PBS listing of its clopidogrel products from 1 April 2008 assuming it was otherwise willing and able to do so. (emphasis added)

- However, his Honour found that the PI did not *actually* stop Apotex from applying to list. It was the first Apotex undertaking that stopped this.

ISSUE 2: DID THE LOSS "FLOW DIRECTLY" FROM THE PI

"practical effect" not sufficient

The loss "flowed directly" from Apotex's undertaking not to apply for PBS listing

- His Honour found at 443:

  In my view, the interlocutory injunction did not directly affect the legal rights, obligations or interests of the Commonwealth. It did not prevent the Commonwealth from receiving and accepting an application for PBS listing by Apotex Australia […]. At most it prevented Apotex Australia from entering the market for clopidogrel in Australia which in turn had the practical effect of denying the Commonwealth the financial benefits it would have obtained were it to have received and accepted an application by Apotex Australia to list its clopidogrel products on the PBS from 1 April 2008.

ISSUE 2: DID THE LOSS "FLOW DIRECTLY" FROM THE PI

"practical effect" not sufficient

The loss "flowed directly" from Apotex's undertaking not to apply for PBS listing

- His Honour found at 445:

> *The terms of the interlocutory injunction did not prevent Apotex Australia from applying for a PBS listing of its clopidogrel products or from taking any other steps to obtain such a listing. Doing so would not have involved a breach of the interlocutory injunction. The Commonwealth's loss was a natural and direct consequence of Apotex Australia not being able to apply to list its clopidogrel products on the PBS with effect from 1 April 2008, which was the precise conduct to which the first Apotex undertaking was directed, but not something the interlocutory injunction expressly or implicitly prohibited. This strongly suggests, in my view, that the loss alleged by the Commonwealth in this case was an indirect consequence of the interlocutory injunction.*

ISSUE 3: WAS THE LOSS REASONABLY FORESEEABLE

- The Court concluded that the fact the PI did not itself prevent Apotex from taking steps to list its generic products on the PBS did not mean that the loss was not reasonably foreseeable, noting that:

  It was reasonably foreseeable at the time Sanofi applied for the interlocutory injunction that, if Apotex Australia was prevented from supplying its clopidogrel products, then it would not make any application to list those products on the PBS for so long as the interlocutory injunction remained in force. Although I found that this was an indirect consequence of the grant of the interlocutory injunction, it was nevertheless a consequence that was reasonably foreseeable at the time the interlocutory injunction was granted.

- It is now common practice for the PBAC to send letters notifying parties that the Commonwealth may, in the event that it suffers loss, elect to claim compensation under the usual undertaking as to damages in the event that the relevant patent is ultimately held to be invalid.

WHAT DOES IT MEAN FOR FUTURE CASES?

- The Court found that the Commonwealth's loss is compensable in theory, and has therefore not shut the door on further claims by the Commonwealth under the usual undertaking.
- The standard injunction terms however prohibit, relevantly, supply.
- Its therefore apparent from the decision that the Commonwealth faces substantial hurdles in relation to any claim under the usual undertaking, including:

  (a) the evidentiary difficulties with proving that the generic would have launched at risk; and

  (b) the legal hurdle in demonstrating that the loss directly flows from the terms of a preliminary injunction where applying for PBS listing is not prohibited.
- The judgement has however been appealed. Accordingly there are further acts to play out before the Innovator's and Commonwealth's rights are finally determined in relation to the usual undertaking as to damages.