HIGH COURT OF AUSTRALIA

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IN THE HIGH COURT OF AUSTRALIA
SYDNEY REGISTRY

BETWEEN

Commonwealth of Australia
Appellant

and

Sanofi (formerly Sanofi-Aventis)
First Respondent

Sanofi-Aventis US LLC
Second Respondent

Bristol-Myers Squibb Investco LLC
Third Respondent

RESPONDENTS' SUBMISSIONS ON THE NOTICE OF CONTENTION

Part I: Certification

1. These submissions are in a form suitable for publication on the internet.

Part II: Issues

2. These submissions address Grounds 1, 3, 4 and 7 of the Notice of Contention filed by the respondents (together, **Sanofi**) (**NOC**; AB548-554). The balance of the NOC is not ripe for determination by this Court and Sanofi respectfully requests that, in the event the appeal is allowed, it be remitted to the Full Court of the Federal Court.

3. The Full Court dismissed the appeal brought by the appellant (**Commonwealth**) against the primary judgment,[1] by:

   a. upholding the first of the two bases on which Sanofi succeeded at trial (described as the 'Apotex Launch and Listing Issue': see FCJ2[10(a)], AB205);

   b. finding that it would not have upheld the second basis on which Sanofi succeeded at trial (described as the 'Directness Issue': see FCJ2[10(b)], AB206); and

   c. not addressing Sanofi's contentions which included: (i) additional 'Directness Issues' regarding two specific components of the Commonwealth's claimed loss; and (ii) the question whether the Commonwealth can be 'adversely affected' for the purpose of a claim on an undertaking as to damages ('Adverse Effect Issue') (see FCJ2[12], AB206-207).

4. Ground 1 of the NOC concerns the Directness Issue, Ground 3 concerns the further directness issues which were not addressed in FCJ2, and Ground 4 relates to the Adverse Effect Issue. Ground 7 concerns an issue as to the effect of the *Therapeutic Goods Act 1989* (Cth) (**TG Act**), which was determined adversely to Sanofi by a different Full Court prior to trial ('TG Act Issue').[2]

5. Accordingly, the issues for determination by this Court that are addressed below are:

   a. ***Directness Issues***: Did the Commonwealth's claimed losses (in their entirety and as to two specific components) 'flow directly' from an interlocutory injunction

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[1] *Commonwealth of Australia v Sanofi (formerly Sanofi-Aventis)* [2023] FCAFC 97; (2023) 411 ALR 315: **FCJ2;** AB198-311; *Commonwealth of Australia v Sanofi (formerly Sanofi-Aventis) (No 5)* [2020] FCA 543; (2020) 151 IPR 237: **PJ;** AB5-178).

[2] *Commonwealth of Australia v Sanofi (formerly Sanofi-Aventis)* [2015] FCAFC 172; (2015) 237 FCR 483: **FCJ1**. Special leave to appeal from FCJ1 was denied: *Sanofi (formerly Sanofi-Aventis) v Commonwealth of Australia* [2016] HCASL 98 (see item 115 of the long-form version of the parties' joint chronology (**PJC**), which is item 00 in the parties' joint book of further materials (**PFM**): PFM78, PFM1312).

restraining GenRx Pty Ltd (later known as, **Apotex** Pty Ltd) from infringing a patent for the drug clopidogrel (**Patent**) that had been granted to Sanofi (**Interlocutory Injunction**)? (See [16]-[54] below).

b. ***Adverse Effect Issue***: Was the Commonwealth a person 'adversely affected' by the operation of the Interlocutory Injunction? (See [55]-[61] below).

c. ***TG Act Issue***: Is the Commonwealth precluded as a matter of law from claiming on the undertaking as to damages given in respect of the Interlocutory Injunction (**Sanofi Undertaking**) by reason of Ch 3, Pt 3-2, Div 2 of the TG Act? (See [62]-[74] below).

Part III: Section 78B of the *Judiciary Act 1903* (Cth)

6. No notice under s 78B of the *Judiciary Act 1903* (Cth) is necessary in this proceeding.

Part IV: Facts

7. Sanofi is an innovator pharmaceutical company, which in 1990 obtained the Patent for clopidogrel, a medication used to reduce the risk of heart disease and stroke (PJC item 0; PFM18). In 1999, Sanofi's clopidogrel products were listed on the Pharmaceutical Benefits Scheme (**PBS**) under two brands, PLAVIX and ISCOVER (PJC item 1; PFM18).

8. Central to the Commonwealth's claim was that, had *generic* clopidogrel products been listed on the PBS earlier than they in fact were, there would have been reductions in the price for clopidogrel under the *National Health Act 1953* (Cth) (**NH Act**), and the Commonwealth's expenditure on the PBS would have been lower than it was in fact. The Commonwealth claimed that this result was within the scope of the Sanofi Undertaking. The circumstances giving rise to the claim were as follows.

9. In 2007, Apotex threatened to launch its own generic clopidogrel products:

a. On 15 August 2007, Apotex requested a bioequivalence statement for its clopidogrel products from the Therapeutic Goods Administration (**TGA**), and gave a certificate under s 26B(1) of the TG Act, to the effect that it did not believe that those products would infringe a valid claim of the Patent (PJC item 41; PFM39, PFM181).

b. On 16 August 2007, Apotex commenced proceedings against Sanofi to revoke the Patent (**Patent Proceeding**) (PJC item 42; PFM39).

c. On 17 August 2007, Apotex obtained registration of its clopidogrel products on the Australian Register of Therapeutic Goods (**ARTG**) (PJC item 43; PFM39, PFM209), and notified Sanofi that it had obtained that registration and had commenced the Patent Proceeding (PJC item 44; PFM39-40, PFM233).

d. On 24 August 2007, Sanofi requested from Apotex an undertaking (*inter alia*) that it would not make, offer for sale, sell or otherwise exploit any product within the claims of the Patent during its term (PJC item 48A; PFM41-42, PFM241).

e. On 28 August 2007, Apotex declined to give that undertaking (PJC item 48B; PFM42, PFM245).

f. On 29 August 2007, Sanofi provided a certificate under s 26C of the TG Act to the TGA, to the effect that it intended to commence proceedings against Apotex for infringement of the Patent (PJC item 50A; PFM43, PFM257).

g. On 1 September 2007, Apotex applied to the **Department** of Health to list its clopidogrel products on the PBS from 1 December 2007, on the understanding that the application could be deferred or withdrawn without triggering a 12.5% price decrease if written notification was provided by 12 October 2007 (PJC item 51; PFM45, PFM261).

h. On 3 September 2007, Sanofi sought undertakings (*inter alia*) that Apotex would not (i) make, offer for sale, sell or otherwise exploit any product falling within the claims of the Patent during its term (**Supply Undertaking**); or (ii) seek to list its clopidogrel products on the PBS until the determination of any application for an interlocutory injunction (**PBS Listing Undertaking**) (PJC item 52A; PFM46-47, PFM329).

i. On 5 September 2007, after Apotex was informed that its application for PBS listing was not received by the relevant deadline and could not be accepted for a 1 December 2007 listing on the PBS, Apotex withdrew the application (PJC items 54-55, 58; PFM47-49, PFM334, PFM337, PFM345).

j. On 6 September 2007, Apotex declined to give the Supply Undertaking but indicated it would provide the PBS Listing Undertaking provided that any interlocutory application was determined by 11 October 2007 (PJC item 57; PFM48-49, PFM341).

k. On 13 September 2007, there was a directions hearing before Bennett J in the Patent Proceeding at which a short timetable for interlocutory proceedings was

made, and a trial within 6 months was foreshadowed (PJC items 59-59A; PFM50-51, PFM349).

l. On 17 September 2007, Sanofi filed its Defence in the Patent Proceeding and a Cross-claim which included applications for interlocutory injunctions to the effect of the Supply Undertaking and PBS Listing Undertaking (PJC item 67; PFM57, PFM397). Sanofi offered the usual undertaking as to damages in respect of each of those injunctions (PJC item 67G; PFM59, PFM477).

m. On 18 September 2007, Gyles J heard Sanofi's interlocutory applications (PJC item 69; PFM59-61, PFM495). His Honour indicated that he did not see any proper basis on which the Court could prevent Apotex from taking steps to list its clopidogrel products on the PBS. Apotex informed the Court that if an injunction on supply were ordered it would undertake not to apply for PBS listing during the period of that restraint.

n. Apotex's stated reasons for taking that position were commercial or strategic: PBS listing without the ability to supply would be of no commercial benefit to it and would result in a 12.5% price reduction on clopidogrel products which would see it make 'enemies in the industry' (PJC item 69; PFM59-61, PFM495). The 'enemies' it would make would include pharmacists (its customers) who would see their dispensing margins reduced in the event of a price reduction.

o. On 21 September 2007, Gyles J delivered reasons orally to the effect that an interlocutory injunction preventing supply of Apotex's clopidogrel products should be granted, and indicated that the Patent Proceeding would be fixed for final hearing before him commencing on 28 April 2008 (PJC item 73; PFM62). It was known at the time that his Honour was due to retire in August 2008, and would need to deliver judgment before then (PJ[565], AB148).

p. On 25 September 2007, upon Sanofi giving the Sanofi Undertaking, the Interlocutory Injunction was ordered restraining Apotex from infringing the Patent (PJC item 74; PFM62, PFM590, 593). Separately, and *without a cross-undertaking as to damages* given by Sanofi, Apotex gave an undertaking not to seek PBS listing for its clopidogrel products pending determination of the Patent Proceeding, or further order (**Apotex Undertaking**) (PJC item 74; PFM62, PFM590, PFM593).

10. Sanofi was successful at trial in the Patent Proceeding (PJC items 85-86; PFM68-70, PFM635, PFM637, PFM643, PFM651, PFM661, PFM665), but not on appeal (PJC

item 89; PFM71), and special leave to appeal to this Court was refused (PJC item 98; PFM73). Following the decisions at trial and on appeal, orders were made (including a stay of orders of the Full Court), and undertakings were given by Sanofi, which in general terms preserved the status quo. Apotex's clopidogrel products were not listed on the PBS until 1 May 2010 (PJC item 102; PFM74), a month after another generic company's clopidogrel products were listed on the PBS (PJC item 101; PFM73).

11. On 4 May 2010, Apotex and two related entities made an application for compensation on the Sanofi Undertaking, and its later undertakings (PJC item 103; PFM74).

12. Almost three years later, on 11 April 2013, the Commonwealth made an application for compensation on the Sanofi Undertaking (PJC item 108; PFM75). This was the first occasion on which the Commonwealth had made such an application in respect of an injunction restraining the supply of a generic pharmaceutical product.

13. The Commonwealth's claim required it to establish two counterfactual propositions, namely, that had the Interlocutory Injunction not been granted:

    a. Apotex, despite having withdrawn its application for PBS listing from 1 December 2007 and learning the timing of an early trial and judgment in the Patent Proceeding, would have applied 'at risk' of patent infringement for a PBS listing from 1 April 2008; and

    b. the **Minister** or her delegate would have exercised the discretion under s 85(6) of the NH Act to grant such an application.

14. The Apotex Launch and Listing Issue is concerned with the first of those counterfactual propositions, and is addressed in the Commonwealth's Notice of Appeal (**NOA**; AB545-547). The second counterfactual proposition is covered by NOC Ground 2, which would (on the approach suggested in [2] above) be remitted for determination by the Full Court in the event that the appeal is allowed.

Part V: Argument on the Notice of Appeal

15. The Apotex Launch and Listing Issue raises a question of fact on which Sanofi succeeded before all four judges below. Sanofi's response to the NOA is to be addressed in later submissions.

Part VI: Argument on the Notice of Contention

Directness Issues – NOC Grounds 1 and 3

The entirety of the Commonwealth's claimed loss

16. The primary judge held that the Commonwealth's claimed loss did not 'flow directly' from the Interlocutory Injunction because that order 'did not directly affect the legal rights, obligations or interests of the Commonwealth' (see PJ[443], AB121), and Apotex's inability to apply for PBS listing was 'the direct and immediate consequence of the Apotex Undertaking', and not the Interlocutory Injunction (see PJ[451], AB123). His Honour found that, 'but for' the Interlocutory Injunction, the Apotex Undertaking would not have been given; and, 'but for' the Interlocutory Injunction, there would have been no restraint preventing Apotex from applying for PBS listing (see PJ[432], AB118-119). However, as the primary judge emphasised, Apotex could have applied for and obtained PBS listing without breaching the Interlocutory Injunction, and the Apotex Undertaking was not supported by a cross-undertaking as to damages (PJ[445]-[446], [451], AB121-123).

17. The expression 'flow directly' is drawn from decisions of this Court (see FCJ2[46]-[47], AB216).[3] At first instance in *Air Express,* Aickin J held that the available damages 'should be those which *flow directly* from the injunction and which could have been foreseen when the injunction was granted' (at 266-267, emphasis added). Justice Aickin held that the expression was consistent with the 'prima facie guide' provided in the decided cases (see 261-266). On appeal, Barwick CJ agreed with Aickin J's reasons (at 309); Gibbs J adopted a proposition found in *Kerr on Injunctions* and derived from ***Smith v Day*** (1882) 21 Ch D 421 (both of which had been cited by Aickin J) that damages ought to be confined to 'the natural consequence' of the injunction (at 312); Stephen J agreed with Aickin J, with an irrelevant exception (at 315-316); and Mason J (in dissent) nonetheless observed that a claimant's entitlement to compensation is in respect of loss which is 'the natural consequence of the grant of the injunction' (at 323). The passage from Aickin J's judgment including the expression 'flow directly' was approved in the unanimous judgment of this Court in *European Bank* (at 439[18]); their Honours also quoted with approval the approach of

[3] See ***Air Express*** *Ltd v Ansett Transport Industries (Operations) Pty Ltd* [1981] HCA 75; (1981) 146 CLR 249 at 266-267 per Aickin J, which was approved in ***European Bank*** *Ltd v Evans* [2010] HCA 6; (2010) 240 CLR 432 at 439[18].

the primary judge in that case, which (consistent with Aickin J's dictum) addressed directness distinctly from the foreseeability of the kind of loss suffered (see 442[29]).

18. The expression 'flow directly' captures two concepts: 'flow' imports causation in fact; and 'directly' imports a limitation such that not all 'but for' causal consequences are to be compensated (including foreseeable ones). Contrary to the Full Court's conclusion, the authorities surveyed by Aickin J do support the view that 'directness' should be understood as requiring that the event which occasions the loss be restrained by the injunction.[4]

19. The *first* error in the Full Court's reasoning was to infer that the primary judge's reasoning implicitly proceeded on the footing that any interposed causal step in the chain of causation was inconsistent with direct causation (FCJ[48], AB216-217). As the Full Court acknowledged, the primary judge used no such language. Nor did his reasoning imply it. Rather, his reasoning focussed on two matters: the primary judge commenced by correctly rejecting the Commonwealth's submission that its legal obligations were directly affected by the Interlocutory Injunction (PJ[442]-[443], AB120-121). In the context of a claim by a third party on an undertaking, this was a material consideration. Next, he took into account that, in considering whether a claim by the Commonwealth on the Sanofi Undertaking could be sustained, it was important to pay attention to the precise terms of the undertaking and the Interlocutory Injunction, and their intent, determined objectively (PJ[445]-[456], AB121-122). Here the terms of the Sanofi Undertaking directed attention to the consequences of the *operation* of the injunction. That operation did *not* extend to preventing an application for PBS listing. The making of an application for PBS listing was instead the subject of the Apotex Undertaking. Once that undertaking was volunteered by Apotex, it was a complete and sufficient cause of its failure to seek PBS listing. Further, the Apotex Undertaking aided an objective assessment of the content of the Sanofi Undertaking.

20. The primary judge was correct.

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[4] *See Smith v Day* at 428 per Brett LJ (the loss was not a 'natural and immediate consequence' of the injunction), and 430 per Cotton LJ (damages should be 'confined to loss which is the natural consequence of the injunction'); ***Ex parte Hall**; Re Wood* (1883) 23 Ch D 644 at 652 per Cotton LJ and 653 per Bowen LJ (rejecting the claim on the independent basis that the loss had not been a natural consequence of the injunction and the undertaking did not extend to making good a wrongful act outside the orders); *Schlesinger v Bedford* (1893) 9 TLR 370 at 371 per Lindley LJ (rejecting a claim for losses 'not fairly consequential upon the injunction'; *Re an Arbitration between Pemberton and Cooper* (1912) 107 LT 716 at 718 per Bankes J (recoverable damage 'necessarily and naturally flowed' from the effect of the interlocutory injunction); *Douglass v Bullen* (1913) 12 DLR 652 at 655 per Britton J (confining damages to 'the immediate natural consequences' of the injunction).

21. The two key aspects of the counterfactual that required proof by the Commonwealth were the making of an application for PBS listing by Apotex, and the acceptance of such an application by the Minister (see [13] above). The Interlocutory Injunction restrained neither. What Sanofi undertook to make good were adverse effects of the *operation of the Interlocutory Injunction*, and in a context where PBS listing was the subject of a distinct undertaking. The Interlocutory Injunction did not operate to enjoin Apotex from applying for PBS listing. Its right to apply was unaffected by the order. Even more plainly, the order did not affect the Commonwealth's rights and powers under the NH Act. The order did not *operate* in relation to PBS listing at all, either as regards Apotex or the Commonwealth. It is not to the point that the *practical* effect of the Interlocutory Injunction was that Apotex would not seek PBS listing (because it would attract commercial disadvantages, would have no commercial advantage, and would entail legal risk: FCJ[27], AB210).

22. The Full Court's *second* error was to treat the primary judge's supposed implicit holding as to interposed causal steps as inconsistent with *Air Express* (FCJ2[67], AB221-222). Their Honours considered that the scenario in which 'Ansett's interlocutory injunction caused the official not to issue the licence and the non-issue of the licence then caused the loss claimed' was 'the same kind of interposed causal step which Sanofi now contends defeats a claim on the undertaking'. That reasoning is mistaken.

23. In *Air Express*, an order restraining the issuance of an import licence was a sufficient cause of Air Express being unable to import the aircraft. It was the direct and immediate cause of its inability to do so. And the injunction, though not issued against Air Express, directly affected Air Express' rights, by depriving it of the right to have an application for the exercise of the discretion to grant a licence considered on its merits. This case is different. An application for PBS listing was not restrained. And if it were made it could have been considered by the Minister on its merits.

24. Further, an interposed causal step which was unaffected by the Interlocutory Injunction was Apotex's commercial or strategic decision (given effect when it volunteered the Apotex Undertaking) that, if it was enjoined from the supply of its clopidogrel products, it would not make an application for PBS listing while the Patent Proceeding was being conducted. No such occasion for voluntary decision-making presented itself in *Air Express*.

25. The *third* error in the Full Court's reasoning involved a finding that, while there were 'interposed causal steps', the Commonwealth's loss nonetheless 'flowed directly' from the Interlocutory Injunction by reason of 'a series of links … in the chain of causation' (FCJ2[63], AB220-221). The Full Court's reasons may be summarised as follows.

26. *First*, the 'practical effect' of the Interlocutory Injunction was to foreclose a PBS listing application by Apotex (which required an assurance, albeit without legal effect (FCJ[24], AB209), that the product could be supplied), and prevent compliance with the statutory obligation to supply upon listing (see s 99AEB of the NH Act) (see FCJ2[35]-[44], AB213-215).

27. *Second*, even if the Apotex Undertaking was causally connected to the claimed loss, its presence in the causal chain did not mean that the loss did not also flow directly from the Interlocutory Injunction (see FCJ2[45]-[77], AB215-224).

28. *Third*, the absence of an undertaking as to damages in respect of the Apotex Undertaking did not provide 'contextual support' for indirectness where the Apotex Undertaking alone could not be the *sine qua non* of the Commonwealth's claimed loss because it was part of a suite of orders made and undertakings given (see FCJ2[78]), AB224-225).

29. *Fourth*, the Full Court attached significance to the absence of 'explicit disclosure' at the time the Interlocutory Injunction was ordered of the possible significance of the Apotex Undertaking being given without an undertaking as to damages in respect of it (see FCJ2[79]-[81], AB225).

30. Those reasons should not be accepted. The interposed causal steps in this case included steps involving voluntary decision-making on the part of both Apotex and the Minister, which ought to have led the Full Court to conclude that the loss did not 'flow directly'.

31. The 'causal chain' connecting the Interlocutory Injunction and the Commonwealth's claimed loss included the following links: (a) 'but for' Apotex being restrained from supplying, it would not have volunteered the Apotex Undertaking; (b) 'but for' the Apotex Undertaking, Apotex would have applied for PBS listing of its clopidogrel products from 1 April 2008; (c) had Apotex applied for listing, the Minister would have approved that application; and (d) had Apotex's clopidogrel products been listed on the PBS from 1 April 2008, subsidies paid by the Commonwealth to pharmacists for clopidogrel for 7-8 years thereafter would have been lower than that it in fact paid.

32. The Full Court appears not to have treated link (b) as an interposed causal step because Apotex had no commercial reason to apply for listing of its clopidogrel products once it was restrained from supply: the absence of a listing application was thus said to be a 'practical effect' of the Interlocutory Injunction.

33. However, that only goes to demonstrate that the connection with the Commonwealth's claimed loss is an indirect one. Putting the Apotex Undertaking to one side, the situation here is the flip side of that in *Ex parte Hall*. There, the injunction created a motive for the respondent (a receiver in bankruptcy) to engage in the conduct that caused the claimant loss (restraining the holder of a bill of sale and preventing him from taking possession of the goods, which were later lost). Here, the injunction created a motive for Apotex not to engage in conduct (applying for PBS listing from 1 April 2008) that would have given the claimant (the Commonwealth) a benefit. In each case the connection between the loss and the order is indirect. Similarly, in *Smith v Day*, even if the injunction made the right to lease of the claimant's property less valuable, that loss was not recoverable. The fact that the claimant here is a third party, as opposed to the party restrained, makes the position *a fortiori*.

34. A further flaw in the Full Court's analysis is that it does not grapple with the fact that the steps up to an application by Apotex for PBS listing (ie, links (a) and (b) identified in [31] above) do not perfect the Commonwealth's claim: link (c) is essential.

35. As noted above, the Full Court 'defer[red] a determination of what kind of interposed causal step is sufficient to prevent a loss flowing directly from an interlocutory injunction to a time when that question needs to be answered in a concrete fashion' (FCJ[77], AB224). However, if the Commonwealth's claim were to succeed this case called for that question to be answered, as regards the role of the Minister under s 85(6) of the NH Act. Sanofi submits that, had the Full Court undertaken the whole of the required task, it would have answered the question on the Directness Issue differently.

36. In *Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth* [2018] FCA 1556; (2018) 136 IPR 8 (***Sigma v Wyeth***), a case factually similar to the present, Jagot J addressed the directness requirement in determining the claims made by three categories of claimants: (a) enjoined generics; (b) manufacturers which had supply contracts with those enjoined generics in place at the time the relevant injunctions were ordered; and (c) manufacturers which had expectations that they would receive orders from other generics with whom there were no contracts before the interlocutory injunctions were

ordered (see [206]). The Commonwealth had also been a party to that case, but its claim was settled (see [3]).

37. As to the first of those categories of claimants, her Honour found a sufficient connection between the injunctions that restrained the generic companies and their lost opportunity to exploit the rights associated with ARTG registrations, including by the prospect of making sales to pharmacists (at [798(1)]). As to the second and third categories of claimants (ie, manufacturers/suppliers who claimed the lost opportunity to supply generics), Jagot J required more than a mere expectation that some financial consequence would follow from the generics' freedom to sell their products (see [226]-[227]). Provided they could discharge their burden to establish causation, those suppliers with extant contracts were entitled to compensation for having been deprived of the opportunity to supply the enjoined generics pursuant to those contracts. But those suppliers without contracts in place were unsuccessful at this hurdle: 'to the extent that [parties] claimed for loss of the opportunity to supply other generics with the products pursuant to potential contracts which did not exist at the time the interlocutory injunctions were granted and which would have depended on future negotiations … the loss was not a direct or natural consequence of the injunctions. The putative contracts remained dependent on the future negotiations and the unrestricted choices of … those other generics' (at [227]).

38. Contrary to FCJ2[75], AB224, Sanofi did address the position of both the second and third categories of claimants referred to in [226] and [227] of *Sigma v Wyeth*. Sanofi expressly submitted that the position of the Commonwealth in this case (as it would have been in *Sigma v Wyeth*) is analogous to the third category of claimants.[5] The Commonwealth's putative loss depended on, quite apart from the commercial decision of Apotex to seek PBS listing at risk of patent infringement, the Minister's exercise of the discretion under s 85(6) of the NH Act in favour of listing. It is not to the point that the Commonwealth succeeded in persuading the primary judge that that would have occurred (see PJ[421], AB116, subject to NOC Ground 2). Justice Jagot's conclusion with respect to the claims of suppliers without contracts at the time the relevant interlocutory injunctions were ordered was not based on a failure to make good the factual contention that 'potential contracts' would have been entered into – the point was one of directness, focusing on the operation of the orders at the time that they were

[5] Transcript of proceedings before the Full Court, 18 February 2021, T169.12-170.14 (PJC item 135; PFM81, PFM1767-1768).

made. The position of the Commonwealth is the same. At its highest, the Commonwealth lost the potential to exercise its discretion to approve a PBS listing application by Apotex, the effect of which could have yielded it savings. That is equivalent to the uncompensated suppliers in *Sigma v Wyeth* who lost the 'potential' to enter contracts that could have earned them profits.

39. In those circumstances the Commonwealth's asserted financial loss is not properly characterised as flowing directly from the Interlocutory Injunction.

40. As to the significance of the Apotex Undertaking among the suite of orders and undertakings recorded on 25 September 2007, it should be noted the Commonwealth was aware of the proceedings (PJ[597], AB157) but did not seek to intervene or make submissions. Had it done so, it could have sought to have the terms of the Sanofi Undertaking extended to cover losses of the kind it now claims, or urged the Court to require Sanofi to give a cross-undertaking in respect of the Apotex Undertaking. It did neither.

41. There is no reason to conclude that the omission of any reference in the Sanofi Undertaking to the effect of the Apotex Undertaking was inadvertent. Apotex did not seek such an undertaking, Sanofi did not offer it, and the Court did not require it. That was despite Sanofi having offered to give an undertaking as to damages in respect of the injunction it had sought against PBS listing (PJC item 67G; PFM59, PFM477). The opposite inference is more sound: that the absence of such an undertaking was deliberate.

42. As to the finding that Sanofi needed to make "explicit disclosure" of the consequences that might follow for third parties, Sanofi provided the usual undertaking for the coercive relief it obtained, and was otherwise a bystander to Apotex's voluntary undertaking not to seek PBS listing. Third parties, including the Commonwealth, had the protection of the Sanofi Undertaking, as far as it went,[6] and Apotex's unilateral conduct in respect of PBS listing (whether in accordance with an undertaking to the Court or otherwise) was not something for which Sanofi had bargained or obtained relief, or which Sanofi could control. Further, the Commonwealth's claim, brought 6 years later, was a novel one. It was not submitted or put to any of Sanofi's witnesses

[6] As addressed below in relation to NOC Ground 7, the Commonwealth has separately legislated for itself a remedy where an interlocutory injunction is wrongly obtained by an innovator. Those provisions of the TG Act, which Sanofi submits preclude as a matter of law the Commonwealth's present claim on the Sanofi Undertaking, were in place when the Interlocutory Injunction was ordered: see *US Free Trade Agreement Implementation Act 2004* (Cth).

at first instance that Sanofi failed to discharge its duty of candour in seeking and obtaining the Interlocutory Injunction . In those circumstances, the absence of explicit disclosure of the potential effect of Apotex's voluntary undertaking on the Commonwealth, if the Commonwealth were to bring a novel claim for damages, should not enter the analysis.

43. For all those reasons, the entirety of the Commonwealth's claimed loss did not flow directly from the Interlocutory Injunction. This Court should uphold NOC Ground 1 and dismiss the Commonwealth's claim.

Claimed losses in relation to PDPRs and combination products

44. Sanofi's unreached grounds of contention in the Full Court relevantly included the question whether the Commonwealth could recover for losses said to be referable to (a) 'price disclosure price reductions' (**PDPRs**) to clopidogrel made under the NH Act,[7] and (b) the price of 'combination products' (comprising clopidogrel and aspirin) which were first listed on the PBS in December 2009 (FCJ2[12], AB206-207).

45. Any loss attributable to PDPRs is not an immediate or necessary consequence of the Interlocutory Injunction because, even assuming that the direct effect of the order is held to have extended to preventing the PBS listing of a first generic brand of clopidogrel in April 2008, such a listing would not, without more, have produced any savings to the Commonwealth under the PDPR mechanism.

46. That is because the claimed PDPRs were not to be taken for granted. Their occurrence and amount depended on: (a) commercial choices made by numerous independent actors over a long period; and (b) legislative and regulatory acts of the Commonwealth from time to time. Each of those matters undermines the directness of any connection between the Interlocutory Injunction and the claimed PDPR losses. To adopt the terminology of the Full Court, there are numerous 'interposed causal steps' which deprive the relationship of the necessary directness. Three points are made.

47. *First*, it is not the case that PBS listing of Apotex's clopidogrel products from 1 April 2008 would certainly have resulted in PDPRs. The Commonwealth's evidence at trial was to the contrary: of the four drugs with a first reporting period under the PDPR regime commencing on 1 May 2008 (ie, clopidogrel's counterfactual first reporting

[7] In short, a PDPR could be made to the price of a PBS listed drug that was the subject of generic competition if the actual price paid by pharmacists (as a result of discounting) was on average more than 10 percent below the approved price (see PJ[71]-[76], AB29-30).

period), a PDPR was made in respect of only *one* of them in that cycle.[8] Moreover, the primary judge found that, even if Apotex's clopidogrel products had been listed on the PBS from 1 April 2008, Sanofi's success at first instance would have seen those products removed from the market in August 2008 (PJ[498], AB132), with the consequence that there would have been no PDPRs in this 'interrupted supply counterfactual' (PJ[664], AB170).

48. *Second*, the occurrence of any PDPR depended on the actual prices at which clopidogrel products were sold by *all* suppliers in the relevant period. In the counterfactual, that would have depended on the prices at which Apotex supplied, the prices at which Sanofi supplied, the market share each achieved and maintained, and whether any other generic suppliers entered the market (and the timing of their entry, the prices they each offered, and the market shares they each achieved). Those matters in turn would have depended on the 'unrestricted choices' of countless other third parties (wholesalers, pharmacists, doctors, and patients).

49. *Third*, the Commonwealth's claimed PDPR losses depend on the legislative acts and regulatory decisions which were made in the decade from September 2007. That the Commonwealth made substantial changes to the rules by which PDPRs were calculated under the NH Act and the applicable regulations in the relevant period undermines the suggestion that related losses flowed directly from the Interlocutory Injunction. For example:

    a. On 31 July 2009, the regulations were amended to prescribe PDPR dates on 1 April and 1 August in any year (reg 37K). Before this change, there were no prescribed price reduction dates.

    b. On 1 December 2010, the regime was altered to provide for Expanded and Accelerated Price Disclosure (**EAPD**). A third price reduction date was added, 1 December (reg 37K); and a 'Guaranteed Adjustment Proportion' (**GAP**) price reduction was set for 1 April 2012 (s 99ADJ).

    c. On 1 October 2012, the calculation provisions were amended to make the 'approved ex-manufacturer price' the base price, rather than the 'approved price to pharmacists', and the GAP price reduction was repealed.

[8] Affidavit of Felicity McNeill sworn 28 November 2014 at [157]-[158] (PJC item 111AA; PFM76, PFM1083-1084).

d. 'Simplified Price Disclosure' arrangements were introduced to the NH Act on 13 March 2014 and the regulations on 3 June 2014. These consolidated the EAPD disclosure cycles into a rolling 12 month cycle, including 6 month data collection periods (regs 37C, 37F-37S), and set new PDPR dates (s 99ADH).

e. The NH Act was amended on 27 June 2015 to introduce flow-on price reductions for combination items (s 99ADHB), and provide for originator information to be excluded from the price calculations (s 99ADB(6A) and (6B)). The regulations were amended accordingly on 1 May 2016 (regs 37SB and 37SC).

50. The fact that the rules of the PDPR regime could be, and were, changed by the Commonwealth from 2007 onwards, and that such change affected the way in which its claimed loss is calculated (based on the actions of thousands of market participants), undermines the notion that PDPRs flowed directly from the Interlocutory Injunction.

51. Further points apply in relation to the claim that the Interlocutory Injunction had a direct impact on the Commonwealth in respect of the cost of subsidies for combination products. At the time the Interlocutory Injunction was ordered, no clopidogrel plus aspirin combination product was registered on the ARTG (the first were registered on 23 September 2009), and none was listed on the PBS (the first were listed on 1 December 2009),[9] and the combination products were covered by a separate patent which was not due to expire until 2017,[10] and it was not challenged during the period of any relevant restraint.

52. Moreover, the claimed losses in relation to combination products depend upon a series of assumptions as to the outcome of pricing negotiations that would have been conducted between the Commonwealth and Sanofi in 2008 and 2009; they make the direct impact of events in 2007 on the Commonwealth's later position particularly implausible.

53. Specifically, the steps required to reach the Commonwealth's claimed counterfactual price for the combination products were as follows:

a. but for the Interlocutory Injunction, Apotex's clopidogrel *monotherapy* products would have been listed on the PBS on 1 April 2008 and remained listed, triggering the PDPR regime;

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[9] Commonwealth's Amended Points of Claim, [27] and [58] (PJC item 112AA; PFM77, PFM1101-1102, 1107).

[10] Annexure RAW-11 to the Affidavit of Robert Wilson affirmed 8 June 2012 at 186 (PJC item 103AA; PFM74, PFM789).

b. but for the Interlocutory Injunction, the market for clopidogrel *monotherapy* from 1 April 2008 would have operated to give rise to a PDPR in a particular amount as at 1 April 2010;

c. had Sanofi commenced price negotiations in respect of combination products in December 2008 (as it in fact did), and requested that those products be listed at the monotherapy price (as it in fact did), the Commonwealth: (i) would have sought to stall negotiations for almost 8 months to after 31 July 2009 (contrary to what it in fact did), and succeeded in that tactic; (ii) negotiated with Sanofi on the basis that the combination products' price on 1 December 2009 should *not* be the same as for the monotherapy product at that time, but should instead be the future (lower) monotherapy price as at 1 April 2010, after an upcoming PDPR (contrary to what it in fact did); and (iii) succeeded in obtaining Sanofi's agreement to that position (which was against its interests).

54. It follows that no loss in respect of PDPRs, or different pricing for the clopidogrel with aspirin combination products directly flowed from the Interlocutory Injunction. NOC Ground 3 should be upheld.

Adverse Effect Issue – NOC Ground 4

55. Sanofi challenges the conclusion of the primary judge, which was not addressed in FCJ2, that the Commonwealth's claim does not fail because the Commonwealth could not be 'adversely affected' by the Interlocutory Injunction (PJ[571]-[586], AB149-154; FCJ2[12], AB207).

56. Sanofi's submission is based on the cumulative effect of a series of considerations unique to the Commonwealth's status and role in relation to the matters the subject of the litigation. The primary judge rejected those arguments (see PJ[574], [581], [586], AB151-152, 154), mainly by analogy with scenarios in which private law claims are brought by the Commonwealth (see PJ[576], [578]-[580], [583], AB151-153). The primary judge erred, and NOC Ground 4 should be upheld, for the following reasons.

57. The Commonwealth is not an ordinary litigant, and its claim against Sanofi is not an ordinary litigant's claim. The Commonwealth is a polity established by a proclamation under s 3 of the *Commonwealth of Australia Constitution Act 1900* (Cth) (**Constitution**). This union is governed by laws passed by Parliaments which owe their legitimacy to the Constitution. Those laws include laws conferring benefits on the community or members of it, and laws requiring fiscal exactions to fund the functions

of government, including the payment of legislated benefits. The laws of the Commonwealth define its own liabilities and rights, subject only to the Constitution.

58. The Commonwealth does not suffer any compensable 'loss', and is not 'adversely affected' when, in accordance with its own laws and policy objectives, it funds the PBS as it operates from time to time. The Commonwealth does not suffer a 'loss' when it pays subsidies under the PBS in accordance with the terms of that regime, in particular since the Commonwealth maintains control of the decisions to list medicines to the PBS, the prices at which they are listed, and the regulatory regime by which those prices are adjusted. The position is *a fortiori* when the alleged loss is attributable to the operation of orders in respect of rights granted and regulated by laws of the Commonwealth, the *Patents Act 1990* (Cth), the TG Act and the NH Act.

59. A claim by the Commonwealth brought pursuant to an undertaking as to damages is quite different to a situation in which the Commonwealth has a claim for breach of contract or in tort, where there is a *liability* to the Commonwealth as a consequence of a legal wrong. In the present case, Sanofi has no 'liability' to the Commonwealth, and there is no cause of action upon which the Commonwealth sues (*European Bank* at 438-439[14]). No wrong has been committed.

60. The present case is not only one in which no wrong has been committed, but also one in which the claimed loss arises simply from the intended operation of laws of the Commonwealth, specifically: (a) a scheme for the approval of safe and efficacious medicines for the benefit of citizens and residents (under the TG Act and through the TGA); (b) a scheme for the subsidisation of medicines as a matter of social welfare (under the NH Act and through the Department); and (c) a regime for the granting of patents to encourage innovation, including medical innovation (under the *Patents Act* and through IP Australia and, before it, the Australian Patent Office). Without any wrong being committed by Sanofi, the operation of those various schemes and institutions has resulted in the Commonwealth paying a certain amount out by way of subsidies in respect of clopidogrel. The Commonwealth does not suffer a 'loss' in those circumstances any more than it does when a taxpayer earns less income (thus reducing his or her income tax payment), a firm decides to incur expenditure eligible for an R&D tax offset, or when a person suffers an injury or new medical condition and so begins purchasing a PBS subsidised product. Rather, in all such cases, the Commonwealth sees its objectives, as embodied in its laws, achieved.

61. NOC Ground 4 should be upheld, and the Commonwealth's claim dismissed.

TG Act Issue – NOC Ground 7

62. Sanofi challenges the Full Court's conclusion that the Commonwealth is not precluded as a matter of law from recovering compensation pursuant to the Sanofi Undertaking by reason of Ch 3, Pt 3-2, Div 2 of the TG Act (see FCJ1[1], [118]). Specifically, Sanofi submits that, since the Commonwealth has enacted a specific regime for it to claim compensation in the event that an innovator pharmaceutical company obtains an interlocutory injunction and delays generic entry by *wrongly* asserting patent rights, there is a negative implication to the effect that the Commonwealth cannot claim on the usual undertaking as to damage where there is no such wrongdoing.

63. The TG Act regulates, *inter alia*, the registration of therapeutic goods on the ARTG. Registration is a pre-condition to PBS listing under the NH Act. For the purpose of this ground of contention, the key provisions of the TG Act operate as follows.

64. A generic applicant for the listing of a therapeutic good on the ARTG, which seeks to satisfy the statutory safety or efficacy requirements by relying on information provided by the innovator, is required to give a certificate under TG Act, s 26B(1)(a) if it believes in good faith and on reasonable grounds that it will not market the therapeutic good in a manner that would infringe a valid claim of a patent (**s 26B(1)(a) certificate**). A different certificate is given if the generic does not take a position on infringement of a relevant patent, but has given notice to the patentee (**s 26B(1)(b) certificate**).

65. Where a s 26B(1)(a) certificate or s 26B(1)(b) certificate has been given, and the innovator intends to commence patent infringement proceedings in relation to the therapeutic good, the innovator must give a certificate under TG Act, s 26C(3) stating that the proceedings are commenced in good faith, have reasonable prospects of success, and will be conducted without unreasonable delay (**s 26C(3) certificate**).

66. If the innovator obtains an interlocutory injunction against a generic which has given a s 26B(1)(a) certificate restraining it from infringing the patent, and the court later declares that the s 26C(3) certificate was false or misleading, or there was a breach of any undertaking given in the certificate, the court is empowered by s 26C(8) to make an order that the innovator pay the Commonwealth compensation for any damages sustained or costs incurred as a result of the grant of the interlocutory injunction. Similar sanctions apply where a generic gave a s 26B(1)(b) certificate, an interlocutory injunction was obtained, and certain other conditions are met (s 26D(4)-(5)).

67. An evident legislative purpose of ss 26C(8) and 26D(4)-(5) is to address the concern that an interlocutory injunction granted in favour of an innovator may delay the PBS

listing of a generic's products, with consequential impacts on the cost of the PBS for the Commonwealth (that is, losses of the kind claimed in this case).

68. As noted above, prior to the commencement of the Patent Proceeding, Apotex gave a s 26B(1)(a) certificate, and Sanofi gave a s 26C(3) certificate (PJC items 41, 50A; PFM39, PFM43, PFM181, PFM257). Accordingly, the Commonwealth's right of recovery under the TG Act scheme was limited to the circumstances identified in s 26C(8). Since the parties conducted the Patent Proceeding extremely expeditiously between the September 2007 interlocutory hearings and the trial commencing in April 2008 (as required by Gyles J), and Sanofi in fact succeeded at that trial (with a permanent injunction replacing the Interlocutory Injunction until the appeal was determined), plainly no relief was available to the Commonwealth under that provision. In those circumstances, the Commonwealth has instead sought to rely on the general law right under the Sanofi Undertaking, which was available to 'any person whether or not a party, adversely affected by the operation of' the Interlocutory Injunction.

69. Since the scheme of the TG Act confers specific rights subject to conditions, a principle of statutory construction is engaged to the effect that ss 26B, 26C and 26D implicitly exclude the Commonwealth's general rights that might otherwise arise.[11] '[T]he limited statutory entitlement conferred by that section exhibits a sufficient legislative intention to exclude recovery at common law' (cf *Paterson Constructions* at [59] per Gageler J, as his Honour then was; see also [157]-[159] per Nettle, Gordon and Edelman JJ).

70. The Commonwealth's statutory right to compensation for 'any damages sustained, or costs incurred … as a result of the grant of the interlocutory injunction' under ss 26C(8) and 26D(5)(b) occupy the same field as the general law right to claim on the usual undertaking as to damages given by an innovator for an interlocutory injunction against a generic. It would subvert the statutory scheme if the Commonwealth were entitled to seek equivalent relief to that which is available under the TG Act pursuant to the general law, but without the stipulated statutory preconditions having been satisfied.

[11] *Mann v* ***Paterson Constructions*** *Pty Ltd* [2019] HCA 32; (2019) 267 CLR 560 at 591[59] per Gageler J, citing *Comptroller-General of Customs v* ***Kawasaki Motors*** *Pty Ltd (No 2)* (1991) 32 FCR 243 at 258 and ***Chippendale Printing*** *Co Pty Ltd v Federal Commissioner of Taxation* (1996) 62 FCR 347 at 366-369.

71. In *Kawasaki Motors* at 263, Hill and Heerey JJ noted that it was improbable that a statutory scheme was supplementary to general law rights in circumstances where it was hard to see 'why any person would adopt the [statutory] procedure … which would seem to be greatly more restrictive than that applicable at common law'. The same observation may be made in relation to the position of the Commonwealth. It is improbable that it would ever invoke TG Act, ss 26C(8) or 26D(5), where they each require a finding by a court of a wrong on the part of the innovator in obtaining the interlocutory injunction, whereas the general law does not (cf *European Bank* at 438-439[14]).

72. In that regard, it is telling that the Commonwealth has now made three claims on usual undertakings as to damages to recover expenditure on the PBS that is said to have been occasioned by a delay in a generic PBS listing as a result of an interlocutory injunction: (a) the proceedings below (in which the Commonwealth's claim has not been upheld); (b) *Sigma v Wyeth* (in which the Commonwealth's claim was settled); and (c) a claim that has not reached a first instance determination (see *Otsuka Pharmaceutical Co., Ltd v Generic Health Pty Ltd (No 3)* [2020] FCA 222). In contrast, no claim has ever been made by the Commonwealth under the TG Act mechanism.

73. If the present claim is allowed to be conducted on general law principles, the 'carefully formulated legislative controls' under the TG Act will have been bypassed by the Commonwealth (cf *Chippendale Printing* at 359). The result will be that the statutory scheme is subverted and the legislature's intention frustrated. The legislation manifests an intent that the Commonwealth ought be limited to the qualified rights that the legislature conferred under the TG Act in cases of this kind.

74. NOC Ground 7 should be upheld, and the Commonwealth's claim dismissed.

Part VII: Estimate

75. Sanofi estimates that it will require up to 7 hours to present its combined arguments on the NOA and NOC.

Dated: 30 April 2024

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