



HIGH COURT OF AUSTRALIA

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Details of Filing

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Important Information

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**IN THE HIGH COURT OF AUSTRALIA
SYDNEY REGISTRY**

ON APPEAL FROM THE FULL COURT OF THE FEDERAL COURT

BETWEEN:

Commonwealth of Australia
Appellant

Sanofi (formerly Sanofi-Aventis)
First Respondent

Sanofi-Aventis US LLC
Second Respondent

Bristol-Myers Squibb Investco LLC
Third Respondent

**APPELLANT'S SUBMISSIONS ON THE RESPONDENTS' NOTICE OF
CONTENTION**

Part I: Certification

1. This submission is in a form suitable for publication on the internet.

Part II: Statement of issues

2. By their Notice of Contention (**NOC**), the Respondents (**Sanofi**) contend that the decision below should be affirmed on seven grounds. One of those grounds, concerning the requirements of directness, was rejected by the Full Court below: NOC [1], AB 549. Five of the grounds were not decided by the Full Court: NOC [2]-[6], AB 550-553. The final ground, NOC [7] (AB 553-554), was not argued by Sanofi below after being the subject of a stated case rejected by a differently constituted Full Court in 2015 (*Commonwealth of Australia v Sanofi (formerly Sanofi-Aventis)* [2015] FCAFC 172; (2015) 237 FCR 483) (**Stated Case**) and this Court refusing Sanofi's application for special leave to appeal.¹
3. Sanofi asks this Court to determine four of the NOC grounds and remit the balance to the Full Court. The four grounds pressed raise the following issues.
4. First, the content of the equitable requirement that, to be compensable, a claimed loss must "flow directly" from the interlocutory order. By NOC [1] Sanofi contends that none of the Commonwealth's losses satisfy this requirement. By NOC [3] (AB 550-551) Sanofi contends that the "flow directly" requirement is at least not satisfied by two portions of the Commonwealth's loss which it seeks to present as factually more attenuated than other aspects of the Commonwealth's claimed loss.
5. Second, the meaning of "any person, adversely affected" in the usual undertaking as to damages. Specifically, whether loss to the Commonwealth polity, as represented by the executive branch, and which loss flows from the interaction of an interlocutory order made by the judicial branch with the operation of the legislatively regulated Pharmaceutical Benefits Scheme (**PBS**), is loss of a kind suffered by a juristic "person" within the equitable concept of "any person, adversely affected": NOC [4] AB 551.
6. Third, whether this Court should entertain NOC [7] which raises an argument that was: (i) the subject of a stated case to a differently constituted Full Court to which both the Commonwealth and Sanofi were parties; (ii) rejected by that Full Court;² (iii) the subject of an unsuccessful application for special leave to appeal; and (iv) not re-

¹ *Sanofi (formerly Sanofi-Aventis) v Commonwealth of Australia* [2016] HCASL 98; *Wyeth & Anor (3 Applications) v Commonwealth of Australia* [2016] HCASL 99.

² *Stated Case* at [109] (Kenny and Nicholas JJ). Dowsett J agreed on this point at [1].

agitated before the Full Court below. If the answer to that question is “yes”, then the fourth issue is whether, Chapter 3, Part 3-2, Division 2 of the *Therapeutic Goods Act 1989* (Cth) (**TG Act**) precludes the Commonwealth recovering compensation by reason of Sanofi’s contention that the TG Act provisions constitute a code.

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

7. The Commonwealth has issued a notice under s 78B of the *Judiciary Act 1903* (Cth).

Part IV: Contested facts

8. There are no contested facts. However, Sanofi’s summary of the circumstances in which Apotex gave its undertaking on 25 September 2007 in its submissions filed on 30 April 2024 (**RS**) at [9(m)]-[9(p)] is incomplete. So too is Sanofi’s summary of the history of these proceedings as they relate to NOC [7] at RS [12]-[13]. More complete summaries of those matters are at paragraphs [23]-[26] and [53] respectively.

Part V: Argument

(a) Directness: NOC [1] and [3]

9. The Commonwealth’s claimed loss comprises the difference between the inflated amount of subsidies the Commonwealth actually paid for supply of clopidogrel to patients under the PBS in the real world in the absence of the Apotex clopidogrel products being listed on the PBS from 1 April 2008, and what the Commonwealth would have paid in subsidies in the counterfactual world had the Apotex clopidogrel products been listed from that date.
10. By NOC [1] and [3] Sanofi leaves unchallenged (as it did in the Full Court) the primary judge’s finding that all the Commonwealth’s claimed losses were reasonably foreseeable losses at the time the interlocutory injunction was granted: PJ [456]-[460], [462]-[463] AB 124-126; PJ [452] AB 123. Notwithstanding foreseeability, Sanofi contends that even if the Commonwealth succeeds on its appeal in establishing that Apotex would have obtained listing of its generic clopidogrel products on 1 April 2008 in the absence of the injunction and thereby triggered substantial reductions in the amount of subsidies payable by the Commonwealth for supplies of clopidogrel under the PBS thereafter, none of the Commonwealth’s claimed losses “flowed directly” from the interlocutory injunction.
11. The issue raised by NOC [1] is the meaning of Aickin J’s statement in *Air Express Ltd*

v Ansett Transport Industries (Operations) Pty Ltd (1981) 146 CLR 219 at 266-267 – as adopted in *European Bank Limited v Evans* (2010) 240 CLR 432 at [18] and [29] – that compensable losses are those which “flow directly” from an injunction. Should “flow directly” be interpreted – as the Full Court did (see [13]-[14] below) – having regard to equity’s concern with substance over form such that equity will compensate for losses sustained, including by third parties, which are the obvious, practical (and here also inevitable) consequence of a person enjoined not doing that which the interlocutory order sought to prevent? Or should “flow directly” be interpreted, as Sanofi urges, formalistically and against the practical concerns of equity to compensate only where the loss follows “immediately” (in the sense of the next event in the causative chain after an interlocutory order is made), or alternatively only where the terms of the injunction interfere, as a matter of law, with a person’s legal right to do something?

12. NOC [3] raises the same conceptual issues as NOC [1]; it is in truth a contention that two portions of the Commonwealth’s loss are more factually attenuated than others, so at least those losses did not “flow directly” even if the rest did.

The meaning of “flow directly”

13. The Full Court identified the equitable requirement that claimed losses from an interlocutory injunction “flow directly” from that injunction as concerned with the practical, substantive effect of an injunction understood in all the circumstances relevant to its making and the giving of the corresponding undertaking as to damages: FC [37]-[44], AB 213-215; FC [79]-[81], AB 225.
14. Where loss occurs by reason of a chain of events consequent upon the making of an order, whether the loss satisfies the “flow directly” requirement turns not on characterisations of whether the outcome is immediate, or happens after an “interposed causal step”, but rather by making an “*evaluative judgment*” as to whether any step in the chain – any “interposed step” between the making of the order and the suffering of loss – is such as to cause the loss not to be one which “flow[s] directly”. The evaluative judgment considers “*the nature of the interposed step and the circumstances more broadly, assessed having regard to the equitable rationale for the award of damages*”: FC [60], AB 219. The “flow directly” requirement does not impose bright-line formalistic tests or taxonomies borrowed from other areas of law: FC [45], AB 215-216; FC [59], AB 219; FC [68], AB 222; FC [77], AB 224; FC [81], AB 225. Indeed, the requirement is – as is demonstrated by the passages from *Air Express* and *European*

Bank quoted at FC [46]-[47], AB 216 – merely one “view” or approach to giving form to the underlying equitable intent that recoverable loss be that which “*is just and equitable, or fair and reasonable, in all the circumstances*”: see also FC [81], AB 225.

15. By NOC [1] Sanofi challenges the Full Court’s decision on several bases, unified by the common proposition that “‘*directly*’ imports a limitation such that not all ‘*but for*’ causal consequences are to be compensated (including foreseeable ones)”: RS [18]. The content of the “limitation” for which Sanofi contends is more difficult to nail down.
16. At times, Sanofi seems to suggest the enquiry is whether the injunction interfered, as a matter of law, with a person’s legal right to do something. Thus at RS [18] Sanofi argues that “*directness should be understood as requiring that the event which occasions the loss be restrained by the injunction*”; and at RS [21] Sanofi argues that the injunction here “*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*”; see also RS [23] (“*An application for PBS listing was not restrained*”).
17. At other points, Sanofi seems to suggest that the “limitation” is a distinction between “direct” loss and “indirect” loss. The distinction apparently turns on whether:
 - (a) the injunction is by itself sufficient to cause the loss to follow (i.e. to “perfect” it (RS [34])) or lead to a self-executing loss (RS [38]-[39]), such as to satisfy the requirements of “flow directly” on Sanofi’s construction of it; or
 - (b) whether other steps in the real world might also need to occur, such as the acceptance of an application by Apotex for PBS listing by the Minister, which Sanofi suggests would lead to the loss being characterised as “indirect” and not loss which “flows directly”: see, e.g. RS [33]-[35].
18. By these two somewhat inconsistent approaches to the meaning of “flow directly”, Sanofi contends that “[i]t 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)”: RS [21]. What is “to the point”, apparently, is that the inevitable practical effect of the interlocutory injunction and the expressed intention of Sanofi’s application for interlocutory relief should be put to one side and the Court engage in a formalistic and technical assessment of whether the order, in terms, precluded Apotex from exercising a legal right to apply for PBS listing (or the Minister from exercising

the power to list Apotex's brand), or otherwise operated so immediately and directly such that in the counterfactual world, aside from the making of the order, no decision-making or act would have been required by the party enjoined or any other person to give rise to the loss claimed.

19. The Commonwealth supports the conclusions reached by the Full Court on the question of directness for the reasons it gave. Sanofi has shown no error in the Full Court's understanding and application of the "flow directly" requirement.
20. First, the Full Court correctly identified that the "flow directly" concept is directed to enabling the Court to do what is just and equitable, or fair and reasonable, in all the circumstances. The Full Court adopted an understanding of the meaning of "flow directly" which enables the Court to do that fundamental task in the manifold of circumstances which might ordinarily arise unconstrained by rigid formulations not tethered to that purposive intent: see FC [46]-[47], AB 216³ and see also FC [58], AB 219 and FC [81], AB 225. Sanofi's submissions at RS [21]-[23] involve an attempt to construe "flow directly" as an excessively demanding and rigid test (*viz.* to impose a requirement that an injunction interfere with legal rights). Were such a test to apply, it would deprive equity of an ability to compensate persons, including third parties, for the practical consequences of an interlocutory injunction unless the undertaking given had been given other than in the usual form, or the interlocutory order had been precisely worded to interfere with legal rights (which may not be possible in the circumstances including because of questions of the Court's power). No rule of equity is relied upon to support such rigidity and limitation on the scope of the usual undertaking and equity's associated ability to do practical and substantive justice.
21. Further, were Sanofi's contentions accepted, it would have profound consequences for the courts and litigants, at the time of granting interlocutory relief and extracting an undertaking as to damages, to consider the various interests (including of third parties) which might be affected and whether and how the injunction ought to be worded such that in terms it operates by reference to legal rights. Alternatively, should such wording not be possible but reasonably foreseeable adverse consequences to the party enjoined and/or third parties are anticipated as likely or even probable, the usual undertaking would not be sufficient in many cases to afford the protection and jurisdiction courts of equity require as a condition for granting equitable relief. Courts and parties would

³ Reproducing Aickin J in *Air Express* at 266-267 and *European Bank* at [18] and [29]; see also *European Bank* at [16]-[17] referring to Mason J in *Air Express* at 324.

need to consider alternative forms of wording of the undertaking as to damages, such a process being inefficient and potentially ineffective. The purpose of the usual undertaking as to damages is to provide a form of words that will give the courts the jurisdiction and comfort they need that should the moving party for the injunction ultimately turn out to be unsuccessful in the substantive case, equity will be able, retrospectively, to do substantive justice as between not only the parties but to protect innocent third parties as well. Sanofi's proposed limitation on the content of "flow directly" is at odds with that fundamental purpose of extracting the undertaking, at the time interlocutory relief is granted.

22. Second and relatedly, looked at from the perspective of the courts when called upon to award compensation pursuant to undertakings previously given, Sanofi's construction leads to the potential for judicial impotence whenever an injunction, though intended to have the practical effect of depriving a person's legal right of any practical utility or value, nonetheless is not *expressly* worded to prohibit a person exercising that now practically useless right. Although the Commonwealth claims, as a third party, on Sanofi's undertakings, the construction of the interlocutory injunction must be the same regardless of whether the claimant is a party or third party absent any compelling rationale (which Sanofi has not given).
23. The facts of this case illustrate the problem. They are summarised at FC [17]-[32], AB 208-212. The Full Court correctly explains why the primary judge erred in concluding, from that factual substratum, anything other than that the Commonwealth's claimed loss flowed directly from the injunction restraining supply (and other acts): FC [34]-[44], AB 213-215. Understood in its objective context, the wording of the injunction was intended to prevent – "*at least in a practical if not legal sense*" (FC [25], AB 210) – Apotex applying for PBS listing in two ways.
24. The first way was brought to the attention of Gyles J by Senior Counsel for Sanofi, Mr Bannon SC, who submitted that Apotex could not "*plausibly apply for listing without indicating they're going to be able to supply*": FC [21], AB 209.⁴ That was because, first, an administrative requirement was that any listing application by Apotex be accompanied by a written assurance of supply on the proposed listing date (which requirement, having regard to the terms of the proposed injunction on supply, Apotex could not practically meet), and secondly, even if Apotex nevertheless obtained PBS listing, the wording of the injunction would prevent it from complying with supply

⁴ Referring to item 69 (PFM vol 2/tab 60/p. 518 (lines 35-37)).

obligations under s 99AEB of the *National Health Act 1953* (Cth) which could result in the delisting of Apotex's products and which was also an offence (s 99AEH(2)): FC [22]-[25], AB 209-210.

25. The second way was that if Apotex's clopidogrel products were listed on the PBS, that would trigger an automatic 12.5% reduction in the price of Sanofi's clopidogrel products without any benefit to Apotex if it could not also supply its products: FC [26]-[28], AB 210-211. The reduction in Sanofi's clopidogrel price would also have an indirect negative effect on the profits of pharmacists for the reasons given at FC [26], AB 210. As Mr Catterns QC, Senior Counsel for Apotex, explained to Gyles J, a PBS listing without the ability to sell "*will only damage our friends*" (i.e. Sanofi), was "*of no benefit to us*" and would make Apotex "*enemies in the industry*": FC [28], AB 211.⁵ Because of those practical effects, Mr Catterns QC indicated that "*if your Honour makes an injunction against us selling, we would agree on an appropriate undertaking that would fix that up*": FC [28], AB 211.⁶ That proposed efficiency measure rendered moot the jurisdictional matter troubling Gyles J (correctly, as it transpired) as to whether the Court had power to make the order sought by Sanofi to restrain Apotex from applying to list on the PBS: FC [20], AB 209. More fundamentally it simply made explicit that which would inevitably follow once the interlocutory injunction was granted.
26. At the end of the contested hearing, Gyles J reserved his decision and then on 21 September 2007 gave his reasons orally as to why Sanofi was entitled to an injunction restraining Apotex from supplying its clopidogrel products. With the benefit of those oral reasons, the parties prepared agreed short minutes which his Honour made at a hearing on 25 September 2007 at the same time as publishing his revised reasons. The orders included the Apotex Undertaking which Mr Catterns QC reminded the Court was being given because Gyles J had determined to make the interlocutory injunction restraining Apotex from supplying and to save the jurisdictional argument raised by his Honour: FC [31], AB 212.⁷
27. It is artificial to construe from the face of the orders any suggestion that the injunction would not and did not have a direct effect on whether Apotex would apply to list. The circumstances in which the injunction was made, and the undertaking given, revealed the contest was over as soon as the Court indicated it would make the injunction

⁵ Reproducing item 69 (PFM vol 2/tab 60/pp. 575 (line 32)-576 (line 29)).

⁶ Reproducing item 69 (PFM vol 2/tab 60/pp. 575 (line 32)-576 (line 29)).

⁷ Reproducing item 74 (PFM vol 2/tab 63/p. 591 (lines 9-40)).

restraining Apotex from supplying clopidogrel: FC [37]-[44], AB 213-215. Sanofi's submission at RS [19] that, once the Apotex Undertaking was "*volunteered ... it was a complete and sufficient cause of its failure to seek PBS listing*", is inaccurate. There is no evidence that when Gyles J queried his power to restrain Apotex from seeking listing, and when Mr Catterns QC dealt with the argument in the practical way he did, the parties were thereby intending to relieve Sanofi of the burden of the proffered undertaking by reference to which it had commenced and conducted the entire contested hearing, namely an undertaking to protect against losses whether from supply or listing or both.⁸

28. Third, and relatedly, the Full Court was correct to reject Sanofi's attempt to suggest some formalistic interpretative guidance might be gained from the fact that the Apotex Undertaking was not supported by Sanofi's undertaking as to damages: FC [79], AB 225. Sanofi reagitates those submissions in this Court (RS [40]-[42]) and takes umbrage at the Full Court's finding that if Sanofi intended its technical wording of orders to exclude liability to compensate the Commonwealth for PBS losses, it required "*explicit disclosure*" to Gyles J especially in circumstances where the impact of the injunction on the PBS "*much influenced*" his Honour in concluding that damages would not be an adequate remedy if Apotex's challenge to the Patent failed: FC [79]-[81], AB 225. That was all the more so given that his Honour's understanding of the potential for PBS consequences if the injunction was not granted was based on the evidence given on this topic by Sanofi's witnesses, Messrs Dick and Lindsay,⁹ and that Mr Bannon SC had told Gyles J that: "*[t]he government hasn't applied to be a party to these proceedings, but our undertaking as to damages, as your Honour would know, is not limited to the parties*".¹⁰
29. Additionally, it is relevant that at the time the interlocutory order was made and the undertaking given Sanofi was ordered to provide \$40 million in security within 28 days "*pending the determination of the amount of compensation, if any, that the Court may consider should be paid to [Apotex] should it be found to have been adversely affected by [the interlocutory injunction]*".¹¹ The giving of that security can only be

⁸ See the notice of motion Sanofi filed on 17 September 2007 at item 67 (PFM vol 2/tab 53/pp. **405-406**); Sanofi's outline of submissions in support of its notice of motion at paragraphs [1]-[2] at item 67G (PFM vol 2/tab 59/pp. **478-479**) and Mr Bannon SC's submissions to Gyles J at item 69 (PFM vol 2/tab 60/p. **505** (lines 1-10), p. **519** (lines 23-24)).

⁹ As to which see especially item 67C (PFM vol 2/tab 55/pp. **427-429** at [25]-[35]) (Mr Dick) and item 67D (PFM vol 2/tab 56/pp. **440-449** at [6]-[42]) (Mr Lindsay).

¹⁰ See item 69 (PFM vol 2/tab 60/p. **519** (lines 23-24)).

¹¹ See item 74 (PFM vol 2/tab 63/p. **594**).

explained as contemplating – and as representing to the Court that it was contemplated – that the interlocutory injunction was capable of causing adverse consequences of a significant quantum which the Court may in due course consider appropriate to be compensated by Sanofi pursuant to its undertaking as to damages. Clopidogrel was not a drug with any significant private market;¹² for Apotex to make any substantial profits on supply depended on Apotex supplying to the PBS market, which required listing. If – as Sanofi now seeks to contend – the PBS-related losses consequent upon the grant of the interlocutory injunction did not “flow directly” from that injunction, one might ask: for what was the security proffered given Apotex’s lost profits in the order of \$40 million would have required PBS listing to be sustained?

30. Fourth, and as the Full Court correctly explained, in many other branches of law a “flow directly” requirement is not interpreted to exclude consequential losses, or to require self-executing loss be established in order that compensation be payable: see FC [54]-[57], AB 218-219, see also FC [68], AB 222. No different approach ought to be taken in equity, a jurisdiction in which flexibility and concern with substance over form and technicality is a defining hallmark. That approach is consistent with the reasoning in *Air Express* (FC [65]-[67], AB 221-222) and *Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth* [2018] FCA 1556; (2018) 136 IPR 8 at [226] which demonstrate that the application of the “flow directly” requirement does not exclude all consequential losses: FC [72]-[73], AB 222-223 and FC [75]-[76], AB 224.
31. The “directness” requirement in “flow directly” is thus not concerned with distinctions between direct loss and consequential loss (and thus between self-executing loss and loss which might flow from events in a chain as per RS [33]-[39]). It is instead concerned with identifying an adequate causal link between the interlocutory injunction and claimed loss having regard to the purpose of the injunction and the purpose of the undertaking as to damages in the usual form.
32. *Sigma* aptly illustrates this proposition. On the one hand Jagot J accepted that claimants whose business was to manufacture pharmaceutical products, and who in fact had a contract for supply with the relevant generics who were enjoined from importing product to Australia, suffered loss (i.e. loss of profits on supply) which was “*the direct and natural consequence of the interlocutory orders which prevented supply*”: at

¹² Sanofi’s affidavit evidence before Gyles J revealed that 95% of clopidogrel sales were to pharmacists (as opposed to hospitals) and products sold through the pharmacy channel were “generally covered by the Pharmaceutical Benefits Scheme”: item 67C (PFM vol 2/tab 55/pp. 425 [16] and 432 [52]) (Mr Dick).

[226]. On the other hand, for those manufacturer claimants who were not able to prove that they had in place supply agreements with the enjoined generics at the time the interlocutory injunctions were granted and under which orders for product might be placed, Jagot J found their losses were not loss that “*was a direct or natural consequence*” because they “*remained dependent on the future negotiations and the unrestricted choices of other generics*”: at [227], see also FC [74], AB 223.

33. Sanofi has sought in this Court to suggest that the Commonwealth’s loss is like those suppliers in *Sigma* who failed (see RS [37]-[38]). That comparison ought not be accepted. The Commonwealth had in place a detailed statutory scheme for subsidising the cost of medicines. Much like the position of those manufacturers in *Sigma* who had a supply contract under which orders could be placed at the time the interlocutory injunction was granted, the Commonwealth had in place a statutory framework by which brands could be listed on the PBS. The Commonwealth did not lose the “potential” to list Apotex products in circumstances where Apotex would have obtained listing in accordance with the statutory framework (and nor did the successful suppliers in *Sigma* lose the opportunity to accept orders from the generics). Rather, the Commonwealth lost the PBS savings which would have occurred because of Apotex not doing that which it would have done absent the injunction (just as the successful suppliers in *Sigma* lost the profits that they would have made from the orders the generics would have placed with them).
34. Fifth, little was or is to be gained from an analysis of ancient case law relied on by Sanofi below (and relied upon again in this Court at RS [18]) but which – as the Full Court correctly found – “*do not support a definitive view one way or the other on the question of whether the existence of an interposed causal step negates a finding that damage flowed directly from an injunction*” and “*indeed, a closer inspection of passages relied upon by Sanofi suggest that they may in fact hinder rather than aid its submission*”: FC [61], AB 219-220 see also FC [62]-[64], AB 220-221 and FC [49], AB 217.
35. The primary judge made the necessary, unchallenged findings as to the purpose and practical effect of the injunction, namely that it, in terms, restrained supply, but in practical effect restrained Apotex from seeking PBS listing: PJ [428]-[432], AB 118-119. The Apotex Undertaking only made explicit that which Apotex could not do because of the interlocutory injunction. From the moment the interlocutory injunction was made the Commonwealth was exposed to loss by way of paying higher amounts

under the PBS than it otherwise would have. That was enough to satisfy equity's requirement of "flow directly" and the Full Court was correct to so find.

NOC [3]: are some parts of the claimed loss distinguishable?

36. By NOC [3] Sanofi contends that at least two portions of the Commonwealth's claimed loss did not meet the "flow directly" requirement because they are more attenuated than other aspects of the claimed loss.
37. The Commonwealth's position is that NOC [3] ought to be remitted. This is because the ground is interrelated with, and logically sequential to, determination of ground 3 of the Commonwealth's Further Amended Notice of Appeal to the Full Court (**FANOA**) (AB 192-193) which the Full Court did not determine and which the Commonwealth has sought, by proposed order 3 of its Appeal to this Court (AB 547) to be remitted to a differently constituted bench of the Full Court if the Commonwealth succeeds on its grounds of appeal to this Court. It would be counterproductive and inefficient for this Court to determine NOC [3] without also determining (which no party asks it now to do) the issues the subject of FANOA ground 3.
38. The problem may be explained this way. Ground 3 of the FANOA challenged the primary judge's approach to constructing the counterfactual for the purposes of quantifying the Commonwealth's compensable loss: AB 192. There was some complexity to construing the counterfactual in this case because, although Sanofi was ultimately wholly unsuccessful in the patent litigation, that end result was only reached on appeal, and in the interim both Apotex and Sanofi had some success at trial before Gyles J, and Gyles J granted a final injunction on 19 August 2008: PJ [100]-[108], AB 37-39. At the hearing of the Commonwealth's claim for compensation, Sanofi argued that if it were unsuccessful on the issues that are now the subject of Grounds 1 and 2 of the appeal to this Court (and any other defences), the Commonwealth's loss was 'stopped' as at the date that Gyles J wrongly made the final injunction, 19 August 2008. The trial judge indicated that he would have adopted this approach had he awarded the Commonwealth compensation: PJ [530]-[567], AB 140-149. By FANOA grounds 3 and 4, the Commonwealth challenged the primary judge's approach to the counterfactual and quantification.
39. The first portion of loss the subject of NOC [3] concerns the difference between the Commonwealth subsidy for clopidogrel monotherapy products supplied under the PBS in the real and counterfactual worlds *from and after* 1 April 2010. Specifically, NOC [3] is concerned with the impact on quantum of any additional reductions to the

Commonwealth subsidy from 1 April 2010 that might have occurred had Apotex brands of clopidogrel been listed from 1 April 2008 and had reductions known as “price disclosure price reductions” taken effect. Those reductions are the consequence of the application of legislative provisions intended to more closely match, where there is generic competition, the amount of subsidy paid by the Commonwealth to pharmacists and other dispensers to the average prices wholesalers actually sell those medicines to pharmacists and other dispensers. In the real world, such was the impact of generic competition upon market prices after generic entry finally occurred from 1 April 2010 that, as soon as clopidogrel was eligible to take a price disclosure price reduction after that generic entry, it did so and more followed thereafter: PJ [16], AB 17; PJ [675], AB 172. The first portion of the Commonwealth’s loss challenged by NOC [3] accounts for the two-year delay in such reductions taking effect by reason of Apotex’s clopidogrel products not being listed from 1 April 2008. Sanofi contends this loss did not “flow directly” because it turns upon how competitors would have behaved in the “counterfactual” world from two years earlier than they competed in the real world, as well as the outcome of various regulatory changes. As RS [47] makes plain, Sanofi’s submissions on NOC [3] are inherently interrelated with contentions about the proper construction of the counterfactual for the purposes of quantification.

40. Similarly, the second portion of loss challenged by NOC [3] concerns subsidies paid by the Commonwealth, after 1 December 2009, for a combination product comprising clopidogrel plus aspirin in a single tablet. In the real world, the Commonwealth agreed with Sanofi to list the combination item on the PBS on 1 December 2009 at a price which reflected the prevailing price of clopidogrel on that date: PJ [465], AB 126. The logic of this part of the Commonwealth’s claim was that had the prevailing price been lower for clopidogrel monotherapy in the absence of the injunction, the Commonwealth would have subsidised the combination product by a commensurately lower amount as well: PJ [467], AB 126. Necessarily, this aspect of the Commonwealth’s loss depends on findings as to what would have been the prevailing price of clopidogrel in the counterfactual world at this time, an issue which again can be determined only after determination of the appropriate approach to constructing the counterfactual (and hence determining ground 3 of the FANOA), as well as the position in respect of price disclosure price reductions to clopidogrel in the counterfactual world. So much is made plain by RS [53(a)], [53(b)].
41. Accordingly, this Court ought to determine the question of legal principle as to the content of “flow directly” raised by NOC [1], but remit NOC [3] to a differently

constituted Full Court which can determine it after and in the context of determining the interrelated issue of the appropriate counterfactual agitated by FANOA [3] and [4].

(b) Whether the Commonwealth is “any person ... adversely affected”: NOC [4]

42. By NOC [4] Sanofi contends that the Commonwealth is not “adversely affected” within the meaning of the usual undertaking as to damages, or otherwise a person who has suffered “compensable loss”, because the claimed loss reflects “*costs incurred in the operation of a legislative scheme for social welfare*” and “*the operation of the Commonwealth’s own laws governing the PBS*”: NOC [4], RS [58], [60]. Sanofi contends that despite suffering hundreds of millions of dollars of such losses, they are not compensable and in fact it is “*in the interests of the Commonwealth*” to suffer them because they reflect the impact on the polity of orders made by the judicial branch “*in aid of rights asserted under the laws of the Commonwealth*”: NOC [4].
43. The more accurate characterisation of the Commonwealth’s losses is that they reflect the impact on the polity of an interlocutory order made by the judicial branch in aid of rights asserted by Sanofi and which order has ultimately been found by that same branch to be wrongly made because Sanofi’s assertions of a legal right were bad in law. If the Commonwealth’s appeal succeeds, then the judicial branch will also have found that the interlocutory order was also causative of very significant losses to the Commonwealth polity as represented by the executive branch, because it had the effect of sustaining to Sanofi’s advantage a Commonwealth-subsidised monopoly that would otherwise have been subject, by the operation of law, to very significant reductions in the amount of Commonwealth-funded subsidies consequent upon the entry of generic competition precluded by the interlocutory injunction. The issue raised by NOC [4] is whether equity – with all of its concerns with doing that which is “just and equitable, or fair and reasonable, in all the circumstances” (*Air Express* at 266-267) – intends for the concept of “any person adversely affected” to exclude the collective interests of the polity in recovering the inflated subsidies paid to the benefit of commercial operators who, but for equity’s interlocutory intervention, would never have been entitled to the support of such rivers of gold under Commonwealth law.
44. There can be no doubt that the Commonwealth is a “person” within the meaning of Sanofi’s undertakings. In *Chief Executive Officer, Aboriginal Areas Protection Authority v Director of National Parks* [2024] HCA 116, Gordon and Gleeson JJ cited numerous cases of this Court for the propositions that “[t]he Commonwealth and States are distinct **persons** under the Constitution” and “[t]he Commonwealth as a legal

person is comprised of three branches separated under the Constitution: the Parliament (Ch I), the Executive Government (Ch II) and the Judicature (Ch III)” (emphasis added).¹³ Justice Edelman similarly noted that the “Commonwealth” is a “legal person” (or “public person”) with three dimensions of power.¹⁴

45. As explained in the Stated Case reasons, the ordinary and natural meaning of the word “person”, includes the Crown.¹⁵ The Full Court continued “[g]iven that the usual undertaking as to damages is required to be given in a wide range of situations (including where the Commonwealth is a respondent), there can be no possible justification for adopting an interpretation of the words “any person” that includes some legal entities (eg a corporation) but not others (eg a body politic)”.¹⁶ So much was recognised Mr Bannon SC on behalf of Sanofi at the hearing before Gyles J when he submitted that the government had not applied to be a party but that Sanofi’s undertaking “is not limited to the parties”.¹⁷ Sanofi does not challenge that finding.
46. The challenge for Sanofi then is to identify a principled basis on which, although the Commonwealth is a “person” within the undertakings, it is somehow incapable of being “adversely affected” by orders damaging it. Sanofi’s submissions fall short of doing that. Sanofi advances an argument not dissimilar to that advanced by the Wyeth parties on the Stated Case, which the Full Court soundly rejected.¹⁸ The argument is that when the Commonwealth Parliament creates an entitlement to a benefit which will ultimately be paid out of the Consolidated Revenue under s 83 of the *Constitution* then the Commonwealth can never be adversely affected by an order made by a Commonwealth Court because it is just the Commonwealth causing damage to itself which it could avoid by amending its statute or some other action: RS [58], [60].
47. That argument, which amounts to saying that the Commonwealth is incapable of being protected under an undertaking as to damages where damage flows from the operation of an injunction interacting with Commonwealth laws, is entirely inconsistent with s 64 of the Judiciary Act which relevantly provides that “[i]n any suit to which the Commonwealth ... is a party, the rights of parties shall as nearly as possible be the

¹³ *Chief Executive Officer, Aboriginal Areas Protection Authority v Director of National Parks* [2024] HCA 116 (*CEO AAPA v DNP*) at [80]. See further the cases cited at footnotes 109 to 111.

¹⁴ *CEO AAPA v DNP* at [141]-[143].

¹⁵ See *Stated Case* at [109] (Kenny and Nicholas JJ) citing *McGraw-Hinds (Aust) Pty Ltd v Smith* (1979) 144 CLR 633 at 649 (Stephen J); *Madras Electric Supply Corporation Ltd v Boarland* [1955] AC 667 at 692 (Lord Tucker).

¹⁶ *Stated Case* at [109] (Kenny and Nicholas JJ). Dowsett J agreed on this point at [1].

¹⁷ See item 69 (PFM vol 2/tab 60/p. 519 (lines 23-24)).

¹⁸ *Stated Case* at [109] (Kenny and Nicholas JJ). Dowsett J agreed on this point at [1].

same, and judgment may be given... as in a suit between subject and subject”.

Section 64 is a complete answer to Sanofi’s argument.

48. The argument also offends basic notions of the separation of powers. It seems to characterize the Commonwealth, with its legislative arm and its judicial arm, as some indivisible juristic person without properly respecting the fairly obvious point that when the court, as the judicial arm of the Commonwealth, grants an order, that order can have effects upon the Commonwealth as it can upon other persons, by the operation of statutes. Sanofi was urging Gyles J to grant the interlocutory injunction on the basis that the Commonwealth in its judicial arm had power to accept an undertaking which would protect the Commonwealth in its executive arm, administering the law laid down by its legislative arm.
49. The result of the interlocutory injunction was a real and substantial overpayment by the Commonwealth of PBS subsidies, the primary beneficiary of which was Sanofi. Such effects are within the concept of adverse effect. They were within Sanofi’s contemplation when it approached the Court for an injunction. Its evidence before Gyles J concerned the operation of the PBS and the effect it would have on Sanofi should Apotex’s clopidogrel products be listed on the PBS.¹⁹ That evidence was a key reason for his Honour making the injunction that he did: see FC [79], AB 225.²⁰
50. The assertion by Sanofi that the Commonwealth’s claim is somehow not available because Sanofi did not commit a “legal wrong” is incorrect: *cf* RS [59]-[60]. There is no authority for that proposition, which adds a gloss to the wording of the undertaking and is inconsistent with the requirements stated by the High Court in *European Bank*. The purpose of the undertaking (referred to by Mason J in *Air Express* at 324, in remarks applied in *European Bank* at [15]-[18]) is to compensate injury caused by the maintenance of the status quo. There is no superadded requirement of wrongfulness; it is enough that the person was not ultimately successful in the proceedings.²¹
51. The various analogies that Sanofi seeks to draw, including by reference to taxation consequences, are inapt: *cf* RS [60]. The present case contains the additional critical feature that the interlocutory injunction, ultimately seen to be wrongly granted, was directed to preventing consequences under the PBS. It thereby caused a greater

¹⁹ As to which see especially item 67C (PFM vol 2/tab 55/pp. 427-429 at [25]-[35]) (Mr Dick) and item 67D (PFM vol 2/tab 56/pp. 440-449 at [6]-[42]) (Mr Lindsay).

²⁰ See *GenRx Pty Ltd v Sanofi-Aventis* [2007] FCA 1485; (2007) 73 IPR 502 at [15].

²¹ *Air Express* at 261-262 (Aickin J), 310 (Barwick CJ), 311 (Gibbs J), 318, 319-320 (Stephen J), 324-325 (Mason J).

depletion of the Consolidated Revenue Fund by way of appropriation under s 83 of the Constitution than would have occurred had the injunction not been granted and the PBS left to operate as it otherwise would have with Apotex's entry. Each of Sanofi's analogies assumes no more than that facts exist on which, on a complete working out of the law, particular financial consequences for consolidated revenue have occurred. The facts of this case go well beyond those matters. In addition, it ought not be assumed that there may not be compensable loss to the Commonwealth where depletion of consolidated revenue occurs by the interaction of an injunction with Commonwealth laws. Sanofi seeks to make much by reference to taxation consequences, but none of those issues have been tested in this case. The Commonwealth did not seek to establish, as one of the heads of compensable loss under the undertaking, any lost taxation receipts in the real world compared to the counterfactual. Nor was there any attempt to quantify such receipts or to explore the issues of directness that a claim for compensation for any lost taxation receipts might have given rise to. An untested assumption as to what the position might have been had a claim for lost taxation receipts been made should not drive the analysis here.

(c) The TG Act: NOC [7]

52. NOC [7] asserts error by the Full Court below but, as is made clear by RS [62], the substance of NOC [7] is not an attack on any conclusion reached by the Full Court below in response to any argument put to it, but rather an attack on a conclusion reached by a differently constituted Full Court on the Stated Case. Specifically, Sanofi seeks to argue that Ch 3, Pt 3-2, Div 2 of the TG Act creates a specific regime for the Commonwealth to claim compensation in the event that an originator obtains an interlocutory injunction and delays generic entry "by *wrongly* asserting patent rights" and this gives rise to a negative implication that the Commonwealth cannot claim on the usual undertaking as to damages "*where there is no such wrongdoing*": RS [62].
53. The procedural history does not support this Court entertaining NOC [7]. Relevantly:
- (a) On 11 May 2015 Nicholas J made orders that there be a case stated in a number of proceedings pending in the Federal Court, including the proceedings in which the Commonwealth claimed on Sanofi's undertakings,²² that raised a common question, namely: "*Is the Commonwealth of Australia precluded, as a matter of law, from recovering compensation pursuant to any of the Undertakings as to*

²² The other proceedings were those concerning Wyeth parties finally resolved by the judgment in *Sigma*.

Damages by reason of [Ch 3, Pt 3-2, Div 2 of the TG Act]?”²³

- (b) On 7 December 2015 a Full Court, the composition of which included Nicholas J, answered that question in the negative. It held that ss 26B, 26C and 26D of the TG Act “*were not intended to supersede or displace a person’s right to recover on an undertaking as to damages in the ordinary way*”.²⁴
- (c) Applications for special leave to appeal to this Court filed by Sanofi and the Wyeth parties²⁵ were refused (Bell and Gageler JJ), noting there was “*no reason to doubt the correctness of the Full Court’s conclusion*”.²⁶

54. Sanofi made no attempt to re-agitate this issue before the primary judge. Nor did Sanofi raise the argument before the Full Court below, notwithstanding that it alleges, by NOC [7], error by that Court in not accepting such an argument. In this Court, Sanofi does not seek to bring a second special leave application from the Stated Case. Nor do its submissions on NOC [7] seek to identify any new argument now being put which was not put to the Full Court on the Stated Case or raised in the unsuccessful special leave applications. That should be the end of NOC [7].

55. If this Court entertains NOC [7], the Commonwealth answers it as follows.

56. First, it is telling that not once in its submissions in support of NOC [7] does Sanofi mention, let alone engage with or identify error in, the reasons of the Full Court addressing the very arguments Sanofi makes on NOC [7].

57. Second, the premise of Sanofi’s argument is that the statutory and general law remedies “occupy the same field” and extend “equivalent relief”: RS [70]. The Full Court in the Stated Case persuasively found to the contrary. In particular:

- (a) s 26C may provide an important remedy where a patentee and generic settle prior to final hearing, or where no proceedings are commenced (at [53], [76]), both being circumstances to which the usual undertaking is not directed;
- (b) s 26D(3) provides the Commonwealth with rights to appear at and be heard in a proceeding generally well beyond the field of relief available to the Commonwealth as a non-party in a case such as the present: at [80]; see also [7] (Dowsett J);

²³ *Stated Case* at [21]-[23]. The defined term “Undertakings as to Damages” referred to, inter alia, Sanofi’s undertakings: see the form of the full case stated at [45].

²⁴ *Stated Case* at [105] (Kenny and Nicholas JJ; Dowsett J agreeing at [1]).

²⁵ See PFM item 114C/vol 3/tab 94/p. **1151**, PFM item 114D/vol 3/tab 95/p. **1167**.

²⁶ *Sanofi (formerly Sanofi-Aventis) v Commonwealth of Australia* [2016] HCASL 98; *Wyeth & Anor (3 Applications) v Commonwealth of Australia* [2016] HCASL 99.

- (c) s 26D(3) may also have the effect of ensuring the Commonwealth can claim on an undertaking as to damages in those jurisdictions where the usual form of it is limited to damage suffered by a party: at [80];
- (d) s 26D(5) has “*considerably enhanced*” the power of a court to award compensation to a generic applicant because, where it applies, “*at the very least*” it provides a court “*with far more flexibility in assessing compensation than would be the case if the application for compensation were to be determined in accordance with the general law*”, and in particular this includes the possibility to assess and award compensation “*on the basis of an account of the gross profits [of the patentee] ‘without requiring the ... applicant to establish or quantify its actual loss’*”: at [87]; see also at [9] (Dowsett J); and
- (e) as to awards of compensation to the Commonwealth or a State or Territory, there is also an enlargement (not equivalence) of the relief available. This is because, where it applies, the statute, unlike the general law, does not incorporate any requirement of foreseeability (at [88]-[90]). It may also be – as Dowsett J found at [11] – that the statutory formula is “*much simpler*” than the formula used in the form of the usual undertaking as to damages, potentially avoiding any discretionary arguments about disentitling conduct in equity, or arguments about the meaning of the expressions “*adversely affected*” and “*by the operation of the interlocutory order or undertaking*” used in the usual form in equity.

58. Third, Sanofi’s submissions mischaracterise the legislative purpose of the provisions. At RS [67] it is said that the “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”. However, as is implicitly recognised by Sanofi itself at RS [62], the legislative purpose of ss 26C(8) and 26D(4)-(5) is narrower and differently focused; it is directed not to the circumstances of any grant of an interlocutory injunction in patent litigation but to disincentivising and addressing circumstances where a patentee “wrongly” (RS [62]) asserts patent rights in the sense identified at ss 26C(5), 26C(8)(d) and 26D(4)(c). The Full Court described those circumstances as involving the giving of a false or misleading certificate to the Commonwealth (at [98]); as involving conduct by the patentee “*tantamount to an abuse of process*” (at [81]) and as the commencement of “*misconceived or speculative infringement proceedings*”: Dowsett J at [6]. If there is the requisite element of fault,

the statute *enhances* the relief which can be given under the undertaking beyond what could be given at general law.²⁷ In other words, ss 26C(8) and 26D(5) provide a statutory regime for the imposition of specific and additional sanctions on a putative patentee in such circumstances of fault and improper conduct.

59. Fourth, Sanofi offers no reasoning, beyond its bare assertions of equivalency of rights, concordance of field of operation, and characterisation of purpose addressed above, to support its conclusory assertions that 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*” (RS [73]) and that to find to the contrary involves some subversion or frustration of legislative intent: at RS [70], [73].
60. By contrast, the Full Court offered compelling arguments to the contrary not addressed by Sanofi. These include: (i) the absence of any express words suggesting such an intention (at [91]); (ii) the absence of any inconsistency or incompatibility that arises by holding that the prescribed court can make an award of compensation under the usual undertaking as to damages in accordance with general law as well as pursuant to the TG Act regime where applicable (at [102]-[106]);²⁸ and (iii) the fact that Sanofi’s construction would inevitably require also construing the TG Act as cutting down the ability of a generic applicant (and also State and Territory claimants) to claim on undertakings as to damages only where there is “wrongdoing” by the patentee of the kind addressed in ss 26C and 26D: see [92]-[93]. As the Full Court found, such a view of the Act is “*likely to produce results that are inconvenient and unjust*”: at [96]. For example, a generic applicant who gives a s 26B(1)(b)(iii) notice to the patentee would be so limited, but not a generic applicant who does not, nor any manufacturer supplier of the generic applicant. There is no support for such inconvenient and unjust outcomes in either the terms of the amending act by which ss 26B-26D were added to the TG Act²⁹ (the long title of which suggests “its principal purpose” was directed to complying with obligations under the US-Australia Free Trade Agreement), nor in the terms of that Free Trade Agreement: at [94]-[95], [112]-[113].
61. Properly understood, the TG Act provisions leave wholly intact the general law’s non-

²⁷ This construction was accepted in the *Stated Case*: see [75]-[76] (concerning s 26C) and [77]-[90] (concerning s 26D) and [91]-[106] (as to why Ch 3, Pt 3-2, Div 2 of the TG Act is not exhaustive) (Kenny and Nicholas JJ).

²⁸ At which paragraphs the Full Court distinguished *Chippendale Printing Co Pty Ltd v Federal Commissioner of Taxation* (1996) 62 FCR 347 (see also at Dowsett J at [16]-[18] who also dealt with *Comptroller-General of Customs v Kawasaki Motors Pty Ltd [No 2]* (1991) 32 FCR 243).

²⁹ *US Free Trade Agreement Implementation Act 2004* (Cth): see *Stated Case* at [48], [112] (Kenny and Nicholas JJ).

fault-based undertaking as to damages for the ordinary case, but *add* a fault based remedy for the egregious case, thereby expanding compensation liability, and operating as an additional deterrent, for the wrongdoing the focus of the provisions.

62. One final point should be made. Sanofi effectively seeks to resile from the undertakings it gave by submitting that the Commonwealth may not recover other than pursuant to Ch 3, Pt 3-2, Div 2 of the TG Act. Mr Bannon SC did not foreshadow the possibility of raising the construction of ss 26C and 26D of the TG Act for which Sanofi now agitates either during the contested hearing or when he gave the undertaking notwithstanding that he referred to those very provisions in argument before Gyles J.³⁰ Given that the role of the court in assessing damages is to award compensation which is just and equitable, any limitations that Sanofi wanted to place on the undertaking ought to have been sought, or explicitly disclosed, at the time they were given: see *Stated Case* at [20] (Dowsett J) and see also FC [81], AB 225.

Part VI: Time required for presentation of oral argument

63. The Commonwealth previously estimated taking 3.5 hours in chief on its notice of appeal (and 1 hour in reply), not including any submissions on the notice of contention. Sanofi's submissions state that it "*estimates that it will require up to 7 hours*" to address its arguments on the notice of appeal and the notice of contention.
64. The Commonwealth remains hopeful that the matter may be heard within a total hearing time of 2 days and no more than 2.5 days. Subject to Sanofi agreeing to limit itself to a commensurate amount of time, the Commonwealth estimates that it could present its combined arguments in chief on the notice of appeal and notice of contention within 4 hours and would require 1 hour to 1.5 hours in reply.

Dated: 3 June 2024



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³⁰ See for example, item 69 (PFM vol 2/tab 60/pp. 565 (line 1)-566 (line 45)).

**IN THE HIGH COURT OF AUSTRALIA
SYDNEY REGISTRY
ON APPEAL FROM THE FULL COURT OF THE FEDERAL COURT**

BETWEEN:

Commonwealth of Australia
Appellant

Sanofi (formerly Sanofi-Aventis)
First Respondent

Sanofi-Aventis US LLC
Second Respondent

Bristol-Myers Squibb Investco LLC
Third Respondent

**ANNEXURE TO THE APPELLANT'S SUBMISSIONS ON THE RESPONDENTS'
NOTICE OF CONTENTION**

Pursuant to Practice Direction No. 1 of 2019, the Appellant sets out below a list of the statutes and statutory instruments referred to in these submissions.

No.	Description	Version	Provision(s)
1.	<i>The Constitution</i>	Compilation prepared on 29 July 1977 (current)	S 83
2.	<i>Judiciary Act 1903 (Cth)</i>	Compilation prepared on 18 February 2022	Ss 64, 78B
3.	<i>National Health Act 1953 (Cth)</i>	Compilation prepared on 24 August 2007	Ss 99AEB, 99AEH
4.	<i>Therapeutic Goods Act 1989 (Cth)</i>	Compilation prepared on 25 March 2015	Ch 3, Pt 3-2, Div 2
5.	<i>US Free Trade Agreement Implementation Act 2004 (Cth)</i>	Compilation prepared on 1 January 2005	Sch 7