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

and

Sanofi (formerly Sanofi-Aventis)
First Respondent

Sanofi-Aventis US LLC
Second Respondent

Bristol-Myers Squibb Investco LLC
Third Respondent

APPELLANT'S SUBMISSIONS

Part I: Certification

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

Part II: Statement of issues

2. The First Respondent went to equity to obtain the benefit of interlocutory restraints preserving, pending determination of the validity of its **Patent**, a valuable monopoly for the supply to patients in Australia of a blockbuster drug (**clopidogrel**) subsidised by the Commonwealth under the Pharmaceutical Benefits Scheme (**PBS**). Ultimately, the Patent was found invalid. The Commonwealth sought compensation pursuant to undertakings in the usual form given by the Respondents (**Sanofi**) in return for that lucrative interlocutory relief. Below, Sanofi successfully argued that the Commonwealth had not proven that the party restrained, **Apotex** Pty Ltd, would in fact have done that which Apotex had told the Court, on the application for interlocutory relief, it would do if not enjoined, namely apply for PBS listing for its generic brand of clopidogrel and compete with Sanofi to supply clopidogrel in Australia.

3. The two issues are as follows.

4. First, where it emerges that an interlocutory injunction has been wrongly granted and a person claims on a supporting undertaking as to damages, what evidential burdens do the claimant and respondent each bear on causal questions about what would, hypothetically, have happened in the absence of the Court's intervention?

5. Second, does equity require a claimant for compensation to lead direct hindsight evidence, or is it prepared to draw inferences about what a person would *likely* have done based on contemporaneous evidence of that person's plans, instructions and conduct anticipating that an injunction might not be granted?

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

6. A notice under s 78B of the *Judiciary Act 1903* (Cth) is not required.

Part IV: Citations

7. The primary judgment (**PJ**) is *Commonwealth of Australia v Sanofi (formerly Sanofi-Aventis) (No 5)* [2020] FCA 543; 151 IPR 237 (Nicholas J). The judgment of the Full Court (**FC**) is *Commonwealth of Australia v Sanofi (formerly Sanofi-Aventis)* [2023]

FCAFC 97; 411 ALR 315; 174 IPR 66 (Besanko, Yates and Perram JJ).

Part V: Relevant facts found or admitted below

(a) Overview

8. The first interlocutory injunction was granted by Gyles J in September 2007: PJ [11], [86], [89], Appeal Book (**AB**) 16, 33-34. It had the practical effect of preventing Apotex from applying to list its clopidogrel products on the PBS in circumstances where such a listing would have significantly reduced the subsidies paid by the Commonwealth for supplies of clopidogrel to patients: FC [9], AB 204-205. Apotex prevailed in the Patent Proceedings on appeal.[1] Thus Sanofi was never entitled to the benefit of court-aided restraints preserving its valuable monopoly in the interim.

9. By application filed on 11 April 2013 (the **Commonwealth Compensation Claim**), the Commonwealth sought approximately $325 million in compensation plus interest and costs, representing the difference between: (i) the subsidies the Commonwealth paid for supplies of clopidogrel under the PBS on and from 1 April 2008 (the date the Commonwealth contended Apotex would have obtained PBS listing absent the interlocutory injunction), and (ii) the amount the Commonwealth would have paid had Apotex obtained PBS listing on that date: PJ [22], [139], AB 19, 46; FC [9]-[10], AB 204-205. The primary judge dismissed the Commonwealth's application (some 31 months after reserving his decision). The Full Court dismissed an appeal by the Commonwealth (some 28 months after reserving its decision).

10. Central to the outcome below was the approach taken to the assessment of whether the Commonwealth had proven that, if not enjoined, Apotex would have sought PBS listing of its brand of clopidogrel. The primary judge found that the Commonwealth's case suffered *"from an evidentiary deficiency"* which could not be made good without calling Dr Bernard "Barry" Sherman, the CEO and Chairman of Apotex's parent company (**Apotex Canada**) to give direct hindsight evidence of past hypothetical facts: PJ [348]-[349], AB 100-101. The Full Court upheld that conclusion: FC [215]-[220], AB 265-267.

11. That conclusion was based on an erroneous understanding of the evidential burden of

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1 See *Apotex Pty Ltd v Sanofi-Aventis* [2009] FCAFC 134; (2009) 82 IPR 416 (special leave refused).

parties for claims upon undertakings as to damages and the approach equity takes to hypothetical historical facts. The errors were compounded by a failure to avert to critical evidence and submissions made by the Commonwealth.

12. Even before one descends into the detail of the factual material before the courts below, the conclusion reached below is, on an initial impression, surprising and most unlikely. This was a case where Apotex vigorously contested the imposition of any interlocutory restraints being imposed upon it. The Commonwealth led an extensive evidential case on the question of whether Apotex would have listed if not enjoined, based on: (i) contemporaneous internal documentary records of Apotex and Apotex Canada in the lead up to the grant of the interlocutory injunction; (ii) the sworn (and unchallenged) testimony at the hard-fought hearing before Gyles J which recorded Apotex's intention to list if not enjoined; (iii) the admissions made by Senior Counsel for Apotex to Gyles J at the hearing of Sanofi's application for the interlocutory relief that if not enjoined from supplying its generic brand of clopidogrel, Apotex would apply to list on the PBS; (iv) Apotex's offering, in support of its position that no interlocutory injunction should be imposed on it, substantial security to be provided by Apotex Canada of $50 million within 28 days with liberty to Sanofi to apply to increase it; and (v) the communications sent by Apotex to pharmacists in August 2007. There was not one sentence in that material which contained any statement of an intention in 2007 *not* to apply to list if not enjoined.

13. The detail of that evidentiary case, and the findings made in respect of it, are addressed in Part VI. In doing so, these submissions refer to documents using the same **item numbering** as used in the Full Court's judgment (FC [99], AB 230), and which is also used in the joint short-form and long-form chronologies the parties have prepared for this Court. The most critical documents have been reproduced in the Parties' Joint Book of Further Materials (**PFM**). The balance of this Part records other contextual matters found below and of relevance to the Notice of Appeal (AB 546) or to those grounds in the Notice of Contention that Sanofi has advised it is pressing before this Court: AB 550-554 (being grounds 1, 3, 4 and 7, with the balance to be remitted to the Full Court).

(b) Clopidogrel and the Patent

14. In Australia, clopidogrel can only be prescribed by medical practitioners and is usually

prescribed to patients who have suffered – or are at risk of suffering – a heart attack or stroke: PJ [1], AB 15. At all material times clopidogrel was a high-volume drug on the PBS responsible for significant Commonwealth expenditure. In the financial year ending 30 June 2008, the Commonwealth's payments under the PBS in respect of clopidogrel totalled approximately $171 million. That was the third highest total expenditure for any drug listed on the PBS that year: PJ [21], [681], AB 18, 174.

15. On 1 November 1999, two brands of clopidogrel were listed on the PBS, namely Plavix (the brand marketed by a subsidiary of the First Respondent) and Iscover (the brand of a related entity of the Third Respondent). Because the brands were co-marketed, they were treated as a single brand under the PBS, at least for the purposes relevant to this proceeding: see PJ [2] AB 15. They remained the only clopidogrel products on the PBS until 1 April 2010 when the first generic brand of clopidogrel was listed on the PBS shortly after the Patent Proceedings concluded: PJ [16], [132], AB 17, 44-45.

(c) Sanofi's interim injunction application to restrain generic supply of clopidogrel

16. Apotex[2] commenced the Patent Proceedings on 16 August 2007 by seeking orders revoking the Patent: PJ [7], [80], AB 16, 32. On 17 September 2007, Sanofi filed a defence and cross-claim alleging infringement of the Patent: PJ [80], AB 32. It also filed a notice of motion seeking two interim injunctions upon Sanofi, by its Counsel, giving the usual undertaking as to damages.[3] The first prayer sought to restrain infringement of the Patent; the second prayer sought to restrain Apotex from "*taking any steps to obtain listing of any of the [Apotex] Clopidogrel products under the [PBS] maintained by the Commonwealth under the National Health Act 1953 (Cth)*": PJ [81], AB 32.[4] Sanofi filed evidence as to the potential loss it would suffer in the absence of interim relief, all of which was predicated on the assumption that Apotex's clopidogrel products would be listed on the PBS unless Apotex was enjoined: PJ [87]-[88], AB 34.

17. On 18 September 2007, Gyles J heard Sanofi's motion: PJ [82], AB 32. As to the second prayer, Gyles J indicated that he did not see any proper basis on which the Court could prevent Apotex from applying to list its clopidogrel products on the PBS: PJ [84], AB 32.[5] Senior Counsel for Apotex, Mr Catterns QC, responded that if the

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2 Until 20 September 2007, Apotex Pty Ltd was called GenRx Pty Ltd: FC [5] AB 203.
3 See item **67** (PFM vol 2/tab 54/pp. 405-406).
4 Reproducing item **67** (PFM vol 2/tab 54/p. 406).
5 Referring to item **69** (PFM vol 2/tab 60/p. 518 (lines 16-20)).

Court was to enjoin Apotex from selling, it would agree an appropriate undertaking not to take steps to list its clopidogrel products on the PBS because Apotex did not *"want to be listed on the PBS"* if it could not sell: PJ [84]-[85], AB 33.[6]

18. On 21 September 2007, Gyles J delivered reasons orally for concluding that an interlocutory injunction should be made preventing Apotex from bringing to market its clopidogrel products if Sanofi gave the usual undertaking as to damages: PJ [86], AB 33-34. In his revised reasons, published on 25 September 2007, his Honour explained that in concluding that damages would not be an adequate remedy if the challenge to the Patent failed, he was *"much influenced by the effects of disturbing the status quo, particularly as it relates to the operation of the PBS"*: PJ [86], AB 34.[7]

19. On 25 September 2007, the parties provided Gyles J with agreed short minutes based on the reasons his Honour had given orally. Orders were made preventing Apotex from bringing to market its clopidogrel products upon Sanofi giving the usual undertaking as to damages. The orders noted an undertaking by Apotex not to list its clopidogrel products on the PBS pending final hearing: PJ [11], AB 16.[8]

(d) Determination of the Patent Proceedings

20. On 12 August 2008, Gyles J delivered judgment on Apotex's claim for revocation and Sanofi's claim for infringement.[9] Some claims of the Patent were upheld; others revoked. On 19 August 2008, orders were made which included a final injunction restraining Apotex from, among other things, supplying its clopidogrel products: PJ [101]-[108], AB 37-39. On the same day, Apotex filed an appeal from Gyles J's judgment and orders. On 8 September 2008, Sanofi filed a cross-appeal: PJ [109], AB 39. On 15 September 2008, Moore J made interlocutory orders, by consent, pending determination of the appeal and cross-appeal, and which included a further undertaking as to damages given by Sanofi: PJ [109]-[116], AB 39-41.

21. On 29 September 2009, the Full Court found the Patent wholly invalid.[10] Upon Sanofi giving another undertaking as to compensation, the Full Court stayed the setting aside of the orders made at first instance pending determination of any special leave

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6 Reproducing item **69** (PFM vol 2/tab 60/p. 576 (lines 13-15)).
7 See *GenRx Pty Ltd v Sanofi-Aventis* [2007] FCA 1485; 73 IPR 502 at [15].
8 See item **74** (PFM vol 2/tab 63/p. 594).
9 *Apotex Pty Ltd (formerly GenRx Pty Ltd) v Sanofi-Aventis* [2008] FCA 1194; 78 IPR 485.
10 *Apotex Pty Ltd v Sanofi-Aventis* [2009] FCAFC 134; 82 IPR 416.

application filed by Sanofi: PJ [121]-[122], AB 42-43. On 12 March 2010, the High Court refused Sanofi's application for special leave to appeal.[11]

(e) Generic brands of clopidogrel finally listed on the PBS

22. On 1 April 2010, **Sandoz** Pty Ltd obtained listing of its generic brand of clopidogrel on the PBS: PJ [132], AB 44-45. Apotex became the second generic company to have its clopidogrel products listed on the PBS on 1 May 2010: PJ [132], AB 44-45.

(f) Compensation claims on the Sanofi undertakings

23. On 4 May 2010, Apotex filed an interlocutory application seeking approximately $138 million in compensation under the three undertakings Sanofi had given to the Court (the **Apotex Compensation Claim**): PJ [133], AB 45. The Commonwealth Compensation Claim was filed subsequently: PJ [139], AB 46; FC [10], AB 205.

24. Apotex and Sanofi settled the Apotex Compensation Claim on 4 November 2014 in accordance with the terms of a Settlement Deed. Clause 6 of that deed provided that Apotex agreed not to assist voluntarily in any way or encourage the Commonwealth in relation to its Compensation Claim. On 19 April 2017, Nicholas J declared unenforceable clause 6 in so far as it prevented Apotex from releasing any witness or prospective witness from any obligation of confidence in respect of the information relevant to the Commonwealth Compensation Claim:[12] PJ [134]-[136], AB 45-46.

25. On 11 May 2015, the Federal Court made orders that there be a case stated in four proceedings 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 Damages by reason of Chapter 3, Part 3-2, Division 2 of the Therapeutic Goods Act 1989 (Cth)?* On 7 December 2015, the Full Court answered that question in the negative.[13] Sanofi (and two other parties) filed applications for special leave to appeal from the Full Court's judgment. The High Court (Bell and Gageler JJ) refused those applications, noting there was *"no reason to*

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11 In accordance with the Full Court's orders, the stay ceased upon the High Court pronouncing its order refusing special leave: PJ [131], AB 44. The High Court refused a second application made by Sanofi seeking special leave to appeal from the Full Court's orders setting aside Gyles J's orders on 13 November 2015: *Sanofi-Aventis v Apotex Pty Ltd* [2015] HCATrans 300.

12 *Commonwealth of Australia v Sanofi (formerly Sanofi-Aventis)* [2017] FCA 382.

13 *Commonwealth of Australia v Sanofi (formerly Sanofi-Aventis)* [2015] FCAFC 172; 237 FCR 483.

doubt the correctness of the Full Court's conclusion".[14]

(g) The Pharmaceutical Benefits Scheme

26. The PBS is a scheme for subsidising the cost of drugs: see Pt VII of the *National Health Act 1953* (Cth) (**NHA**); PJ [36], AB 21. Pt VII applies to drugs *"declared by the Minister, by legislative instrument"* (see s 85(2)): PJ [37], AB 22). Drugs in relation to which a declaration is in force are "listed" drugs: s 84(1).

27. Commonwealth subsidies in respect of the supply of PBS-listed drugs to patients are paid to dispensers (usually, pharmacists). The amount of subsidy paid in respect of any particular brand of drug is determined by reference to the "dispensed price" or "Commonwealth Price" for that brand. The Schedule of Pharmaceutical Benefits (**PBS Schedule**) lists the brand names of drugs available under the PBS and records a dispensed price for the maximum quantity permitted to be dispensed for each brand: PJ [39], AB 22. For each supply of a brand to a patient under the PBS, the dispenser is entitled to receive from the Commonwealth the dispensed price less a co-payment made by a patient to the dispenser (s 99): PJ [60], AB 27; FC [2], AB 202.[15] The NHA caps the amount of patients' co-payments: PJ [59], AB 27.[16]

28. Where multiple brands of a medicine are listed on the PBS, the PBS Schedule will indicate whether the brands are equivalent and can be substituted: s 84AJ. If a prescription specifies one brand, a pharmacist may substitute another provided that the PBS Schedule indicates that substitution is permissible, the prescriber has not indicated on the prescription that substitution is not allowed, and the patient consents.[17]

29. The hearing and determination of Sanofi's interlocutory application for interim relief occurred in the context of well-publicised, transformative amendments to the NHA which took effect on 1 August 2007. The amendments sought, among other matters, to reduce significantly the amount the Commonwealth would thereafter pay in subsidies once a first generic brand was listed on the PBS for a medicine.

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

15 The dispensed price is calculated by reference to a maximum price for sales of the brand to wholesalers and pharmacists. The Minister and "responsible person" (s 84AF) for the brand can agree the appropriate maximum price. Until 30 September 2012, the price agreed was the "approved price to pharmacists" (**AP2P**), and since that date it has been the "approved ex-manufacturer price" (**AEMP**): PJ [61], AB 28.

16 On 1 August 2007, this was $31.30 for a general patient and $5.00 for a concessional patient: see s 87.

17 See item **67C** (PFM vol 2/tab 55/p. 428 at [31]).

30. One effect of the amendments was to impose, upon a first generic brand of drug being listed, an automatic and immediate 12.5% price reduction to the earlier listed brand of the same drug: ss 99ACF(1) and 99ACH, PJ [47], AB 24. Once the 12.5% statutory price reduction took effect, the amendments further provided for 2% price reductions at nominated intervals thereafter (unless the brand was affected by other price reductions of a higher magnitude: ss 99ACF and 99ACI, PJ [66], AB 28-29), and a new "price disclosure" regime that provided for further price reductions to all listed brands to occur where in effect the subsidy paid by the Commonwealth under the PBS significantly exceeded the price actually being paid for that drug by pharmacists: see ss 99AD, 99ADB(4)-(6), reg 37F of the *National Health (Pharmaceutical Benefits) Regulations 1960* (Cth) and PJ [71]-[72], [75], AB 29-30. The amendments also imposed supply obligations on the responsible person for the newly listed generic brand (Pt VII, div 3C), including that they must supply their brand for up to 24 months beginning on the day that the brand is listed (see ss 99AEC-99AED): PJ [45]-[53], [64], AB 24-26, 28.

(h) The practicalities in 2007 of listing a generic brand on the PBS

31. In 2007, the first step that a supplier of a generic brand (a **generic company**) had to take to be able to sell its brand in Australia, and have it listed on the PBS, was to apply to the Secretary of the **Department** of Health and Ageing for the brand to be registered on the Australian Register of Therapeutic Goods (**ARTG**) under the *Therapeutic Goods Act 1989* (Cth): PJ [40], AB 22. The applicant was required to provide comprehensive evidence of the generic brand's quality, safety and efficacy to support the application. The generic company could rely on the original data submitted by the originator for registration of the originator brand on the ARTG if the period of data exclusivity had expired: PJ [226], AB 69. If the generic company's application relied on that original data, then it was required to demonstrate that the generic brand was bioequivalent to the originator brand.

32. Once the generic brand was registered on the ARTG, the second step was to apply to the Department to list the generic brand on the PBS. An applicant was required, among other things, to provide a written assurance that sufficient stock of its generic brand would be available on the proposed date of the drug being listed on the PBS to meet anticipated demand: PJ [40]-[44], [58], AB 22-23, 27.

33. At all relevant times, if the listing of a first generic brand would result in a price

reduction for the originator brand, the generic brand could only be listed on 1 April, 1 August or 1 December. The application for listing had to be lodged by 1 December for a listing on 1 April in the following calendar year: PJ [41], AB 22.

Part VI: Argument

(a) First error: evidential burdens

34. The primary judge's "factual analysis" of whether Apotex would have applied to list its clopidogrel products on the PBS from 1 April 2008 (PJ [197]-[351], AB 65-101) approached the evidence, and questions of proof, on the wrong footing. The error was compounded by the primary judge's overlooking of critical evidence and submissions made by the Commonwealth. The primary judge failed to articulate that the Commonwealth's burden was to establish no more than a "*prima facie*" case, thereafter shifting an evidential burden to Sanofi to raise any countervailing considerations.

35. On appeal, the Full Court repeated the primary judge's error as to principle and made further errors in its own analyses of the primary record. The Full Court failed to accept that the Commonwealth's evidential burden was to establish a *prima facie* case that, without the injunction, Apotex would likely have sought and obtained PBS listing, thereafter shifting an evidential onus to Sanofi to show a countervailing reason why this would not likely have occurred. In reaching that conclusion, the Full Court: misunderstood the principle (*cf* FC [87]-[90], AB 227-228; see also [374], 304-305), misapplied it (*cf* FC [88]-[93], AB 227-229), and wrongly found it was unsupported by authority: *cf* FC [88], [94]-[97], AB 227, 229-230. Further, the Court took an atomised approach asking whether each item of evidence *"by itself could be material to the overall finding"* (*cf* FC [132], [147], AB 239-240, 246), or limited to whether that item, together with a limited set of other material, shows the "*existence*" of a fact in the real world (as opposed to whether one hypothesis is more probable than the other): *cf* eg FC [118], [132], [143], [240], AB 234-235, 239-240, 244, 272. That approach was wholly inconsistent with the three-step approach outlined below at [36]-[43]. Further, and as demonstrated below at [46]-[90], articulated and applied correctly the principle would have made a difference: *cf* FC [88], AB 227.

(b) The correct principle as to evidential burdens

36. Core to a claim for compensation pursuant to an undertaking as to damages is a causal

hypothesis: without the interlocutory injunction, an event which the injunction prevented would likely have happened with a beneficial financial consequence for the claimant. Before a claimant can have any prospect of a favourable outcome, it must (**Step 1**) explain why the event would likely have happened without the injunction (**reason A**) and lead some evidence from which a court could reach that conclusion. This is what is meant by a *prima facie* case. If the claimant satisfies Step 1, the evidential burden shifts to the respondent (**Step 2**). If it wishes to contest the claimant's causal hypothesis, it must advance an alternative hypothesis: that the event would not have happened because of some other reason (**reason B**). The respondent's evidential burden is to lead evidence from which a court could conclude that reason B would likely have led to the event not occurring. That evidence will only be "sufficient" to discharge the respondent's burden if it is capable of supporting that conclusion. If the burden is not discharged, the claimant's *prima facie* case stands unanswered.

37. **Step 3** is only reached if the respondent discharges its evidential burden (putting aside reply evidence opportunities). Here, the Court must assess which of the two competing hypotheses is more probable than not. The Court must bring all the relevant evidence relied upon by the parties to that task. It must ask whether, having regard to the corpus of evidence as a whole, it is more probable than not that reason A (with all its consequences) would have prevailed or reason B (with all its consequences). That requires drawing inferences about what would likely have happened based on the evidence of what had already happened, and assuming rational, commercial decision-making from the point the hypothetical world departs the real world (i.e. from the date the injunction was granted).

38. The principle is supported by authority: *cf* FC [88], [94]-[97]; AB 227, 229-230. In ***Air Express*** *Ltd v Ansett Transport Industries (Operations) Pty Ltd* (1981) 146 CLR 249, Stephen J (at 320) and Mason J (at 332) each said that a claimant bore an onus to establish a *prima facie* case to make out a right to compensation.

39. Contrary to FC [94], AB 229, Stephen J addressed this issue (at 320) where his Honour said (emphasis added): *"... it is for the claimant under an undertaking to establish by evidence, or by inference from evidence, a prima facie case both that the grant of the injunction was a cause of his damage and that but for it he would not have suffered that damage."* There was no direct evidence in *Air Express* about the effect of either the litigation or the injunction upon the grant of permission to import the aircraft. *"All*

that appeared" on the evidence was the sequence of events comprising (i) the Minister announcing that he had approved the import of the aircraft, (ii) the litigation commencing the next day and the injunction being granted and continued thereafter, and (iii) "*despite the Minister's statement, the permission was not in fact granted"*: at 317 (Stephen J). Stephen J held that that mere sequence of events did not discharge the claimant's onus of establishing a *prima facie* case. His Honour further stated that that paucity of evidence also did not support the inference that Aickin J had drawn that the Minister, not wishing to risk the Commonwealth being held liable for damages at the suit of Ansett, *"would, despite his announcement, change his mind"*: at 318. Stephen J described that line of thought as "*speculation rather than permissible inference from proven facts"*: at 318.

40. Mason J distinguished between questions of onus on the ultimate question of causation and proof at 332 (emphasis added):

> *... Air Express bears the onus of showing the necessary causal connexion ... that is, that the damage would not have been sustained but for the injunction. The crucial question is whether by establishing the sequence of events it has done enough to discharge that onus by making out a prima facie case.*
>
> *Unless the circumstances indicate otherwise, when it appears that damage flows from the non-performance of an act and the performance of that act has been restrained by an interim injunction, the inference will generally be drawn that the damage has been occasioned by the injunction. That, I think, is the conclusion which I would draw here ... Ansett might have made out countervailing circumstances by proving that it was Government policy to leave the question to the Court once proposed Government action is challenged in legal proceedings, or perhaps by calling Halton to give evidence of what he would have done had the inunction not been granted. Ansett took neither of these courses. Instead, it invited the primary judge to speculate on what would have occurred had no injunction been granted.*

41. Whilst Mason J and Stephen J differed on whether a *prima facie* case may be established by merely the procedural "sequence of events", their Honours were aligned that the claimant's evidential burden at Step 1 is only to establish a *prima facie* case (at 320, 332), and that a respondent (and the Court) cannot speculate about countervailing considerations without evidence of their existence and likely effect (at 318, 332). That approach is consistent with the passage in ***Purkess*** *v Crittenden* (1965) 114 CLR 164 at 168 (Barwick CJ, Kitto and Taylor JJ). Once a plaintiff establishes a *prima facie* case that an act has caused loss (e.g. negligence causing incapacity), it is

(emphasis added):

> *...not enough for the defendant merely to suggest the existence of a progressive pre-existing condition in the plaintiff or a relationship between any such condition and the plaintiff's present incapacity. On the contrary ... both the pre-existing condition and its future probable effects or its actual relationship to that incapacity must be the subject of evidence (ie either substantive evidence in the defendants case or evidence extracted by cross-examination in the plaintiff's case) which, if accepted, would establish with some reasonable measure of precision, what the pre-existing condition was and what its future effects, both as to their nature and their future development and progress, were likely to be.*

42. Adopting the three-step approach explained at [36]-[37] above, the different conclusions reached in each judgment in *Air Express* are explicable as follows. **Aickin J** reached Step 3, finding positively in Ansett's favour that it was probable that no import permission would have been granted if there was no injunction: at 282. However, his Honour reached that affirmative conclusion by reference to a reasoning process Stephen J (at 318) and Mason J (at 332) considered to involve impermissible speculation of the Minister's intentions. **Barwick CJ** endorsed Aickin J's reasons: at 309-310. **Gibbs J** agreed with Aickin J's conclusion that it was probable the Secretary would not have granted the licence, but said if that involved impermissible speculation, then the claimant still failed for absence of proof of causation: see 314. **Stephen J,** in contrast to Aickin J, never reached Step 3. On the basis the claimant had not passed Step 1 (a *prima facie* case), Stephen J held the claimant also failed to discharge the legal onus. **Mason J** concluded the claimant had passed Step 1 and Ansett did not discharge its evidentiary burden at Step 2; consequently the claimant's *prima facie* case was sufficient to discharge also the legal onus and prove causation.

43. Thus on the appeal, one judge (Stephen J) decided the case at Step 1; one judge (Mason J) decided it at Step 2; one judge decided it at Step 3 (Barwick CJ, adopting the reasoning of Aickin J); and Gibbs J appears to have decided it on the basis the claimant would lose either at Step 1 or (if reached) at Step 3.

44. Authorities in other areas of law reflect this principle. These include: *Potts v Miller* (1940) 64 CLR 282 at 308-309 (Williams J); *Gould v Vaggelas* (1984) 157 CLR 215 at 238-239 (Wilson J, Gibbs CJ and Dawson J agreeing at 219 and 262), 250-251 (Brennan J); *Momcilovic v The Queen* (2011) 245 CLR 1 at [665] (Bell J); *Henderson*

v Queensland (2014) 255 CLR 1 at [89]-[91] (Gageler J, in dissent but not as a matter of principle); *Berry v CCL Secure Pty Ltd* (2020) 271 CLR 151 at [29], [39], [41]-[42] (Bell, Keane and Nettle JJ), [65]-[73] (Gageler and Edelman JJ); *Poricanin v Australian Consolidated Industries Ltd* [1979] 2 NSWLR 419 at 425–426 (Hope and Glass JJA); *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd [No 2]* (2012) 204 FCR 494 at [73] (Keane CJ), [207] (Bennett and Yates JJ); *Auimatagi v Australian Building and Construction Commissioner* (2018) 267 FCR 268 at [96] (Allsop CJ, Collier and Rangiah JJ); *Commissioner of Police v Zisopoulos* [2020] NSWCA 236; (2020) 299 IR 314 at [67]-[73], [84]-[88] (Bell P, Macfarlan JA agreeing at [95]), [98]-[99] (Macfarlan JA); and *Delor Vue Apartments CTS 39788 v Allianz Australia Insurance Ltd (No 2)* [2020] FCA 588; 379 ALR 117 at [289] (Allsop CJ).

45. Whilst recognising that the evidential principle is not a creature of equity, it is important to appreciate the significance of the equitable context and the concerns of equity where this principle is applied in claims for compensation pursuant to an undertaking as to damages. As Jagot J observed in ***Sigma*** *Pharmaceuticals (Australia) Pty Ltd v Wyeth* (2018) 136 IPR 8, whilst a respondent is not precluded from contending that the injunction made no difference (despite this being inconsistent with the position put to the court to obtain the injunction), *"[i]nconsistent assertions of that kind would justify close scrutiny and a degree of scepticism because inconsistency may involve permitting a party who has obtained equity not to do equity"*: at [319]; see also [286]. English practice also reflects this principle. In *Yukong Line Ltd v Rendsburg Investments Corp* [2001] 2 Lloyd's Rep 113 at 120 Potter LJ (Thorpe LJ and Hale LJ agreeing) observed "*If the [claimant] shows that he has suffered loss which was prima facie or arguably caused by the order, then the evidential burden of any contention that the relevant loss would have been suffered regardless of the making of the order in practice passes to the defendant and an inquiry will be ordered*".[18]

(c) Application of the correct principle would have made a difference

46. **Step 1.** The starting point is the basic insight of Mason J in *Air Express* at 332 that:

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[18] See also *Lunn Poly Ltd v Liverpool & Lancashire Properties Ltd* [2006] EWCA Civ 430 at [42]-[44] (Neuberger LJ, Scott Baker and Auld LJJ agreeing); *Fiona Trust v Privalov* [2014] EWHC 3102 (Comm); 2 CLC 551 at [36]-[40] (Andrew Smith J); *SCF Tankers Ltd (formerly known as Fiona Trust & Holding Corpn) v Privalov* [2018] 1 WLR 562 (CA) at [46] (Males J) quoting *F Hoffmann-La Roche & Co AG v Secretary of State for Trade and Industry* [1975] AC 295 at 361 (Lord Diplock); contra *Ennismore Fund Management Ltd v Fenris Consulting Ltd* [2022] UKPC 27 at [67].

> *[u]nless the circumstances indicate otherwise, when it appears that damage flows from the non-performance of an act and the performance of that act has been restrained by an interim injunction, the inference will generally be drawn that the damage has been occasioned by the injunction.*

47. In the present case, the Commonwealth's hypothesis was that, had the interlocutory injunction not been granted, Apotex would likely have applied by 1 December 2007 for its clopidogrel products to be listed on the PBS from 1 April 2008 and started taking orders (i.e. launched) well before 1 April. The Commonwealth established Step 1 not only by the inferences generally drawn, but in spades by evidence of Apotex's conduct before the injunction was granted (further summarised below). That evidence fell to be assessed in light of a proper understanding of the options available to a company seeking to list its generic brand on the PBS after 1 August 2007 in circumstances where the originator's brand was the only listed brand and there was a relevant unexpired patent. We set out that context first, then summarise the relevant evidence.

48. **Context.** The first option for a generic company in Apotex's position was to wait until the patent expired before taking steps to apply to list on the PBS. Under this option, the generic company would not be exposed to the risk of liability for the originator's legal costs in the event of a failed action seeking to revoke the patent, nor to any risk of damages or account of profits for infringing the patent. On the other hand, it would be exposed to the risk of other generic companies entering the market and achieving listing of their generic brands on the PBS at the same time; possibly leading to vigorous competition, and much lower margins to be earned by the generic company.

49. The second option was for the generic company to commence proceedings seeking to revoke the patent but at the same time undertake not to take steps to list on the PBS or launch until after the proceedings, and appeals, had been resolved finally in its favour. The generic company would be exposed to the risk of the originator's legal costs if the action failed but no risk of damages or account of profits. On the other hand, this option would offer a low reward because the generic company would expose its hand to the market over the period of the revocation suit. Other companies could take steps to list their generic products on the PBS if the patent was revoked. The generic company would be very likely to face potentially intense competition from other generic companies almost immediately, as it would under the first option, limiting any first

mover advantage, and limiting potential profits from being the first generic brand listed on the PBS.

50. The third option was for the generic company to begin to take steps to have its product listed on the PBS while the patent was unexpired, prepare a case challenging the validity of the patent and inform the originator that it will be suing for revocation and is preparing to sell and complete the steps to have its products listed on the PBS unless enjoined. This option is high risk given the potential legal costs against the generic company if its action failed *and* because the generic company assumes the risk that if it successfully resists any application to enjoin it, the moment it listed it would trigger the 12.5% statutory price reduction. The originator would then almost inevitably start suffering significant losses of two kinds: (i) by reason of reduced payments for supply under the PBS (in line with the reduced subsidy payable by the Commonwealth); and (ii) loss of profits and market share to the extent the generic company launches its product at a price lower than the originator and attracts sales, including to pharmacists. If, after the final hearing and all appeals, the generic company is unsuccessful in revoking the patent, it would face substantial damages for the losses and/or account of profits. On the other hand, the option is high reward – if the generic company obtains listing on the PBS ahead of possible rivals, it stands to make significant profits immediately and will keep those profits if successful in its revocation suit.

51. **Commonwealth's evidential case.** Against that background, the Commonwealth's evidence of what Apotex would have done if not enjoined was as follows.

52. Identifying the clopidogrel opportunity in Australia: As early as March 2006, Apotex identified the clopidogrel market in Australia as a market into which it could enter with its generic products: PJ [219], AB 68. Roger Millichamp, the Managing Director of Apotex,[19] instructed his senior management team to prepare regular launch forecasts and plans for all key generic product launches, including clopidogrel: PJ [198], [220], AB 65, 68. The then Vice President of Sales at Apotex Canada, Michael Weingarten, described to Dr Sherman the forecast figures provided as *"a very conservative scenario, with [Apotex] taking a 20% generic segment market share. The reality is, assuming that we have a solid patent strategy, that we should be the only generic on*

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[19] See organisation chart at item **2** (PFM vol 1/tab 2/p. 84).

the market on approval in October 2007": see PJ [223], AB 69.[20] The reference to having a *"solid patent strategy"* reflected that the Patent was not due to expire until 4 February 2013. Dr Sherman responded that by October 2007 *"the litigation should be over in both the US and Canada"* and instructed that *"[i]f we win, we will launch at risk in Australia on approval"*: PJ [224], AB 69.[21] The reference to the litigation in the US and Canada was to the ongoing efforts by Apotex US and Apotex Canada to launch Apotex's generic clopidogrel products in those countries and the efforts by Sanofi to restrain them: PJ [201]-[217], AB 65-68. The primary judge found that in June 2006 it was "*Dr Sherman's intention to launch at risk once TGA approval was obtained (expected to be obtained by October 2007) but only if Apotex succeeded"* in the US and Canada: PJ [225], AB 69. There was no challenge to that finding on appeal, nor is that finding challenged in this Court.

53. Applying for ARTG registration: On 27 June 2006, Apotex submitted to the TGA, for acceptance as of 30 June 2006, a dossier seeking registration of its generic clopidogrel products on the ARTG. The 30 June date was the *"earliest possible date"* after the *"data exclusivity period"* expired, being a period during which Sanofi (as submitter of the original data supporting the quality, safety and efficacy of its clopidogrel products for registration on the ARTG) could have objected to the TGA relying upon Sanofi's data to evaluate Apotex's clopidogrel products: PJ [226], AB 69.

54. Developing a plan to launch: By at least February 2007, Apotex had developed a plan to launch if not enjoined, which no longer depended upon the outcome of the litigation in the US or Canada: PJ [231], AB 71. The plan was set out in an email on 20 February 2007, from Dr Sherman to Mr Weingarten, Ivor Hughes (legal practitioner) and Mr Millichamp: see PJ [229], AB 70.[22] It stated (emphasis added):

> *Plan is as follows:*
> *[redacted]*
> *2. In May or June, we will file suit in Australia to invalidate the patent. [redacted]*
> *3. We will then advise Sanofi that we will launch unless they move for and obtain an injunction, in which case they will have to give an undertaking for our damages.*

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20 Reproducing item **8** (PFM vol 1/tab 7/p. 108). See also FC [277], AB 279 referring to item **6** (PFM vol 1/tab 4/pp. 88-89).
21 Reproducing item **8** (PFM vol 1/tab 7/p. 108).
22 Reproducing item **15** (PFM vol 1/tab 10/p. 118).

4. If they do not give an undertaking for our damages and do not get an injunction, we will launch.

55. The plan was restated several times, including in April 2007: *"Australia is first up and Barry's instruction is to attempt to launch at risk and then invalidate"*: see PJ [233], AB 71.[23]

56. Compelling reasons supported the instructions in 2007 to launch clopidogrel in Australia "at risk". First, Apotex Canada was an aggressive company that had a strategy of identifying weak patents and launching generic medicines "at risk". In 2006, Apotex Canada had identified the clopidogrel patent as weak, and sought to launch clopidogrel products at risk in Canada and the US: *cf* FC [260]-[267], AB 276-277. Second, Australia was a new market for Apotex, Apotex was in an *"investment phase"* and clopidogrel was a *"blockbuster"* drug, with enormous sales and potential to bolster Apotex's competitiveness, including on a range of other drugs in Australia: *cf* FC [268]-[270], AB 277-278. Third, in August 2006, Apotex Canada had launched clopidogrel at risk in the US and made over US$1 billion in sales in one week before Sanofi obtained an interlocutory injunction: *cf* FC [271]-[272], AB 278. Even after a settlement with Sanofi in the US, Apotex Canada kept $442 million of that one-week revenue: see PJ [210], [217], AB 67, 68.

57. Reconfirmation of decision to launch: On 25 June 2007, Mr Millichamp sent an email to Andrew Kay, President of Apotex International Inc, setting out the *"expected timetable of events going forward"*: PJ [237], AB 72-73.[24] Later that day, Mr Kay asked Dr Sherman to *"please re-confirm or otherwise our approach in Australia"* and *"[d]o you want us to continue to launch and to invest in the revocation proceedings?"*: PJ [241], AB 74.[25] A flurry of emails, which are heavily redacted, and to which lawyers for Apotex and Apotex Canada were also parties, followed on 26 June 2007: PJ [242], AB 74.[26] In those emails, Dr Sherman was asked to "*advise when you have decided whether to pursue revocation of the enantiomer patent, and if you wish us to*

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[23] Reproducing item **16** (PFM vol 1/tab 12/p. 126).
[24] Reproducing item **19** (PFM vol 1/tab 14/p. 136).
[25] Reproducing item **20** (PFM vol 1/tab 15/p. 142).
[26] Referring to items **20A** (PFM vol 1/tab 16/p. 145), **20B** (PFM vol 1/tab 16/p. 144), **20C** (PFM vol 1/tab 16/p. 144), **20D** (PFM vol 1/tab 16/p. 144), **21** (PFM vol 1/tab 16/p. 144), **21A** (PFM vol 1/tab 17/p. 148).

move to launch at risk": see PJ [243], AB 74-75.[27] Dr Sherman's response to that question – and other emails – were wholly redacted: see PJ [244], AB 75.[28]

58. On 27 June, Mr Millichamp forwarded Dr Sherman's responses to Karen McTavish, National Sales and Marketing Director at Apotex, with the words "*FYI – game on!!!"* (PJ [245], AB 75)[29] and to Apotex Canada's Corporate Project Manager, Mr Haas stating "*[i]f we are successful in avoiding an injunction we will plan to launch subject to Barry's further advice /approval"*: PJ [246], AB 75.[30] Critically, on 28 June, Mr Millichamp wrote again to Mr Haas stating, among other things: "*[redacted] as per instructions from Barry the plan (in outline) for clopidogrel is … 3) If we are successful in defending our position vs Sanofi and an injunction is not granted by the courts then we will launch"*: FC [313], AB 288.[31] This significant email is discussed below at [85]-[88].

59. In a further series of emails on 8-10 August 2007, between Dr Sherman and the most senior executives of Apotex Canada and Apotex involved in the launch, Mr Haas and Mr Millichamp set out the launch plan if not enjoined: see FC [178]-[188], AB 256-259.[32] Mr Kay responded to Mr Millichamp's emails: *"Thanks for the comprehensive update[.] OK by me*" (FC [186], AB 258)[33] and those responsible for stock responded, *"thank you for providing further clarity"* and *"[w]e have aligned our launch plans accordingly":* FC [185], [187], AB 258.[34]

60. Supply arranged for launch: From late June 2007, Apotex planned for supply if it was not enjoined: see FC [124], AB 237,[35] FC [172]-[173], AB 254-255.[36] The plans

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27 Referring to item **21** (PFM vol 1/tab 16/p. 144).
28 Referring to items **22** (PFM vol 1/tab 16/p. 144), **23** (PFM vol 1/tab 17/p. 148).
29 Referring to item **24** (PFM vol 1/tab 18/p. 152).
30 Reproducing item **25** (PFM vol 1/tab 17/p. 148).
31 Reproducing item **29** (PFM vol 1/tab 19/p. 156).
32 Referring to items **34** (PFM vol 1/tab 23/p. 170), **35** (PFM vol 1/tab 23/p. 169), **36** (PFM vol 1/tab 23/p. 169), **37** (PFM vol 1/tab 23/p. 168), **37A** (PFM vol 1/tab 23/p. 168), **38** (PFM vol 1/tab 23/p. 168), **39** (PFM vol 1/tab 24/pp. 172), **40** (PFM vol 1/tab 25/p. 178).
33 Reproducing item **39** (PFM vol 1/tab 24/p. 172).
34 Reproducing items **38** (PFM vol 1/tab 23/p. 168), **39** (PFM vol 1/tab 24/p, 172).
35 Referring to items **26** (PFM vol 1/tab 17/p. 148), **30A** (PFM vol 1/tab 21/p. 164), **30** (PFM vol 1/tab 21/p. 164), **31** (PFM vol 1/tab 22/p. 166), **32**, **37A** (PFM vol 1/tab 23/p. 168), **38** (PFM vol 1/tab 23, p.168), **39** (PFM vol 1/tab 24/p. 172), **40** (PFM vol 1/tab 25/p. 178), **56** (PFM vol 1/tab 40/p. 334), **65** (PFM vol 1/tab 51/p. 376).
36 Referring to item **26** (PFM vol 1/tab 17/p. 148), **29** (PFM vol 1/tab 19/p. 156), **29AA** (PFM vol 1/tab 19/p. 156), **30A** (PFM vol 1/tab 21/p. 164), **31** (PFM vol 1/tab 22/p. 166), **56** (PFM vol 1/tab 40/p. 334), **65** (PFM vol 1/tab 51/p. 376).

included inquiries from Dr Sherman to senior management on 13 and 14 September 2007 (Toronto time), as to whether clopidogrel tablets intended for the US market could be sold in Australia: see FC [251]-[253], AB 273-74.[37]

61. Apotex commenced the Patent Proceedings and notified Sanofi: On 16 August 2007, Apotex commenced the Patent Proceedings. On 17 August 2007, the TGA notified Apotex that it had approved registration of its clopidogrel products on the ARTG effective 21 August 2007: PJ [259], AB 78. Apotex immediately notified Sanofi of the TGA's decision and also informed it that it had commenced the Patent Proceedings and that it was preparing to launch its clopidogrel products into the Australian market in the near future: PJ [259], AB 78.[38] These actions were consistent with Dr Sherman's email of 20 February 2007 (point 3) (see [54] above) and Mr Millichamp's emails of 25 and 28 June 2007, to commence proceedings against Sanofi to invalidate the Patent and then launch unless enjoined: see [57]-[58] above.

62. Apotex announced launch to pharmacists: On 17 August 2007, Apotex notified pharmacists that: (a) its clopidogrel products had been registered on the ARTG; (b) it *"intend[ed] to launch this product into the Australian market in the near future"*; (c) Sanofi may apply for an injunction to prevent it from launching, but that it *"would vigorously defend any such application";* and (d) if Sanofi made such an application *"then the decision whether to launch … will be delayed until the outcome … has been determined"*: PJ [260], AB 78.[39] Upon reading the announcement Sanofi's General Manager, Jeremy Moulding, commented: *"This seems to be very clear evidence of intention to launch and the urgency for an interim injunction*": see FC [119], AB 235.[40]

63. Apotex applied for PBS listing: On 1 September 2007, Apotex submitted a hard copy application to list its products on the PBS effective 1 December 2007: PJ [261], AB 79. Apotex withdrew its application on 4 September 2007, after being told that it had missed the application deadline: PJ [261]-[264]; AB 79. It immediately began making

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37 Reproducing item **61** (PFM vol 1/tab 46/p. 356), and referring to items **65A** (PFM vol 1/tab 51/p. 376), **65B** (PFM vol 1/tab 51/p. 376), **65C** (PFM vol 1/tab 51/p. 376), **66** (PFM vol 1/tab 52/p. 380).
38 Referring to item **44** (PFM vol 1/tab 29/p. 234).
39 Reproducing item **45** (PFM vol 1/tab 30/p. 236).
40 Reproducing item **48** (PFM vol 1/tab 31/p. 238).

arrangements to list on 1 April 2008, being the next available date for a first generic brand to be listed on the PBS: PJ [264], AB 80; FC [164]-[168], AB 250-252.[41]

64. Apotex resisted the interlocutory injunction application: On 17 September 2007, Sanofi filed an application for interim relief seeking, upon Sanofi by Counsel giving an undertaking as to damages in the usual form, two interlocutory injunctions to restrain Apotex from infringing the patent or taking steps to obtain listing of its products on the PBS.[42] Apotex did not consent to the relief sought or the proffered undertaking as to damages from Sanofi. Instead, it mounted an impressive defence to the application. Apotex adduced evidence from Mr Millichamp – which was uncontested – that Apotex intended *"to apply for listing of its clopidogrel 75mg (as hydrogen sulfate) tablets at the next available opportunity, which is by 1 December 2007"* (see FC [295], AB 283)[43] and raised "*a substantial issue as to the validity"* of the Patent.[44] It argued that damages were an adequate remedy and offered substantial security (to be provided by Apotex Canada) of $50 million (to be increased as appropriate *"as the proceeding progresses"*) within 28 days: see PJ [272], AB 82. It gave *inter partes* undertakings that it would keep accounts of its sales until final judgment of the Patent Proceedings and refrain from providing discounts to its clients on its clopidogrel products: see FC [303]-[305], AB 285-286.[45] It arranged, in the days before hearing, for the guarantee to be provided within 28 days or sooner (see PJ [269]-[271], AB 81-82)[46] and confirmed those arrangements after the hearing but before judgment was delivered: see PJ [274], AB 82.[47]

65. Apotex's Senior Counsel, Mr Catterns QC, repeatedly submitted at the hearing of Sanofi's application that, if unrestrained, Apotex would apply for PBS listing for 1 April 2008 and would start taking orders (i.e. launch) before then: see PJ [272], AB 82; FC [28], AB 210-211.[48] Those statements were admissions; the inference is

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41 See items **54** (PFM vol 1/tab 40/p. 334), **56** (PFM vol 1/tab 40/p. 334), **61** (PFM vol 1/tab 46/p. 356), **65** (PFM vol 1/tab 51/p. 376).
42 See item **67** (PFM vol 2/tab 53/p. 405-406).
43 Reproducing item **67B** at [38] (PFM vol 2/tab 54/p. 417).
44 See *GenRx Pty Ltd v Sanofi-Aventis* [2007] FCA 1485; 73 IPR 502 at [12] (Gyles J).
45 Referring to item **64A** (PFM vol 1/tab 50/p. 372).
46 Reproducing some of items **60** (PFM vol 1/tab 45/p. 352) and **60A** (PFM vol 1/tab 45/p. 352) and referring to item **63** (PFM vol 1/tab 47/pp. 360-361).
47 Reproducing some of item **71** (PFM vol 2/tab 62/p. 587).
48 Reproducing item **69** (PFM vol 2/tab 60, pp 575-576 (T79.32-80.29); see also pp. 507–508 (T11.43-12.20).

they were made on considered instructions which must have included those of Apotex Canada which was offering the $50 million guarantee, which had indemnified Apotex for patent infringement and which had obtained, among other things, rights to control any patent infringement litigation: see FC [263], AB 276.[49]

66. The above matters more than established the Commonwealth's *prima facie* case at Step 1. The only real dispute was the June confirmation of the plan developed in February 2007 (see [54] above), which is considered further below at [85]-[88].

67. **Step 2.** In response to the Commonwealth's case on causation, Sanofi pleaded, not with non-admissions and bare denials but on the basis that Apotex would not have listed *because* of a series of asserted reasons.[50] As per *Purkess* and the principle articulated above, Sanofi had the evidential burden to introduce "sufficient" evidence of the existence and likely effect of each reason. Importantly, causal hypotheses are not mere asserted outcomes; they are competing explanations of what would have happened in the counterfactual and why: *cf* FC[90]-[92], AB 228. The Full Court said that there was evidence pertaining to at least two matters sufficient to raise an alternative reason at Step 2.

68. The first matter was *"evidence tending to suggest that Apotex was better off being restrained with the benefit of the undertaking as to damages than it would have been if it had launched at risk and was exposed to the risk of damages for patent infringement"*: FC [90], AB 228. The Full Court did not identify that evidence. The primary judge's reasons suggest that the evidence may have been emails (dated almost a year *after* the interlocutory hearing) from Mr Kay to Mr Millichamp: the first on 6 August 2008, describing the amount of damages that Apotex might have to pay Sanofi as *"potentially ruinous"* (PJ [302], AB 89)[51] and the second on 12 August 2008, in which Mr Kay's personal view was that Apotex should not launch, even if Gyles J found in its favour in the Patent Proceedings, until any appeals by Sanofi had been determined: PJ [306], AB 90.[52]

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49 Referring to cl 3 of item **14** (PFM vol 1/tab 9/p. 113).
50 *cf* Amended Points of Claim (item **112AA**) at [62]-[64] (PFM vol 3/tab 89/p. 1108); Second Further Amended Points of Defence (item **117**) at [62]-[64] (PFM vol 4/tab 101/pp. 1329-1340).
51 Reproducing some of item **83A** (PFM vol 2/tab 67/p. 618).
52 Reproducing some of item **84** (PFM vol 2/tab 69/p. 628).

69. This was the incorrect approach. The question was not an objective one about whether Apotex was "better off"; the question was what calculation Apotex made at the time and whether Sanofi had supplied "sufficient" evidence of a reason for why Apotex might not have listed even if not enjoined. The Commonwealth led contemporaneous evidence of the calculations that Apotex made in 2007: direct profits of between $9-$21 million in the first year after the launch (see PJ [234], AB 71-72)[53] together with incidental goodwill growth with pharmacists, which justified it offering $50 million security with liberty for Sanofi to apply for more. It led evidence of Apotex's intent given in sworn testimony to Gyles J and the submissions of Senior Counsel which must have been made on instructions. Apotex's refusal to consent to the interim relief sought by Sanofi's notice of motion of 17 September 2007 (relevantly including an undertaking as to damages from Sanofi)[54] put the issue of *Apotex's* intent beyond doubt. If Apotex thought, at the time, that it was better off being enjoined with an undertaking, all it had to do was consent to the orders and save the costs of resisting the offer at hearing. The hearing could add nothing and carried the risk of no injunction being made and no undertaking being given. The Full Court's unwarranted speculation that Apotex might have been playing a "game" to goad Sanofi into seeking an injunction and proffering an undertaking as to damages (FC [129], [134], AB 238-240) is exploded by Apotex's contemporaneous decision *not* to accept Sanofi's undertaking when proffered and consent to the interim relief sought.

70. The second matter was "*evidence that once it was no longer restrained by the injunction after winning its appeal to the Full Court, it still did not launch at risk whilst Sanofi's special leave application was pending in the High Court*": FC [90], AB 228.[55] Apotex's actions in late 2009 and early 2010 were said to be actual evidence of what Apotex would have done in the counterfactual in 2007: FC [90], AB 228. The Court pointed to a calculation of the same kind but done a year or more later in different circumstances, producing a different risk/reward position, which led some persons within Apotex, in differing circumstances (explained below at [73]) to be cautious about listing at risk then: FC [222], [227]-[229], AB 267-269.

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53 Reproducing item **18** (PFM vol 1/tab 13/p. 131).
54 See item **67** (PFM vol 2/tab 53/p. 405).
55 Contrary to FC [90], AB 228 Apotex *was* restrained by the injunction after winning its appeal until the High Court had determined any special leave application by Sanofi: PJ [131], AB 44.

71. What the Full Court does not do at FC [90] (AB 228) or elsewhere in its reasons is explain what alternative reason it is inferring from Apotex's conduct in late 2009/early 2010 about Apotex's true intentions in September 2007. One is left to speculate. Perhaps the thinking is that if Apotex had succeeded in resisting the injunction, it would only then have made a decision on the risk/reward calculus, and it is left unknown what the answer would have been. The Full Court does not explain if it contemplated that the operative decision would be made within the 28 days by which security was due or, if like the primary judge, it considered Apotex had until 1 December 2007 or 14 February 2008 to decide: see PJ [282], AB 84. Either approach presumes it was open to Apotex in the circumstances in which it found itself on 17 and 18 September 2007, to defer making up its mind whether to list and launch.

72. Whatever the Full Court had in mind, the "wait and see" or "decide later" hypotheses cannot sit with the objective realities of the forensic contest as joined by the contested interlocutory hearing, as Apotex and its lawyers would well have known. The contested hearing crystalised the time for Apotex to finalise its intent (to the extent it had not already). Reserving the decision until after the outcome of the hearing was known for the 28-day period in which the $50 million guarantee was to be provided was not an available course: it would have meant deceiving Gyles J at the hearing on 18 September 2007 and then returning to apply to be relieved of that undertaking and explaining the deceit. Reserving the decision until 1 December 2007 or 14 February 2008 was also not an available course: it would have meant providing the $50 million guarantee, informing the market that Apotex had not been enjoined and could now launch (as foreshadowed on 17 August 2017), taking pre-orders, and then potentially backtracking, which would mean commercial humiliation, on top of misleading Gyles J. The "wait and see" or "decide later" hypotheses are at the very least not plausible; they are more aptly characterised as absurd.

73. Furthermore, the Full Court failed to consider how the circumstances in 2007 differed from those in late 2009/early 2010 such that the subsequent events were not capable of explaining Apotex's position in 2007 had it not been enjoined. In September 2007, Apotex was the only generic company with clopidogrel products registered on the ARTG. This was clearly an important factor for Apotex – as late as 14 September 2007, Mr Millichamp assured Mr Kay that no competitor could beat

Apotex to a 1 April 2008 launch because none had ARTG registration and so could not get PBS listing: see PJ [268], AB 80.[56] By contrast, by November 2009, Sandoz had registered its clopidogrel products on the ARTG and by February 2010 Spirit had registered its clopidogrel products: PJ [78], AB 31. It was but a short step for those companies to seek PBS listing. If Apotex had obtained PBS listing at risk in 2009 or early 2010, it would have borne the risk of damages associated with triggering the 12.5% statutory price reduction but would not have enjoyed the rewards of being the first generic company listed for very long because other companies, such as Sandoz, could enter the market (and not bear the risk of having to pay damages associated with the reduction). Even putting that aside, Apotex's internal assessments and emails in 2007 are a far better guide than its assessments in later years as to what Apotex was likely to do in 2007 had it not been enjoined: *cf* FC [276]-[290], AB 279-282.[57]

74. The result was that the Commonwealth's *prima facie* case at Step 1 stood unanswered by either of the matters referred to at FC [90], AB 228. All that remained was the primary judge's suggestion that two related developments in September 2007 could have led Dr Sherman to conclude, by 1 December 2007 or 14 February 2008, that it might be preferable not to launch at risk even if Gyles J had refused the interlocutory injunction: see PJ [278], AB 83; FC [355], AB 300.

75. The first development occurred in early September 2007, when Apotex learned that its application to list its clopidogrel products on the PBS on 1 December 2007 had been filed too late for that to occur, and that the earliest possible date for a PBS listing was now 1 April 2008: see PJ [279], AB 83.[58] That development was fully known to Apotex and to Dr Sherman *before* Mr Catterns QC and Mr Millichamp gave their unequivocal and uncontested statements and evidence to the Court on 17 and 18 September 2007: see PJ [280], AB 83. Sanofi never put forward any basis to impugn Mr Catterns QC's instructions. Nor did Sanofi challenge paragraphs 38 and

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56 Referring to, and reproducing some of, items **60B** (PFM vol 1/tab 44/p. 349), **60C** (PFM vol 1/tab 44/p. 348).

57 Referring to (in order) items **6** (PFM vol 1/tab 4/p. 88), **7** (PFM vol 1/tab 5/p. 92), **120** (PFM vol 4/tab 103/p. 1380 at [38]-[39]), **18** (PFM vol 1/tab 13/p. 130), **60** (PFM vol 1/tab 45/p. 352), **60A** (PFM vol 1/tab 45/p. 352), **71** (PFM vol 2/tab 62/p. 586).

58 Reproducing item **54** (PFM vol 1/tab 40/p. 334).

39 of Mr Millichamp's affidavit of 17 September 2007 that Apotex intended to list and launch if not restrained: see FC [295], AB 283.[59]

76. The second development was that on 21 September 2007, Gyles J confirmed that there would be an early final hearing, fixed before himself to commence on 2 April 2008: PJ [281], AB 84. Yet the Court had foreshadowed this very possibility at the 13 September directions hearing, which Mr Millichamp conveyed to Mr Kay, who reported to Dr Sherman, on 13 September 2007.[60]

77. Both developments were therefore known or factored in when Apotex "crossed the Rubicon" by opposing the orders sought in Sanofi's notice of motion of 17 September 2007 and affirmatively deposing to Gyles J that it intended to list and launch. In any event, the primary judge's suggestion assumes that Dr Sherman had not made a decision to apply for PBS listing by 18 September 2007. That assumption is false for the reasons given above at [72] and further below at [83]-[88].

78. The result was that there was nothing left to carry forward to Step 3.

79. Supposed gap in the Commonwealth's case: The case that Sanofi ran before the primary judge was to try to create a gap in the Commonwealth's case at Step 1 (see FC [295]-[305], AB 283-286 where the Full Court attempts to explain the findings the primary judge made about the supposed gap). That supposed gap was as follows.

80. First, an email Mr Millichamp sent Mr Haas on 27 June 2007 (see [58] above), properly construed, indicated that Dr Sherman had not made any decision to launch at risk; rather, he was allowing the strategy to go forward but was adopting a "wait and see" approach: FC [114], AB 233.

81. Second, the letter Apotex sent to pharmacists on 17 August 2007 (see [62] above) was ambiguous and was consistent with Dr Sherman and Apotex deferring their decision whether to launch at risk until after the result of the interlocutory injunction was known. Sanofi submitted (and the primary judge and the Full Court accepted) that the

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[59] Reproducing item **67B** (PFM vol 2/tab 54/p. 417).

[60] See item **59A** (PFM vol 1/tab 44/p. 349). Parts of this email are reproduced at PJ [267], AB 80 and FC [140]-[141] AB 242-243 but neither refer to that part of the email notifying Mr Kay that "*The indication from the judge was that they want to move towards a final trial sooner rather than later. The next six months was mentioned, subject to availability of expert witnesses etc.*"

letter, especially the statement *"the decision whether to launch these products will be delayed until the outcome of that application [being Sanofi's application] has been determined"* did not publicly commit Apotex to launching in the event no interlocutory injunction was granted and meant the decision to launch was to be delayed: PJ [260], AB 78-79; FC [118]-[120], AB 234-236.

82. There are numerous answers to the "supposed gap" case that Sanofi ran.

83. First, there was not a single document from Dr Sherman in evidence from 2007 which indicated he was wavering in his desire to launch at risk in Australia if not restrained. He was copied on numerous emails about implementation; he sought confirmation on 8 August 2007 that his plan was being implemented (FC [322], AB 290)[61] and on 14 September 2007 sought confirmation that US stock could be supplied in Australia: see FC [251], AB 273-274.[62]

84. Second, it is inconsistent with Apotex vigorously contesting Sanofi's notice of motion, the admissions Mr Catterns QC made before Gyles J, the testimony of Mr Millichamp of 17 September 2007, and the offer of $50 million security: see [64]-[65] above.

85. Third, it rests upon a false doubt. When the email from Mr Millichamp to Mr Haas on 27 June 2007 (see [58] above) is read with other emails before and after that email (see [57]-[58] above), it is clear Dr Sherman did not give an instruction to pause the strategy that he had, until then, allowed to be implemented, in favour of a "wait and see" approach requiring Mr Millichamp (or someone else) to revert later for re-confirmation of the plan. The words "*subject to Barry's further advice/approval"* in the email of 27 June appeared in an email between colleagues not intended for close scrutiny by courts years later, and in circumstances where Dr Sherman's role as the ultimate decision-maker in the Apotex group left open the possibility that, for example, the precise details of supply arrangements might change or Dr Sherman might have some advice about how particular elements of the plan should be implemented.[63] To acknowledge as much is not to turn the plan of Dr Sherman – as reconfirmed by him

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61 Reproducing item **36** (PFM vol 1/tab 23/p. 169).
62 Reproducing item **61** (PFM vol 1/tab 46/pp. 356–357).
63 Mr Millichamp's evidence in cross-examination was that he "*already had the instructions on what to do"* (PJ [249], AB 76). The primary judge rejected Mr Millichamp's evidence on this email (PJ [250]-[251], AB 76-77), but did so in circumstances where his Honour failed to consider how other relevant emails before and after this email bore upon its construction.

that very day (as is made clear by the next email) – into a provisional decision to launch if not enjoined.

86. Even if that construction of the 27 June email is debatable, the emails sent on 28 June make clear that Dr Sherman had approved each step of the strategy that followed. On 28 June, Mr Millichamp wrote again to Mr Haas stating, among other things (emphasis added):[64]

> *[redacted] as per instructions from Barry the plan (in outline) for clopidogrel is … 3) If we are successful in defending our position vs Sanofi and an injunction is not granted by the courts then we will launch …*
>
> *We are not sure that we can launch yet so need to know if we should place orders in anticipation or should wait. Barry has made it clear that he does not want to waste money on launch activities until we are clear on what we can do.*

87. The underlined passages reproduced above disclose that Mr Millichamp had received the necessary instructions from Dr Sherman, including on the more practical steps of implementation of the strategy. The primary judge ignored the email. Although the Full Court referred to it, its reasoning did not grapple with the key line ("*as per instructions from Barry the plan (in outline) for clopidogrel is*"). There were then further emails on 28 June wherein Mr Haas sought clarification of the plan: FC [144], AB 245;[65] [146], 245; [66] [150], 247.[67] Mr Millichamp replied on 29 June (FC [153], AB 247-48):[68]

> *I was probably not clear enough in my mail to you … The scenario I referred to was in the event that we avoid the imposition of an injunction granted in favour of Sanofi. We will be free to sell until final trial, and after, if we are successful. In the instance that we are successful we will need stock ready for a December PBS listing … if we are not successful in avoiding an injunction then the matter will go to final trial which could be a year or so (or longer) away. That's why Barry does not want us to make stock right now and incur unnecessary expense.*

88. There is no equivocation in the above emails about the setting in train of each step of the strategy. The step of making stock is one that Dr Sherman does not want to take until it is known that an injunction has been avoided as he does not want to spend

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64 FC [313], AB 288, reproducing item **29** (PFM vol 1/tab 19/p. 156).
65 Reproducing item **29AA** (PFM vol 1/tab 19/p. 156).
66 Reproducing item **29A** (PFM vol 1/tab 20/p. 160).
67 Reproducing item **30** (PFM vol 1/tab 30/p. 164).
68 Reproducing item **31** (PFM vol 1/tab 22/p. 166).

money making stock only for Apotex to be enjoined from selling that stock. That concern is justified when regard is had to Apotex's experience in the US being enjoined one week after launching at risk: see [56] above. It also reflects the 3-4 months between the time of lodging an application to list a first generic product on the PBS and the time that stock had to be available for purchase at pharmacies for Apotex to meet its supply obligations under the NHA: see [30] and [33] above.

89. Fourth, it rests upon a further false doubt resulting from a misinterpretation of the letter Apotex sent to pharmacists in August 2007: PJ [288], AB 86; FC [118]-[120], [135], AB 234-236, 240-241. The statement upon which Sanofi (and the courts below) placed weight must be read in context. At that stage, Apotex anticipated that Sanofi would apply to enjoin it from launching. There was a risk that it might be unsuccessful in resisting that application and that, if it was enjoined, it could not launch.

90. **Step 3.** On a proper analysis of the evidence before the Courts below, Step 3 is not reached. Had it been reached then, having regard to the evidence as a whole (see [52]-[88]), it was more probable (51%) than not that Apotex would have taken steps to apply for PBS listing from 1 April 2008. The supposed gap that Sanofi created as to the Commonwealth's case at Step 1 was inconsistent with the evidence before the Court and the proper inferences to be drawn from that evidence. There was no contemporaneous statement made in the lead up to the grant of the interlocutory injunction of a plan not to list even if not enjoined. Against the evidence the Commonwealth marshalled, the fact the listing date had moved to April 2008, or that there might have been a final hearing in April with a judgment later in 2008, is not capable of establishing, on the balance of probabilities, that Dr Sherman's plan of February and June 2007 had been overtaken or that Apotex was otherwise unlikely to have seen it through. The purported causal hypothesis that Apotex was better off being restrained with the benefit of the undertaking than it would have been if it had launched at risk (FC [90], AB 228) is based on an absurdity: see [72] above.

(d) Second error: the requirement to call Dr Sherman

91. The decisions below effectively turned hindsight evidence into a *requirement* of proof absent contemporaneous material establishing that the decision-maker had already made an irrevocable decision and/or addressed all countervailing considerations later raised by the respondent: PJ [339]-[349], AB 98-101; FC [220], AB 267. If the correct

principle as to evidential burdens is adopted, the need for a claimant on an undertaking as to damages to lead direct hindsight evidence from relevant decision makers falls away.

92. In *Sigma,* Jagot J described direct hindsight evidence on a claim for compensation as being *"inherently unreliable"*: at [280]; see also [399], [402]. There are many cautionary observations in the authorities about the value of hindsight evidence: at [274]-[277]. An interval of many years between the hypothetical events and the hearing of a claim for compensation also supplies *"sufficient reason, of itself, to cast significant doubt on the reliability of the evidence no matter how honest and careful the witness"*: at [278]. Rather, *"a more reliable guide to what would or might have happened is inference from available contemporaneous material and objective contemporaneous circumstances assuming rational commercial decisions rather than the evidence of witnesses speaking many years later in the context of litigation":* at [281]; see also [286]. Her Honour's application of that approach to Sigma's claim demonstrates equity's preparedness to draw an inference of how a person was likely to have acted by reference to how the person had in fact acted and their expressed intentions prior to equity's intervention (in the form of interlocutory relief) preventing events from unfolding as they otherwise would have: see [355], [418], [420], [436], [457], [459] and [464]. This Court should affirm that approach.

93. Once the evidence the Commonwealth and Sanofi adduced is assessed using the three-step approach explained at [36]-[37], including the drawing of inferences that arose from those materials, there was no "evidentiary deficiency" left to be filled in the Commonwealth's case as to what Dr Sherman would have done if the injunction were refused: PJ [348]-[349], AB 100-101; FC [217]-[221], [230]-[231], [353]-[373], [381]-[383], AB 266-267, 289-290, 299-304, 307-308. The evidence showed that Dr Sherman's decision to launch clopidogrel at risk in Australia was not "provisional" on 27 June 2007 or at any time before the interlocutory hearing: see [85]-[88] above.

94. In any case, there was no scope to resort to the rule in *Jones v Dunkel* in relation to the Commonwealth's case and its "failure" to call Dr Sherman. Had Dr Sherman been called, he would have given hindsight evidence as to matters that *might* have occurred ten years prior. Such evidence is likely to have been *"inherently unreliable"* for the reasons given by Jagot J in *Sigma* summarised above at [92] and would have been of

little to no value when set against the direct contemporaneous evidence of his intention. It was not necessary to call Dr Sherman to elaborate on what was already proven by that evidence, nor possible to call him to give evidence as to what he had said in those emails which were privileged. The Commonwealth had already taken all steps available to tender all relevant contemporaneous records, including by challenging the terms of a Settlement Deed forbidding Apotex assisting the Commonwealth (see [24] above) and had unsuccessfully challenged the clauses in the Settlement Deed relating to privilege and made an unsuccessful application that privilege had been waived.[69]

95. Using the three-step approach, if either party was required to call Dr Sherman to avoid a *Jones v Dunkel* inference being drawn against it, then it was for Sanofi to call Dr Sherman. In *Air Express* Mason J (who was ultimately in dissent on the conclusion to be reached on the evidence) expressed the view that it was for the plaintiff, who had sought to erect *"countervailing circumstances*", in that case to call the Secretary or the Minister to make out that case, and not the claimant's onus to disprove those circumstances: see at 332 (Mason J); *cf* Gibbs J at 314; FC [374], AB 304-305. By analogy with *Air Express*, Dr Sherman's evidence was relevant to Sanofi's case at Step 2 and it was therefore necessary for Sanofi to call him.

Part VII: Orders sought

96. The Commonwealth seeks the orders set out in the Notice of Appeal: AB 547.

Part VIII: Time required for presentation of oral argument

97. The Commonwealth estimates its oral submissions on the notice of appeal will take 3.5 hours in chief and 1 hour in reply. It will provide an estimate for oral submissions on Sanofi's notice of contention when responding to that notice.

Dated: 30 April 2024

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[69] See *Commonwealth of Australia v Sanofi (formerly Sanofi-Aventis) (No 4)* [2017] FCA 979.

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

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.	*National Health Act 1953* (Cth)	Compilation prepared on 24 August 2007	Sections 84, 84AF, 84AJ, 85, 87, 99, 99ACF, 99ACH, 99ACI, 99AD, 99ADB, 99AEC, 99AED
2.	*National Health (Pharmaceutical Benefits) Regulations 1960* (Cth)	Compilation prepared on 1 August 2007	Regulation 37F