



HIGH COURT OF AUSTRALIA

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Details of Filing

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IN THE HIGH COURT OF AUSTRALIA
SYDNEY REGISTRY

BETWEEN

Commonwealth of Australia
Appellant

and

Sanofi (formerly Sanofi-Aventis)
First Respondent

Sanofi-Aventis US LLC
Second Respondent

Bristol-Myers Squibb Investco LLC
Third Respondent

RESPONDENTS' SUBMISSIONS ON THE NOTICE OF APPEAL

Part I: Certification

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

Part II: Issues

2. These submissions address the Notice of Appeal (NOA; AB545-547), and the Commonwealth's opening submissions in support (CNOAS). Defined terms in Sanofi's opening submissions in support of the NOC (SNOCS) are maintained.

Background

3. The forensic background is as follows. *First*, the Commonwealth's claim was that the cause of its loss was the Interlocutory Injunction, in that but for that order, Apotex would have 'launched at risk' and supplied its clopidogrel products under the PBS from 1 April 2008 despite the fact that the Patent was unrevoked at that time. *Secondly*, the Commonwealth explicitly declined to put its case on the footing of a loss of opportunity (T1055.27-T1056.42; *cf* the claimants in *Sigma v Wyeth* at [152]-[205]). *Thirdly*, the Commonwealth accepts that from first to last it bore the legal or persuasive onus on the question of causation (Commonwealth's Special Leave Reply at [5], [8]). *Fourthly*, the applicable standard of proof is defined by s 140(1) of the *Evidence Act 1995* (Cth): 'In a civil proceeding the court must find the case of a party proved if it is satisfied that the case has been proved on the balance of probabilities'. *Finally*, since Sanofi is in no sense a wrongdoer (*Air Express* at 310, 319), the facilitation principle has no role to play (*cf Cessnock City Council v 123 259 932 Pty Ltd* [2024] HCA 17).
4. The Commonwealth's claim was rejected at trial, and unanimously on appeal, on the basis that, having regard to all the evidence, the Commonwealth had not discharged the legal burden of proof. That is, it had failed to establish, to the ordinary civil standard, that Apotex would have launched at risk if not restrained. The primary judge found that:
 - a. the person responsible for any decision to launch at risk was Dr Bernard 'Barry' Sherman, the global head of the Apotex group (see, eg, PJ[251], [339], [495], [556], AB77, 98, 132, 146);
 - b. Dr Sherman had deferred making a final decision until after the outcome of the interlocutory application was known (PJ[251], [287], AB77, 86);
 - c. at that point there were powerful commercial reasons for Dr Sherman to prefer not to launch at risk if Apotex had not been restrained, including that the damages it might have to pay exceeded the expected profit by five to seven times (PJ[296], [311], [317], AB88, 90, 92). This consideration was highlighted by the unusual circumstance that the final hearing on the validity of the Patent was to occur within

a month of launch, and a first instance judgment was to be delivered within five months (PJ[289], [349], AB86, 101). In the counterfactual, Apotex would enjoy only a short opportunity to profit, after which, if it failed on revocation, it faced having to destroy product, cancel orders, refund customers (pharmacies) for stock they could not sell, and pay damages to Sanofi that would not be limited to the value of its sales (because of the 12.5% price reduction, which might never be reversed). It later described these prospects (correctly) as ‘potentially ruinous’ (PJ[302], AB89);

- d. the evidence of the witness called by the Commonwealth as to Apotex’s likely conduct in the counterfactual, Mr Roger Millichamp, Apotex’s local managing director, was ‘unconvincing’, ‘not ... persuasive’ and ‘unsatisfactory’, in light of the contemporaneous documents (PJ[250], [317], [338], AB76, 92, 98); and he was not the decision-maker – Dr Sherman was; and
 - e. in *those* circumstances (and, contrary to CNOAS[5], *not* because of a supposed requirement that ‘a claimant for compensation lead direct evidence’), it was significant that Dr Sherman had not been called by the Commonwealth, and that the decision not to call him was wholly unexplained (PJ[346], AB100).
5. In that context, the primary judge was not persuaded that Apotex would have obtained a PBS listing for its clopidogrel products from 1 April 2008 ‘even if the interlocutory injunction had not been granted’ (PJ[351], AB101). That is, the Commonwealth had not discharged the legal burden which it is common ground that it bore.
 6. The Full Court’s detailed review of the evidence found no error in that conclusion (FCJ2[12], [14], AB207). The Commonwealth’s principal complaint before the Full Court, at a factual level, was that the primary judge had overlooked items of evidence and submissions (Further Amended Notice of Appeal Ground 2(b), AB191; FCJ2[102], AB230-231). After a detailed consideration of each item relied on by the Commonwealth, the Full Court rejected this ground. No equivalent ground is advanced in this Court. The NOA invokes no challenge to any specific finding of the primary judge or the Full Court. Rather the ultimate challenge is as to conclusions concerning the discharge of the evidentiary and legal onus (Ground 2). That gives rise to two difficulties for the Commonwealth. The *first* is that the grounds of appeal in this Court do not identify error by reference to what the Full Court had been required to determine by the Commonwealth’s grounds of appeal in that court (*cf* FCJ2[10(a)], AB205). The *second* is that there are coordinate findings by the courts below. The Commonwealth does not engage with the requirement to establish ‘special reasons such as plain

injustice or clear error' for this Court to disturb such concurrent findings of fact (see *Kozarov v Victoria* [2022] HCA 12; (2022) 273 CLR 115 at [49] per Gageler and Gleeson JJ; see also [67] per Gordon and Steward JJ).

7. As regards an evidentiary onus, the premise for the Commonwealth's argument is that the law requires evidence to be assessed through a rigid three step framework: NOA[1(a)] (AB546), CNOAS[36]-[37]. As to this schema: *first*, as is apparent from the authorities relied on at CNOAS[41] and [44], the Commonwealth's argument is not that some special rule applies to claims in equity generally, or to a claim on an undertaking as to damages in particular. *Secondly*, the supposed rule is not stated in any decision of this or any other Australian court, or in any authority relied on by the Commonwealth. *Thirdly*, this includes *Air Express*. None of the judgments in that case even refers to an evidentiary onus. And the observations of Mason J and Stephen J on which the Commonwealth relies are divorced from their context in a way that promotes misunderstanding, are not expressed by reference to the Commonwealth's schema, and, as interpreted by the Commonwealth, do not reflect the majority's reasoning, which is unchallenged. *Fourthly*, the Commonwealth's schema is inconsistent with the warning against the imposition of any rigid formulation on the process for claims of the present kind in *European Bank* at [17]. *Fifthly*, the submission involves a misapprehension as to the meaning of an evidentiary onus, and its significance. *Sixthly*, the proposition advanced in this Court was not advanced in the same way at trial. *Seventhly*, the Full Court addressed the case on the alternative footing that the Commonwealth's point was correct, and held it did not avail the Commonwealth, having regard to the limits of the submission it advanced, and the evidence that had been marshalled by Sanofi (FCJ2[89]-[93], AB227-229). There is no challenge to the Full Court's assessment of the scope of the Commonwealth's appeal to that court.
8. *Finally*, the Commonwealth's argument as to evidentiary onus raises a false issue. In this case there was only *one* causation question: would Apotex have sought and obtained PBS listing if not restrained from selling? In accordance with the general principles of proof in civil proceedings, the Commonwealth was required to prove that theory of causation and this burden did not shift. The Commonwealth bore that burden on the balance of probabilities, by reference to all the evidence adduced. It failed to do so. Questions of evidentiary onus were immaterial.
9. Predicated on its schema, the Commonwealth then asks this Court to 'descend[] into the detail of the factual material before the courts below' (CNOAS[12]), and reach a different conclusion on the evidence to that of the primary judge and the Full Court.

10. As to the discharge of Sanofi’s evidential onus at Step 2, the Commonwealth wrongly contends that Sanofi did not put the Commonwealth to proof at trial,¹ and refers only to reasons identified in the SFAPOD [62]-[63] (PFM1329-1340) as to why Apotex would not have listed its products on the PBS absent an injunction (CNOAS[67]). The Commonwealth submits that Sanofi was required ‘to introduce “sufficient” evidence of the existence and likely effect of each reason’, and did not do so (CNOAS[67]-[74]). The Full Court reached a different conclusion, applying *Purkess v Crittenden* (1965) 114 CLR 164 (FCJ2[90]-[92], AB228). Points of defence are not in any event to be treated as pleadings in the strict sense. All that happened here was that some circumstances falling within the scope of the causation case the Commonwealth had to establish were highlighted by Sanofi in order to avoid surprise.
11. One of the identified reasons for why Apotex would not have listed on the PBS from 1 April 2008 was that the unrevoked Patent ‘exposed Apotex to the risk of substantial damages’.² The Full Court found any evidential onus on Sanofi to be discharged by material directed to that concern. Specifically, there was (FCJ2[90], AB228):
- a. ‘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’; and
 - b. ‘evidence that once [Apotex] 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’.
- In the latter case, the evidence indicated that Apotex’s decision was influenced by the former consideration: FCJ2[222], [227]-[231], AB267-270.
12. In the alternative to its claimed success at Step 2, the Commonwealth says that, if Step 3 is reached, then contrary to the findings in the courts below ‘it was more probable (51%) than not that Apotex would have taken steps to apply for PBS listing from 1 April 2008’ (CNOAS[90]). However the contention is put on the basis that, if Step 3 is reached, Sanofi had to establish ‘*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’ and that it failed to do so (CNOAS[90], emphasis added). Step 3 involves a plain reversal of the legal onus.

¹ See Second Further Amended Points of Defence (SFAPOD) [62(c)] and [63(f)], where (in relation to the effect of the Interlocutory Injunction) the Sanofi parties ‘*otherwise deny paragraph 62 of the Points of Claim*’ and ‘*otherwise deny paragraph 63 of the Points of Claim*’ (PFM1334, 1340).

² See SFAPOD [62(b)] and [63(d)] (PFM1329-1330, 1337).

13. On the factual findings themselves, the Commonwealth's central assertion is that it is 'absurd' to posit that a generic pharmaceutical company would contest an interlocutory injunction on the basis that it intended to supply the patented product and then, if not restrained, not give effect to that intention. The Commonwealth submits that this would have involved Apotex both 'deceiving' the Court and subjecting itself to 'commercial humiliation' (CNOAS[72]). But there is no deceit in informing a Court of an intention to do something and then later changing that intention with the benefit of further consideration or new information (including information that there will be an early final judgment). As for 'humiliation', the Commonwealth did not argue this at trial, and does not point to evidence to support it. On the contrary, Apotex had specifically informed its customers that 'the decision *whether* to launch' would be delayed until any interlocutory injunction application was determined (see [83] below). If Apotex had not launched and then succeeded in revoking the Patent at trial, customers would only have been relevantly delayed in receiving stock by a period of only five months. Further, Apotex did not expect to succeed in resisting the interlocutory injunction (PJ[252]-[255], AB77-78) and it had reasons to contest it apart from freeing itself to launch at risk (see [60] below).
14. The Commonwealth has not succeeded on *any* of its three steps in the courts below:
 - a. **Step 1:** Neither the primary judge nor the Full Court found that a *prima facie* case in support of compensation was established (*cf* [4] above).
 - b. **Step 2:** Sanofi's points of defence did not limit it to affirmatively establishing a 'reason B', and in any event the Full Court held that Sanofi had met any 'evidential' burden it might face (see [11] above).
 - c. **Step 3:** There are concurrent findings against the Commonwealth on satisfaction of the legal onus, based on the documentary record, a rejection of the critical evidence of the Commonwealth's principal witness, and the absence of evidence from the real decision-maker (see [4]-[6] above).
15. As for the second matter raised by the Commonwealth (CNOAS[5]), it even more plainly raises a false issue. Neither the trial judge nor the Full Court suggested that 'equity require[s]' a claimant to lead 'direct hindsight evidence'. Rather, they found, after a detailed consideration of the documentary and testimonial evidence *in this case*, that it did not discharge the Commonwealth's burden of proof, precisely because it left the court to speculate (*cf Air Express* at 317-318 per Stephen J) as to what the real decision-maker on behalf of Apotex would have done in the circumstances that obtained at the relevant time (PJ[348]-[349], FCJ2[220], [231], AB100-101, 267, 270).

16. Against that background, the submissions that follow address the:
 - a. **Evidential burdens issue:** Does a claimant on an undertaking as to damages succeed, where it does no more than outline a *prima facie* case in support of compensation, and the respondent does not establish an alternative *prima facie* case as to what would have occurred if an interlocutory injunction had not been granted? Sanofi submits the answer is ‘no’ (see [24]-[102] below).
 - b. **Mode of proof issue:** Does a claimant on an undertaking as to damages have to lead evidence (documentary or testimonial, direct or circumstantial), sufficient to prove, on the balance of probabilities, the position of the person on whose decision the claim depends? Sanofi submits the answer is ‘yes’ (see [103]-[110] below).
17. These submissions also address, in relation to each issue, the question whether, in point of fact, the Commonwealth’s approach would have made a difference. Sanofi submits that in each case the answer is ‘no’.

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

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

Part IV: Facts

19. SNOCS[7]-[12] provide an overview of the events relevant to the Commonwealth’s claim. Further detail relevant to the Commonwealth’s counterfactual theory may be seen in the PJC, which refers to primary documents contained in the PFM. The critical sequences are addressed in Part V below.
20. The Commonwealth submits that it ‘led an extensive evidential case’ on whether Apotex would have listed if not enjoined (CNOAS[12]). However, the Commonwealth glosses over its ‘most important’ witness, Mr Millichamp (PJ[148], AB51).
21. Seven affidavits from Mr Millichamp were read by the Commonwealth (PJC items 67B, 67F, 76A, 85DD, 103CC, 108AA, 120; PFM407, 473, 599, 651, 807, 935, 1370). As it ultimately emerged, his evidence was that Dr Sherman was the relevant decision-maker as to whether Apotex would launch at risk, but that decision had been made by Dr Sherman conclusively, and communicated by email, on 20 February 2007 and was not subsequently qualified. (PJ[149], [339], AB51, 98).
22. A challenge to Mr Millichamp’s evidence was upheld in key respects (eg, PJ[338]-[340], AB98-99). In particular, the primary judge did not accept that the 20 February 2007 email was an instruction on which Mr Millichamp would have considered himself entitled to act in late 2017 without reverting to Dr Sherman. That conclusion was undisturbed on appeal.

Part V: Argument on the Notice of Appeal

23. As addressed below, Apotex’s internal and external communications disclosed (subject to significant claims of privilege) a fluid decision-making process, involving consideration of particular circumstances at particular times, and accommodating variation of apparently settled plans by Dr Sherman. The material before the primary judge was inconclusive on the factual proposition advanced by the Commonwealth (PJ[286]-[291], AB86-87). The Full Court agreed, describing ‘an evidentiary lacuna’, in respect of which the primary judge ‘declined to speculate about what Dr Sherman would have done’ (FCJ2[219]-[220], AB267). That was why the Commonwealth’s claim failed. It cannot be resuscitated by adopting a different schema for the assessment of evidence.

Evidential burdens issue – NOA Ground 1

24. To succeed on NOA[1] (AB546), the Commonwealth must persuade this Court that the Full Court erred in two respects: *first*, that the Full Court was wrong to reject the Commonwealth’s three step schema, which the Full Court did on the basis that it does not find support in the authorities (FCJ2[88], [94]-[97], AB227, 229-230; *cf* CNOAS[36]-[45]); and *secondly*, that the Full Court was wrong to reject the submission that, if such a decision-making process were adopted, it would have altered the result (FCJ2[88]-[93], AB227-229; *cf* CNOAS[46]-[90]). The Commonwealth fails at both hurdles.

Preliminary observations

25. As observed in *Cessnock* at [128], citing the work of Professor Williams, ‘Burdens and Standards in Civil Litigation’ (2003) *Sydney Law Review* 165 at 168 the expression ‘evidentiary onus’ can be ‘used to mean different things’. As the author explains:

In the first sense the evidential burden means the burden of adducing evidence on an issue on pain of having the trial judge determine that issue in favour of the opponent. ...

The second sense in which the expression ‘evidential burden’ is used includes the burden resting upon a party who appears to be at risk of losing on a given issue at a particular point in the trial. The party is under an evidential burden in the sense that if the party does not produce evidence or further evidence he or she runs the risk of ultimately losing on that issue. ...

The former involves a question of law, while the latter involves merely a tactical evaluation of who is winning at a particular point in time. Among commentators who in fact distinguish between these two concepts, the expression ‘evidential

burden’ is commonly reserved for the former notion and the expression ‘tactical burden’ or ‘provisional burden’ is used to refer to the latter notion.

26. This distinction is well understood (see *Henderson v Queensland* [2014 HCA 52; (2014) 255 CLR 1 at [90] per Gageler J; *Cross on Evidence*, 10th Australian Edition at [7210]; *Cross and Tapper on Evidence* 13th ed at 123; Cowen and Carter, *Essays on the Law of Evidence*, 1956, Oxford, at 242-3). As the cited authors make clear, an evidentiary onus in the second sense may shift during the course of a hearing. The distinction is not addressed in the Commonwealth’s submissions; however, it seems clear that they use ‘evidentiary onus’ in the first sense.

The three-step decision-making process is unsupported by authority

27. The Commonwealth submits that the principle for which it contends is established by statements of Stephen J at 320 and Mason J at 332 in *Air Express* (CNOAS[38]). However, that is not the interpretation of *Air Express* that was adopted in *Coshott* at [18(e)], *Specsavers* at [7] and [15], *Sigma v Wyeth* at [122] and [144], PJ at [26]-[27] (AB19-20), or FCJ2 at [94]-[97] (AB229-230). In each of those judgments, proof by the claimant(s) on the balance of probabilities was required.
28. The Commonwealth diverges from those decisions because its reading of *Air Express* is mistaken. That case concerned a claim for loss sustained by Air Express by virtue of an injunction obtained by Ansett restraining permission for the import of two aircraft by Air Express. Sitting at first instance, Aickin J dismissed the claim, finding that it was probable that no import permission would have been granted even if there was no injunction on foot, having regard not to any testimony of the Commonwealth decision-maker (who was not called) but to inferences available from the circumstances (including the extent of the prejudice to the Commonwealth if the permission were granted and it ultimately failed in the litigation) (at 281-282).
29. On the Commonwealth’s proposed approach, that would not have occurred:
- a. the injunction restrained the very conduct which caused Air Express’ claimed loss, which would have raised a *prima facie* case (Step 1: CNOAS[36], [40]);
 - b. Ansett did not call the decision-maker to discharge any ‘evidential’ onus on it to propound an alternative theory as to what would have occurred absent the injunction (Step 2: CNOAS[36]); and
 - c. that would have left the *prima facie* case raised by Air Express ‘unanswered’, in the absence of ‘two competing hypotheses’ for the Court to evaluate on the balance of probabilities (Step 3: CNOAS[37]).

30. However, the decision of Aickin J was affirmed on appeal by Barwick CJ, Gibbs and Stephen JJ; Mason J dissenting.
31. The appellant in *Air Express* contended for the position which the Commonwealth now advances: that, once it was shown that the injunction restrained an act, and loss flowed from the non-performance of the act, the onus lay on the other party to prove facts enabling it to avoid or reduce liability (eg, that the loss would have been suffered in any event) (at 307-308). The respondent argued that the onus was on the claimant to prove its case, and it had to call the necessary witnesses (at 309) – that is the position adopted by the primary judge and affirmed by the Full Court here. The dismissal of the appeal in *Air Express* entails a rejection of the Commonwealth’s submission.
32. The reasons of the Court for dismissing the appeal are also inconsistent with the Commonwealth’s position.
33. Barwick CJ expressed his ‘complete agreement’ with Aickin J’s reasons (at 309-310). That is inconsistent with the Commonwealth’s position.
34. Gibbs J explicitly addressed the onus question, stating that the claimant ‘must prove that the damage he has sustained was caused by the making of the order’, and ‘must show that the making of the order was a cause without which the damage would not have been suffered’ (at 313). His Honour confirmed that the applicable evidentiary standard was the ‘balance of probabilities’ (at 314) and, critically, that the onus ‘does not shift’ to the party against whom the undertaking is sought to be enforced to ‘disentangle’ damage from the injunction and damage which had *a concurrent cause such as the litigation itself* (at 313). Gibbs J also said that the claimant’s failure to call the Secretary or the Minister raised an inference ‘that their evidence was not likely to assist its case’ (at 314). Those reasons are inconsistent with the Commonwealth’s case.
35. Stephen J said that ‘the proper approach’, consistent with Gibbs J, was that ‘unless [the claimant] can show that the injunction was a *causa sine qua non* its claim must fail’ (at 316). His Honour found that the injunction was *a* cause of the loss claimed (at 317), but whether there was a concurrent cause depended on speculation as to what the decision-maker would have done (at 318). Since there was an evidentiary deficiency regarding whether permission would have been granted absent an injunction, the question of onus was critical (at 318). Stephen J found that the *claimant failed because it had not called evidence* of what the decision-maker would have done (at 320). That is, the claimant bore the relevant onus. That is inconsistent with the Commonwealth’s case. It is irrelevant whether it seeks to characterise this as a finding at Step 1 or Step 3

(*cf* CNOAS[42]). It is a rejection of the proposition that the *respondent* must adduce evidence of an alternative cause of loss than the injunction itself.

36. The part of Stephen J's reasons relied on by the Commonwealth at CNOAS[39] is at the end of his Honour's judgment. The passage is as follows, adding in italics a sentence omitted by the Commonwealth (at 320):

[I]t 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. *In the present case Air Express failed to establish that but for the injunction there would have been a grant to it of permission to import the aircraft.*

37. In the context of his Honour's preceding reasoning, that statement cannot support an argument that a claimant need only raise a *prima facie* case before a substantive burden of proof ('evidential' or not) shifts to the respondent. Stephen J's statement means rather that Air Express had failed to establish even a *prima facie* case (*cf* CNOAS[42]), so that no inquiry as to damages was called for (*cf* *Air Express* at 254 and 268 (per Aickin J), finding that it was 'a proper case for an inquiry, whatever the result of the inquiry may be'). The Full Court, correctly, did not accept that Stephen J endorsed the principle for which the Commonwealth contends (FCJ2[94], AB229).
38. Stephen J also emphasised that in a claim on an undertaking the respondent is in no sense a wrongdoer, so the approach to an award is, if anything, less generous to a claimant than in tort or contract (at 319-320; and see also 310 per Barwick CJ).
39. Mason J's dissenting view on the merits in *Air Express* was produced by a different assessment of the evidence to that of the majority. His Honour did not simply identify a three-step schema which would, on the Commonwealth's argument, lead more or less directly to a reversal of the judgment of Aickin J. Instead his Honour engaged in a detailed examination of the facts, and explained why his inferences from that body of material would have been different from those of Aickin J (at 326-335). There are indications that that assessment may have been influenced by his Honour's appreciation of the practicalities of Commonwealth executive decision making (eg, at 333). Be that as it may, Mason J's judgment is not properly understood as erecting any approach to the assessment of evidence on an application of this kind that differs from the other members of the Court or detracts from the proposition his Honour stated at 325: '[I]t is for the party seeking to enforce the undertaking to show that the damage he has sustained would not have been sustained but for the injunction'. If this is wrong,

and the reasoning of Mason J departs from that of the other members of the Court, it must be rejected as it is in dissent.

40. Further, even if Stephen J's judgment is also read in accordance with the Commonwealth's submissions, only two judges could be taken to have endorsed that position. That would not be authority for the principle for which the Commonwealth contends. It is inconsistent with the decision and reasoning of the majority, and that of Aickin J. Further, Mason J was in dissent. A *ratio* cannot be constructed by a conglomeration of the reasoning of dissenting and concurring judges (*Dickenson's Arcade Pty Ltd v Tasmania* (1974) 130 CLR 177 at 188 per Barwick CJ; *Federation Insurance Ltd v Wasson* (1987) 163 CLR 303 at 314).
41. The Commonwealth's effort to draw support from *Purkess*, is also misdirected (cf CNOAS[41]). Barwick CJ, Kitto and Taylor JJ expressly rejected the proposition (which *Watts v Rake* (1960) 108 CLR 158 had been said to support) that once a plaintiff established a *prima facie* case that incapacity was a result of injuries inflicted by the defendant's negligence, the legal burden of establishing that the incapacity was wholly or partially the result of some pre-existing condition then rested on the defendant (at 167). Quoting from *Phipson on Evidence*, their Honours distinguished between the burden 'of establishing a case', and that 'of introducing evidence' (at 167-168). '[T]he burden of proof in the first sense is always stable, the burden of proof in the second sense may shift' (at 168). The reference to the latter burden 'shifting' indicates that the burden being addressed is the tactical burden, not an evidentiary burden in the first sense described by Williams. It is so treated in *Cross* at [7210], n 173.
42. The quotation from *Purkess* at CNOAS[41] cannot be taken as contradicting what had been said at 167. Rather it addresses a pragmatic question of proof (the tactical onus), applicable when, as Windeyer J put it, there is a question as to whether disability that *has been shown* to be caused by the tort had an independent concurrent cause (at 170-171). The trier of fact is not *practically* called on to address such a question unless the defendant adduces or can refer to evidence which gives the proposition sufficient substance. As Windeyer J put it, 'some material is required to support that suggestion. It is in this sense and at this stage that a burden of adducing evidence is upon the defendant' (at 171). The *quality* of that evidence was addressed by the plurality by reference to the trial judge's decision on the ultimate issue; that is, the evidence of an alternative, independent cause was so exiguous that it was proper for the trial judge to treat the defendant's negligence as the cause of the appellant's disability (at 168-169).

43. Further, the causation question in this case does not entail any attempt to set up an independent concurrent cause of the loss. There was only one causation question: would Apotex have sought and obtained PBS listing if not restrained from selling? That it may have had conflicting considerations to weigh is not to the point. And in any event, the considerations (the business opportunities offered by launch at risk and the business risks of the same) were in no sense independent. As Gibbs J said in *Air Express*, the effects of such considerations are not for the respondent to ‘disentangle’ (at 313).
44. The balance of the Commonwealth’s submissions on the issue of principle claim support from (a) authorities in other areas of law, (b) *Sigma v Wyeth*, and (c) English practice (CNOAS[44]-[45]). The reliance is misplaced.
45. *Sigma v Wyeth* was cited by the Full Court (FCJ2[96], AB229), *against* the Commonwealth’s reading of *Air Express*. Jagot J did not commence by pointing to a *prima facie* case in favour of compensation inferred from the existence of interlocutory injunctions, and then consider countervailing theories as to what would have occurred. Rather, her Honour applied the ordinary civil standard to the question whether the claimants had suffered ‘some loss’, which was found in the lost opportunity to exercise rights associated with ARTG registrations (for the generic claimants) and contractual rights to supply those generics (for the product manufacturers/suppliers) (see, eg, *Sigma v Wyeth* at [122], [144], [152], [174], [187], [210]). Damages were then assessed by reference to the percentage likelihood of those losses arising (see, eg, [17], [178], [181], [210]). Once her Honour examined the claimants’ internal documents and legal advice, claims that any of them would be the ‘first mover’ to list on the PBS and trigger a 12.5 percent price reduction for venlafaxine, which could attract a potential liability to Wyeth, were ascribed possibilities from 0% to 20% (see [17], [188], [283]).
46. The other Australian authorities cited (CNOAS[44]) apply the civil standard of proof, with the legal onus remaining with the moving party where there is a factual dispute, while (tactical) evidential onuses may shift in the process of proof. No three-step schema is outlined, the ordinary civil standard for final relief is not displaced by an intermediate standard, and a defendant is not required to establish an alternative hypothesis to that of the plaintiff. For example:
 - a. In *Potts v Miller* (1940) 64 CLR 282 at 308-309, Williams J accepted that ‘*prima facie* evidence of some damage sustained by the plaintiff by reason of the untrue statements in question’ was ‘enough to entitle him to an inquiry as to the amount of damages which he has sustained by such statements’ in accordance with

Chancery Division practice (the practice applied in *Air Express*). The practice saves a defendant ‘the trouble and expense of going into evidence which will be useless if the plaintiff fails to establish any liability’ (at 308).

- b. In *Gould v Vaggelas* (1984) 157 CLR 215 at 238-239, Wilson J (Gibbs CJ and Dawson J agreeing at 219 and 262) observed that ‘a plaintiff carries the burden of establishing every element of his cause of action’. In cases of deceit there is a ‘natural inference of fact’ that ‘the false representations played at least some part in inducing the plaintiff to enter into the contract’ (at 238). But a defendant has ‘no more than an evidentiary onus’ to point to ‘circumstances which tend to rebut the inference’ (at 238). Then, ‘[w]hen all the facts are in’, the court must determine ‘on the balance of probabilities’ whether ‘the misrepresentations ... contributed to the plaintiff’s entry into the contract’, and ‘[t]he onus to show that they did is a condition precedent to relief and rests at all times on the plaintiff’ (at 238-239; see also Brennan J at 250-251).
- c. In *Momcilovic v The Queen* [2011] HCA 34; (2011) 245 CLR 1 at [665], Bell J emphasised that an evidentiary onus ‘is not an “onus of disproof”’, and said (in the context of criminal proceedings) that it may be ‘discharged by evidence adduced in cross-examination of witnesses in the prosecution case’ or ‘by reference to evidence adduced by the prosecution in chief’.
- d. In *Henderson*, Gageler J (as his Honour then was), explained the inferential process reasoning for a conclusion on the balance of probabilities. One scenario that his Honour canvassed was that, ‘a party who bears the legal burden of proving the happening of an event or the existence of a state of affairs on the balance of probabilities can discharge that burden by adducing evidence of some fact the existence of which, *in the absence of further evidence, is sufficient to justify the drawing of an inference that it is more likely than not that the event occurred or that the state of affairs exists*’ (at [89], emphasis added). That is, a claimant’s evidence is still required to meet the civil standard of proof, and if an onus shifts to the other party, this is ‘nothing more than the practical need (sometimes referred to as a “tactical burden”) for an opposing party to adduce further evidence if that party wants to prevent such an inference of fact actually being drawn’ (at [90]).
- e. In *Berry v CCL Secure Pty Ltd* [2020] HCA 27; (2020) 271 CLR 151 at [39], Bell, Keane and Nettle JJ cited *Purkess* for the proposition that, although a claimant bears the ultimate burden of establishing its case on the balance of probabilities, the burden of introducing evidence shifts ‘as one scale of evidence or the other

preponderates'. Their Honours referred to a 'natural inference' where a wrongdoer purposely chose to achieve a certain result by deceit, and the consequence that follows if the fraudster does not adduce evidence that it would have brought about the same result by lawful means. At [65]-[73], Gageler and Edelman JJ similarly observed that the 'legal onus is constant', and found that the wrongdoer's pleaded defence on causation 'was left devoid of evidentiary foundation' because its witness was 'thoroughly disbelieved by the primary judge in findings undisturbed on appeal to the Full Court'. Here, on the contrary, Sanofi is not a wrongdoer (*Air Express* at 310 per Barwick CJ, and 319 per Stephen J), and the problem for the Commonwealth was that its evidence was unable to sustain its case.

- f. In *Poricanin v Australian Consolidated Industries Ltd* [1979] 2 NSWLR 419 at 425-426, Hope and Glass JJA quoted from an article by Justice Denning (as his Lordship then was), 'Presumptions and Burdens' (1945) 61 *L.Q.R.* 379, which explained an approach to proof at odds with the Commonwealth's. After noting that 'relevant facts or circumstances are often said to raise a "presumption" or make a "prima facie" case', the author stated: 'It is a mistake to raise these provisional presumptions into propositions having the force of law. They are recognized by the law but their force depends on ordinary good sense rather than on law' (at 380). Further, the author states that a respondent 'may seek to repel the inference by argument, as by submitting that the facts proved only raise a suspicion as distinct from a legitimate inference; or by contradicting the evidence: or by giving evidence of other facts to explain why the fact in issue should not be inferred; or by raising suspicions which counter-balance the presumptions' (at 379-380). This runs counter to the Commonwealth's Step 2, which requires the respondent to advance an alternative hypothesis (a 'reason B') and lead evidence that reason B would likely have led to the event not occurring (*cf* CNOAS[36]).
- g. In *Commissioner of Police v Zisopoulos* [2020] NSWCA 236; (2020) 299 IR 314 at [68], Bell P (as his Honour then was) noted that the distinction between an evidentiary burden and the legal burden 'was a familiar one regularly drawn by courts and tribunals'. His Honour referred to the judgment of Lord Donaldson of Lynton MR in *Amoco Oil Co. v Parpada Shipping Co. Ltd (The "George S.")* [1989] 1 Lloyd's Law Reports 369 at 370, which stated that it is 'trite law that the legal burden lies upon the claimant', and explained the usual cut and thrust of a trial in which a defendant must do enough to prevent the plaintiff's claim being accepted, or alternatively establish another defence.

47. Finally, the Commonwealth's reliance on English practice by reference to *Yukong Line Ltd v Rendsburg Investments Corp* [2001] 2 Lloyd's Rep 113 is mistaken (*cf* CNOAS[45]). That case concerned not an *assessment of damages* but whether there would even be an *inquiry into damages*. Potter LJ (with whom Thorpe and Hale LJ agreed) affirmed that 'the court will ordinarily order an inquiry as to damages in any case where it appears that loss *may* have been caused as a result' (at [33], emphasis in original). The question whether there should be an inquiry into whether the claimant has sustained any damage is considered by reference to a *prima facie* case, but that is not the standard by which compensation is ultimately assessed (see also [35]).
48. Further, as is alluded to at CNOAS n 18, *Ennismore Fund Management Ltd v Fenris Consulting Ltd* [2022] UKPC 27 stands against the Commonwealth's principle. In that case, the Privy Council held that cases such as *SCF Tankers Ltd v Privalov* [2018] 1 WLR 5623 do not stand for the proposition that an enjoined party succeeds by establishing only a *prima facie* case of loss. To the contrary, it remains incumbent on an enjoined party to prove on the balance of probabilities that but for the injunction it would have acted in a particular way and hence suffered loss (*Ennismore* at [64]-[67]).
49. In light of the foregoing, the Commonwealth cannot show error in the rejection of the three-step decision-making process for which it contends, and the appeal should fail.

The Commonwealth's submission does not reflect its case below

50. As to the principle sought to be established, it is differently expressed by the Commonwealth in this Court than it was in the courts below. In the Full Court, the relevant error at trial was said to be that the primary judge had failed to hold that the Commonwealth needed to establish no more than 'a *prima facie* case that its damage directly flowed from the grant of the interlocutory injunction' (Further Amended Notice of Appeal (FANOA), Ground 2, Particular (a), AB190-191; FCJ2[85], AB226), which the Commonwealth's submissions distinguished from proof 'on the balance of probabilities' (at [69], [94], PFM1685, 1691). However, the primary judge had recorded that it was 'common ground' that the question whether Apotex would have applied for PBS listing absent the Interlocutory Injunction was 'to be decided on the balance of probabilities' (PJ[26]-[27], AB19-20). That was consistent with the Commonwealth's written submissions to his Honour, which sought findings on the balance of probabilities (at [58], [78], [200]; PFM1552, 1559, 1589).
51. In the Commonwealth's written submissions to the Full Court, the position in the FANOA was expanded to accommodate a response to its *prima facie* case, by 'shifting an evidential onus to Sanofi to raise any countervailing considerations' (at [43]; see

also [53]; PFM1677, 1680). The Commonwealth submitted that Sanofi had to ‘make good’ the contentions on which it relied, and thereby ‘disprove’ the *prima facie* connection it had established (at [53]-[54]; PFM1680; emphasis added).

52. The Full Court held that the Commonwealth’s suggested approach was ‘not required by any binding or persuasive authority’, and was inconsistent with the way in which *Air Express* has been applied in the caselaw (FCJ2[96], AB229).
53. The Full Court also held (accepting Sanofi’s submission at [46]; PFM1715) that, even if an evidential onus did shift to Sanofi, that onus was discharged by material that had been adduced before the primary judge (FCJ2[89]-[91], AB227-228 citing *Purkess* at 167-168 and 170-171). ‘[I]t remained for the Commonwealth to discharge its persuasive burden’ on the Apotex Launch and Listing Issue (FCJ2[92], AB228). That is the issue on which the Commonwealth failed below (PJ[351], AB101; FCJ2[12], [14], [93], AB207, 229). The decision in *Purkess*, which is now at the centre of the Commonwealth’s argument (CNOAS[41]), was not referred to in its written submissions in the Full Court (see, relevantly, PFM1671-1673, 1679-1680, 1760).
54. In this Court, the Commonwealth puts its case subtly differently again. It asserts (in the absence of an existing finding) a *prima facie* case in support of its claim, and seemingly seeks to avoid consideration of its factual contention on the whole of the evidence and to the ordinary civil standard. While acknowledging a Step 3 (the application of the legal onus), the Commonwealth suggests that that step is ‘not reached’ (CNOAS[90]) *unless* there are ‘two competing hypotheses’ between which the Court must choose the ‘more probable’ (CNOAS[35], [37]). The implicit proposition that a party bearing the legal onus is entitled to judgment without the tribunal of fact being satisfied on all the evidence that its case is proved on the balance of probabilities is contrary to principle and authority.
55. Further, Sanofi was not asked at trial to establish such a competing hypothesis (or reason B), and the Commonwealth accepted in opening that it had been put to proof (T37.3-26). An obligation to advance a reason B at trial might have altered the conduct of the hearing (*cf Suttor v Gundowda Pty Ltd* [1950] HCA 35; (1950) 81 CLR 418).

The application of the three-step process would not have made a difference

56. As noted at [10] above, if this Court finds that the Commonwealth’s three-step approach should have been applied below, that does not immediately assist the Commonwealth since no finding has been made establishing any of those steps. Before turning to the evidence which stands against the Commonwealth at each step, two observations are made regarding the introductory aspects of Part V(c) of the CNOAS.

57. *First*, the Commonwealth's reference to a passage from Mason J in *Air Express* at 332 (see CNOAS[46]) begs the question: did the circumstances indicate otherwise than that Apotex being restrained by the Interlocutory Injunction caused damage to flow to the Commonwealth from the non-performance of an application for PBS listing? Sanofi submits that the Commonwealth has not established Step 1 either by inferences generally drawn or 'in spades' by evidence of Apotex's conduct (CNOAS[47]).
58. *Secondly*, CNOAS[48]-[50] purport to state the universe of commercial 'options' where a generic company considers listing a product on the PBS that is subject to an unexpired patent. It is unsupported by evidence. In any event, that outline does not cover what occurred in the present case. As summarised at PJ[10]-[16], AB16-17, Apotex was enjoined prior to trial with an undertaking as to damages, then after it *lost* at trial and a final injunction was ordered it procured a further undertaking as to damages as the price of agreeing to a stay on revocation of certain patent claims (PJ[105]-[107], AB38-39), and it also remained off the market with an undertaking as to damages after it *won* in the Full Court and Sanofi sought special leave. This was concrete evidence, not hypothetical, and not in circumstances remote from the position in September 2007, as to Apotex's actual weighing of the options.
59. The Full Court was alive to this. As noted above, their Honours emphasised the evidence relied upon by Sanofi to the effect that Apotex both appreciated that it 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 acted accordingly (FCJ2[90], AB228). Further, the Full Court observed that an option available to Apotex prior to the commencement of proceedings was to 'signal' that it was going to launch 'in order to goad Sanofi into seeking an interlocutory injunction and proffering an undertaking as to damages' (FCJ2[129], AB239). That possibility is exemplified in *Sigma v Wyeth* (eg, [450], [457], [778]).
60. Similarly, a generic company may also adopt a strategy, as Apotex did, of seeking to impress its customers by showing that it would 'fight the innovators in court if need be' (T308.37-40, PFM1506). It is an error to assume, as the Commonwealth does, that a generic company which resists an interlocutory injunction must be doing so because it has an irrevocable intention to supply the relevant product if not restrained.
61. In fact, the evidence adduced at trial demonstrated the sophistication in Apotex's decision-making (including in relation to the role of the usual undertaking as to damages), and the flexibility it had in its approach to dealings with a patentee.

The original plan

62. The evidence concerning Apotex's intentions to market clopidogrel in Australia relevantly commences in mid-2006. A financial model was provided to Mr Millichamp on 16 May 2006 (PJ[222], AB69; PJC item 7A; PFM101) and, on 19 June 2006, forecasts based on an October 2007 launch (including estimated margins and market shares) were provided by Mr Michael Weingarten (then Mr Millichamp's immediate superior) to Dr Sherman (PJ[223], AB69; PJC item 8; PFM107).
63. Dr Sherman responded promptly (PJ[224], AB69; PJC item 8; PFM107):

By [October 2007] the litigation should be over in both US and Canada. If we win, we will launch at risk in Australia on approval. If we lose in US and Canada, we will not launch.
64. That is, Dr Sherman intended to take the counsel of overseas courts on the validity of counterpart patents for clopidogrel, and launch in Australia only if successful overseas. However, Apotex Canada lost those contests in the US and Canada between the time of Dr Sherman's June 2006 email and the October 2007 timeframe to which it referred.
65. **Canada:** As at June 2006, an appeal was pending from an order of prohibition which prevented the issuance of a notice of compliance by the Canadian Minister of Health until expiry of Sanofi's Canadian patent (PJ[201]-[202], AB65-66). That appeal was dismissed on 22 December 2006 (PJ[202], AB66).
66. **United States:** As at June 2006, a settlement of US patent proceedings between Apotex Canada and Sanofi had been denied regulatory approval (which the parties learned in May 2006), and the same position would arise in respect of a second settlement in late July 2006 (PJ[210], AB67). A launch of clopidogrel by Apotex in the US was then enjoined at the suit of Sanofi on a preliminary basis in August 2006, and on a final basis in June 2007 (PJ[214]-[215], AB67-68).
67. Dr Sherman's June 2006 plan for Australia was not put into effect, presumably because the pre-conditions in the North American litigation did not come to pass. Whatever commercial success Apotex Canada ultimately procured under a further settlement with Sanofi (*cf* CNOAS[56]), its arguments on validity of patents for clopidogrel were not upheld, no doubt affecting Apotex's perceived prospects of success in Australia.

A revised plan

68. On 20 February 2007, Dr Sherman sent an email to Mr Weingarten and Mr Ivor Hughes (a lawyer who advised on intellectual property issues in Canada, the US and Australia), which was copied to Mr Millichamp (PJ[229], AB70; PJC item 15;

PFM118). Subject to a redaction by Apotex for privilege, that email disclosed a ‘[p]lan’ (emphasis added):

[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.

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

69. As the primary judge observed, the email ‘reflects a clear awareness on Dr Sherman’s part of the requirement for Sanofi to give an undertaking as to damages in return for any interlocutory injunction that it may obtain’ (PJ[231], AB71).
70. Dr Sherman’s 20 February 2007 email was sent when the US patent dispute was in its final week of hearing (PJC item 14A, PFM22). The reference to ‘*May/June*’ may have been when it was anticipated that the decision in the US would be known (as noted above, that decision was in fact handed down in June 2007). However, the primary judge found that the position in Australia by this time ‘no longer depended on the outcome of the litigation in Canada or the United States’ (PJ[232], AB71).
71. The greater significance of Dr Sherman’s February 2007 email at trial was that Mr Millichamp said that it was the one and only instruction on which he relied for the plan to launch clopidogrel at risk if Apotex was not enjoined (PJ[339], AB98). That was a development in the case. As opened in writing (at [97] and [99]) the Commonwealth had relied on Mr Millichamp as the relevant decision-maker. That position was to change in the course of the trial. The Full Court explains the progression of the Commonwealth’s case theory at FCJ2[380]-[383], AB307-308. The Commonwealth came to focus on the 20 February email as the ‘Rubicon’ (*cf* CNOAS[77]) for a decision to launch. Now the Commonwealth has a new theory.
72. The primary judge did not accept Mr Millichamp’s claim that, based on the February 2007 email, he was ‘entitled to act in late 2007 without reverting, either directly or indirectly, to Dr Sherman for the purpose of obtaining confirmation of that instruction and the necessary final approval from him authorising a launch at risk’ (PJ[340], AB98-99). His Honour also found Mr Millichamp’s evidence regarding a 27 June 2007 email which suggested a different position to be ‘most unconvincing ... largely non-responsive and evasive’ (PJ[250], AB76-77). That document is addressed below.

A re-confirmation?

73. On 22 June 2007, Mr Millichamp sent an email to his superior at that time, Mr Andrew Kay, to make a ‘recommendation ... that we should launch’ (PJ[234], AB71-72; PJC item 18; PFM 131). Mr Millichamp was seeking the approval of Mr Kay, following an adverse result in the US litigation delivered on 19 June 2007 (PJC item 17, PFM24).
74. Mr Kay replied twice to Mr Millichamp. The first of his messages sought ‘a timetable scenario of events going forward’ (PJ[237], AB72; PJC item 18; PFM130). The second put that request in a context which indicated how broad the options were at that time (PJC item 18; PFM130): ‘I know one option is not to apply for PBS listing’.
75. On 25 June 2007, Mr Millichamp provided the requested timetable, and adverted to the possibility that Apotex Canada might have changed its position (PJ[237], AB72-73; PJC item 19; PFM136, emphasis added):

[T]his is what we are planning but *if there is a different approach that is proposed from your side we will be happy to take that advice and recommendation.*

76. On 25 June 2007, Mr Kay asked Dr Sherman to ‘re-confirm or otherwise our approach in Australia’, and, ‘Do you want us to continue to launch and to invest in the revocation proceedings?’ (PJ[241], AB74; PJC item 20; PFM142). The next day, Mr Kay asked again, in terms that made clear that no final decision had been made: ‘Please advise *when you have decided* whether to pursue revocation of the enantiomer patent, and if you wish us to move to launch at risk’ (PJC item 21; PFM144; emphasis added).
77. Dr Sherman’s two responses to Mr Kay on 27 June 2007 were wholly redacted (PJ[244], AB75; PJC items 22 and 23; PFM144, 148). The absence of that evidence, including any uncertainties, nuances or contingencies that Dr Sherman’s emails may contain, did not assist the Commonwealth to meet its burden of proof. No direct evidence of Dr Sherman’s intentions to launch at risk in response to Mr Kay’s inquiries on 26 and 27 June 2007 was before the Court (*cf* CNOAS[85]).
78. On 27 June 2007, Mr Millichamp forwarded Dr Sherman’s messages to Ms Karen McTavish, the National Sales and Marketing Director at Apotex, with the words ‘*FYI – Game on!!!*’ (PJ[245], AB75; PJC item 24; PFM152), and also separately to Apotex Canada’s Corporate Project Manager, Mr Stephen Haas (PJC item 25; PFM148). Mr Millichamp’s email to Mr Haas (which is also heavily redacted for privilege) is more circumspect (PJ[246], AB75; PJC item 25; PFM148; emphasis added):

[redacted]

[redacted] *If we are successful in avoiding an injunction we will plan to launch subject to Barry’s further advice / approval.*

If anything changes I'll let you know.

79. On 28 June 2007, at 10.28pm, Mr Millichamp sent a second email to Mr Haas, copied to others, which said (FCJ2[313], AB288; PJC item 29; PFM156; emphasis added):
[redacted] *as per instructions from Barry the plan (in outline) for clopidogrel is as follows:*
- 1) Seek to revoke the Sanofi patents at time of TGA approval – circa end July start August this year.
 - 2) Sanofi will apply for interlocutory relief. If they get it and we are enjoined we will not be able to launch until after final trial (if we are successful) which could be 18 months away from now or more.
 - 3) *If we are successful in defending our position vs Sanofi and an injunction is not granted by the courts then we will launch.*
 - 4) *We will not be able to get PBS listing until earliest December 07.*
 - 5) Therefore if we are successful and are able to launch we will need product (blister packed by Apotex) in Australia ideally end October but latest Mid November. ...
80. The Commonwealth seeks to make much of the unqualified ‘instructions from Barry’ referred to in Mr Millichamp’s email to Mr Haas on 28 June 2007, in contrast to the qualified position in his 27 June 2007 message to the same recipient (CNOAS[58], [87]). However, it is not suggested that Mr Millichamp had different instructions on 28 June 2007 than he had on 27 June 2007. Indeed, In his oral evidence, Mr Millichamp maintained that he was relying on instructions from February 2007 (T301.14-19; PFM1499; T304.15-32; PFM1502). That implicitly rejects the idea that there was some material instruction, not revealed by the documents, from Dr Sherman in late June 2007. There is no evidence of intervening instruction from Dr Sherman.
81. That leaves the Commonwealth to submit that the language of the email referring to ‘further advice/approval’ should be read as referring only to precise details of supply arrangements or advice as to implementation of the plan (CNOAS[85]). That understanding was not offered by Mr Millichamp in his testimony (PJ[249], AB76). Both the trial judge and the Full Court instead found the language of the email, taken in context, to be inconsistent with the Commonwealth’s case as ultimately advanced (PJ[246]-[251], AB75-77; FCJ2[174], AB255). Indeed the Full Court, on this topic and generally, paid tribute to the trial judge’s ‘most thorough and searching excavation of the very complicated factual questions which this case generated’ (FCJ2[387],

AB310). Those coordinate findings as to the proper interpretation of the emails are not the subject of a ground of appeal in this Court. Further:

- a. Mr Millichamp, in responding to the commonsense proposition that important business decisions would generally be finally made at the latest possible time, so that they could be made with the benefit of the most up-to-date information, gave evidence that while ‘key strategic decisions’ were often made early there would be ‘variations to the decision’ or ‘tactical changes’ as ‘matters change’ or ‘move along’ (see transcript extract at PJ[283], AB84). That is consistent with Dr Sherman keeping under review whether Apotex should launch at risk; and
 - b. Mr Haas (who had seen Dr Sherman’s own messages the day before) did not consider that Mr Millichamp’s 28 June 2007 email contained a launch plan that was to be put into action without further reference to Dr Sherman. To the contrary, he replied and queried, ‘Is Barry in the loop [on] the strategy below (potentially launch end October but latest Mid November)?’ (PJC item 29A; PFM160).
 - c. The interpretation of the email adopted by the trial judge and the Full Court is harmonious with the text of Apotex’s communication to pharmacists (see below).
82. The Full Court accepted that the primary judge did not refer to Mr Millichamp’s 28 June 2007 email, but that was because ‘he correctly did not think it was material’ in light of earlier and later emails concerning launch planning (FCJ2[141], AB243).

No promises

83. Other documents also confirm that any decision to launch at risk was subject to Dr Sherman’s ‘further advice and approval’. On 17 August 2007, Mr Millichamp provided a letter to the Apotex sales team, which was sent to its pharmacist customers. The letter stated (PJ[260], AB78-79; PJC item 45; PFM236; emphasis added):

GenRx Pty Ltd obtained registration of clopidogrel 75mg (as hydrogen sulfate) tablets under the provisions of the TGA on 17th August 2007. We intend to launch this product into the Australian market in the near future However, before launching these products we need to take the actions outlined below:

- GenRx has applied to the Federal Court of Australia for an order to revoke Sanofi-Aventis's patent covering clopidogrel and its pharmaceutically acceptable salts ...
- Sanofi-Aventis may respond to our application for revocation of its patent and signalled intention to launch by applying for an interim injunction to prevent us from launching our product into the Australian market. Of course, we would vigorously defend any such application. However, if they do this, we will not

seek PBS listing for clopidogrel or take orders from pharmacists until the outcome of that application has been determined. ...

- *Assuming Sanofi-Aventis do apply for an interim injunction, then **the decision whether to launch these products will be delayed** until the outcome of that application has been determined (one or two months). We will continue to keep you informed of the status of the proceedings.*

Regardless of the outcome of Sanofi-Aventis application for an interim injunction (should they make one), we will continue with our challenge to the validity of the clopidogrel patent before the Federal Court of Australia. *We anticipate that the revocation proceedings for Australian Patent No. 597784 would be likely to proceed to trial within approximately 12-18 months.*

84. As the primary judge found, and the Full Court affirmed, ‘Apotex ... had not committed itself to launching in the event no interlocutory injunction was granted’ (PJ[288], AB86; FJC2[118], AB235). Contrary to the Commonwealth’s submissions, there was no ‘false doubt’ as to Apotex’s intentions in its public statement (*cf* CNOAS[89]). The second bullet point of the letter explained that Sanofi ‘may’ apply for an interlocutory injunction, in which case Apotex would ‘not seek PBS listing ... or take orders from pharmacists’ until the outcome of that application was known. However, the third bullet point provided cover for Apotex *not* to press ahead with a launch even if it were free to do so.
85. There was no ‘misinterpretation’ of Apotex’s letter to pharmacists by the courts below (*cf* CNOAS[89]). The two scenarios addressed by the Commonwealth’s submissions are not what the key text addresses, which is that ‘the decision *whether to launch*’ would await the interlocutory decision (PJ[288], AB86; FJC2[118], AB235; emphasis added). (That Sanofi interpreted the letter as a threat of patent infringement is beside the point: FCJ2[119]-[120], AB235; *cf* CNOAS[62]).
86. As to this deferral of a final decision, Mr Millichamp accepted that there was value in waiting to see a judgment on an interlocutory injunction application (PJ[283], AB84-85; PFM1511-1512). For example, a judgment refusing an injunction on the balance of convenience may express strong views adverse to the likelihood of revocation, which may cause a commercial decision-maker to reflect on the risks of a launch, in comparison with its rewards. Apotex had good reasons to keep its options open.

Changed circumstances

87. The position stated by Apotex to its customers in August 2007 was inconsistent with the Commonwealth’s case that the plan to launch was fixed and not subject to further

consideration by Dr Sherman (FCJ2[120], [155], AB235-236, 248-249). In particular the letter to pharmacists suggested that any plan in June 2007 was not fixed, or could be overtaken by subsequent events. The position was, as Mr Millichamp said in June 2007, ‘subject to Barry’s further advice/approval’. Two events did then alter the decision-making parameters for Dr Sherman.

88. *First*, Apotex’s anticipated launch date moved back 4 months. To the extent that a plan was made by Dr Sherman in the first half of 2007, it was a decision with a temporal component – it involved PBS listing from 1 December 2007. However, that had to be revisited because Apotex missed the 1 September 2007 application deadline:
- a. Apotex made an application dated 1 September 2007 to list on the PBS from 1 December 2007 (PJ[261]-[263], AB79), and sought confirmation that it could ‘defer or withdraw this application ... without triggering the 12.5% price decrease providing we notify you in writing by or before the 12th October 2007’.
 - b. However, the application did not reach the Department until 4 September 2007. Apotex was informed that it had missed the deadline (PJ[10], AB16).
 - c. On 4 September 2007, Apotex withdrew the application. The next possible PBS listing date was then 1 April 2008 (PJ[264], AB79-80).
89. *Second*, the anticipated timing of a trial decision came forward by many months. Apotex’s communication to its customers anticipated a hearing in 12 to 18 months from mid-August 2007 (PJ[260], AB78-79; PJC item 45; PFM236). A judgment would have been expected to follow an indefinite period later. However, the proceedings moved faster than that because of an event which occurred *after* Gyles J indicated on 21 September 2007 that an interlocutory injunction would be made:
- a. On Thursday, 13 September 2007, a directions hearing was conducted by Bennett J (PJC item 59; PFM372). A short track to a final hearing was foreshadowed, but the first priority was a prompt interlocutory hearing (PJC item 59A; PFM349).
 - b. On Monday, 17 September 2007, Sanofi filed its defence and cross-claim, and sought interlocutory relief by motion (PJC item 67; PFM399, 405).
 - c. On Tuesday, 18 September 2007, Gyles J heard the interlocutory application. At the conclusion of the hearing, his Honour indicated that he would ‘deliver judgment and deal with directions at 9.30 on Friday’ (PJC item 69; PFM580).
 - d. On Friday, 21 September 2007, Gyles J delivered reasons orally as to why an interlocutory injunction should be granted, and informed the parties that the proceeding would be fixed for a final hearing before him commencing on 28 April

2008 (PJC item 73). That was the first point at which the hearing date was known to the parties. Also, the identity of the trial judge was significant: Gyles J's retirement date was 22 August 2008, and accordingly a judgment needed to be delivered by then (PJ[565], AB148).

90. The Commonwealth submits that the change in the PBS listing date was known to Apotex when it resisted imposition of an injunction on 18 September 2007 (CSNOAS[75]). That is so, but the Commonwealth is wrong that '[b]oth developments [referred to above] were ... 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 deposed to Gyles J that it intended to list and launch' (CNOAS[77]). The timing of the final hearing and judgment from Gyles J could not have been taken into account in any 'considered instructions' from Dr Sherman to resist Sanofi's interlocutory application on 18 September 2007 (*cf* CNOAS[65]).

The Commonwealth's evidentiary deficiency

91. The primary judge attached significance to 'the coincidence of events that ... led to both a PBS listing on 1 April 2008 (in the counterfactual scenario in which no interlocutory injunction was granted) followed by the commencement of the trial of the patent proceeding ... later that month was a result of developments that could not have been anticipated until about the time the interlocutory application was determined' (PJ[341], AB99). To be clear, the position had developed as follows:
- a. In August 2007, Apotex was contemplating a launch on 1 December 2007, with a trial commencing between August 2008 and February 2009. If a judgment was delivered between early and the middle of 2009, that would mean approximately 18 months of sales from the time of its PBS listing to a first instance decision.
 - b. No different understanding of Apotex is suggested up to the interlocutory hearing before Gyles J. That period includes when undertakings not to launch and list were sought by Sanofi on 24 August 2007 (PJC item 48A; PFM241) and 3 September 2007 (PJC item 52A; PFM329), in exchange for undertakings as to damages. Those undertakings were declined by Apotex when a 1 December 2007 PBS listing was still in play (PJC item 57; PFM341).
 - c. When the interlocutory injunction application was made on 17 September 2007 and heard on 18 September 2007, Apotex understood that a trial might be set down as soon March 2008 (subject to the availability of expert witnesses), but it did not have a clear expectation as to when a decision would be made, or how long that would be after a 1 April 2008 PBS listing.

- d. Only after Gyles J delivered his oral reasons in relation to Sanofi's interlocutory application on 21 September 2007, and made directions to determine the matter himself before his August 2008 retirement, did Apotex appreciate that it would have a judgment within 5 months of a 1 April 2008 PBS listing.
92. The question for the primary judge concerned only that last scenario, and that was one on which there was no indication of Dr Sherman's attitude, whether drawn from responses to his 27 June 2007 emails, or Apotex's position in response to Sanofi's notice of motion filed on 17 September 2007.
93. That was why the primary judge found the Commonwealth's case to suffer from an evidentiary deficiency which could not be 'made good by drawing inferences from correspondence written by Dr Sherman in the lead up to the hearing of the interlocutory application' (PJ[349], AB101; see also PJ[286], AB86). His Honour specifically found that it could not be inferred that, 'if Dr Sherman had known that the trial of the patent proceeding would commence in the same month that Apotex ... obtained a PBS listing of its clopidogrel products (triggering a 12.5% statutory price reduction), that he would have, in those circumstances, authorised Apotex ... to obtain such a listing before judgment was delivered or, at least, until the trial had concluded (by which time he and his colleagues and his legal advisers may have had a clearer view of the strength of Sanofi's case)' (PJ[349], AB101). The Full Court affirmed the primary judge's finding that the Commonwealth's evidence did not address the critical decision point for Apotex (FCJ2[99]ff, especially [174], [189], [193], [211]-[220], AB230ff).
94. It is on the basis of the evidence and findings referred to in [62]-[93] above, together with the commercial considerations implied by the material discussed below, that Sanofi submits that this Court would, in the particular circumstances of this case, hesitate to make a finding of a *prima facie* case established by the Commonwealth, (at Step 1), let alone a finding on the balance of probabilities on all the evidence (at Step 3), inconsistently with the decisions of the primary judge and Full Court. As to the position at Step 1, the relevant sense in which a *prima facie* case needs to be established, on the authorities referred to at CNOAS[44], is not the interlocutory standard addressed in, eg, *Australian Broadcasting Corporation v O'Neill* [2006] HCA 46; (2006) 227 CLR 57 at [65] per Gummow and Hayne JJ). Rather, there must be evidence sufficient to justify the drawing of an inference that 'it is more likely than not that the event occurred' (see *Henderson* at [89] per Gageler J).

Apotex's consideration of risk and reward

95. The balance of the evidence to which Sanofi draws attention is directed to the discharge of any evidential onus it bears (at Step 2), and for the purpose of the consideration of the whole of the evidence on the balance of probabilities (at Step 3).
96. In this regard, Sanofi certainly did more than 'merely to suggest' (per *Purkess* at 168) some result different to that which the Commonwealth sought to establish. Sanofi did not simply 'speculate' in closing submissions to the primary judge that there might be reasons for Apotex not to have listed on the PBS even if the Interlocutory Injunction had not been ordered. The primary judge, and the Full Court, found Sanofi to have extracted evidence by cross-examination, and to have relied on documents in the Commonwealth's case, regarding the significance to Apotex's decision-making of a potential liability for patent infringement (consistent with SFAPOD [62(b)] and [63(d)]; PFM1329-1330, 1337).
97. The commercial question regarding whether the *risk* of a launch by Apotex while the Patent remained unexpired and unrevoked was exceeded by the *reward* available was front and centre throughout the hearing. For example:
 - a. The risk of patent infringement was part of the calculus dating back to 2006, when successes overseas were preconditions to a launch here (PJ[224], AB69).
 - b. Mr Millichamp testified that Apotex Canada was 'aware there was a huge exposure, or a very substantial exposure' in a launch at risk (PJ[315], AB91). That was also reflected in a June 2007 estimate of up to \$70M in damages for one year's impact of the automatic price reduction (PJ[312], AB91; PJC item 19; PFM135).
 - c. An analysis provided to Mr Kay in July 2008 showed an exposure of \$166M (five times potential profit) if Apotex launched after success at trial but lost on appeal. Mr Kay said that 'the best outcome would be that we win at first instance, [Sanofi] appeal and the injunction remains in place pending appeal [so] we don't expose ourselves to potentially ruinous damages, but would collect damages off [Sanofi] for the further period of being off the market in the event the [Sanofi] appeal fails' (PJ[293]-[306], AB87-90; PJC items 80, 80A, 80C, 83A; PFM609, 617).
 - d. Following Apotex's success on appeal in September 2009, it estimated a potential exposure to Sanofi of \$650M (six times potential profit) over four years if this Court intervened (PJ[310]-[311], AB90; PJC item 89A; PFM673). Despite the result in the Full Court, Sanofi and Apotex provided further undertakings to preserve the *status quo* pending determination of an application for special leave,

which was rejected in March 2010 (PJ[16], AB17). Apotex elected to rely on an undertaking as to damages and avoided any exposure to damages.

98. Assuming the Commonwealth's schema, there was ample material from which a Court could conclude that Step 2 was satisfied by Sanofi, discharging any evidential onus on it. That material supported the contention that Sanofi had pleaded: the absence of an interlocutory injunction would not have been the end of Apotex's decision-making as to whether the risk of liability for infringement was outweighed by the commercial reward of a launch at risk. Accordingly, it remained for the Commonwealth, on all the evidence, to satisfy the tribunal of fact of the matter for which it contended.
99. The Commonwealth appears to suggest that reference to events in 2008 or 2009 cannot be used as evidence at Step 2 since they post-date the relevant decision point (CNOAS[69]-[70]). However, there was no error in the Full Court's reasoning: it is elementary that 'evidence of the later occurrence of an event can be probative of the earlier probability of that event occurring' (*Paciocco v Australia and New Zealand Banking Group Ltd* [2016] HCA 28; (2016) 258 CLR 525 at [169] per Gageler J (as his Honour then was); see also *R v Biber* [2018] NSWCCA 271 at [27] per Meagher JA, Hoeben CJ at CL and Fagan J, rejecting the proposition that later conduct could not be relevant to an inquiry as to the respondent's intent at an earlier time).
100. As to the other points made by the Commonwealth in relation to Step 2, *first*, the submission that no document from Dr Sherman in 2007 'indicated he was wavering in his desire to launch at risk in Australia' (CNOAS[83]) ignores that Dr Sherman's relevant emails were redacted. There is no material document from Dr Sherman on either side of the record. That cannot assist the party with the burden of proof. The Commonwealth also does not grapple with the fact that all of Dr Sherman's relevant emails precede 21 September 2007, at which point the decision-making parameters changed. There is no evidence that Dr Sherman had decided (illogically) to launch at risk 'come what may'. The changed circumstances thus had to be confronted.
101. *Secondly*, insofar as the Commonwealth relies on preparations for launch (CNOAS[60]), the Full Court's conclusion at FCJ2[174], AB255 is unimpeached:

The critical aspect of the supply arrangements, such as they were, was that it remained open to Apotex to decide not to launch without having incurred any substantial expense. Once that is appreciated, the Commonwealth's submission that the trial judge ought to have considered these matters before making the finding at J [340] must fail. Far from undercutting the trial judge's conclusion at J [340], the paucity of the arrangements for supply which had been made

demonstrate only that Dr Sherman's instruction not to waste money on launch activities was consistent with Dr Sherman taking the position that he would wait and see the outcome of the injunction application before making the decision.

102. The Commonwealth cannot show error in the decision of the Full Court, and accordingly the appeal should be dismissed.

Mode of proof issue – NOA Ground 2

103. The second error asserted by the Commonwealth is that the courts 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' (CNOAS[91], emphasis in original, citing PJ[339]-[349], AB98-101; FCJ2[220], AB267). That contention fails at its premise.
104. Neither the primary judge nor the Full Court expressly or implicitly imposed a requirement for hindsight or direct testimonial evidence. Both courts addressed the case as it had been advanced by the Commonwealth, finding that it suffered from an evidentiary deficiency where the Commonwealth bore the onus of establishing that Apotex would have listed its products on the PBS at risk. The evidence (including contemporaneous documents) indicated that any decision to launch at risk was subject to Dr Sherman's 'further advice/approval', and there were powerful objective reasons for him to withhold that approval or pursue a different strategy.
105. Far from engaging in speculation about what Dr Sherman would have done in the period from about 21 September 2007 to early 2008, without evidence from him or material from which an inference could be drawn about his thinking in the relevant circumstances, the primary judge quite correctly *declined* to speculate, and the Commonwealth failed to discharge its onus (FCJ2[219]-[220], AB267).
106. There is no tension between that position and comments by made Jagot J in *Sigma v Wyeth* as to the weight to be given to hindsight evidence (*contra* CNOAS[92]). *First*, the relevance of those comments is that, given the objective circumstances, including the asymmetrical risks and rewards involved in launching at risk, the Commonwealth might well have failed to discharge its onus even if Dr Sherman had given the evidence sought by the Commonwealth. Such was the position faced by the generics in *Sigma v Wyeth*, who all led direct evidence from their executives but failed to establish, to a probability of 51% or greater, that they would have supplied under the PBS at risk.
107. *Secondly*, the Commonwealth *did* adduce direct testimonial evidence as to the Apotex counterfactual, from Mr Millichamp. But he was the wrong witness. And his evidence

was at odds with the contemporaneous documents (eg, PJ[250]-[251], AB76-77; FCJ2[386], AB309). That reasoning is thus consistent with *Sigma v Wyeth*.

108. The broader proposition apparently contended for by the Commonwealth is that all hindsight evidence of intention is unreliable, and the only evidence of value in a case of the present kind is ‘direct contemporaneous evidence’ (CNOAS[94]). However, that proposition too is unhelpful to the Commonwealth since *direct* contemporaneous evidence is precisely what it did *not* have. Dr Sherman’s relevant emails were wholly redacted, and the Commonwealth now seeks to establish its case by relying on *indirect* evidence, and particularly inference from the words and conduct of others (Apotex employees and its lawyers) as to what Dr Sherman said, and what he would have done.
109. As to *Jones v Dunkel*, there was below a ground of appeal directed to the point at CNOAS[95] (ground 2(c)(ii), AB191) but there is not here. In any event the argument conflates a question of onus with the role of adverse inferences in fact finding. The Commonwealth does not challenge *Air Express*, which supports a *Jones v Dunkel* inference in this case (at 314 per Gibbs J; and see per Stephen J at 317-318 and 320).
110. Further, the authorities concerning the role of an evidential onus do not impose on Sanofi a need to establish any proposition on the balance of probabilities. It discharged any onus that it had to bring forward evidence contrary to the Commonwealth’s case. That is, it is both contrary to *Air Express* and a reversal of the legal onus, for the Commonwealth to say that it was for Sanofi to call Dr Sherman in opposition to the claim (*cf* CNOAS[95]).
111. Finally, for the reasons submitted above, if there was an error of the type asserted by the Commonwealth, it did not make any difference to the result.

Part VI: Argument on the Notice of Contention

112. Sanofi will supplement the arguments made in the SNOCS in its submissions in reply.

Part VII: Estimate

113. Sanofi maintains its estimate provided in SNOCS[75] that it will require up to 7 hours to present its combined arguments on the NOA and NOC.

Dated: 3 June 2024

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