HIGH COURT OF AUSTRALIA

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Details of Filing

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Important Information

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IN THE HIGH COURT OF AUSTRALIA
SYDNEY REGISTRY

ON APPEAL FROM THE FULL COURT OF THE FEDERAL COURT

BETWEEN:

Commonwealth of Australia
Appellant

Sanofi (formerly Sanofi-Aventis)
First Respondent

Sanofi-Aventis US LLC
Second Respondent

Bristol-Myers Squibb Investco LLC
Third Respondent

APPELLANT'S REPLY TO THE RESPONDENTS' SUBMISSIONS ON THE NOTICE OF APPEAL

Part I: Certification

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

Part II: Reply

2. The usual form of an undertaking as to damages is expressed to protect third parties. Claims on undertakings as to damages necessarily involve questions of past hypothetical fact: what would have happened but for the court's intervention in support of a legal right asserted by a party that was ultimately shown to have no legal basis? In some cases, the hypothetical exercise might well be difficult. In others, as in this one, it ought to be straightforward even if the party giving the undertaking may be motivated to suggest the exercise needs to be far more complicated and fraught with uncertainty. That is why the three-step structure is important. It reflects equity's concerns in cases of this kind, as well as the realpolitik of the circumstances.

3. Here, the answer on the claim for compensation by a third party ought to have been straightforward: (a) Apotex refused to accept Sanofi's undertaking and consent to the injunction, contested the application for the injunction and offered security of $50M with liberty to top up; (b) Sanofi has never directly challenged the sworn evidence of Apotex and the submissions of Apotex's Senior Counsel before Gyles J that Apotex would do the very thing that Sanofi now says Apotex would not have done; (c) discovery of Apotex's internal documents did not suggest any attempt to deceive Gyles J; and (d) before Gyles J, Senior Counsel for Sanofi recognised that the Commonwealth would be protected by the injunction.

4. Sanofi does not confront those issues. Rather, it submits that (a) the Commonwealth's schema is inconsistent with authorities and involves *"a misapprehension as to the meaning of an evidentiary onus, and its significance"* (Respondents' appeal submissions (**RAS**) [7]); (b) even if the schema applies, the Commonwealth does not succeed (RAS [14]); and (c) the case the Commonwealth advances before this Court is inconsistent with its case in the Courts below: RAS [7]. Those submissions are wrong: Sanofi mischaracterises the Commonwealth's appeal submissions (**CAS**) on the correct legal principle, advances theories unsupported by the evidence, and incorrectly captures how the Commonwealth put its full case before the Courts below.

The attack on the Commonwealth's submissions as to principle misfires

5. Sanofi makes the following errors on the correct legal principle.

6. The *first error* is to conflate the concepts of <u>legal onus</u> (which, on a question of

causation rests always on a claimant) and evidentiary burden (which may shift during the hearing): *cf* RAS [3], [7], [25]. The principle articulated at CAS [36]-[37] reflects that conceptual distinction: *cf* RAS [25]-[26]. It is consistent with the description in *Henderson v Queensland* (2014) 255 CLR 1 at [90] (Gageler J) that evidence adduced by the party bearing the legal burden of proof may give rise to a *"presumption or inference of fact"*, which will create a *"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 in the circumstances of the case"*: *cf* RAS [26], [46(d)]. It is also consistent with the approach taken in cases such as ***Air Express*** (1981) 146 CLR 219 and ***Purkess*** *v Crittenden* (1965) 114 CLR 164 where (unlike in *Henderson*) the court is grappling with assertions by parties of past or future hypothetical facts: see further [7]-[8] below.

7. The *second error* is related, being Sanofi's attempt to refute the Commonwealth's articulation of principle by cherry-picking from different aspects of the judgments in *Air Express* without recognising which parts were directed to questions of legal onus or evidentiary burden (and, if the latter, at what step): RAS [28]-[40]. While it is correct that the appeal from Aickin J was dismissed, that did not *"[entail] a rejection of the Commonwealth's submission"*: *cf* RAS [31]. The Commonwealth maintains that its analysis of *Air Express* at CAS [39]-[43] is correct, including because (unlike Sanofi's analysis) it appropriately delineates as to which issue (legal onus or evidential burden (and if the latter, at which step)) the statements in each judgment were directed.

8. The *third error* is to argue that "*[t]he Commonwealth's effort to draw support from Purkess"* is *"misdirected"* because the plurality rejected the possibility of any shifting legal onus: RAS [41]. The Commonwealth does not argue for a shifting of the legal onus; rather, it draws upon the principles about evidentiary burdens in the context of hypothetical fact-finding that the plurality in *Purkess* stated at 167 in the passage reproduced at CAS [41] and is consistent with those parts of Windeyer J's judgment (at 170-171) upon which Sanofi itself relies: RAS [42].

9. The *fourth error* is to submit that the Commonwealth's reliance on ***Sigma*** *Pharmaceuticals (Australia) Pty Ltd v Wyeth* (2018) 136 IPR 8 and other areas of law is misplaced: RAS [7], [44]-[48]. The Commonwealth does not rely upon *Sigma* to argue that inferences from the existence of the interlocutory injunction are enough to establish a *prima facie* case and that countervailing theories as to what would have occurred absent the injunction are then to be considered: *cf* RAS [45]. Sanofi's

submission mischaracterises the Commonwealth's principle and the approach Jagot J took in *Sigma*: see CAS [45]. As to the other areas of law, the Commonwealth does not rely upon the cases at CAS [44] to argue that the *"ordinary civil standard"* for relief is *"displaced by an intermediate standard"* or that a defendant is *"required to establish an alternative hypothesis to that of the plaintiff"*: *cf* RAS [46]. Rather, those cases reflect that the principle as stated by the Commonwealth has resonance with the approach taken in other contexts.

10. The *fifth error* is the not-so-subtle use of pejorative labels to describe the Commonwealth's principle (eg, *"a rigid three step framework"* (RAS [7])) to avoid confronting the real problem the principle poses for Sanofi's case. Rigidity is an inapt description of how the principle works in practice. The problem for Sanofi is that the three-step approach exposes that the reasoning underpinning Sanofi's defence on causation is smoke and mirrors: see paragraphs [12]-[22] below. The important point is that the three-step approach is a benefit, not a drawback. It provides an analytical tool capable of enabling equity, when adjudicating claims on undertakings as to damages, to identify fairly and pragmatically whether the Court's orders have been the cause of damage to a party, including – as in this case – a third party.

11. The *sixth error* is to assert that the Commonwealth's argument as to evidentiary onus raises a false issue: *cf* RAS [8]. The question for the Courts below was what would have happened if Gyles J had not made the injunction? On that question, the parties had competing hypotheses, and it was the Court's task, if it reached Step 3, to assess which hypothesis was correct: see CAS [37]. It adds nothing to say that there was only *one* causation question or that the Commonwealth was required to prove its theory of causation and that the legal burden did not shift: *cf* RAS [8], [43]. That submission by Sanofi hides that there was one causation decision which was a choice between two competing causal hypotheses (the Reason A advanced by the Commonwealth and any Reason B advanced by Sanofi).

Smoke and mirrors: Sanofi's submissions as to Steps 1 and 2

12. Sanofi pleaded to the Commonwealth's case on causation that, if the injunction had not been made, Apotex would not have sought PBS listing for a series of reasons.[1] Before this Court, Sanofi advances three theories. It is not clear if the theories are directed to refuting that the Commonwealth met its evidential burden at Step 1, or

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[1] *cf* Amended Points of Claim at [62]-[64], item 112A (PFM vol 3/tab 89/**p. 1108**); Second Further Amended Points of Defence at [62]-[64], item 117 (PFM vol 4/tab 101/**pp. 1329-1340**).

showing that Sanofi satisfied its evidential burden at Step 2. Not all the theories were run at trial; one not run at trial (the "game" theory) is sourced in the Full Court's reasons. In any case, each theory should have been rejected by the Courts below.

13. The *first theory* is that at the time of the hearing before Gyles J, Apotex had deferred making a decision on whether to apply for PBS listing until after the outcome of Sanofi's interlocutory application was known. On this theory, Mr Millichamp's evidence of what Apotex intended to do was his personal inclination, not evidence of what Apotex (as directed by Dr Sherman) would do once the time for a decision to be made arose: see RAS [4(b)], [83]-[90], [100]. The theory rests primarily on a reading of a letter from Apotex to customers on 17 August 2007 (**August Letter**)[2] as delaying a decision to launch, and the supposed premise that Apotex had no need to decide by the time the interlocutory application was heard.

14. As to the August Letter: Sanofi emphasises (RAS [83]) the third bullet point that says *"[a]ssuming 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)"*. Sanofi submits that this *"provided cover for Apotex not to press ahead with a launch even if it were free to do so"*: RAS [84]. However, Sanofi reads the bullet point without any regard to its context, as did the primary judge (PJ [288], AB 86) and Full Court: FC [118], AB 235. The context was this: Apotex knew that Sanofi may apply for an injunction to restrain it from launching and knew that, if the injunction was made, it could not launch.

15. The reading Sanofi now gives the August Letter is contrary to the reading Sanofi's General Manager (Mr Moulding) gave it on 21 August 2007, when he said *"[t]his seems to be very clear evidence of intention to launch and the urgency for an interim injunction"*: CAS [62]. Mr Moulding's reading is consistent with Sanofi, three days later, demanding that Apotex *"immediately cease and desist ... from making, authorising others to make, offering for sale, selling or otherwise exploiting [Apotex] Clopidogrel or any other product which falls within any of the claims of the Patent"*: see PJ [336], AB 294.[3] It is also consistent with Sanofi's application, a month later, for two interlocutory injunctions: one restraining manufacture and supply, and another restraining Apotex from taking steps to obtain PBS listing: see FC [18], AB 208. Sanofi's application, and Mr Moulding's statement, are admissions as to the most

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[2] Item 45 (PFM vol 1/tab 45/**p. 236**).
[3] Referring to item 48A (PFM vol 1/tab 32/**p. 243**).

obvious way the letter should be read. They are consistent with the evidence of Sanofi's Director of Public Affairs to Gyles J and the primary judge, that he believed that if the injunction was not made Apotex would apply to list: see PJ [373], AB 106.[4] In not one piece of evidence to which Sanofi refers is there any contemporaneous record prior to the grant of the injunction of an intent to defer making a decision until *after* Sanofi's application had been determined: *cf* RAS [100].

16. In many respects, the August Letter is a distraction. The supposed premise of Sanofi's first theory (that a decision *could* be delayed and hence *was* delayed) is false. The application for the interlocutory injunction required Apotex to decide what it would do if not enjoined. That was why Mr Catterns QC, Senior Counsel for Apotex, could submit in September 2007 that Apotex was going to apply for PBS listing if not enjoined. That submission could not have been made if, in truth, Apotex had not yet made a decision. Nor could Apotex's witness, Mr Millichamp, give sworn evidence to Gyles J[5] that Apotex was going to launch if, in truth, Apotex had deferred its decision. Unless Apotex – through Mr Catterns QC and Mr Millichamp – deceived Gyles J (a submission which has never been put), those submissions and that evidence preclude any finding that Apotex had not yet made a decision to launch.

17. Importantly, when given the opportunity before the primary judge to test whether Apotex had deceived Gyles J, Senior Counsel for Sanofi did not put to Mr Millichamp that his evidence was a sham. Nor did Senior Counsel put to him that he or Apotex deceived Gyles J or that Mr Catterns QC was on a frolic of his own in submitting that Apotex would launch. And at no time before the Courts below did Sanofi submit that Mr Millichamp or Mr Catterns QC misled Gyles J as to whether Apotex would launch if not enjoined. It is true that Sanofi submitted that Mr Millichamp "*had deliberately sought to mislead the Court*" but that submission (which the primary judge rejected) was based upon an allegation that Mr Millichamp's affidavits falsely "*conveyed the impression that the decision to launch at risk in Australia was one for Mr Millichamp to make*": PJ [331], [338]; AB 96-97, 98.[6]

18. Sanofi now attempts to get around this problem with a <u>second</u> theory: *"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*

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[4] See the affidavit of P Lindsay (17 September 2007) at [17], item 67D (PFM vol 2/tab 56/**p. 443**).
[5] See First Millichamp Affidavit (17 September 2007) at [38], item 67B (PFM vol 2/tab 54/**p. 417**).
[6] See cross-examination of Mr Millichamp at T 334.5-334.13 at item 124 (PFM vol 4/tab 105, **p. 1532**).

information that there will be an early final judgment)": RAS [13]. That submission is entirely contrary to Sanofi's first theory that, at the time of the hearing before Gyles J, Apotex had deferred making a decision. The second theory assumes that a decision to launch *had* been made at the time of the hearing before Gyles J but that, had Apotex been successful in resisting the injunction, it would have changed its mind. There are several problems with this second theory. First, it is inconsistent with the case run at trial and found by the primary judge. Second, to the extent it suggests that it is realistic to hypothesise Dr Sherman might have changed his mind, the *"further consideration or new information"* to which Sanofi refers (see RAS [88]-[91]) was known to Dr Sherman when Gyles J heard Sanofi's injunction application: see CAS [75]-[77]. The information upon which Sanofi relies for this speculative theory was not information which fell so outside the contingencies which would have been factored into the decision (such as a factory fire after September 2007) as to create any real likelihood that Apotex would have reopened its analysis of the risks and rewards of a decision to launch: *cf* RAS [95]-[99]. Sanofi fails at Step 2 on this second theory.

19. Once the first and second theories are rejected, there was no evidentiary deficiency that could be filled only by calling Dr Sherman to give evidence as to the decision he would have made if the injunction was not granted: *cf* RAS [91]-[93], [105]-[108].

20. The *third theory* Sanofi now advances is that Apotex was goading Sanofi into seeking an interlocutory injunction and proffering an undertaking as to damages because it *"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"*: RAS [59]. Sanofi submits this theory *"is exemplified in Sigma",* although the paragraphs from *Sigma* upon which that submission relies summarise evidence <u>in that case</u> supporting the findings that the generic company was seeking an undertaking (at [450], [457]) and that its preferred course was to do *"a deal"* rather than launch at risk: at [778].

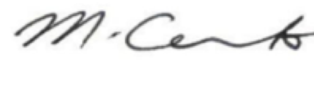
21. The only contemporaneous evidence that Sanofi points to in support of the third theory is the same letter it relies upon for the first theory. This time the August Letter is a *"signal"* that Apotex was going to launch even though it never intended to do so: RAS [59]. The theory is exploded by Apotex's decision not to accept Sanofi's undertaking and not to consent to the interim relief sought when offered <u>ahead</u> of the hearing before Gyles J: see CAS [69]. If Apotex was truly "goading" Sanofi, why did it risk Gyles J not making the injunction and possibly requiring it to give the $50M security (with liberty to top up)? Sanofi has no answer to that question.

22. The further limb of this *third theory* is to the effect that Apotex was adopting a strategy *"of seeking to impress its customers by showing that it would 'fight the innovators in court if need be'"*: RAS [60]. This contention appears to be based upon agreement by Mr Millichamp in cross-examination before the primary judge that *"one of [his] business strategies in this period was to impress [his] customers by what a fighter Apotex was"* and that *"it would fight the innovators in court if need be"*: RAS [60].[7] Sanofi wants to draw from that exchange that Apotex engaged in puffery when it sent the August Letter and had no real intention to launch. That is a long bow to draw. Mr Millichamp's response is consistent with Apotex having commenced proceedings against Sanofi seeking to revoke the Patent the day before the August Letter was sent and with the letter referring expressly to those proceedings.[8]

The Commonwealth's case before this Court is consistent with its case below

23. Sanofi asserts that the Commonwealth's principle as to the proper evidentiary onus *"was not advanced in the same way at trial"* or was *"differently expressed"* in the Courts below: RAS [7], [23], [50]-[55]. Quite what Sanofi wants the Court to do with this assertion is not stated. In any event, the three-steps were set out in the Commonwealth's application for special leave and its reply and repeated at the oral hearing of the application.[9] Special leave having been granted, the Commonwealth does not require further leave to rely upon the three-step approach.[10] In any case, each step is derived from authorities that both parties relied upon in writing and orally in the Courts below: see eg FC [85], [87], AB 226-227.

Dated: 12 July 2024



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7 Citing item 124 (PFM vol 4/tab 106/**p. 1506**).
8 See item 45 (PFM vol 1/tab 30/**p. 236**).
9 *Commonwealth of Australia v Sanofi (Formerly Sanofi-Aventis) & Ors* [2023] HCATrans 184 (18 December 2023), see eg lines 5-27, 177-182, 245-247, 343-349, 772-782.
10 *Federal Commissioner of Taxation v Travelex Ltd* (2021) 271 CLR 605 at 618-619 [19] (Kiefel CJ, Keane, Gordon and Edelman JJ).