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 OUTLINE OF ORAL SUBMISSIONS

PART I INTERNET PUBLICATION

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

PART II PROPOSITIONS TO BE ADVANCED IN ORAL ARGUMENT

1. On the NOA, in issue are the ultimate findings at **PJ** [286], [348]-[349], [351]; **FC** [14].

NOA [1]: EVIDENTIAL BURDENS

2. **CP 17** states the legal onus on a claimant. **CP 18** correctly states equity's allocation of evidential burdens, and their content, on causal questions involving past hypothetical facts: CAS [36]-[37]; CAR [6], [8]-[9].

3. As per **CP 19,** the 3-step approach is supported by authority; it is an appropriate analytical tool by which to consider: (1) whether a "prima facie" case has been established; (2) whether, if a competing case has been advanced by a respondent, it is sufficient; and (3) if both have, whether the claimant bearing the legal onus has established causation on the balance of all the evidence: **CAS** [38]-[45], **CAR** [6]-[11]. See: *Air Express*; *Purkess v Crittenden* at 168, 170-171; *Berry v CCL* at [37]-[41], [65]-[66], [71]; *Henderson* at [89]-[91]; *Sigma* at [317]-[319]. ***Cf*** **FC** [87]-[88]; [94]-[98].

4. **Legal onus.** The Commonwealth bore the legal onus to persuade that: (i) first, the order was as a matter of fact a cause of Apotex not listing on the PBS; and (ii) second, if no injunction had been granted on 25 September 2007, Apotex would have gone on to supply its products to wholesalers and pharmacists from 1 April 2008 under the PBS and, in connection with that course, applied by 1 December 2007 for PBS listing from 1 April 2008. The first is not in dispute: **PJ** [428]-[432].

5. **Evidential burden - step 1.** The Commonwealth led a *prima facie* case that Apotex had formed and communicated, most critically to the court, an intent to list and launch if not restrained, which was powerful evidence of what it would have done had the injunction been sought but not granted: **CP 1-13**; **CAS** [47]-[66]; **CAR** [13]-[22].

6. **CP 1 and 2:** Apotex's external communications evidenced the fact and content of its formed intention to list and launch if not enjoined. This was powerful evidence, inconsistent with the critical finding that Apotex had deferred making a decision (**PJ** [251], [287], [340]) and which gave rise to the finding of an "evidentiary deficiency" in the Commonwealth's case (**PJ** [341], [349]): **FC** [14].

7. Overview of PJ/FC errors on **CP 1 and 2**: Save in respect of the evidence in **CP 1(b)** (the letter to pharmacists, which the primary judge and Full Court construed divorced from its context at **PJ** [288]; **FC** [118], [120], [155], [174]), the primary judge did not grapple with the evidence in **CP 1** which was inconsistent with the "deferred decision" theory. To the extent the primary judge referred to the other evidence in **CP 1**, there was no consideration of whether it recorded an intention of Apotex, the significance thereof, or the cumulative value of the corpus of evidence in **CP 1**. The Full Court largely examined whether an item of evidence had been *referred to* by the primary judge, or whether an item *by itself* could sustain the ultimate inference of intention, rather than reviewing for whether the primary judge had, in assessing whether a *prima facie* case was established, grappled with the relevance of the item's content individually *and* cumulatively.

8. Detail of errors: **CAS** [61]-[66], [75]-[77], **CAR** [16]

- as to **CP 1(a)** (notice to Sanofi): **PJ** [259];
- as to **CP 1(c)** and **(e)** (refusal to back down): **PJ** [265], **FC** [336]-[339];
- as to **CP 1(e1)** (first return of revocation suit): **PJ** [266]-[267], **FC** [140];
- as to **CP 1(e2)** ($50m security offer): **PJ** [267]-[271], **FC** [204]-[205], [304];
- as to **CP 1(f)** and **(g)** (Millichamp evidence and submissions of Catterns QC): **PJ** [272], **FC** [176]-[177], [295]-[305], [341]-[346]; and
- as to **CP 1(h)** (security offered to court): **PJ** [267]-[272], **FC** [204]-[205], [304].

9. Sanofi's response to **CP 2** impermissibly seeks to read the **CP 1** statements as subject to an implied qualification not supported by any finding below and inconsistent with the context in which they were made: **CAR** [18].

10. **CP 3 and 4:** The finding of an "evidential deficiency" (**PJ** [341], [349]) involved error; the primary judge impermissibly permitted Sanofi's speculation of countervailing circumstances (the "coincidence" of two events supposedly post the injunction) to give rise to a false doubt and "gap" in the Commonwealth's *prima facie* case when, in the real world, Apotex had already made a decision to launch/list if not enjoined *and maintained it* (to Gyles J) *even after* acquiring knowledge of the first event and in clear anticipation of the second: **PJ** [264], [266]-[267], [278]-[282], [284]. [286]-[287], [289], [341], [348]-[349]. The Full Court failed to pick up the error: **FC** [219]-[221], [354]-[355]. **CAS** [75]-[77]; **CAR** [18].

11. **CP 5 and 6:** Sanofi's contemporaneous assessment that Apotex intended to launch/list was confirmation of how to interpret Apotex's letter to pharmacists and that Apotex's intentions were as put to Gyles J. The primary judge did not deal with this evidence; the Full Court endorsed that approach and did not address the case made by the Commonwealth: **FC** [119]-[120], [331], [336]-[339]; **CAR** [15], [17].

12. **CP 7, 8, 9:** Sanofi's offer to Apotex of an undertaking as to damages would have protected Apotex against all loss if it were enjoined. Apotex's election not to take that course was powerful confirmation that Apotex's intention was exactly as it had stated to Sanofi, the market and Gyles J. Neither court below grappled with this; **FC** [90] is the closest, but wholly misconceived: **CAS** [69], **CAR** [21].

13. **CP 10: the ultimate, logical inferences arising:** The evidence in **CP 1-9** directly evidenced and/or gave rise to very strong inferences that Apotex had formed an intent to launch/list if not enjoined and, in the counterfactual world, would have carried through with that intent. **CAS** [53], [61]-[66], [75]-[77], [90], [93]; **CAR** [12]-[22].

14. **CP 10A-F and 11-13:** No different result follows from the evidence as to the commercial and legal practicalities of the circumstances Apotex was in (**CP 10A-10F**) or Apotex's contemporaneous internal communications (**CP 11-13**): *cf* **SP 3, 4, 5, 6, 8**.

15. The basis of the "deferred decision" theory is an email of 27 June 2007 (**PJ** [246]-[251], [287]; **FC** [114], [135]) superseded by an email on 28 June (**PFM** vol 1/tab 19/ p. 156) and later conduct. The primary judge did not refer to the most critical ones: see agreed **long form chronology,** entries for tabs 17-22, 23-25, 35, 40, 51. The Full Court approached this material individually (and sometimes itself missing key elements) and introduced its own speculative theories: **FC** [129] (as to tab 18, "game on"), **FC** [117], [137], [172(b)], [173]-[175], [239(c)], [240] (as to tab 19, but missing the critical line "as per instructions from Barry…"), **FC** [313]-[314] (as to tab 19, this time reproducing the critical line but no attempt to engage with it); **FC** [155] (tabs 20 and 22, "I was probably not clear enough in my mail to you"), **FC** [124], [175] (as to the balance, but assessed individually and in a context of the above errors): **CAS** [52]-[60]; [82]-[88].

16. There is no evidence of Dr Sherman giving an internal instruction not to launch/list or of formulating such a plan or having such an intention: **CP 12**; **CAS** [83].

17. **Step 2.** Sanofi's "reason B" is that Apotex would not have listed because the unrevoked Patent "exposed Apotex to the risk of substantial damages": **RAS** [11], embracing

FC [90]; see also **SP 8** ("powerful reasons…to prefer not to launch at risk"). The "evidence" relied on to support reason B (**SP 8, 9, 10**) is not "sufficient"; it is not evidence from which a court *could* conclude Apotex would not have listed - including because the "better off being restrained" theory, allied to the "goading" strategy (**RAS** [11(a)], [59]-[60]) is assertion and speculation, not evidence, and logically flawed. The "powerful reasons" theory in **SP 8** is divorced from Apotex's contemporaneous calculus and decision-making process. And the reliance on Apotex's later conduct in 2008 and 2009-2010 after the final hearing and during the appellate process is insufficient because that occurred in a different context, over a different timeframe, and where Apotex already had the benefit of the 2007 undertaking as to damages: see response to **SP 9** and **CP 14-15**: **CAS** [67]-[74]; **CAR** [20]-[22].

18. **Step 3.** The courts below did not assess the probability of the parties' competing hypotheses by reference to the corpus of evidence as a whole or on a proper approach to past hypothetical fact finding in equity (see **NOA [2]** below). If step 3 is reached and done correctly, the Commonwealth must win: **CAS** [34]-[35], [90], [93].

NOA [2]: PAST HYPOTHETICAL FACT FINDING

19. **CP 26 and 27** correctly state equity's approach to past hypothetical fact-finding: see *Sigma* [273]-[286], [319], [436], [447]; **CAS** [91]-[92].

20. Below, hindsight evidence effectively became a *requirement* 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: *cf* **PJ** [339]-[349]. However, there was no need for the Commonwealth to lead direct hindsight evidence from Dr Sherman: **CP 26-28**, **CAS** [34], [91], [93]-[95]; **CAR** [19]. If either party was required to call Dr Sherman, then it was for Sanofi, as the party which sought to erect "countervailing circumstances", to call him: **CP 28**; **CAS** [95].

ON THE NOTICE OF CONTENTION

21. **NOC [1].** Legal principle. Sanofi's conception of "flow directly" pressed in this court is narrow and rigid ("that the event which occasions the loss be restrained by the injunction": **SP 24**; see also **SP 22, 23, 25-26**). That conception is erroneous because it is unsupported by the authorities and the purpose of the jurisdiction: *Air Express* at 266-267; *European Bank* [15]-[18] and [29], citing *Mansfield* at [33], *R v Medicines Control*

Agency at 314. **CP 31, 32** correctly state the content of "flow directly". See also **FC** [51]-[53], [58]-[77]; ***Sigma*** [447], [226]-[227]. **CNoCS** [11], [13]-[22], [30]-[34].

22. NOC [1] also ignores the critical facts which equity would regard as relevant to the content and application of "flow directly" in the particular case. Sanofi propounded to the court a causal chain (Apotex would apply to list; the Minister would grant the listing; there would be inevitable reductions in the PBS subsidies paid to the detriment of Sanofi and the gain of the Commonwealth) as the basis for the damages which it would recover if successful at the final hearing but which, because of quantification difficulties, should instead be protected by an interlocutory injunction: Sanofi written submissions to Gyles J (**PFM** vol 2/tab 59/pp. 490-492 [26]-[29]); Lindsay affidavit (**PFM** vol 2/tab 56/p. 442-449 [13]-[42]). Gyles J granted the injunction on those representations and Sanofi's assurance that the Commonwealth was protected by the undertaking: **CP 35-37**.

23. Equity's concept of "flow directly" would not permit Sanofi to deny the Commonwealth recovery for its inverse losses dependent upon the same causal chain: **CP 29, 30**; see also **FC** [17]-[32], [37]-[38], [57]-[60], [75]-[76], [79]-[81]. See also Sanofi's provision of $40m of security the utility of which for Apotex depended on the same causal chain: (**PFM** vol 2/tab 63/ p. 594). To do otherwise would allow Sanofi to approbate and reprobate. **CNoCS** [10], [23]-[29], [33], [35].

24. **NOC [3]** is premature: the issue was not decided below *nor* was a related, anterior ground raised by the Commonwealth (FANOA [3]) necessary to supply the Court with the findings of fact for 2008-2010 relevant to any assessment of "flow directly". If reached, it should be dismissed for the same reasons as NOC [1] and the findings on foreseeability in the counterfactual at **PJ** [461]-[481], **CNoCS** [37]-[41]; *cf* **SP 20-21**.

25. **NOC [4]** was not determined below: **FC** [12]. If entertained, it fails because it is inconsistent with the purpose of the jurisdiction and involves approbating and reprobating: **CP 35-39**. It is also infected by a flawed understanding of the Commonwealth as a legal person, which is capable of suffering damage by the judicial arm's intervention prior to the determination of merits: **CP 40-41**, **CNoCS** [42]-[51].

26. **NOC [7]** should not be entertained because the point cannot be raised by notice of contention and because of the wider circumstances in **CP 42-44**. If reached, it fails for the reasons given on the Stated Case: **CP 45-46**, **CNoCS** [52]-[62].

4 September 2024

Justin Gleeson **Fiona Roughley**