HIGH COURT OF AUSTRALIA

NOTICE OF FILING

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Details of Filing

File Number:	S169/2023
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Important Information

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Form 27F – Outline of oral submissions

Note: see rule 44.08.2.

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' OUTLINE OF ORAL SUBMISSIONS

Part I: Certification

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

Part II: Propositions the Respondents intend to advance in oral argument

Notice of Appeal Grounds 1 and 2

The Commonwealth's principle is illusory and unsupported by authority

2. The Commonwealth accepts that the 'legal onus … on a question of causation rests always on a claimant': **CRSA** [6]. But it says that the 'correct' legal principle concerning 'evidential burdens' was not recognised in the Courts below: **CSA** [36]-[37].

3. The sense in which the Commonwealth uses the expression 'evidential burden' is the second referred to in **SSA** [25]. But a 'tactical burden' of that kind does not raise 'a question of law' and 'involves merely a tactical evaluation of who is winning at a particular point in time': **SSA** [25].

4. The Commonwealth raises no issue of principle that could alter the result in this proceeding. An *ex post facto* recognition of a tactical burden that may have placed Sanofi in jeopardy of losing had it not responded to the Commonwealth's case is of no moment after Sanofi won at trial, and that result was confirmed unanimously by the Full Court.

5. In any event, the Commonwealth's 'principle' is not supported by authority. The result and reasoning in *Air Express Ltd v Ansett Transport Industries (Operations) Pty Ltd* (1981) 146 CLR 249 contradicts the Commonwealth's principle: **SSA** [31]-[38].

6. Moreover, the Commonwealth's reliance on *Purkess v Crittenden* (1965) 114 CLR 164 and *Henderson v Queensland* (2014) 255 CLR 1, which address the respective significances of legal and tactical burdens, is mistaken: **SSA** [41]-[42], [46(d)].

The application of the Commonwealth's principle would not have made a difference

7. The primary judge and the Full Court were correct to conclude on all the available evidence that the Commonwealth had failed to prove that Dr Sherman would have approved a launch at risk in the particular circumstance of this case: **SSA** [91]-[102].

8. Specifically, the evidence indicated that Dr Sherman's final approval was necessary before a launch at risk – a decision which did not fall to be made until after the decision on injunctive relief. There was no evidence addressing how he would have responded to the

decision-making parameters existing at that time had no injunction been imposed: **SSA** [4(b)], [91]-[93].

9. The Commonwealth does not engage with the requirement to establish 'special reasons such as plain injustice or clear error' for this Court to disturb concurrent findings of fact (see *Kozarov v Victoria* [2022] HCA 12; (2022) 273 CLR 115 at [49]: **SSA** [6].

10. Even if the principle proposed by the Commonwealth were to be applied , it would fail at either the first or third step: **SSA** [14].

11. As to ***Step 1***, neither the primary judge nor the Full Court found that a *prima facie* case in support of compensation was established: **SSA** [14(a)].

12. As to ***Step 2***, the Full Court addressed the case on the footing that the principle applied, and held that that did not avail the Commonwealth: **SSA** [7]. Sanofi answered the Commonwealth's case by evidence, cross-examination and argument including direct contemporaneous evidence as to how Apotex Pty Ltd (**Apotex**) would act if not restrained in almost identical circumstances: **SSA** [10]-[11]; [98]-[99].

13. As to ***Step 3***, 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: **SSA** [4]. There are concurrent findings against the Commonwealth on its failure to satisfy the legal onus: **SSA** [6].

The mode of proof issue

14. The Commonwealth asserts a further error by the Courts below in 'effectively turn[ing] 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': **CSA** [91].

15. The premise is false. Neither the primary judge nor the Full Court imposed such a requirement: **SSA** [104]. Rather, without evidence from Dr Sherman, or material from which an inference could be drawn about his thinking, the primary judge correctly declined to speculate as to what he would have done, and accordingly the Commonwealth failed to discharge its onus: **SSA** [105]. It is wrong to submit that Dr Sherman's evidence would have been of no utility.

Notice of Contention Grounds 1 and 3

The entirety of the Commonwealth's claimed loss

16. 'Flow directly' encapsulates two enquiries which constrain the award of just compensation under the usual undertaking as to damages: 'flow' imports causation in fact; 'directly' imposes a further limit and directs attention to the operation of the injunction and the naturalness or immediacy of the asserted loss: **SSC** [17]-[18]. The concept of 'directness' reflects the purpose and terms of the undertaking and obligation to do equity: **SRSC** [7]-[9].

17. The fact of there being more than one step in a causal chain is not fatal to a claim on an undertaking, but the number and character of the intervening steps are material to directness, especially where they involve decisions about matters outside the scope of the restraint: **SSC** [19], [22]-[24]; **SRSC** [4]. The primary judge did not proceed on the basis that any interposed causal step was fatal (cf FCJ2 [48]).

18. *Smith v Day* (1882) 21 Ch D 421 and *Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth* [2018] FCA 1556; (2018) 136 IPR 8 are authority that interposed negotiated or discretionary outcomes will support a conclusion that loss was not direct: **SSC** fn 4.

19. The interlocutory injunction restrained Apotex from infringing the patent, including by making or selling its clopidogrel products. Taking steps to list on the PBS would not have infringed the patent and was not restrained by the injunction: **SSC** [19]-[20]. The objective context, including the conduct of the hearing before Gyles J, the reasons given by Gyles J, and Apotex's undertaking not to apply to list, confirm that the injunction was not intended to restrain PBS listing: **SSC** [19]-[20].

20. The undertaking as to damages required Sanofi to pay just compensation in relation to the adverse effects of the interlocutory injunction only; no cross-undertaking was required by the Court in relation to Apotex's undertaking not to apply to list its clopidogrel products on the PBS: **SSC** [19]-[20]. The Commonwealth could have sought leave to appear to protect its position against delayed PBS listing but did not: **SSC** [40]-[42].

21. The Commonwealth's asserted losses flow from Apotex and other generics not applying to list clopidogrel products on the PBS effective 1 April 2008. Other generics were not restrained at all. Apotex was not restrained from listing by the injunction but by Apotex's simultaneous undertaking not to list. The undertaking not to list was not conditional on the operation of the injunction and came into effect at the same time as the injunction.

22. The Commonwealth's asserted losses also do not 'directly flow' from the injunction because they depend on series of steps including choices made by Apotex and the Minister concerning listing Apotex's clopidogrel products on the PBS which were not within the scope of the interlocutory injunction: **SSC** [31]-[39]; **SRSC** [5].

23. The Full Court's reasons do not conduct the analysis of directness called for by the authorities and fail to give effect to the objective intention of the undertaking and injunction: **SSC** [25]-[35].

Losses arising from PDPRs and combination products

24. The Commonwealth's asserted losses by reason of price disclosure price reductions (**PDPRs**) do not flow directly from the injunction because, in addition to the matters in [16]-[23] above, whether any PDPRs would have occurred depended on hypothetical commercial choices made by third parties (wholesalers, pharmacists, doctors and patients), and the extent of any PDPRs depended on those matters together with legislative and regulatory changes made by the Commonwealth after the interlocutory injunction was granted: **SSC** [45]-[50].

25. The Commonwealth's asserted losses in relation to combination products do not flow directly from the injunction because, in addition to the matters in [16]-[23] and [24] above, they depended on a hypothetical negotiation between the Commonwealth and Sanofi having a particular outcome: **SSC** [52]-[54].

26. The facts relevant to whether losses arising from PDPRs and combination products flow directly are not in dispute and have been agreed in the Sanofi Parties' Presentation Document for Oral Argument at [20]-[21]. Remitter is not appropriate: **SRSC** [10]-[13].

Notice of Contention Ground 4

27. The payment of fiscal benefits pursuant to law is not an 'adverse effect' on the Commonwealth. Payments are made, not in the exercise of a capacity which the body politic has in common with other persons, but in a unique capacity engaging both legislative and executive dimensions of its personality: **SRSC** [14]-[16]; see *Williams v Commonwealth* (2012) 248 CLR 156 at [150]-[159].

28. Even on the premise that less would have been paid had an interlocutory injunction not been granted, payments according to a law of this kind are not an adverse effect, but reflect the achievement of the Commonwealth's health policy objectives. The Commonwealth has legislative and executive control at all relevant times over: the listing of

drugs; the incidence and magnitude of any subsidy and the associated maximum price; the circumstances in which the subsidy and maximum price may change; and the rights and duties appertaining to patents and potentially infringing conduct by generics seeking to enter the market: **SSC** [57]-[60].

29. Section 64 of the *Judiciary Act 1903* (Cth) does not operate to dissolve the distinctive position of the Commonwealth in these respects: **SRSC** [17]-[18].

30. References to PBS costs before Gyles J comprehended the potential application of ss 26C or 26D of the *Therapeutic Goods Act 1989* (Cth) (**TGA Act**): cf **CP37**.

Notice of Contention Ground 7

31. Sanofi is not precluded from maintaining NOC Ground 7, by either the Full Court's stated case judgment, or the refusal of special leave to appeal that judgment: **SRSC** [19].

32. Sections 26C and 26D of the TGA Act exhaustively provide for the Commonwealth's rights to be compensated for damages sustained or costs incurred as a result of an interlocutory injunction granted in favour of a patentee resisting market entry by a generic springboarding off the patentee's previously analysed data as to safety: **SSC** [62]-[74].

33. Sections 26B, 26C and 26D distinguish between springboarders which can and cannot certify a belief they are not infringing a patent. The distinction would be obliterated if ss 26C and 26D were construed as providing additional instead of substituted remedies: **SSC** [73]; **SRSC** [20].

34. The Commonwealth's rights to compensation arise exclusively 'pursuant to' s 26C(8) or pursuant to the usual undertaking as modified by s 26D(5). Those rights are subject to the tailored preconditions in those subsections: **SSC** [69]-[71]; **SRSC** [20]-[21].

35. Sanofi's construction is supported by the legislative purpose and the implementation of Australia's international obligations under the US Free Trade Agreement: **SRSC** [21].

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John Sheahan

(02) 8239 0211

john.sheahan@banco.net.au