HIGH COURT OF AUSTRALIA

NOTICE OF FILING

This document was filed electronically in the High Court of Australia on 12 Jul 2024 and has been accepted for filing under the *High Court Rules 2004*. Details of filing and important additional information are provided below.

Details of Filing

File Number:	S169/2023
File Title:	Commonwealth of Australia v. Sanofi (formerly Sanofi-Aventi
Registry:	Sydney
Document filed:	Form 27E - Respondents' Reply on Notice of Contention
Filing party:	Respondents
Date filed:	12 Jul 2024

Important Information

This Notice has been inserted as the cover page of the document which has been accepted for filing electronically. It is now taken to be part of that document for the purposes of the proceeding in the Court and contains important information for all parties to that proceeding. It must be included in the document served on each of those parties and whenever the document is reproduced for use by the Court.

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' REPLY ON THE NOTICE OF CONTENTION

Part I: Certification

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

Part II: Reply on the Notice of Contention

2. Maintaining the defined terms used in Sanofi's opening submissions (**SNOCS**), this reply addresses the Commonwealth's submissions on the NOC (**CNOCS**).

Directness Issues – NOC Grounds 1 and 3

The entirety of the Commonwealth's claimed loss

3. The Commonwealth's response may be summarised as follows:

a. Sanofi advances 'inconsistent approaches' to the meaning of 'flow directly' – sometimes contending that any interposed step between the act restrained by an injunction and loss is fatal, and sometimes contending for a lesser restriction (CNOCS[15]-[18]).

b. The 'evaluative judgment' on directness (as Sanofi characterised it in the Full Court: FCJ2[60], AB219) should be made without reference to the 'ancient case law' or a clear test (CNOCS[14], [20], [34]). Instead, the Commonwealth favours an 'unconstrained' approach as to the 'adequate causal link between the interlocutory injunction and claimed loss' to serve 'the underlying equitable intent' (CNOCS[14], [20], [31]).

c. Sanofi would require courts and litigants to consider, when an injunction is granted and an undertaking given, the interests that may be affected, in order 'to afford the protection and jurisdiction courts of equity require' as a condition for the order (CNOCS[21]-[22]).

d. The Sanofi Undertaking should extend to the Commonwealth where the Interlocutory Injunction prevented 'in a practical if not legal sense' Apotex applying for PBS listing (CNOCS[23], quoting FCJ2[25], AB210). By the order preventing both supply and Apotex offering discounts to compensate pharmacists for the impact wrought by PBS price reductions, there was 'a direct effect' on Apotex and the Commonwealth, and the Apotex Undertaking 'only made explicit that which Apotex could not do' (CNOCS[24]-[27], [35]).

e. Contrary to SNOCS[38], and consistent with *Sigma v Wyeth*, the Commonwealth is similarly situated to a manufacturer with an extant supply contract, rather than one with only the 'potential' to yield a benefit from a generic being unenjoined (CNOCS[32]-[33]).

4. Sanofi maintains its submissions in chief and replies as follows. *First*, as to subparagraph 3.a. above, Sanofi does not advance 'inconsistent approaches'. The authorities support a limitation on recovery beyond mere causation. That limitation is captured by the expression 'flow *directly*' as used in *Air Express* at 267 by Aickin J (emphasis added), and approved in *European Bank* at [18]; and by the qualifying words 'natural', 'immediate' and

'necessary' in the earlier authorities cited at SNOCS[18], fn 4. And the role of that limitation is emphasised by the basal consideration that a claimed loss must flow from *the operation of the injunction.* It is submitted that directness is not satisfied where the event which 'occasioned loss' (failure to seek and obtain PBS listing) was not restrained by the injunction (SNOCS[17]-[18], [21], [23]). That requirement does not mean that *any* interposed causal step is inconsistent with directness. So, the need to acquire raw materials, packaging and distribution channels are all necessary elements of a causal chain for the sale of a product. They do not mean that loss of sales does not flow directly if supply is restrained. But the requirement will not be satisfied where the event alleged to have occasioned loss (again, Apotex failing to seek and obtain PBS listing) is an 'unrestricted choice' (per *Sigma v Wyeth* at [227]); that is, unrestricted in that the injunction does not constrain it, one way or another.

5. The Commonwealth's claimed loss depended on both: (i) a decision by Apotex whether to apply to list (which was not restrained by the Interlocutory Injunction but rather by the Apotex Undertaking which was unsupported by the Sanofi Undertaking); and (ii) if Apotex did apply, a decision by the Minister to exercise the statutory discretion to approve the application (SNOCS[13]). A claim based on those *two* unrestricted choices (in a longer causal chain) is not 'direct' in accordance with the reasoning and results in *Air Express*, *Ex parte Hall*, *Smith v Day* and *Sigma v Wyeth* (SNOCS[22]-[39]).

6. That position does not offend the 'purpose of the undertaking as to damages' (cf CNOCS[31]). Rather, it gives effect to it, by appropriately excluding losses caused by choices that were not constrained by the Court's order. The Commonwealth submits that Apotex's choice whether to apply to list was impacted in a 'practical sense'. However recovery on that footing is not easily reconciled with the terms of the Apotex Undertaking. And it leaves out of account the further, separate decision of the Minister.

7. *Second*, as to subparagraphs 3.b. to 3.d. above, it is the judgment of Aickin J, affirmed in *European Bank*, that is the source of the statement that the court generally should adopt a 'just and equitable' or 'fair and reasonable' approach to compensation on an undertaking as to damages, and that in most cases this will be satisfied by recovery of loss which flows directly from the injunction: *Air Express* at 266-267. That is, giving content to the expression 'directly' reflects the object of the undertaking. This is consistent with the fact that the undertaking is an application of the maxim that 'he who seeks equity must do equity', and the proposition that the maxim does not empower a court to impose any term merely because it considers it reasonable, but only terms which flow from the defendant's legal or equitable rights: *Meagher, Gummow and Lehane's Equity: Doctrines and Remedies*, 5th ed, [3-050].

8. In addition, an *ex post facto* search for the practical consequences of an injunction

diminishes predictability of outcome on a claim on an undertaking and thus denies litigants the ability to make reasonably informed decisions as to whether to pursue the remedy.

9. *Third,* as to subparagraph 3.e. above, the Commonwealth passes over its own role in whether a drug will be listed on the PBS. The discretion under s 85(6) of the NH Act is reposed in the Minister. Its exercise has the equivalent effect on the Commonwealth's 'loss' as a decision by a corporation as to whether or not to pursue a supply contract. In each case, the presence of a discretion unrestricted by the injunction undermines a direct connection.

Claimed losses in relation to PDPRs and combination products

10. The Commonwealth correctly identifies the effect of NOC Ground 3: two portions of the Commonwealth's alleged loss, comprising $274M of the total $325M claimed (PJ[22], AB19), are factually more removed from the Interlocutory Injunction than the rest (cf CNOCS[12]). Even if the Full Court's approach to directness is upheld here, Sanofi submits that those losses did not 'flow directly' from the Interlocutory Injunction (SNOCS[44]-[54]).

11. The Commonwealth does not engage with that contention, and submits that NOC Ground 3 ought not be addressed in this Court, and should instead be remitted for consideration with Ground 3 of the Commonwealth's Further Amended Notice of Appeal in the Full Court (AB192-193), if this appeal is upheld (CNOCS[37]).

12. Sanofi responds as follows. If this Court upholds NOA Ground 1 but rejects NOC Ground 1, the parties (and other courts and litigants) will require guidance as to what causal steps are relevant to the analysis. Moreover, it would not be appropriate to 'defer a determination of what kind of interposed causal step is sufficient' (FCJ2[77], AB224) where that issue immediately arises as to the bulk of the Commonwealth's claim.

13. In addition, the Commonwealth's argument for remitter of NOC Ground 3, that it and FANOA Ground 3 both relate to events after the Interlocutory Injunction was replaced by a final injunction in the Patent Proceeding (CNOCS[38]-[40]), ignores their distinct conceptual bases for denial of recovery for the Commonwealth's alleged PDPR losses.

Adverse Effect Issue – NOC Ground 4

14. The 'principled basis' on which the Commonwealth as a person is incapable of being adversely affected by the interlocutory injunction issued in this case (cf CNOCS[46]) is the character of the Commonwealth personality, unlike others and conceded at CNOCS[44], as one 'comprised of three branches' or 'dimensions of power'.

15. The tripartite character means that, in any specific context, precision is required about the dimension of power in which the Commonwealth person is said to be adversely affected, or is said to suffer loss or damage. Many interactions occur in the exercise of capacities that

the Commonwealth has in common with capacities that persons generally have: *Pape v Federal Commissioner of Taxation* (2009) 238 CLR 1 at [126]. Those capacities, which might be supported or modified by statute, form part of the Commonwealth's executive power: *Hocking v Director-General of the National Archives of Australia* (2020) 271 CLR 1 at [75]. Acting through its executive dimension in some such capacity, the Commonwealth can suffer loss, for example, on a breach of contract or a trespass to land or other property.

16. Distribution of fiscal benefits to subjects lacks this character. It does not involve the Commonwealth acting in a purely executive dimension in a capacity that persons generally have, or in a manner akin to its subjects: cf *Williams v Commonwealth* (2012) 248 CLR 156 at [151]-[159]. It involves the performance of legal duties which are unique to the Commonwealth body politic and which are legally performed by the body politic itself. Thus, NH Act, s 85(1) expresses simply that benefits in respect of pharmaceutical benefits are to be 'provided by the Commonwealth'. They are provided in accordance with statutory criteria and their provision does not 'adversely affect' the Commonwealth just because they involve expenditure and the statute might have operated differently but for an injunction, itself granted under Commonwealth law.

17. This analysis is not inconsistent with *Judiciary Act 1903* (Cth), s 64 or the separation of powers (cf CNOCS[47]-[48]). The bald assertion that s 64 would assimilate the Commonwealth's position to that of a subject is wrong. It may be doubted whether s 64 dissolves the special disabilities of the Commonwealth, as distinct from giving subjects rights they otherwise would not have: *Australian Securities and Investments Commission v Hellicar* (2012) 247 CLR 345 at [150]-[151]. The 'as nearly as possible' qualification preserves situations in which the law, though applying both to Commonwealth and subject, has a differential operation. Section 64 does not 'alter the nature of respective rights in relation to different subject matters': *Austral Pacific Group Limited v Airservices Australia* (2000) 203 CLR 136 at [16], citing *Commonwealth v Western Australia (The Mining Act Case)* (1999) 196 CLR 392 at [81], [126]-[137], [165], [246]-[248]. For example, an equitable action for breach of confidence affords different protection to private versus government information: *Commonwealth v John Fairfax & Sons Ltd* (1980) 147 CLR 39 at 51-52; see also Finn, 'Claims Against the Government Legislation' in Finn (ed), *Essays on Law and Government Vol 2* (1996) 25-48.

18. Sanofi does not contend that compensation on an undertaking requires 'superadded … wrongfulness' (cf CNOCS[50]). Sanofi embraces the lack of any wrongfulness element. That distinguishes the Commonwealth's position here, where it merely asserts an entitlement to be put in a counterfactual position based on how its laws would have operated in the

counterfactual, from a situation where it *is* owed a liability in its executive dimension.

TG Act Issue – NOC Ground 7

19. There is no impediment to NOC Ground 7 (cf CNOCS[53]-[54]). FCJ1 was interlocutory and made in the exercise of original jurisdiction. The earlier refusal of special leave did not affirm the decision in any binding or preclusive sense: *North Ganalanja Aboriginal Corporation v Queensland* (1996) 185 CLR 595 at 643. The point now arising as a contention, after final judgment, no purpose would be served by renewing the application for special leave.

20. The Commonwealth's response is essentially that the TG Act provides *additional* remedies to the Commonwealth in cases of *fault* and this denies the negative implication that any entitlement to claim general law remedies in cases of no-fault is displaced. However, the negative implication does not depend on the scheme being more restrictive in all respects (although the fact that it is so in important respects is a significant indicator). The negative implication is not denied by the existence of some 'enhancement' of the general law. It arises from the *exhaustive* provision for the Commonwealth's recourse on a patentee's undertaking. That is discerned from the detailed regime, including limitations on relief, as well as modifications of the general law. The provisions do not simply provide additional statutory recourse; s 26D(5) expressly regulates 'the usual undertaking'. The Full Court wrongly reasoned from the Commonwealth's characterisation about 'enhancing' the Court's remedial powers (FCJ1[90]) to an absence of the negative implication.

21. The Commonwealth also provides no answer to the critical point of legislative history: the TG Act provisions implemented Australia's international obligations under the US Free Trade Agreement. The statutory scheme for recovery reflects a carefully legislated balance calculated to ensure that patentees are notified of proposed new entry and are not unduly deterred from seeking interlocutory relief. Exposure to compensation, not just to a generic manufacturer enjoined from entering the market, but to the polity subsidising the cost of medicines is a deterrent that the TG Act designedly addressed. A general law claim such as that now made by the Commonwealth would so dwarf the calibrated deterrent under the TG Act for 'abusive' conduct, that it cannot sensibly co-exist with the statutory scheme.

Dated: 12 July 2024

John Sheahan
(02) 8239 0211
john.sheahan@
banco.net.au

James Hutton
(02) 8001 0225
hutton@
elevenwentworth.com

Simon Fitzpatrick
(02) 8224 3010
saf@
7thfloor.com.au

Brendan Lim
(02) 8228 7112
blim@
elevenwentworth.com