

HIGH COURT OF AUSTRALIA

GORDON A-CJ,
EDELMAN, STEWARD, JAGOT AND BEECH-JONES JJ

COMMONWEALTH OF AUSTRALIA

APPELLANT

AND

SANOFI (FORMERLY SANOFI-AVENTIS) & ORS

RESPONDENTS

Commonwealth of Australia v Sanofi
[2024] HCA 47

Date of Hearing: 4 & 5 September 2024

Date of Judgment: 11 December 2024

S169/2023

ORDER

Appeal dismissed with costs.

On appeal from the Federal Court of Australia

Representation

J T Gleeson SC and F T Roughley SC with G Watson Keesing and
M F Caristo for the appellant (instructed by Corrs Chambers Westgarth)

J C Sheahan KC with J J Hutton SC, S Fitzpatrick and B K Lim for the
respondents (instructed by Jones Day)

Notice: This copy of the Court's Reasons for Judgment is subject to
formal revision prior to publication in the Commonwealth Law
Reports.

CATCHWORDS

Commonwealth of Australia v Sanofi

Damages – Undertaking as to damages – Where interlocutory injunction obtained to prevent manufacture or sale of generic pharmaceutical products – Where compensation sought for loss suffered as result of generic products not being listed on Pharmaceutical Benefits Scheme ("PBS") – Whether generic products would have been listed on PBS but for interlocutory injunction – Counter-factual approach – Whether onus of proof discharged.

Appeals – Standard of review – Ultimate appellate court – Where concurrent factual findings of lower courts – Whether special or exceptional circumstances – Whether plain injustice or clear error – Whether concurrent findings not clearly wrong – Whether concurrent findings open and compelling.

Onus of proof – Shifting evidential onus – Whether rigid legal rule applied for proof of loss arising from undertaking as to damages.

Words and phrases – "clear error", "concurrent findings", "counter-factual", "evidential onus", "interlocutory injunction", "onus of proof", "plain injustice", "special or exceptional circumstances", "standard of review", "ultimate appellate court", "undertaking as to damages".

National Health Act 1953 (Cth), ss 99ACB, 99ACH.

Introduction

1 The important point of law in this appeal is to reaffirm the limited
circumstances in which this Court should review findings of fact made by a
primary judge, which were not disturbed by the intermediate appellate court. The
principled approach taken by this Court, reaffirmed in these reasons, is common
to many ultimate appellate courts in the common law tradition. That principle is
that, absent special or exceptional circumstances such as plain injustice or clear
error, this Court will not engage in a detailed review of concurrent factual findings
of lower courts. This approach applies a fortiori to concurrent findings of facts and
counter-facts that are made as steps towards an ultimate finding of facts. The
principle is a pragmatic one based upon an important need for triage. For every
appeal that is heard by an ultimate appellate court, with a limited capacity to hear
appeals, another appeal (or, as in this case, sometimes more) will not be heard.

2 This appeal does not concern any individual rights, nor expose any plain
injustice or clear error.

3 The first respondent, which collectively with the other respondents may be
described as "**Sanofi**", held a patent in a number of jurisdictions including
Australia in respect of the drug clopidogrel which is usually prescribed to patients
who have suffered, or are at risk of suffering, a heart attack or stroke. Sanofi earned
annual worldwide revenue from sales of clopidogrel equivalent to more than
\$1 billion. Clopidogrel had been supplied by Sanofi in Australia in tablet form
since 1998 and it was first listed on the Pharmaceutical Benefits Scheme ("**PBS**")
on 1 November 1999.

4 The Apotex group of companies was at all material times a substantial
manufacturer and distributor of generic medicines worldwide. It developed a
generic clopidogrel product which it sought to bring to market in Australia. On
25 September 2007, Sanofi gave the usual undertaking as to damages in support
of an interlocutory injunction granted by Gyles J of the Federal Court of Australia
that prevented Apotex Pty Ltd ("**Apotex**" or "**Apotex Australia**") from competing
with Sanofi by manufacture and sale of a generic competitor to Sanofi's patented
drug, clopidogrel. That interlocutory order recorded that Apotex undertook not to
take steps to obtain PBS listing of its clopidogrel products.

5 The Federal Court of Australia granted Sanofi a final injunction restraining
Apotex on 19 August 2008. That final injunction was set aside by the Full Court
of the Federal Court in accordance with reasons given on 29 September 2009. The
Full Court made orders to that effect on 13 October 2009, allowing Apotex's appeal

and ordering that Sanofi's patent be revoked. Sanofi's application for special leave to appeal was refused by this Court on 12 March 2010.

6 The appellant, the Commonwealth of Australia ("the **Commonwealth**"), then sought compensation from Sanofi on the undertaking as to damages for loss it says it suffered as a result of Apotex being prevented from supplying clopidogrel generic pharmaceutical products and obtaining PBS listing for those products. The Commonwealth claimed that without the interlocutory injunction (supported by the undertaking as to damages) Apotex would have obtained listing of its clopidogrel products on the PBS on 1 April 2008.

7 The Commonwealth alleged that Sanofi's conduct in seeking and obtaining the interlocutory injunction prevented reduction in prices for clopidogrel products that would have arisen from Apotex's PBS listing of those products on 1 April 2008 and which consequently led the Commonwealth to suffer approximately \$325 million in losses (excluding interest and costs). But based on findings of the primary judge in the Federal Court of Australia, which were not disturbed by the Full Court of the Federal Court of Australia ("the **Full Court**"), and were not in issue in this Court, around \$314 million of the Commonwealth's asserted loss of \$325 million was found not to be within the scope of the undertaking as to damages. Specifically, other than in respect of around \$11 million of the alleged losses, the interlocutory injunction and the undertaking given in support of it were "totally eclipsed"¹ by the grant of the final injunction.

8 After a trial that ran for 17 days, the primary judge concluded that the Commonwealth had not discharged its onus, and was "not persuaded that Apotex ... would have sought and obtained a PBS listing of its clopidogrel products from 1 April 2008 even if the interlocutory injunction had not been granted".² This was particularly so due to the combined effect of two important events which occurred shortly before the interlocutory injunction was granted. The second event, in combination with the first, had the potential to transform radically any calculus as to Apotex's future action. No evidence about the effect of these two events on Apotex was called from the central person in the Commonwealth's "camp",³

1 *Fenris Consulting Ltd v Ennismore Fund Management Ltd* [2022] 2 CILR 1 at 21 [50] (Privy Council), quoting *Ennismore Fund Management Ltd v Fenris Consulting Ltd* [2020] 2 CILR 147 at 191 [110].

2 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 309 [351].

3 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 411 ALR 315 at 393 [358].

3.

Dr Bernard (known as "Barry") Sherman. Dr Sherman was the co-founder of Apotex Inc ("**Apotex Canada**"), its Chief Executive Officer and Chairman, the "ultimate controller"⁴ of the Apotex group (including Apotex Australia), and the person who would make the ultimate decision about listing on the PBS.⁵ The ultimate conclusion of the primary judge, as well as his Honour's reasoning, was unanimously affirmed by the Full Court after a wide-ranging appeal over seven days. That analysis was not clearly wrong and was not productive of injustice.

9 One submission made by the Commonwealth before the Full Court, which was heavily relied upon in this Court, was that at the hearing of the interlocutory injunction, but prior to the second event, senior counsel for Apotex had told the Court that Apotex intended to apply for PBS listing if there was no interlocutory injunction granted. An undertaking as to damages was offered by Apotex. The Commonwealth, quite properly, did not make a submission that such a statement by senior counsel could somehow create an estoppel precluding Apotex from arguing that Dr Sherman might subsequently have decided not to apply for PBS listing despite the second event. Indeed, the Commonwealth conceded that subsequent events (such as a factory burning down) might have led Dr Sherman not to make that application. Even assuming that senior counsel's instructions on this point had been given by Dr Sherman, Dr Sherman's approach to PBS listing after the second event would have depended upon the strength of Dr Sherman's prior intention to apply for PBS listing. But Dr Sherman was not called by the Commonwealth. And nothing about the strength of any intention of Dr Sherman could be inferred from Apotex's offer of an undertaking as to damages. If no interlocutory injunction had been granted but Apotex subsequently decided not to seek PBS listing and undertook not to do so, Sanofi would have consented to orders permitting withdrawal of the undertaking in a heartbeat.

10 Since it was common ground that Dr Sherman's intention to apply for PBS listing was not absolute or fixed, this Court was invited to engage in a minute analysis of the evidence at trial in order to ascertain the nature of Dr Sherman's intention in the counter-factual scenario that the injunction had not been granted. The central question on this appeal is whether this Court should overturn many concurrent and unanimous findings of fact in the courts below in circumstances where: (i) the consequences for the Commonwealth that follow from those findings are insignificant to it; (ii) the Commonwealth's grounds of appeal in this Court, specifically the broadly expressed second ground of appeal, cannot be read

4 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 281 [199].

5 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 307 [339].

4.

as a rolled up ground of appeal that effectively invites this Court to run a new trial and to revisit all of the particular grounds of appeal before the Full Court which raised no point of general public importance; (iii) the record before this Court of the proceedings in the courts below is incomplete and involves only a selection of evidence, transcripts and submissions; (iv) the findings of the primary judge and the Full Court were open and are not clearly wrong; and (v) it is not open to the Commonwealth on a third hearing of the issues to revisit findings of fact.

11 The answer to the central question is, emphatically, "no".

Issues and non-issues: the scope of the appeal

12 There were two grounds of appeal in this Court. Those grounds identified the issues in this appeal. The scope of the appeal is governed by the grounds of appeal. At no point did the Commonwealth seek to amend or enlarge its grounds of appeal in this Court.

(1) First ground of appeal – question of law

13 The first ground of appeal in this Court was principally a question of law. That legal issue, as raised in the special leave application, concerned the onus of proof in a claim made on an undertaking as to damages. The first ground alleged that the Full Court erred in failing to hold: (i) that the Commonwealth's evidential burden was to establish a *prima facie* case that its loss flowed directly from the interlocutory injunction; and (ii) that, once that was established, an evidential burden shifted to Sanofi to establish that Apotex would not have sought listing on the PBS even if not enjoined (**ground 1(a)**). The second, and subsidiary, ground of appeal concerned the application to findings of fact of the proper approach to the question of onus. The Commonwealth submitted that it had discharged its evidential burden but Sanofi did not (**ground 1(b)**).

14 If the Commonwealth failed on ground 1(a), ground 1(b) was not reached. At one point in oral submissions, the Commonwealth all but abandoned ground 1(a). The Commonwealth properly accepted that adoption of a methodological approach based upon a shifting evidential onus, in the sense of a burden of adducing evidence,⁶ was not required in every case and that the proposed shifting evidential onus, after a *prima facie* case was established, was merely a way of undertaking a rigorous counter-factual analysis. That was correct. The Commonwealth's proposed shifting evidential onus, as articulated in ground 1(a),

6 Williams, "Burdens and Standards in Civil Litigation" (2003) 25 *Sydney Law Review* 165 at 168.

5.

is inconsistent with the approach of this Court in *European Bank Ltd v Evans*,⁷ that the methodology of assessment of compensation on an undertaking as to damages "cannot be constrained by a rigid formulation". An evidential onus might shift to a defendant in circumstances where the defendant's wrongdoing has made proof of loss difficult or impossible⁸ or where adducing particular evidence is peculiarly within the power of the defendant.⁹ But these are flexible principles of civil proof which did not arise in the circumstances of this case. Those principles do not justify a rigid legal rule that a party asserting that it has suffered loss arising from an undertaking as to damages must prove only a prima facie case of loss.

15 Further, properly understood, none of the reasons for decision in this Court in *Air Express Ltd v Ansett Transport Industries (Operations) Pty Ltd*¹⁰ support the Commonwealth's proposed shifting onus. In that case, Air Express sought an inquiry as to damages arising from an undertaking as to damages and compensation for losses suffered from the interlocutory injunction that the undertaking had supported. The interlocutory injunction prevented Air Express from being granted permission to import aircraft into Australia. Whilst it may be that a plaintiff who claims compensation under an undertaking as to damages need only show a prima facie case to obtain an inquiry as to damages,¹¹ the primary judge (Aickin J) and the majority of the Full Court (Barwick CJ, Gibbs and Stephen JJ) held that Air Express was not entitled to compensation because it had not proved that but for the interlocutory injunction it would have obtained the permission and imported the aircraft.¹² A prima facie case, or proof of only the possibility of loss, was insufficient; although the absence of a prima facie case would plainly prevent even an inquiry as to damages. As Gibbs J said, rejecting a submission that there is a shifting onus: the party "who seeks to enforce the

7 (2010) 240 CLR 432 at 439 [17].

8 *Armory v Delamirie* (1722) 1 Strange 505 [93 ER 664]; *Houghton v Immer (No 155) Pty Ltd* (1997) 44 NSWLR 46 at 59; *Cessnock City Council v 123 259 932 Pty Ltd* (2024) 98 ALJR 719 at 747 [129]; 418 ALR 304 at 338.

9 *Blatch v Archer* (1774) 1 Cowper 63 at 65 [98 ER 969 at 970]; *Vetter v Lake Macquarie City Council* (2001) 202 CLR 439 at 454 [36].

10 (1981) 146 CLR 249. See also *Fenris Consulting Ltd v Ennismore Fund Management Ltd* [2022] 2 CILR 1 at 26 [67] (Privy Council).

11 *Air Express Ltd v Ansett Transport Industries (Operations) Pty Ltd* (1981) 146 CLR 249 at 254, 268.

12 *Air Express Ltd v Ansett Transport Industries (Operations) Pty Ltd* (1981) 146 CLR 249 at 306, 309-310, 313-315, 317-318, 320.

undertaking, must prove that the damage he has sustained was caused by the making of the order".¹³

16 In this case, therefore, the Commonwealth bore the legal and evidentiary onus of proof in relation to causation of loss within the scope of the undertaking as to damages while the interlocutory injunction persisted in the period between 25 September 2007 and 19 August 2008. The Commonwealth was required to establish on the balance of probabilities that Apotex would have sought and obtained PBS listing but for the interlocutory injunction. To the extent that ground 1(a) was not abandoned, it must be dismissed and, as a result, ground 1(b) is not reached.

(2) *Second ground of appeal – failure to find, by inference from the evidence, in the absence of the interlocutory injunction, that Dr Sherman would have reconfirmed the plan for Apotex to seek PBS listing*

17 The only other ground of appeal in this Court was that the Full Court erred in failing to find, *by inference from the evidence*, that in the absence of the interlocutory injunction, it was likely that Dr Sherman would have reconfirmed the plan for Apotex to seek PBS listing.

18 On its face, the second ground of appeal may appear to be an open-ended invitation for this Court to conduct a new trial, albeit without any new evidence, of the central issue that had been decided unanimously by the primary judge and the Full Court against the Commonwealth. That approach to the second ground of appeal was not how it was initially conceived by the Commonwealth. In seeking special leave to appeal, the proposed second ground of appeal was framed as a mixed question of law and fact with the second ground as a confined application of the first ground. And on this appeal, the Commonwealth's written submissions in support of the second ground comprised less than two pages in total. The submissions were properly and understandably short because the second ground of appeal had been conceived as dependent upon acceptance of the first. The Commonwealth's written submissions had one sentence which read "[t]he evidence showed that Dr Sherman's decision to launch clopidogrel at risk in Australia was not 'provisional' on 27 June 2007 or at any time before the interlocutory hearing". In support of that sentence, the Commonwealth referred to and relied upon earlier paragraphs in its written submissions which, in turn, referred to other documents and the cross-examination of Mr Millichamp, the Managing Director of Apotex Australia at all relevant times.

13 *Air Express Ltd v Ansett Transport Industries (Operations) Pty Ltd* (1981) 146 CLR 249 at 313.

7.

19 The submissions for the Commonwealth were meticulously and powerfully presented but must be rejected. First, as will be explained, it is contrary to principle to undertake such an inquiry, or challenge concurrent findings of fact, where the appeal does not concern any individual rights, nor expose any plain injustice and the findings of both courts below were open and not clearly wrong. Second, the Commonwealth's oral submissions and its case as properly framed in its special leave application and written appeal submissions in this Court, were inconsistent with such an inquiry.

20 Two matters should be emphasised at the outset. First, the Commonwealth's appeal to the Full Court against the fact finding of the primary judge was not simply dismissed. The findings of fact of the primary judge were relevantly confirmed by the unanimous Full Court. And, second, neither of the Commonwealth's grounds of appeal in this Court suggested, let alone asserted, that the Full Court had erred in concluding that the primary judge had addressed, or adequately addressed, one or more of the Commonwealth's submissions at trial or that the Full Court had failed to address one or more of the Commonwealth's submissions on appeal. Nor, unlike the grounds of appeal in the Full Court, did the second ground of appeal in this Court expressly challenge the finding that the Commonwealth had not established that Apotex would have sought and obtained a PBS listing of its clopidogrel products from 1 April 2008 if the interlocutory injunction had not been granted.

21 The second ground of appeal in this Court was an omnibus ground of appeal absent any particularisation. It stood in stark contrast to ground 2 of the notice of appeal filed in the Full Court – that the primary judge erred in concluding that the Commonwealth had not established that Apotex would have sought and obtained a PBS listing of its clopidogrel products from 1 April 2008 if the interlocutory injunction had not been granted. Ground 2 in the Full Court contained detailed particulars. Particular (a) was directed to the contention (rerun in this Court) that the primary judge erred in failing to hold that the Commonwealth's *onus* was to establish a *prima facie* case that its damage flowed directly from the grant of the interlocutory injunction and in failing to find that the Commonwealth had discharged that onus. That was the subject of ground 1 in this court and has been addressed above.¹⁴ Particulars (c) and (d) were not repeated in the grounds of appeal before this Court. Particular (c) alleged that the primary judge erred in concluding that the Commonwealth's case suffered an evidentiary deficiency due to the failure to call Dr Sherman and in failing to address the Commonwealth's submissions "in relation thereto". Particular (d) alleged that the "extreme delay" by the primary judge in delivering judgment allows an appellate court more readily to conclude that arguments and evidence not addressed by the primary judge were

14 See [13]-[16] above.

8.

overlooked and to more readily establish that the other errors alleged by the Commonwealth could be made out.

22 That leaves particulars (b) and (e). Particular (b) in substance, alleged that the primary judge erred by: (i) failing to have regard, when making findings of credit in ten specific paragraphs of his Honour's reasons, and when "speculating" as to what Apotex might have done had the interlocutory injunction not been granted in 36 specific paragraphs of his Honour's reasons, to "relevant, contemporaneous evidence of Apotex's intention to commence selling clopidogrel products and to apply for a PBS listing if no interlocutory injunction was granted" and to "relevant evidence from witnesses called by the Commonwealth"; and (ii) failing to address, either adequately or at all, submissions of the Commonwealth "in relation thereto". The Full Court addressed each aspect of this particular. Particular (e) was expressed in broader terms, alleging that the primary judge ought to have made positive findings "that, if the interlocutory injunction had not been granted, Apotex would in 2007 have launched and sought listing of its clopidogrel products on the PBS, and would have obtained a PBS listing of its clopidogrel products with effect from 1 April 2008". The Full Court held that this particular did not arise where the Full Court did "not detect[] any error in the trial judge's approach to the issues otherwise raised in Ground 2".¹⁵

23 In stark contrast, in this Court, no particulars of the omnibus second ground of appeal were provided by the Commonwealth.

24 The position then is this. There are concurrent findings of fact by the primary judge and the Full Court. In this appeal, the Commonwealth, by its oral submissions, seeks for this Court to review and evaluate a vast body of evidence, much of which is in conflict, where the findings of fact and counter-fact of the primary judge have been relevantly confirmed by a unanimous Full Court.¹⁶ It is therefore necessary, at the outset, to address the applicable standard of review by an ultimate appellate court. And as will be explained, this appeal did not meet that standard - it does not concern any individual rights, any injustice and the findings are not clearly wrong. Any assessment of the Commonwealth's collateral attack upon the concurrent findings of fact in the courts below would have required a far more complete copy before this Court of the record (of evidence, transcript and submissions) showing how the Commonwealth ran its case in the courts below. That material was not before this Court because the Commonwealth had, properly,

15 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 411 ALR 315 at 400 [389].

16 *South Australia v Johnson* (1982) 42 ALR 161 at 167.

attempted to confine the scope of factual dispute on this appeal.¹⁷ In any event, even on the material before this Court, it is not open, based on the Commonwealth's notice of appeal to this Court and the notice of appeal to the Full Court, for a new case to be developed involving a third set of findings of facts and counter-facts.

Appellate review of facts

25 It is a well-established principle that an ultimate appellate court — a second appellate court — "should *not*, in the absence of special reasons such as plain injustice or clear error"¹⁸ (also referred to as "special circumstances"¹⁹ or "compelling circumstances"²⁰), disturb concurrent findings of fact.²¹ That principle is "long standing". Its importance has not diminished, but rather increased, "in the circumstances of modern litigation".²²

26 That principle reflects, and is rooted in, the nature of an appeal to this Court. An appeal to an intermediate court of appeal is, typically, an appeal by way of rehearing.²³ Under s 73 of the *Constitution*, an appeal to this Court is different; it

17 See [49] below.

18 *Louth v Diprose* (1992) 175 CLR 621 at 634 (emphasis added).

19 *Waltons Stores (Interstate) Ltd v Maher* (1988) 164 CLR 387 at 434-435.

20 *New South Wales v Fahy* (2007) 232 CLR 486 at 534 [153].

21 *The Commonwealth v Introvigne* (1982) 150 CLR 258 at 274; see also at 262; *South Australia v Johnson* (1982) 42 ALR 161 at 167; *Waltons Stores (Interstate) Ltd v Maher* (1988) 164 CLR 387 at 434-435; *Louth v Diprose* (1992) 175 CLR 621 at 634; *Bridgewater v Leahy* (1998) 194 CLR 457 at 471 [43]; *Kozarov v Victoria* (2022) 273 CLR 115 at 134 [49].

22 *Roads and Traffic Authority of New South Wales v Dederer* (2007) 234 CLR 330 at 334 [5].

23 See, eg, *Federal Court of Australia Act 1976* (Cth), ss 27, 30AI; *Supreme Court Act 1933* (ACT), s 37N; *Supreme Court Act 1970* (NSW), s 44; *Supreme Court Act 1979* (NT), s 51; *Supreme Court of Queensland Act 1991* (Qld), s 29(3); *Uniform Civil Procedure Rules 1999* (Qld), r 765(1); *Supreme Court Act 1935* (SA), s 19D; *Criminal Code Act 1924* (Tas), s 409; *Supreme Court Civil Procedure Act 1932* (Tas), s 46; *Supreme Court Act 1986* (Vic), s 10(3); *Criminal Appeals Act 2004* (WA), s 40; *Supreme Court Rules 1971* (WA), O 65, r 8.

is a "strict" appeal concerned with error.²⁴ In the appeal before this Court, the "strict" appeal is brought after the appellant has had a trial of the issues of fact and law following which the primary judge made findings of fact, and then after that, the appellant has had an appeal to the intermediate court of appeal, by way of rehearing, where the intermediate court made substantially the same relevant findings of fact as the primary judge made. As Gleeson CJ said in *Roads and Traffic Authority of New South Wales v Dederer*,²⁵ "[i]n an appeal of this nature, the function of this Court, as a second appellate court and a court of final resort, is not simply to give a well-resourced litigant a third opportunity to persuade a tribunal to take a view of the facts favourable to that litigant".

27 Concurrent findings may exist at different levels of particularity — with or without an element of normative judgment.²⁶ This appeal is concerned with concurrent findings of fact that involved no value judgment. In the application of the "clear error" principle, it is immaterial that the concurrent findings of fact were of primary fact or involved conclusions and inferences drawn from primary facts.²⁷

28 In challenging concurrent findings of fact in this Court, an appellant confronts a high bar — a difficult task.²⁸ The appellant carries the burden of establishing "special reasons such as plain injustice or clear error".²⁹ The high bar is implicit in the requirement that there be *plain injustice* or *clear error*, not merely error.³⁰ If the findings of fact made in the courts below *appear* to be correct, the

24 See, eg, *Mickelberg v The Queen* (1989) 167 CLR 259 at 267; *Roads and Traffic Authority of New South Wales v Dederer* (2007) 234 CLR 330 at 378-379 [164].

25 (2007) 234 CLR 330 at 334 [5].

26 *Graham Barclay Oysters Pty Ltd v Ryan* (2002) 211 CLR 540 at 567 [50]. cf *Bridgewater v Leahy* (1998) 194 CLR 457 at 489-493 [112]-[122] and *Waltons Stores (Interstate) Ltd v Maher* (1988) 164 CLR 387 at 434-435.

27 *Louth v Diprose* (1992) 175 CLR 621 at 634.

28 *Baffsky v Brewis* (1977) 51 ALJR 170 at 172; 12 ALR 435 at 438: "where there have been concurrent findings of fact or concurrent views as to the exercise of a discretion, an appellant has in this Court at least a difficult task in persuading it that nonetheless it ought to set aside such findings or that exercise of discretion" but this Court is "in a proper case able to depart from them".

29 *Louth v Diprose* (1992) 175 CLR 621 at 634.

30 cf *MW v Director-General, Department of Community Services* (2008) 82 ALJR 629 at 660-661 [184]; 224 ALR 205 at 246.

high bar is not cleared and the appellant will not have discharged its burden.³¹ The point that the ultimate appellate court must reach is that it holds a "clear conviction"³² that the findings made at trial *and* confirmed by the intermediate appellate court, understood in light of the arguments put by the parties at trial and on appeal, are clearly wrong.³³ It is not enough that an ultimate appellate court would simply reach a different conclusion of its own.³⁴ It is irrelevant if there were differences in the reasoning of the primary judge and the intermediate appellate court, or if there was a dissentient in the intermediate appellate court.³⁵ By contrast, where the errors made in the courts below lay in fundamental errors of law, then concurrent findings of fact are no insulation.³⁶

- 29 Nothing is gained by parsing and analysing the phrases "plain injustice" or "clear error". Both are expressed in emphatic terms. In many cases clear error will bespeak plain injustice. In other cases, the subject matter of the issues at trial, or the findings made, may permit close attention to whether error has been

31 *Bridgewater v Leahy* (1998) 194 CLR 457 at 471 [43], 472 [47].

32 *Major v Bretherton* (1928) 41 CLR 62 at 70-71, cited by *The Commonwealth v Introvigne* (1982) 150 CLR 258 at 274 and *Roads and Traffic Authority of New South Wales v Dederer* (2007) 234 CLR 330 at 335 [7]. See also *Bridgewater v Leahy* (1998) 194 CLR 457 at 472 [47].

33 *Roads and Traffic Authority of New South Wales v Dederer* (2007) 234 CLR 330 at 334-335 [6], citing *Graham Barclay Oysters Pty Ltd v Ryan* (2002) 211 CLR 540 at 568-569 [53]-[54], which, in turn, quoted *Owners of the "P Caland" and Freight v Glamorgan Steamship Co* [1893] AC 207 at 216.

34 *MW v Director-General, Department of Community Services* (2008) 82 ALJR 629 at 660-661 [184]; 224 ALR 205 at 246, citing *Eastman v The Queen* (2000) 203 CLR 1 at 13 [18], 24 [68], 54 [164], 63 [190] and *Mickelberg v The Queen* (1989) 167 CLR 259.

35 *Louth v Diprose* (1992) 175 CLR 621 at 634; *Bridgewater v Leahy* (1998) 194 CLR 457 at 471 [43]; *Graham Barclay Oysters Pty Ltd v Ryan* (2002) 211 CLR 540 at 568 [52].

36 *Roads and Traffic Authority of New South Wales v Dederer* (2007) 234 CLR 330 at 344 [42]. See also *Fingleton v The Queen* (2005) 227 CLR 166.

demonstrated. Such cases may include ones concerning liberty,³⁷ bodily integrity,³⁸ reputation³⁹ or potential financial ruin.⁴⁰ What is to be emphasised is that the cases in which this Court overturns concurrent findings of fact will be rare. And the Court will not overturn concurrent findings of fact unless the appellant establishes that *both* the primary judge *and* the intermediate court of appeal were clearly wrong to make the findings that they did. This is not such a case.

30 Many decisions of this Court have explained why there is a sense of "trepidation" about interfering in concurrent findings of fact of a primary judge and an intermediate appellate court⁴¹ and why it is not the function of this Court, a final appellate court, to perform the tasks of fact finding and factual review. The task of this Court, an ultimate appellate court, is *not* to undertake an inquiry into a long-concluded trial or to seek to resurrect it. An appeal to this Court is not an appeal by way of rehearing, still less a trial or retrial,⁴² but a strict "appeal" concerned with error.

31 But that is not all. The law values finality, a basic principle of our legal system.⁴³ Appellate restraint in relation to review of fact finding promotes

37 See, eg, *Fennell v The Queen* (2019) 93 ALJR 1219; 373 ALR 433; *Pell v The Queen* (2020) 268 CLR 123; *Bromley v The King* (2023) 98 ALJR 84; 416 ALR 570.

38 *The Commonwealth v Introvigne* (1982) 150 CLR 258 at 262; *Woods v Multi-Sport Holdings Pty Ltd* (2002) 208 CLR 460 at 502-503 [136]-[141].

39 *Australian Securities and Investments Commission v Hellicar* (2012) 247 CLR 345.

40 *Bahr v Nicolay [No 2]* (1988) 164 CLR 604 at 623. See also *Baffsky v Brewis* (1976) 51 ALJR 170 at 172; 12 ALR 435 at 437-438.

41 *Roads and Traffic Authority of New South Wales v Dederer* (2007) 234 CLR 330 at 378 [164]; cf 410-411 [287]. See also *Modbury Triangle Shopping Centre Pty Ltd v Anzil* (2000) 205 CLR 254 at 274 [58]; *Graham Barclay Oysters Pty Ltd v Ryan* (2002) 211 CLR 540 at 634 [262]; *Aktiebolaget Hassle v Alphapharm Pty Ltd* (2002) 212 CLR 411 at 447-448 [95]; *Nominal Defendant v GLG Australia Pty Ltd* (2006) 228 CLR 529 at 552 [74]; *New South Wales v Fahy* (2007) 232 CLR 486 at 534 [153].

42 *Mickelberg v The Queen* (1989) 167 CLR 259 at 267; *Roads and Traffic Authority of New South Wales v Dederer* (2007) 234 CLR 330 at 378-379 [164].

43 See, eg, *Wollongong University v Metwally [No 2]* (1985) 59 ALJR 481 at 483; 60 ALR 68 at 71; *Coulton v Holcombe* (1986) 162 CLR 1 at 8-9; *Liftronic Pty Ltd v*

finality.⁴⁴ Rights of appeal qualify the application of the principle of finality but, absent the potential for injustice, that qualification is not expanded to challenges to concurrent findings of fact unless clear error is shown without the need for minute examination of the facts.

32 These foundational principles are sufficient to support the principle of restraint exercised by this Court, as a final appellate court, in its focus upon injustice and clear error. In other words, contrary to submissions that were made orally on this appeal, the rule does not depend on the *capacity* for this Court to revisit findings of fact, such as in circumstances where the case is primarily documentary and issues of demeanour are subsidiary. Nevertheless, even in those cases, there are further reasons that support the principle.

33 The exercise of appellate caution in reversing findings of fact, let alone concurrent findings of fact, is more than "professional courtesy".⁴⁵ The need for caution recognises, as Lord Hoffmann once observed, that "specific findings of fact, even by the most meticulous judge, are inherently an incomplete statement of the impression which was made upon [them] by the primary evidence".⁴⁶ The "expressed findings are *always* surrounded by a penumbra of imprecision as to emphasis, relative weight, minor qualification and nuance ... of which time and language do not permit exact expression, but which may play an important part in the judge's overall evaluation".⁴⁷ That is unsurprising. In civil cases, a court finds that a disputed event occurred if the occurrence of the event is more probable than not. But fact finding is not a science and, in resolving conflicting evidence, there is often scope for legitimate differences of view about what facts have been proved. These observations about the principle of finality and appellate restraint in an ultimate appellate court are "not inconsistent with doing justice to the parties". Justice has "more than one dimension".⁴⁸ Reformulation of the facts on an appeal can lead to an inherently unfair situation — a factual decision by an ultimate

Unver (2001) 75 ALJR 867 at 875 [44]; 179 ALR 321 at 331; *D'Orta-Ekenaike v Victoria Legal Aid* (2005) 223 CLR 1 at 17 [34]; 20-21 [45]-[46].

44 *Roads and Traffic Authority of New South Wales v Dederer* (2007) 234 CLR 330 at 336-337 [12].

45 *Biogen Inc v Medeva plc* [1997] 1 RPC 1 at 45.

46 *Biogen Inc v Medeva plc* [1997] 1 RPC 1 at 45.

47 *Biogen Inc v Medeva plc* [1997] 1 RPC 1 at 45 (emphasis added).

48 Bell, "Appellate review of the facts" (2014) 39 *Australian Bar Review* 132 at 136-138, 145.

appellate court cannot be further appealed if errors of fact or inference are revealed in the reasons of that court.⁴⁹

34 The well-established principle is also consistent with the criteria for granting special leave to appeal to this Court.⁵⁰ Concurrent findings of fact that are plainly wrong may justify the grant of special leave having regard to the interests of justice in the particular case. But the less apparent the error, and the less the potential for injustice, the less likely it will be that the interests of justice will favour a grant of special leave. The special leave process will generally operate as the mechanism by which this Court ensures that it is only tasked with reconsidering concurrent factual findings where there are special reasons, such as plain injustice. However, as this case shows, where an appellant departs from the case presented in its special leave application, the Court may be in the position of having to consider whether there is "clear error" sufficient to justify disturbing concurrent findings of fact.

35 These matters, taken together with questions about the deployment of the time required by a final court to undertake such a review, combine to reinforce the well-established principle that an ultimate appellate court — a second appellate court — should *not* in the absence of "special reasons", such as plain injustice or clear error, disturb concurrent findings of fact.

36 This is no uniquely Australian view.

37 In Canada, the standard for intervention has been set out and reaffirmed in an unbroken line of cases for decades.⁵¹ As the "second level of appeal",⁵² the Supreme Court of Canada adopts a "principle of non-intervention"; the "Court's role is not to reassess the findings of fact of a judge at the trial level that an appellate court has not questioned", a principle "all the stronger in the face of

49 See, eg, *Rae v International Insurance Brokers (Nelson Marlborough) Ltd* [1998] 3 NZLR 190 at 199.

50 *Judiciary Act 1903* (Cth), s 35A.

51 *HL v Canada (Attorney General)* [2005] 1 SCR 401 at 424-427 [62]-[76] and the authorities cited. See also *Quebec (Director of Criminal and Penal Prosecutions) v Jodoin* [2017] 1 SCR 478 at 501 [51].

52 *Quebec (Director of Criminal and Penal Prosecutions) v Jodoin* [2017] 1 SCR 478 at 501 [51].

concurrent findings of both courts below"⁵³ *unless* there is a "*palpable and overriding error* in the ... analysis of the facts".⁵⁴ "Palpable and overriding error", although used as "an elegant and expressive description of the entrenched and generally applicable standard of appellate review of the findings of fact at trial",⁵⁵ does not displace alternative formulations of the governing standard of "clearly wrong",⁵⁶ "absolutely wrong"⁵⁷ or "clearly wrong or erroneous".⁵⁸ Reflecting the principle of non-intervention, the Court will not reverse concurrent findings "even though the evidence on which the courts below based their findings of fact might appear weak".⁵⁹

38 In the United States, where judicial review of findings of trial courts does not have the statutory or constitutional limitations on judicial review of findings by administrative agencies or by a jury, from at least the 1940s the Supreme Court of the United States has adopted what has been described as the "heavy burden

53 *Quebec (Director of Criminal and Penal Prosecutions) v Jodoin* [2017] 1 SCR 478 at 501 [51] (emphasis added), quoting *St-Jean v Mercier* [2002] 1 SCR 491 at 509 [45], which, in turn, quotes *Ontario (Attorney General) v Bear Island Foundation* [1991] 2 SCR 570 at 574.

54 *Quebec (Director of Criminal and Penal Prosecutions) v Jodoin* [2017] 1 SCR 478 at 501 [51] (emphasis added); *HL v Canada (Attorney General)* [2005] 1 SCR 401 at 410 [4].

55 *HL v Canada (Attorney General)* [2005] 1 SCR 401 at 421 [55]. The reference to the "generally applicable standard of appellate review" reflects the fact that in Canada the non-intervention principle applies to intermediate appellate courts: *Quebec (Director of Criminal and Penal Prosecutions) v Jodoin* [2017] 1 SCR 478 at 501 [51].

56 See, eg, *HL v Canada (Attorney General)* [2005] 1 SCR 401 at 421 [55], quoting *Housen v Nikolaisen* [2002] 2 SCR 235 at 253 [22], 296 [103].

57 *Trans-Canada Shoe Ltd v Travelers Indemnity Co* [1976] 2 SCR 46 at 53-54 and the authorities cited.

58 *Trans-Canada Shoe Ltd v Travelers Indemnity Co* [1976] 2 SCR 46 at 53-54, quoting *Sénésac v The Central Vermont Railway Co* (1896) 26 SCR 641 at 646.

59 *Trans-Canada Shoe Ltd v Travelers Indemnity Co* [1976] 2 SCR 46 at 54, citing *George Matthews Co v Bouchard* (1898) 28 SCR 580.

under the 'two-court rule':⁶⁰ "[a] court of law, such as this Court is, rather than a court for correction of errors in fact finding, cannot undertake to review concurrent findings of fact by two courts below in the absence of a *very obvious and exceptional showing of error*".⁶¹ The Court must be "left with the definite and firm conviction that a mistake has been committed".⁶² In *Goodman v Lukens Steel Co*,⁶³ the Court indicated it was "not inclined to examine the record for ourselves absent some extraordinary reason for undertaking this task" where the appellant provides no compelling reason for the Court to do so. In persuading the Court to exercise its jurisdiction to review concurrent findings of fact, the appellant's burden has been described as "heavy".⁶⁴ A finding is not "clearly erroneous" if there is evidence to support it.⁶⁵ In its modern application, the Court has been more interventionist where the decision for review concerns denaturalization⁶⁶ or where

60 *United States v Reliable Transfer Co* (1975) 421 US 397 at 401, citing *Graver Tank & Manufacturing Co v Linde Air Products Co* (1949) 336 US 271 at 275. See also *District of Columbia v Pace* (1944) 320 US 698 at 702; Stern, "Review of Findings of Administrators, Judges and Juries: A Comparative Analysis" (1944) 58 *Harvard Law Review* 70 at 89.

61 *Exxon Co, USA v Sofec, Inc* (1996) 517 US 830 at 841 (emphasis added), quoting *Graver Tank & Manufacturing Co v Linde Air Products Co* (1949) 336 US 271. See also *Berenyi v District Director, Immigration and Naturalization Service* (1966) 385 US 630 at 635; *Goodman v Lukens Steel Co* (1987) 482 US 656 at 665; *Flowers v Mississippi* (2019) 139 S Ct 2228 at 2266.

62 See, eg, *United States v United States Gypsum Co* (1948) 333 US 364 at 395.

63 (1987) 482 US 656 at 665.

64 *United States v Reliable Transfer Co* (1975) 421 US 397 at 401.

65 See, eg, *Williams Manufacturing Co v United Shoe Machinery Corp* (1911) 316 US 364 at 367. In relation to the *Federal Rules of Civil Procedure*, r 52(a)(6), see *Anderson v Bessemer City* (1985) 470 US 564 at 573-575; *Teva Pharmaceuticals USA, Inc v Sandoz, Inc* (2015) 574 US 318 at 324; *Cooper v Harris* (2017) 137 S Ct 1455 at 1465; *Alexander v South Carolina State Conference of the NAACP* (2024) 144 S Ct 1221 at 1270-1271.

66 See, eg, *Baumgartner v United States* (1944) 322 US 665 at 670.

a person's citizenship⁶⁷ or liberty is at stake.⁶⁸ This can be contrasted with the Court's reasoning in *The Conqueror*,⁶⁹ where it held that the large sum of money involved did not justify the Court's reconsideration of concurrent findings of fact.

39 In the United Kingdom, "only in comparatively rare cases" will the Supreme Court of the United Kingdom interfere with concurrent findings of fact by lower courts⁷⁰ and then, "only where it can be shown that *both courts* were *clearly wrong*".⁷¹ In the United Kingdom, a range of adverbs have been used – "clearly", "plainly", "blatantly", "palpably" wrong.⁷²

Counter-factual test and the two issues for the appeal

40 The counter-factual question at trial concerned whether Apotex would have sought and obtained listing of its clopidogrel products on the PBS on 1 April 2008, and hence launched its generic product, if it had not been subject to the interlocutory injunction.

67 See, eg, *Nowak v United States* (1958) 356 US 660 at 663; *Fedorenko v United States* (1981) 449 US 490 at 505.

68 See, eg, *Chaunt v United States* (1960) 364 US 350 at 353; *Costello v United States* (1961) 365 US 265 at 269-270.

69 (1897) 166 US 110 at 136.

70 *Montgomery v Lanarkshire Health Board (General Medical Council intervening)* [2015] AC 1430 at 1465 [97]. The position in the Privy Council is similar, if not stricter: see, eg, *Srimati Bibhabati Devi v Kumar Ramendra Narayan Roy* [1946] AC 508 at 521 (Privy Council); *Central Bank of Ecuador v Conticorp SA* [2016] 2 LRC 46 at 54-57 [4]-[8] (Privy Council).

71 *Montgomery v Lanarkshire Health Board (General Medical Council intervening)* [2015] AC 1430 at 1465 [97], quoting *Higgins v J & C M Smith (Whiteinch) Ltd* (1990) SC (HL) 63 at 82 (emphasis added). See also *Hicks v Chief Constable of the South Yorkshire Police* [1992] 2 All ER 65 at 68.

72 See, eg, *Assicurazioni Generali SpA v Arab Insurance Group* [2003] 1 WLR 577 at 578-579 [9], 584 [197], quoting *Tanfern Ltd v Cameron-MacDonald (Practice Note)* [2000] 1 WLR 1311 at 1317 [32]; [2000] 2 All ER 801 at 808, which, in turn, quotes *G v G (Minors: Custody Appeal)* [1985] 1 WLR 647 at 652; [1985] 2 All ER 225 at 229; but cf *In re B (A Child) (Care Proceedings: Threshold Criteria)* [2013] 1 WLR 1911 at 1943-1944 [92]-[96]; [2013] 3 All ER 929 at 960-961.

41 When a counter-factual inquiry is undertaken, the only facts that should be removed from "real world" lawful activity that has taken place are those that are necessary for the counter-factual.⁷³ As senior counsel for the Commonwealth correctly submitted, the only facts that should be removed from the inquiry in this case are the order by Gyles J on 25 September 2007 granting the interlocutory injunction and anything that is inextricably connected with the order, such as the reasons that his Honour gave for the decision.

42 In assessing the counter-factual by reference to what would have been done in all the circumstances of the real world absent the order of Gyles J and anything inextricably connected with it, the focus is upon what Apotex would have done. As the Full Court correctly concluded (in rejecting the relevance of opinions of the Managing Director of Sanofi), the focus is not upon what others, who did not have all the information and were not in the position of the decision maker, thought that Apotex might have done.⁷⁴

43 In other words, in assessing what Apotex would have done if the interlocutory injunction had not been ordered, all facts in the real world fall to be considered in assessing the counter-factual question with the exception of the order, and then the reasons for decision given by Gyles J, and any other matter inextricably connected with the decision of Gyles J concerning the interlocutory injunction.

44 In applying that approach, there are two issues. A consideration of each shows that this appeal must be dismissed. The first is that the concurrent findings of the primary judge and the Full Court that supported the counter-factual conclusion were open and are not clearly wrong. The second is that, in any event, it was not open to the Commonwealth on this appeal to revisit many of the factual findings that it sought to reopen.

Basis for the concurrent findings – in outline

45 The trial before the primary judge ran for 17 days. The primary judge dismissed the Commonwealth's application for compensation. The primary judge's reasons for decision were detailed — comprising 698 paragraphs and 164 pages. The factual analysis alone took 224 paragraphs and more than 50 pages. The ultimate conclusion of the primary judge, as well as his Honour's reasoning, were relevantly affirmed, unanimously, by the Full Court after a wide-ranging appeal

73 *Bostock v Clayton County, Georgia* (2020) 140 S Ct 1731 at 1739.

74 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 411 ALR 315 at 386 [331].

over seven days. The Full Court's reasons comprise 392 paragraphs and more than 100 pages.

46 In the Full Court in respect of this part of the appeal — ie would Apotex have obtained PBS listing of its clopidogrel products on 1 April 2008 if the injunction had not been granted — the parties prepared an agreed chronology which set out the documents and ID references for the documents which the primary judge referred to as well as those which the primary judge did not refer to ("the **Joint Chronology FC**").

47 In this Court, the parties provided an amended Joint Chronology signed by senior counsel for both parties ("the **Joint Chronology HC**").⁷⁵ The Joint Chronology HC only listed those items relevant to the Commonwealth's grounds of appeal and Sanofi's notice of contention and added some new items which were either before the Full Court but not the subject of a discrete item in the Joint Chronology FC or concerned matters relating to the procedural history of the proceedings. The Joint Chronology HC ran for more than 65 pages and included 244 separate items. It included cross references to other documents including affidavits, court documents, extracts of cross-examination, extracts of submissions before the primary judge and the Full Court, and organization charts. It was divided into Pts A to J:

- A: Pre 2007;
- B: GenRx/Apotex Canada communicate about a possible launch of clopidogrel in Australia;
- C: GenRx communicates with the TGA, Sanofi and its customers about a possible launch of clopidogrel and commences patent revocation proceedings against Sanofi;
- D: PBS Listing Application;
- E: Response to interlocutory injunction application;
- F: Interlocutory hearing;

75 The Joint Chronology HC listed the documents in chronological order and, where relevant, listed the date and time the relevant document was sent or received by reference to Sydney time and Toronto time. In these reasons for decision, the listed Sydney times have been used, unless otherwise specified.

- G: GenRx (now known as Apotex) and Apotex Canada communicate between the grant of the interlocutory injunction and judgment in the patent revocation proceedings about how to respond to a final decision by Gyles J;
- H: Judgment and appeal;
- I: Apotex's PBS listing and claims;
- J: Dramatis Personae.

48 Against each entry, it identified where that entry was addressed by either or both of the primary judge and the Full Court. The "new items" were marked with an asterisk: Pt A (three new items); Pt F (six new items); Pt G (three new items); Pt H (three new items); and Pt I (38 new items). In addition to the Joint Chronology HC, only "[t]he most critical documents" were reproduced in the parties' Joint Book of Further Materials which comprised more than 1760 pages divided into four volumes.

49 As is self-evident, this Court was not provided with a complete, or the same, record as that provided to the Courts below. The Joint Chronology HC was prepared at the request of members of this Court who, having expressed concern that this matter may not be an appropriate vehicle for the grant of special leave, were reassured that a chronology might be "of some considerable use in this Court, and the mysteries will disappear".⁷⁶ The Joint Chronology HC was one (of a number) of steps taken by the Court to seek to confine the issues in dispute between the parties prior to the hearing of this appeal,⁷⁷ and to reduce the material this Court would have to consider.

50 It is both inappropriate and unnecessary to repeat the detailed analysis of the Courts below. Given the manner in which the appeal developed, it is, however, necessary to explain why the concurrent findings of the primary judge and the Full Court were not clearly wrong. Each of the matters below is drawn from the detailed analysis and those concurrent findings.

76 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* [2023] HCATrans 184 (18 December 2023) at 10 [lines 332-349].

77 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* [2023] HCATrans 184 (18 December 2023) at 21-22 [lines 870-895].

(1) *Parties, the patent in respect of clopidogrel, and the North American litigation*

51 The Apotex group of companies was at all material times a substantial manufacturer and distributor of generic medicines worldwide. Mr Roger Millichamp was appointed Managing Director of Apotex Australia (earlier GenRx Pty Ltd and now Apotex Pty Ltd) on 1 March 2006. Mr Millichamp reported to Mr Michael Weingarten (Vice President of Sales at Apotex Canada) from about March 2006 to June 2007, and to Mr Andrew Kay (President of Apotex International Inc) from about June 2007 to late 2008 or early 2009. Mr Weingarten reported to Mr Kay and both were based in the Apotex Canada head office. Both reported to Dr Barry Sherman, the co-founder of Apotex Canada, its CEO and Chairman and the "ultimate controller" of the Apotex group.

52 In short, Mr Millichamp was at the bottom of a reporting chain that culminated with Dr Sherman. It was correctly common ground throughout these proceedings that Dr Sherman called the shots. Dr Sherman would make any significant decisions such as whether Apotex would launch a product in Australia "at risk" of damages for patent infringement.

53 Apotex Canada developed a generic clopidogrel product which it sought to bring to market in the United States, Canada and Australia. Apotex Canada (through its United States affiliate "**Apotex US**") first sought approval to sell generic clopidogrel bisulfate tablets in the United States in 2001. In 2002, Sanofi's United States operation sought to restrain Apotex Canada and Apotex US from infringing its United States patent for clopidogrel. The parties reached a settlement, by an amended settlement agreement, in 2006. However, Apotex Canada and Apotex US sought to avoid the settlement agreement after the agreement was not approved by State Attorneys-General. The United States District Court initially declined to restrain Apotex Canada and Apotex US from launching its product, so the launch proceeded on 8 August 2006. However, on 31 August 2006, a preliminary injunction was granted to Sanofi, restraining Apotex Canada and Apotex US from infringing Sanofi's United States patent.

54 In 2010, Sanofi was awarded US\$442,209,362 in damages (excluding interest and costs), calculated under the amended settlement agreement, representing 50% of the Apotex group's net sales. Despite the size of the US\$442 million damages award, the award was a "highly favourable outcome for Apotex" because the damages were calculated under the amended settlement agreement by reference to Apotex Canada and Apotex US's sales, rather than Sanofi's lost profit. The damages would have potentially been much greater without the benefit of the agreement. In short, with the benefit of the amended

settlement agreement, the launch by Apotex Canada of its product in the United States was not "genuinely 'at risk'".⁷⁸

55 Apotex Canada also sought to launch its clopidogrel product in Canada. An order of prohibition sought by the relevant Canadian Sanofi entities ("**Sanofi Canada**"), and issued by the Federal Court of Canada in 2005, prevented Apotex Canada from obtaining regulatory approval. A final appeal against those orders was dismissed by the Supreme Court of Canada on 6 November 2008. Separate proceedings brought in the Federal Court of Canada by Sanofi Canada, alleging infringement of its Canadian patent, were discontinued in November 2014 (pending an appeal to the Supreme Court of Canada) following the relevant Sanofi Canada and Apotex entities reaching a settlement agreement.⁷⁹

56 The approach taken by Apotex in Australia arose in the context of Apotex Canada's lack of success in litigation in the United States and Canada.

(2) *Events leading up to September 2007*

57 Apotex began to consider launching its generic clopidogrel product in Australia in early 2006. By June 2006, email correspondence between Mr Weingarten and Dr Sherman revealed that Dr Sherman intended to launch the product "at risk" in Australia once Therapeutic Goods Administration approval was obtained, but only if Apotex Canada was successful in its litigation in the United States and Canada (which it was not).

58 On 20 February 2007, Dr Sherman emailed Mr Weingarten and Mr Millichamp, setting out a "[p]lan" for the launch of Apotex's generic clopidogrel product in Australia. Dr Sherman's plan included: filing a claim seeking to invalidate Sanofi's patent in May or June 2007; informing Sanofi of Apotex's intention to launch unless Sanofi obtains an injunction supported by an undertaking as to damages; and launching the product if Sanofi did not give the undertaking and obtain the injunction.

59 By April 2007, albeit without concluded results from the litigation in the United States and Canada, Dr Sherman had changed his mind about launching at risk in Australia only if Apotex Canada was successful in the United States and Canada. In an email from Mr Kay to Mr Lydeamore (Vice President Business

78 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 282-284 [206]-[218].

79 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 282 [201]-[205].

23.

Development at Apotex Canada) on 13 April 2007, Mr Kay repeated Dr Sherman's instructions, "[Dr Sherman]'s instruction is to attempt to launch at risk and then invalidate".

60 On 22 June 2007, three days after Sanofi's United States patent had been upheld in the United States, Mr Millichamp sent an email to Mr Kay, setting out his recommendation that Apotex Australia launch a clopidogrel product in Australia. Attached to that email were tables setting out the projected sales figures in two scenarios should Apotex Australia launch the product. However, that email did not contain any consideration of the financial impact on Apotex should a claim for patent infringement by Sanofi be upheld. The email, including its attachment, was not an assessment of the financial risk versus reward from launching.

61 On 25 June 2007, following an earlier request from Mr Kay, Mr Millichamp provided Mr Kay with further information concerning a proposed launch of Apotex's product. Mr Millichamp explained that he would not propose a launch without PBS listing because sales would be low, "virtually zero without PBS reimbursement", in that scenario. Mr Millichamp said that Apotex should submit an application for listing once it was sure that no injunction would be imposed and that "we will need to let the judge know that we plan to PBS list". Mr Millichamp also estimated the amount of a bank guarantee that might be required from Apotex as security for costs in resisting any injunction could be \$50-70 million for "one year's damages".

62 The same day, 25 June 2007, Mr Kay sent Dr Sherman an email, asking him to "please re-confirm or otherwise our approach in Australia". Mr Kay explained that the approach which he sought to have confirmed was that upon the expected grant of approval by the Therapeutic Goods Administration in July/August 2007, "we will move towards launch and initiate revocation proceed[ing]s [sic]". After some responses and exchanges that were wholly redacted for legal professional privilege, Dr Sherman sent an email to Mr Kay at 11.44am on 26 June 2007, only part of which was not redacted, that said, "[w]e will stay with bisulfate in Australia", but there was no evidence of the context of this email or the conditions upon which such a decision was being made or to be implemented. After this, Dr Sherman sent a further email to Mr Kay at 11.49am, which was entirely redacted. Mr Kay responded to this further email at 11.54am, asking Dr Sherman to "[p]lease advise when you have decided whether to pursue revocation of [Sanofi's] patent and if you wish us to move to launch at risk".

63 On 27 June 2007, two emails were sent by Dr Sherman in response. The content of those emails, received in Australia at 4.44am and 5.12am, was entirely redacted on the basis of legal professional privilege. An email from Mr Millichamp to some of his colleagues at Apotex Australia at 11.23am that day, referring to matters that had been redacted for legal professional privilege, said "FYI –Game

on !!!". Mr Millichamp also emailed Mr Haas (Corporate Project Manager, New Product Demand Planning at Apotex Canada) later that day, saying in a heavily redacted email: "[i]f we are successful in avoiding an injunction we will plan to launch subject to [Dr Sherman]'s further advice/approval".

64 Mr Haas responded to Mr Millichamp at 12am on 28 June 2007 thanking him for the update and asking that "[o]nce known, please advise as to estimated launch date so that I can have forecasts shifted out accordingly". Mr Haas told Mr Millichamp that he would, "however, initiate blister tooling activities to determine timing for providing [Mr Millichamp] with pack count desired for AUS market" as "tooling leadtimes can be as long as 6 months".

65 On 28 June 2007 at 10.28pm, Mr Millichamp forwarded an email to Mr Haas with redacted words that preceded a statement that "as per instructions from [Dr Sherman] the plan (in outline) for clopidogrel is as follows". The plan that was then set out involved seeking to have the Sanofi patents revoked and resisting an application by Sanofi for an interlocutory injunction which, if Apotex were successful, would lead to a launch after PBS listing at the "earliest [in] December [20]07". Mr Millichamp said:

"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."

Mr Millichamp concluded by saying:

"Please confirm when you would like purchase orders raised. We are not sure that we can launch yet so need to know if we should place orders in anticipation or should wait. [Dr Sherman] has made it clear that he does not want to waste money on launch activities until we are clear on what we can do".

66 The same day, 28 June 2007, at 11.02pm, Mr Haas responded by saying that the "[s]trategy from my side is to get everything in place so that we can proceed with commercial manufacture immediately once given the go-ahead". Mr Haas then replied again at 11.44pm saying "One further question[.] Is [Dr Sherman] in the loop the strategy below (potentially launch end October but latest Mid November)?".

67 On 29 June 2007, at 5.19am, Jeremy Desai (Executive Vice-President of Research and Development at Apotex Canada) sent an email to some of his colleagues in Apotex Canada clarifying "our position for Australia". The email stated that: Apotex would be notifying Sanofi of its intention to launch in Australia; Apotex expected Sanofi to sue Apotex; Apotex would litigate Sanofi's patent in

25.

court; Apotex would not be making any launch stocks even though they expected approval in the next couple of months; and Apotex would file "ASAP".

68 On 8 August 2007, Mr Kay said in an email to Mr Haas and Dr Sherman that "[w]e are assuming that [Sanofi's application for interlocutory relief] will be successful and are thus not planning to launch at this stage". Dr Sherman responded to this email, instructing that Sanofi be put on notice as to Apotex's intention to launch the generic clopidogrel products "ASAP". Mr Kay's response the following day is redacted. Mr Millichamp's response to Mr Kay, copying Dr Sherman, is also heavily redacted but includes the passage that if Apotex is successful in defending against an injunction "we would like to launch as soon as possible. The earliest date that we can get PBS (Government reimbursement) listing is Dec 07". Mr Millichamp said that Apotex Australia had asked Mr Haas to prepare a launch plan "so that in the event we are successful we can launch as soon as possible". Plainly, without the context of the heavily redacted email it is impossible to assess the extent to which Mr Millichamp was suggesting an unconditional commitment. Mr Caccamo (Director, Global Demand Planning at Apotex Canada) replied to the heavily redacted email from Mr Millichamp, saying that launch plans had been aligned accordingly. Mr Kay also replied to the heavily redacted email, copying Dr Sherman, saying "[t]hanks for the comprehensive update[.] OK by me", as did Mr Haas, who thanked Mr Millichamp "for providing further clarity". Mr Kay also sent another reply to Mr Millichamp's heavily redacted email, addressed to Mr Millichamp only, saying "[t]his looks fine".

69 Subsequently, Apotex took steps towards having its products listed on the PBS, to commence proceedings against Sanofi seeking to invalidate their patent, and to advertise to the market that they were taking steps to launch a generic clopidogrel product.

70 On 17 August 2007, Mr Millichamp provided a letter to the sales team at Apotex Australia, suggesting it should be circulated to customers, which contained the following information: that Apotex intended to launch its clopidogrel product in Australia; that Apotex had commenced legal proceedings to invalidate Sanofi's patent; that Apotex expected that Sanofi may apply for interlocutory relief to prevent the launch; and that a trial concerning any final relief (in respect of the validity of the patent) would occur within 12-18 months of the date of letter.

(3) *Two unexpected events in September 2007*

71 Two important, but unexpected, events occurred in September 2007. The first occurred on 4 September 2007. The second was held to have occurred on 21 September 2007. By itself, the first event was effectively meaningless to the counter-factual in this case. But when combined with the second event it had

significant potential to change any calculus concerning whether Apotex would launch at risk.

72 The first unexpected event was that Apotex inadvertently missed the 1 September 2007 deadline for applications for PBS listing by 1 December 2007. Apotex's application was unintentionally submitted late, and subsequently withdrawn on 4 September 2007 after being advised by the Department of Health and Aged Care that day that the late submission would not be accepted. As such, at the time of the hearing of the interlocutory injunction, the earliest available PBS listing for Apotex's clopidogrel products was 1 April 2008, with the deadline for applications falling on 1 December 2007. Mr Millichamp advised Mr Kay of the failure to submit the application on time on 4 September 2007. But that email was not copied to Dr Sherman. On 5 September 2007, Mr Haas responded to Mr Millichamp's email to Mr Kay saying that "[c]onsidering the magnitude of this launch, [he] would like to have all upfront activities completed so that [they] are in a favo[u]rable position once [they] are given the green light to manufacture" but that they would not order the packing components until they had "a favourable litigation outcome".

73 The unchallenged, and (in this Court) unchallengeable, finding of the primary judge was that Dr Sherman was only notified that the listing date had been missed by email from Mr Haas on 15 September 2007 (at 2.37am Sydney time). The email quoted the last communication received from Mr Millichamp that in the event that they were successful in defending against an interlocutory injunction application from Sanofi, the earliest that they could get PBS listing was now April 2008 and that, in that case, they required stock in Australia towards the end of February/start of March 2008 "**assuming that we are able to launch**". The emphasis was in the original.

74 The second unexpected event was foreshadowed only in the most general of terms at a directions hearing on 13 September 2007 when the judge who would hear the interlocutory injunction, Gyles J, indicated a preference for an expedited final hearing. It appears that the directions hearing was heard before both Gyles and Bennett JJ. Following the directions hearing, Mr Millichamp emailed Mr Kay with updates including the following, "[t]he indication from the judge was that they want to move towards a final trial sooner rather than later. The next six months was mentioned, subject to availability of expert witnesses etc.". Mr Millichamp's email update also said "Justice Bennett will monitor progress of the case and take control if Justice G[y]les is unavailable. The Judges had clearly read, in detail, and understood our patent revocation submission". This foreshadowing said nothing about what date would be selected, and left open the precise identity of the trial judge and, therefore, the likely period of time that a decision would take. The second unexpected event occurred on 21 September 2007, at the time when Gyles J delivered orally his reasons for granting the interlocutory injunction. At that time,

Gyles J informed the parties that the final hearing would commence before his Honour on 28 April 2008. The significance of this second unexpected event was not merely that the hearing would take place only four weeks after the earliest date for PBS listing. The significance was also that the judge would be Gyles J, who would retire (and therefore have to deliver a decision) by 22 August 2008.

75 Between 15 September 2007, when the first of these unexpected events (the missed deadline for earlier PBS listing) was notified to Dr Sherman, and 18 September 2007, when the hearing of the interlocutory injunction began, there was no evidence of any communication between Dr Sherman and any person in Apotex Australia about the significance of the first unexpected event (and no evidence that Dr Sherman was even aware of the foreshadowed possibility, in vague terms, of the second unexpected event). The emails from Dr Sherman in this period were as follows.

76 On 14 September 2007 (12.26pm Sydney time), Dr Sherman emailed various people in Apotex Canada asking questions about the tablets to be produced and saying: "We may be launching in Australia soon. Also, it is possible that we will relaunch in the US within months.". There was no suggestion that Apotex Canada and Apotex US ever relaunched in the United States.

77 On 15 September 2007 (2.13am Sydney time), Dr Sherman emailed the same people in Apotex Canada asking: "[w]ho will deal with determining if present inventory can be repacked for Australia". It appears that it was in a reply to this email that Dr Sherman was first informed of the missed listing date and that the first available listing date would be 1 April 2008, as set out at [73] above. No emphasis was placed on this point and there was nothing to alert Dr Sherman to the significance of it. Instead, the reply email emphasised (in bold and underlining) only the words "[i]n this case we will require stock in Australia towards the end of February / Start March 2008 assuming that we are able to launch", as set out at [73] above. Dr Sherman replied asking for details about the longevity of the tablets.

(4) *Interlocutory injunction and undertaking as to damages*

78 On 18 September 2007, Sanofi's application for an interlocutory injunction was heard by Gyles J. Apotex offered to provide security for costs of \$50 million if the injunction was not granted. That security for costs would be provided as a bank guarantee but there was no evidence as to the cost to Apotex of the bank guarantee. At the hearing, senior counsel for Apotex "was explicit and direct in stating that Apotex would apply for listing as at 1 April 2008 if there was no

interlocutory injunction".⁸⁰ As to the undertakings as to damages, senior counsel for Sanofi said that "[t]he government hasn't applied to be a party to these proceedings, but our undertaking as to damages ... is not limited to the parties".

79 On 19 September 2007, Mr Millichamp emailed Dr Desai, saying "[w]e are of course hoping that we get some great news on Friday that we are free to sell". This email was not copied to Dr Sherman.

80 On 21 September 2007, in the Federal Court, Gyles J gave oral reasons for decision, granting the interlocutory injunction to restrain Apotex from engaging in conduct that would infringe Sanofi's patent. On 25 September 2007, orders to that effect were made by Gyles J.

81 The interlocutory injunction made by Gyles J was made upon Sanofi giving the usual undertaking as to damages, set out in full below. Sanofi's undertaking extended to compensating third parties for losses suffered. Sanofi was aware that a third party who could suffer loss was the appellant, the Commonwealth of Australia, which might have paid lower pharmaceutical subsidies, if the injunction had not been made, due to the effect of competition in reducing prices. The undertaking and interlocutory injunction were as follows:

"UPON the Respondent/Cross-Claimant [Sanofi] undertaking to the Court to:

- (a) submit to such order (if any) as the Court may consider to be just for the payment of compensation, to be assessed by the Court or as it may direct, to any person whether or not a party, adversely affected by the operation of Order 1 set out below or any continuation (with or without variation); and
- (b) pay the compensation referred to in (a) to the person or persons there referred to.

THE COURT:

1. ORDERS that, pending the determination of the proceedings or further order, the Applicant/Cross-Respondent [Apotex] whether by itself, its directors, officers, servants, agents or otherwise, be restrained from infringing Australian Letters Patent No 597784 (the **Patent**) and, in particular, from engaging in the following acts within

80 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 293-294 [266]-[272].

29.

the patent area (as that term is defined in *Patents Act* 1990 (Cth)), without the license or authority of the Respondent/Cross-Claimant [Sanofi]:

- (a) making, selling or otherwise disposing of the products known as GenRx Clopidogrel, Apo-Clopidogrel, Chemmart Clopidogrel and Terry White Chemists Clopidogrel or any other pharmaceutical composition the active ingredient of which is clopidogrel bisulfate, a compound claimed in claims 1, 3, 10 and 11 of the Patent (collectively, the **GenRx Clopidogrel Products**);
- (b) offering to make, sell or otherwise dispose of the GenRx Clopidogrel Products;
- (c) using or importing the GenRx Clopidogrel Products;
- (d) keeping the GenRx Clopidogrel Products for the purpose of doing any of the acts described in sub-paragraphs (a) to (c) above;
- (e) authorising other people to engage in any of the acts described in subparagraphs (a) to (d) above..."

(5) *Events after the interlocutory injunction*

82 The interlocutory injunction, supported by the undertaking as to damages, had been expressed to be "pending the determination of the proceedings or further order". As Gyles J had informed the parties on 21 September 2007, the hearing concerning the "further order[s]", including the validity of Sanofi's patent and the final injunction, commenced on 28 April 2008. This start date of the hearing was a mere four weeks after the earliest date when Apotex could have obtained PBS listing in order to launch at risk, had the interlocutory injunction not been made. The trial ran for 11 days. The last hearing date was 15 May 2008.⁸¹

83 On 28 July 2008, Mr Millichamp provided Mr Kay, by email, a set of risk/reward calculations for scenarios including the decision that would need to be made if there were success at trial in invalidating Sanofi's patent: "whether or not to launch at risk of the Full Court reversing the judgment on appeal". Mr Millichamp explained that, although the preferred position in Australia was to

81 *Apotex Pty Ltd (formerly Genrx Pty Ltd) (ACN 096 916 148) v Sanofi-Aventis* (2008) 78 IPR 485.

launch, the potential exposure to damages could be in the range of \$166 million. Mr Millichamp asked if Apotex Canada "is comfortable for us to launch at risk of Full Court reversal on Sanofi appeal knowing the potential risk of damages should Sanofi prevail".

84 On 4 August 2008, Mr Smith (the Chief Financial Officer of Apotex Australia) emailed various people, including Mr Millichamp, saying:

"If the Court finds in our favour, then it is likely we will launch but it is not an automatic decision. In this situation, the innovator (Sanofi) would inevitably appeal - and that may require Apotex to give guarantees against possible damages should we lose the appeal. The numbers are very large and this will not be a decision made in Australia!"

85 On 6 August 2008, in an email chain which included Mr Millichamp's email of 28 July 2008 (which provided the risk/reward calculations), Mr Kay emailed Mr Millichamp saying:

"Thinking further about it, I wonder if the best outcome would be that we win at first instance, [Sanofi] appeal and the injunction remains in place pending appeal. That way, 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 [Sanofi's] appeal fails."

86 On 12 August 2008, Mr Kay emailed Mr Millichamp saying:

"As discussed last week my view is that in the event of our success and should [Sanofi] decide to appeal we should in some way allow the injunction to continue, and seek damages should any appeal fail to go [Sanofi's] way."

(6) *Final injunction and the appeal*

87 On 12 August 2008, Gyles J delivered judgment on Apotex's claim for revocation of the Patent, and Sanofi's cross-claim for infringement of it, in Sanofi's favour.

88 On 19 August 2008, the "further orders" contemplated by the interlocutory injunction, being the final determination by Gyles J of the validity of Sanofi's patent, were made following the reasons for decision. Justice Gyles found that four of the claims of the patent were valid and granted a final injunction.

89 On 13 October 2009, following an appeal to the Full Court of the Federal Court, the orders made by Gyles J on 19 August 2008 were overturned and orders were made to revoke the patent and to set aside the final injunction.

31.

90 On 15 February 2010, Apotex finally made an application to list its clopidogrel products on the PBS. The application was expressed to be conditional upon the refusal by the High Court of special leave to appeal from the decision in the Full Court of the Federal Court.

91 On 12 March 2010, special leave to appeal was refused by this Court. The same day, free from any risk, Apotex commenced taking orders for its clopidogrel products. Apotex's first shipment was received on 23 March 2010 and its products were listed on the PBS on 1 May 2010.

(7) *Commonwealth's claim for compensation on the undertaking*

92 On 11 April 2013, more than three years after special leave had been refused, the Commonwealth sought compensation from Sanofi on the undertaking as to damages that Sanofi had given on 25 September 2007. The Commonwealth alleged that it had suffered approximately \$325 million in losses in the period from the interlocutory injunction on 25 September 2007. But, as explained at the outset of these reasons,⁸² about \$314 million of the Commonwealth's alleged losses occurred after 19 August 2008 when Gyles J finally resolved the proceedings for an injunction with his final orders superseding the interlocutory injunction that the undertaking as to damages supported.

(8) *Basis for the counter-factual decision of the primary judge*

93 A central issue before the primary judge in the Commonwealth's claim for compensation on the undertaking concerned a counter-factual question: if the interlocutory injunction had not been made on 25 September 2007, would Apotex have taken the enormous risks of seeking, and obtaining, PBS listing in April 2008 and, upon listing, launching its generic clopidogrel products only: (i) four weeks before a final hearing that might inform the assessment of that risk; and (ii) at most, just over four months before a decision that could remove that risk?

94 On the central counter-factual issue, the primary judge did not make any positive finding. His Honour concluded that the Commonwealth had not proved that before the application deadline of 1 December 2007, Apotex would have sought PBS listing for April 2008 so that Apotex could launch its generic clopidogrel products at risk on or after 1 April 2008. The primary judge's failure to be satisfied that the Commonwealth had proved its counter-factual conclusion was supported by a series of factual findings as to real world events. For reasons which are explained in detail later, it is unnecessary and inappropriate in an appeal to this Court to attempt to recount the entirety of the many factual findings upon

82 See [7] above.

which the primary judge's decision was based. It suffices to emphasise four of the important findings of the primary judge, according to the chronology of events.

95 **First**, the primary judge found that Dr Sherman, rather than Mr Millichamp, was the relevant decision-maker as to whether to launch at risk in Australia. The primary judge did not accept Mr Millichamp's evidence that Dr Sherman's 20 February 2007 email was sufficient instruction on which Mr Millichamp would have been entitled to act to launch at risk in late 2007, without reverting to Dr Sherman for confirmation and final approval.⁸³ That evidence from Mr Millichamp was inconsistent with later email correspondence in which confirmation as to Dr Sherman's present approach to launching at risk had been repeatedly sought from Dr Sherman.⁸⁴ The primary judge also relied upon Mr Smith's email on 4 August 2008 which indicated that even if Apotex was successful in invalidating Sanofi's patent, it was not inevitable that Apotex would launch because there remained the risk of an appeal.⁸⁵

96 **Secondly**, the primary judge found that Dr Sherman could, and did, change his mind at times about launching at risk. The primary judge held that although Apotex's plan to launch at risk was initially dependent on the outcome of litigation in Canada or the United States,⁸⁶ the 20 February 2007 email from Dr Sherman indicated that "Dr Sherman was, at this stage, intending to have Apotex Australia launch at risk in the event that Sanofi did not obtain any interlocutory injunction".⁸⁷

97 **Thirdly**, the primary judge found that Apotex would not launch in Australia without PBS listing. This finding was based upon the 25 June 2007 email from Mr Millichamp. The primary judge found that Dr Sherman was only told on 14 September 2007 (Toronto time) that Apotex had missed the PBS listing date for

83 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 295 [276]-[277].

84 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 307 [339]-[340].

85 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 307 [297].

86 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 286 [232].

87 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 285-286 [229]-[231].

December 2007 (and therefore that the earliest possible listing date would be 1 April 2008).⁸⁸

98 **Fourthly**, the primary judge concluded that the email correspondence in June 2007, particularly the email on 27 June 2007, did not reflect an unconditional intention for Apotex to launch at risk. Rather, that correspondence reflected "an understanding on the part of Mr Kay that it was necessary, or at least desirable, to obtain confirmation from Dr Sherman as to his intention with respect to Australia and whether or not Apotex Australia should seek to revoke the Patent and 'launch at risk'".⁸⁹ The primary judge considered the June 2007 email correspondence in light of the fact that Apotex was not expecting to succeed in resisting an interlocutory injunction⁹⁰ and in light of the 17 August 2007 letter from Apotex Australia to its customers in which Apotex Australia "had not committed itself to launching in the event no interlocutory injunction was granted".⁹¹ The primary judge thus rejected the oral evidence of Mr Millichamp that a decision had been made in February 2007, and that in the 27 June 2007 email Mr Millichamp was merely "covering all angles".⁹²

(9) *Six of the findings of the primary judge on the counter-factual*

99 In addition to those four matters, there were many other interrelated findings of fact that supported the finding of the primary judge that the Commonwealth had not discharged its onus of demonstrating that "Apotex Australia would have sought and obtained a PBS listing of its clopidogrel products from 1 April 2008 even if the interlocutory injunction had not been granted".⁹³ It

88 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 295 [279]-[280].

89 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 289 [243].

90 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 291 [252]-[255]. See also at 292 [260].

91 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 297 [288].

92 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 289-290 [246]-[251].

93 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 309 [351].

suffices to set out six of the findings by the primary judge that supported his Honour's conclusion that the Commonwealth had failed to discharge its onus.

100 **First**, the primary judge held that, in light of his Honour's findings about the email correspondence in June 2007 and the letter of 17 August 2007 as set out above, despite indications by Dr Sherman of an intention to launch at risk in correspondence in February 2007 and June 2007, no *final* decision had been made prior to September 2007. Mr Millichamp had actually accepted in his oral evidence before the primary judge that no final decision had been made but Mr Millichamp had asserted: "[Dr Sherman] could change his mind. I mean, I ... think he would. But — it would be very unlikely".⁹⁴ But the primary judge did not accept Mr Millichamp's evidence that it would be very unlikely that Dr Sherman would change his mind. The primary judge found that evidence "most unconvincing ... largely non-responsive and evasive".⁹⁵

101 There were also several significant findings of the primary judge that supported the conclusion that the indications by Dr Sherman of an intention to launch were only tentative. One of those findings was that advice had been provided to Dr Sherman that Apotex was unlikely to be successful in avoiding an interlocutory injunction,⁹⁶ so that it was not necessary to make such a decision until the interlocutory injunction was decided. The primary judge rejected Mr Millichamp's evidence that "we always believed that all of the claims of the patent were invalid" as not persuasive, in the absence of any legal advice to that effect and in light of Apotex's failure to have the patent invalidated in the United States, and thus rejected Mr Millichamp's assertion that Apotex did not believe the risk of substantial damages would eventuate.⁹⁷ Instead, the primary judge concluded that there was "some advantage to be gained in resisting the interlocutory application even if Dr Sherman was later to decide, based on an up

94 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 290 [249].

95 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 290 [250].

96 See [68] above.

97 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 298 [291].

to date risk/reward analysis, that it would be undesirable for Apotex Australia to launch at risk".⁹⁸

102 Another important finding of the primary judge bearing upon the tentative nature of Dr Sherman's indication of an intention to launch at risk is that there was no evidence of a risk/reward analysis having been undertaken by Apotex at any time before September 2007 which included analysis of Apotex's potential exposure to Sanofi, unlike in 2008 or 2009 when such analyses were undertaken and when the primary judge found that legal advice was sought concerning the exposure of Apotex to damages by a launch at risk.⁹⁹ The primary judge explained that apart from Mr Millichamp's indication on 25 June 2007 that Apotex could be required to provide security to cover \$50-70 million for only "one year's damages", there had been nothing in that correspondence to show that Mr Millichamp had "undertaken any analysis of Apotex's financial exposure if it were to launch its clopidogrel products, obtain a PBS listing for them, but later see its challenge to the validity of the Patent fail".¹⁰⁰ The primary judge explained that such an analysis in 2007 would have supported the conclusion that, in the absence of an interlocutory injunction, Apotex may not have launched at risk prior to the determination of the matter, as it may have calculated there would be little to gain from launching ahead of a final decision.¹⁰¹

103 **Secondly**, as with many other aspects of Mr Millichamp's evidence, the primary judge rejected Mr Millichamp's evidence that Apotex would have "almost certainly" launched at risk if it had not been subject to the interlocutory injunction. Since the decision maker was Dr Sherman and not Mr Millichamp, the primary judge observed that Mr Millichamp had not explained why Dr Sherman would have wished to launch at risk when the final hearing was going to be "in the very near future" (indeed, only four weeks after the earliest date of PBS listing).¹⁰²

98 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 298 [288].

99 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 299 [296], 300 [301], 301 [311].

100 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 287-288 [237]-[240].

101 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 296-297 [282]-[286].

102 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 297 [284].

104 **Thirdly**, in the absence of any calculation of Apotex's potential financial exposure to Sanofi having been undertaken by Apotex in September 2007 (the time of the counter-factual inquiry), the primary judge considered the risk/reward calculations undertaken by Apotex in 2008 and 2009 to be relevant to how Apotex would have made its decision in the counter-factual world where the interlocutory injunction was not granted, particularly in circumstances where two of the scenarios modelled in an email from Mr Millichamp in June 2007 were the same as those projected by Mr Millichamp in July 2008.¹⁰³

105 The primary judge explained that the analysis of risk/reward actually performed by Apotex in July 2008 demonstrated that if Apotex were to win before the trial judge and launch the products, but then subsequently lose on appeal, it would be exposed to approximately \$166 million in damages, which would be more than five times the profits it would be projected to make if the products were launched immediately after the final ruling of the trial judge.¹⁰⁴ The primary judge also had regard to evidence of a further risk/reward analysis undertaken in September 2009 (following the Full Court's decision in favour of Apotex Australia and pending the Full Court's orders giving effect to its reasons) showing "a potential exposure to Sanofi of more than \$650 million".¹⁰⁵

106 **Fourthly**, the primary judge found that the two unforeseen events in September 2007, the earliest possible PBS listing date being delayed until 1 April 2008 and the likely early hearing of the final relief in April 2008,¹⁰⁶ "could have led Dr Sherman to conclude that it might be preferable not to launch at risk even if Gyles J was to have refused the interlocutory injunction".¹⁰⁷ As explained above, Dr Sherman had only been told on 14 September 2007 that the December 2007 PBS listing date had been missed.

103 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 303-304 [322]-[324].

104 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 298-299 [292]-[296].

105 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 301 [310]-[314].

106 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 307 [341].

107 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 295 [278].

107 Further, based on the contents of the letter from Apotex to its customers, and in the absence of evidence to the contrary, the primary judge inferred that Apotex Canada was acting on the understanding that a trial of the validity of the patent and any final injunctive relief would not be heard until between August 2008 and February 2009, with judgment some time later. The primary judge held that Apotex Canada had this understanding until no earlier than 13 September 2007.¹⁰⁸ At the time of the interlocutory injunction hearing on 18 September 2007, Dr Sherman did not know and "may well have" wanted to know, as Gyles J informed the parties on 21 September 2007, that the hearing would commence before his Honour on 28 April 2008 (with the effect that a decision would need to be delivered by 22 August 2008 when Gyles J would retire).¹⁰⁹

108 **Fifthly**, since the Commonwealth chose not to call Dr Sherman, without explanation, there was an absence of any evidence from Dr Sherman, including as to what he would have done when informed of the prospect of an early hearing of the final relief.¹¹⁰ The primary judge drew an inference that, in the absence of evidence as to his availability, the Commonwealth chose not to call Dr Sherman as his evidence would not have assisted its case in this regard.¹¹¹ The primary judge also reasoned that, due to the absence of any evidence from Dr Sherman, the "Commonwealth's case suffer[ed] from an evidentiary deficiency" such that it could not be positively inferred that Dr Sherman would have authorised Apotex to obtain PBS listing for its clopidogrel products.¹¹²

109 **Sixthly**, the primary judge found that several matters demonstrated Apotex's sensitivity to the potentially significant liability for Sanofi's losses. One of those matters was the email correspondence between Mr Millichamp and his superiors in Apotex Canada in July and August 2008, including the concerns about the potential exposure of Apotex to damages expressed in the emails on 28 July

108 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 297 [286].

109 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 298 [289].

110 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 298 [289], 307-309 [342]-[349].

111 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 308 [347].

112 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 309 [349]-[351].

2008 and 4 August 2008. Another matter was Mr Kay's email on 6 August 2008 expressing the view that the best position for Apotex, after final orders and pending an appeal, would be for a final injunction to be granted by the trial judge and for Apotex not to seek a stay of those orders in order to launch at risk because that launch could expose Apotex to "potentially ruinous damages".¹¹³

(10) *Grounds of appeal to the Full Court*

110 In light of the manner in which the appeal to this Court was conducted, it is necessary to set out the Commonwealth's *four* grounds of appeal before the Full Court.

111 Ground 1 was that "[t]he primary judge erred in concluding (at [451]) that any financial loss suffered by [the Commonwealth] as a result of clopidogrel products of [Apotex] not having been listed on the [PBS] from 1 April 2008 was not compensable under [the undertakings] because it was not a loss that *flowed directly* from the existence of the interlocutory injunction granted by Gyles J on 25 September 2007" (emphasis added). That ground of appeal was upheld by the Full Court,¹¹⁴ is the subject of ground 1 of Sanofi's notice of contention filed in this Court, and is addressed later in these reasons.

112 Ground 2 of the Commonwealth's grounds of appeal to the Full Court was a challenge to the fact finding of the primary judge: that "[t]he primary judge erred in concluding (at [351]) that the Commonwealth had not established that Apotex would have sought and obtained a PBS listing of its clopidogrel products from 1 April 2008 if the interlocutory injunction had not been granted". As explained, there were five particulars.¹¹⁵

113 Grounds 3 and 4 were concerned with the assessment of compensation payable to the Commonwealth pursuant to the undertakings including, relevantly, an allegation that the primary judge had erred in applying the correct counter-factual.

113 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 299-301 [297]-[310].

114 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 411 ALR 315 at 335 [83].

115 See [21]-[22] above.

(11) *Decision of the Full Court of the Federal Court*

114 The Full Court dismissed particular (a) of ground of appeal 2. That particular was also the first ground of appeal in this Court. As explained above, the Full Court was correct to dismiss this aspect of the ground.

115 The remainder of the grounds and particulars before the Full Court were primarily concerned with findings of fact and counter-fact. Most of those grounds and particulars were not repeated as grounds or particulars in this Court. It is, therefore, not necessary to set out the reasoning of the Full Court concerning the allegations before the Full Court that: the primary judge had failed to have regard to matters or failed to address matters; the primary judge had erred in concluding that the Commonwealth's case suffered an evidentiary deficiency which could only be made good by calling Dr Sherman; and the primary judge had erred in drawing a *Jones v Dunkel*¹¹⁶ inference from the failure to call Dr Sherman. None of those matters was raised in the notice of appeal in this Court.

116 The reasoning of the Full Court that is directly relevant to this appeal concerns each of the first, second and fourth findings of the primary judge set out above, which the Full Court described as "tributary" findings which "fed into the ultimate finding" that the primary judge was "not persuaded that Apotex Australia would have sought and obtained a PBS listing of its clopidogrel products from 1 April 2008 even if the interlocutory injunction had not been granted".¹¹⁷ Although none of these findings was within the Commonwealth's notice of appeal to the Full Court, in the absence of objection by Sanofi, the Full Court entertained the challenge to each of these findings.¹¹⁸

117 As set out by the Full Court, the tributary findings (corresponding with the first, second and fourth findings of the primary judge as set out in these reasons at [100]-[103] and [106]-[107]) attacked by the Commonwealth on that appeal were: "(a) Dr Sherman had made only a provisional decision to launch at risk ... ; (b) it was not unlikely that Dr Sherman would change his mind about whether to launch at risk ... ; and (c) Dr Sherman might have changed his mind after it became

116 (1959) 101 CLR 298.

117 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 411 ALR 315 at 339 [104]-[105], referring to *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 309 [351].

118 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 411 ALR 315 at 339 [105].

clear that the trial would be in April 2008 with a judgment given by August 2008".¹¹⁹ The Full Court rejected each challenge.

118 As to the first finding by the primary judge set out above, the Full Court rejected all of the Commonwealth's attacks upon the primary judge's conclusion that Dr Sherman had not made a final decision to launch at risk prior to September 2007.¹²⁰ It is unnecessary to descend into the detail of the lengthy discussion of this finding by the Full Court over more than 80 paragraphs of closely reasoned analysis. It suffices to make two points. The first is that little of that analysis was the subject of submissions in this Court. The second is that the aspects of that analysis which were the subject of submissions in this Court did not generally make any reference to the tight reasoning of the Full Court, or to many of the points made by the Full Court.

119 An example of a submission that was repeated a number of times in this Court, but without addressing the nuance of the Full Court's reasons for rejecting it, was that Apotex's firm intention to launch at risk, if the interlocutory injunction was refused, was evidenced by its offer of security for any damages suffered by Sanofi in the amount of \$50 million. But, as the Full Court observed, the cost to Apotex was not \$50 million. The cost depended upon the price to Apotex Canada of a letter of credit in that amount but there was no evidence of that price. Hence, it could not be inferred that a \$50 million security conveyed "a sufficient degree of enthusiasm" that Apotex would apply for PBS listing if not restrained.¹²¹ Further, as the second finding confirmed, the offer by Apotex of security was made before Apotex became aware of both of the events of September 2007, and their significance.

120 As to the second finding of the primary judge set out above (that it was not unlikely that Dr Sherman would change his mind about whether to launch at risk), this was also affirmed by the Full Court. The Full Court rejected the Commonwealth's submission that Apotex Canada and Apotex US had launched at risk in the United States, upholding the primary judge's reasoning that a launch covered by an agreement which limited Apotex Canada and Apotex US's damages

119 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 411 ALR 315 at 339 [104].

120 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 411 ALR 315 at 340-361 [108]-[192].

121 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 411 ALR 315 at 363-364 [204]-[205].

to 50% of its net sales was not a launch at risk.¹²² The Full Court also rejected the Commonwealth's submission that an inference could be drawn as to the strength of Dr Sherman's intention by the \$50 million security offered. The Full Court reiterated the primary judge's conclusion that there was no evidence as to how much it would have cost Apotex to obtain that security.¹²³

121 The Full Court also affirmed the primary judge's reasoning that an inference as to the force of conviction in Dr Sherman's mind could not be drawn from Dr Sherman's email correspondence. The key point was that "the coincidence of the PBS listing date of 1 April 2008 and the trial date of 28 April 2008 was not something which could have been anticipated until the time that the interlocutory injunction application was determined".¹²⁴ The Full Court held that the primary judge was correct not to speculate, in the absence of evidence from Dr Sherman, about the effect that these two events would have had on any intention that he might have had to launch at risk.¹²⁵

122 As to the fourth finding of the primary judge set out above (that the two unforeseen events in September 2007 could have led Dr Sherman to conclude that it might be preferable not to launch at risk even if Gyles J were to have refused the interlocutory injunction), the Full Court again affirmed this finding.¹²⁶ The Full Court observed that the primary judge had not made any positive finding as to what Dr Sherman *would* or *would not* have done in the absence of evidence from Dr Sherman.¹²⁷ In the absence of any evidence from Dr Sherman, and in the absence of any basis to conclude that Dr Sherman had even considered at the time of the interlocutory injunction the impact of the two unforeseen events, the Full Court observed that the primary judge was correct not to speculate about the effect

122 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 411 ALR 315 at 362-363 [198]-[200].

123 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 411 ALR 315 at 364 [205].

124 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 411 ALR 315 at 367 [219].

125 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 411 ALR 315 at 367 [220].

126 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 411 ALR 315 at 373-379 [257]-[294].

127 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 411 ALR 315 at 373 [258].

that such considerations would have had on Dr Sherman¹²⁸ and that a submission that Dr Sherman's instruction would have been to launch at risk was the only inference that could be drawn from the correspondence was "untenable".¹²⁹

123 In this reasoning, therefore, the Full Court unanimously affirmed the first, second and fourth findings set out above. It is noteworthy that the Full Court also affirmed the primary judge's third finding set out above ("the risk/reward analyses ... showed that Apotex stood to lose much more than it stood to gain by launching"¹³⁰), the fifth finding ("[a]n inference about what Dr Sherman would, or would not have done, simply could not be drawn without evidence from Dr Sherman"¹³¹) and the sixth finding ("Apotex stood to lose much more than it stood to gain by launching, mean[ing] that Mr Millichamp's evidence that the business case had changed [by July 2008] could not be correct").¹³² Every one of the six "tributary" findings of fact of the primary judge set out above, and thus each of the findings of fact upon which those findings were based, was therefore unanimously affirmed by the Full Court.

Concurrent findings open and not clearly wrong

124 As explained above, before this Court will engage in a detailed reconsideration of concurrent findings of fact and counter-fact, the error that must appear to be present on a prima facie analysis must be particularly clear in circumstances where the alleged injustice involves no threat to liberty, bodily integrity, reputation or livelihood. On this appeal no error of that clarity was revealed in concurrent findings of fact and counter-fact made by the primary judge and by the Full Court. Without descending into many of the other supporting reasons for the findings of fact of the primary judge or the Full Court, there are

128 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 411 ALR 315 at 367 [220].

129 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 411 ALR 315 at 367 [221].

130 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 411 ALR 315 at 369 [229].

131 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 411 ALR 315 at 369 [231].

132 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 411 ALR 315 at 368-369 [229].

four significant reasons that establish that the concurrent findings not only were open and free from clear error but also are compelling.

125 **First**, it was common ground in this Court that the decision as to whether to launch at risk was to be made by Dr Sherman and any intention that Dr Sherman had to launch at risk in September 2007 was conditional. Dr Sherman was initially more bearish about launching at risk, but wanted to wait, before launching at risk in Australia, to see the results of Apotex Canada and Apotex US's litigation in the United States and Canada. Later, as the primary judge observed, Dr Sherman changed his mind. As the communications above demonstrate, it is impossible to draw any inference about the firmness of any change of mind. The heavy redactions for legal professional privilege deprive many of the key communications of important and essential context. Deprived of that context, the Commonwealth still bore the legal and evidentiary onus to prove, on the available evidence, that the injunction was the cause of its loss.¹³³ Whatever might have been said about the extent to which the heavily redacted communications showed some conditional preparations for launch (and also showed some expressions of uncertainty), it could not be doubted (and was not doubted) that Dr Sherman's intentions on an issue as important as whether to launch at risk, which much later he would become aware could lead to potentially "ruinous damages", were not final.

126 Senior counsel for the Commonwealth was therefore entirely correct to make the proper concession in this Court that any intention of Dr Sherman's to launch at risk prior to September 2007 was conditional. But, he argued, that conditional intention was very firm such that the conditions that might lead Dr Sherman to change his mind after the date of the interlocutory injunction hearing on 18 September 2007 were extreme, such as a factory burning down which would prevent all supply. In other words, the Commonwealth's submission was that the force of conviction with which Dr Sherman held his intention to launch at risk was very strong indeed. The most obvious difficulty with that submission is that Dr Sherman did not give evidence. The force of conviction with which Dr Sherman held any alleged intention to launch at risk was never expressed and it was never tested.

127 Assuming, for the purposes of the counter-factual, that the interlocutory injunction application had been withdrawn prior to any decision by Gyles J, numerous questions would arise which could have been explored in cross-examination with Dr Sherman: Would Dr Sherman have wished to see a risk/reward analysis before finally committing to launch at risk? Had Dr Sherman required such analyses before previous launches at risk? Would Dr Sherman have

133 See [16] above.

considered it significant that the earliest date for PBS listing was only four weeks before the final hearing and at most a little over four months before judgment? In a counter-factual analysis, how would Dr Sherman have reacted to the risk/reward analyses that were done in 2008 and 2009, if he had been provided copies of them in September 2007 after the (hypothetical) refusal of the interlocutory injunction? How would Dr Sherman have explained his decision on 14 August 2008, after the July 2008 analysis had been done, not to take the risk of seeking, from the Full Court, a stay of execution of the final injunction pending appeal, so that PBS listing could be sought, but instead to seek "orders ... preserving Apotex's position viz compensation from Sanofi pending appeal"?

128 These questions are textbook examples of evidentiary gaps where the application of *Jones v Dunkel* is appropriate. As the Full Court correctly observed, in a finding which was not challenged by any ground of appeal, "Dr Sherman's evidence would have undoubtedly elucidated the central issue in this case: what would Dr Sherman have done if the injunction had been refused?"¹³⁴

129 In oral submissions, the Commonwealth focused heavily on a further imponderable that was not able to be explored in cross-examination with Dr Sherman because Dr Sherman was not called. The Commonwealth asserted that there would be serious consequences if Apotex resiled from the statement made by its senior counsel to the Court at the interlocutory injunction hearing to the effect that Apotex intended to launch at risk if the injunction was not made. The issue of the instructions upon which senior counsel made that statement are addressed later in these reasons. But for present purposes, the submission raises the further imponderables: Would Dr Sherman have been deterred from deciding not to launch by the fact that senior counsel for Apotex had told the court on 18 September 2007 that Apotex intended to launch? Even if it could be assumed that Dr Sherman was aware that such a statement might be made (which it cannot be) what was Dr Sherman's approach to resiling from statements about intention made to the Court? What was he advised? How had he acted in the past? He was not called to give evidence and could not be asked.

130 **Secondly**, to the extent that Dr Sherman held an intention in early September 2007 to launch at risk, the concurrent findings of the primary judge and the Full Court were that the two unexpected events in September 2007, operating in combination, had the potential to change Dr Sherman's mind about launching at risk in Australia because they meant that the launch at risk would occur, at the earliest, only four weeks before the trial concerning the validity of Sanofi's patent and in circumstances where a judgment from that trial would be delivered within

¹³⁴ *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 411 ALR 315 at 394 [364].

approximately four months. The situations in the United States and Canada plainly were not comparable to the situation in Australia. And none of the correspondence with Dr Sherman in September 2007 suggested that he was aware of the significance of the two unexpected events.

131 Indeed, the plain and obvious inference is that Dr Sherman was *not* aware of the significance of these two unexpected events at any time before the interlocutory injunction hearing. The first unexpected event had little significance without the second. The importance of missing the listing date in December 2007, and having to wait until April 2008, would fade into insignificance if a trial would not commence, and a decision on the trial would not be received, until, for instance, 2009 or 2010. It was not until after 21 September 2007 that Dr Sherman was aware of the 28 April 2008 trial date for the final relief, which would be only four weeks after the earliest PBS listing date. And it was not until after that same date that Dr Sherman became aware that the trial judge would be Gyles J, with the effect that a decision would need to be given by 22 August 2008, when Gyles J would retire.

132 The Commonwealth sought to dispute the concurrent conclusions that Apotex's calculus of whether to launch at risk had been changed by the two unexpected events in September 2007 by relying upon emphatic statements by senior counsel for Apotex at the hearing of the interlocutory injunction on 18 September 2007 to the effect that Apotex intended to launch at risk if it were not prevented from doing so. Putting to one side the issue of whether the counter-factual analysis requires those statements by senior counsel for Apotex to be ignored because they were inextricably connected to the decision of Gyles J, those statements provide little or no evidence of the conviction by which Dr Sherman held an intention to launch at risk.

133 Although senior counsel must have made that submission on the basis of instructions or evidence, no evidence was given before the primary judge or before the Full Court as to who had provided those instructions. Indeed, in the Full Court it seems to have been assumed that those instructions were provided by Mr Millichamp and not Dr Sherman.¹³⁵ But there was no evidence as to any communication from Dr Sherman from which any emphatic intention to launch could be inferred. Indeed, the communications set out above show that Dr Sherman was only made aware of the missed listing date by a passing reference in an email on 15 September 2007. The importance of this missed date, in light of the early trial date, was not drawn to Dr Sherman's attention and was not clearly apparent to anyone until after 21 September 2007 when it became clear that the earliest date

135 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 411 ALR 315 at 379-380 [296].

of PBS listing was only four weeks before the final trial and that judgment would be delivered within just over four months from that PBS listing date.

134 There were substantial submissions made before the primary judge concerning whether Mr Millichamp's affidavit, which might have been the basis for the statement by senior counsel for Apotex that it would launch at risk if not enjoined, was knowingly false because it omitted any reference to Dr Sherman being the ultimate decision maker and was a deliberate attempt to conceal Dr Sherman as the ultimate decision maker. It was only in Mr Millichamp's seventh affidavit that any reference was made to Dr Sherman. The primary judge found that Mr Millichamp was not "an entirely satisfactory witness" but did not accept that Mr Millichamp "deliberately sought to mislead the Court".¹³⁶ The primary judge reached no conclusion as to whether the affidavit might have unintentionally misled senior counsel. In any event, as explained above, the overwhelming evidence is that Dr Sherman did not know, could not have known, and thus had not considered, the effect of the final trial being held only four weeks after the earliest date for PBS listing, with judgment to be delivered within just over four months from that date.

135 In short, irrespective of whoever provided the instructions to senior counsel and irrespective of Mr Millichamp's views as to whether Apotex would launch at risk, the decision was to be made by Dr Sherman and at the time of senior counsel's submission Dr Sherman did not know that PBS listing could only be achieved four weeks before the final hearing (and, at most, just over four months before a decision) and had not assessed the considerable significance of this.

136 **Thirdly**, in a counter-factual world where the interlocutory injunction had been sought but no decision had been given on it, the concurrent findings of the primary judge and the Full Court were that a risk/return analysis may have affected a final decision as to whether to launch at risk. That risk/return analysis may have provided very powerful reasons not to launch at risk only four weeks before the final hearing which would have led to a decision soon afterwards (due to Gyles J's retirement) that would have removed any risk.

137 As explained above, on 22 June 2007, three days after Sanofi's United States patent had been upheld in the United States, Mr Millichamp calculated the financial upside for a year, in "net margin", of launching at risk. That upside was approximately \$20 million if there was "no Authorised Generic launch" or approximately \$10 million if there was an "Authorised Generic launch". There may also have been some incremental additional benefits (such as that referred to

136 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 307 [338].

47.

by Mr Millichamp on 22 June 2007 of acquiring new customers). But Mr Millichamp did not calculate the downside at that time. Although he recognised that a bank guarantee required to secure one year of Sanofi's damages "could be in the range of" \$50 to \$70 million, that amount was plainly not contemplated as the maximum downside. Mr Millichamp recognised that the amount of security required could increase over time.

138 Compared with the upside of, at best, \$20 million, the downside was enormous. In cross-examination, Mr Millichamp accepted that "certainly [Apotex headquarters] were aware there was a huge exposure, or a very substantial exposure". As the primary judge recognised, in July 2008, Mr Millichamp calculated the downside as \$166 million and evidence of a further risk/reward analysis undertaken in September 2009 showed a potential exposure of more than \$650 million. On top of that, on 25 June 2007 Mr Millichamp had recognised the reputational risk if a launch at risk occurred and an injunction was subsequently ordered restraining supply. In order to minimise that reputational risk, he observed that customers would have to be notified that "this is a high risk launch".

139 The Commonwealth submitted that the risk/reward analyses were irrelevant because Apotex must have known at all stages of the potential for ruinous damages. But the relevant knowledge needed to be held by Dr Sherman since he was the decision-maker. And, although he gave no evidence, the evidence suggests that he was not aware of the extent of the possible damages in September 2007. It is one thing for Dr Sherman to have been aware of a very substantial exposure or downside without the precision of any quantification. It is quite another to perform the exercise with precision, as may have occurred on the counter-factual, of comparing the potential \$20 million upside with a downside of \$166 million or, perhaps on re-assessment, \$650 million, as the risk/reward analyses showed in 2008 and 2009.

140 The Commonwealth submitted that the downside calculations made in July 2008 and September 2009 were based on the erroneous assumption that a 12.5% reduction in price for Sanofi's clopidogrel product, which would be triggered by an at-risk launch from Apotex, could not be reversed. But Mr Millichamp had expressed the strong view in his affidavit evidence that "these price changes could not have been reversed". And there was no evidence that Dr Sherman held a different view. Whether or not this belief of Mr Millichamp was correct (and the primary judge considered that it was not correct¹³⁷) is irrelevant.

137 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 338 [528]-[529].

The counter-factual issue was what Apotex would have done, not what a person in the position of Apotex with a different understanding of the law would have done.

141 The Commonwealth also submitted that the risk/reward analysis in 2008 was not a relevant comparator with the position in September 2007 because it took into account the existence of other generic competitors. Further, the Commonwealth made an overarching submission that, as circumstances had changed since September 2007, analyses undertaken in 2008 and 2009 could only be of limited relevance. As the Commonwealth put it, the loss of the "prime mover advantage", after generic competitors had their clopidogrel products accepted on the Australian Register of Therapeutic Goods in 2008, diminished the benefit Apotex would obtain from launching at risk, compared with the position in September 2007. However, the primary judge had found, in a finding that was not disturbed on appeal and not challenged in any ground of appeal, that other generic competitors were unlikely so long as the patent proceeding, including any appeal, remained on foot. Indeed, this finding reflects what actually occurred, as no generic competitor's clopidogrel product was PBS listed until 1 April 2010, after Sanofi was refused special leave to appeal the Full Court's decision invalidating Sanofi's patent. Moreover, the "prime mover advantage" was (correctly) never treated by Apotex Canada as an end in and of itself. It was a benefit to be weighed with other benefits and risks and was included as a benefit in the first of the models in the July 2008 analysis, and underpinned the September 2009 analysis with an assumption of a 40% market share to Apotex as prime mover. Yet, as discussed above, on all modelled scenarios the downsides of launching at risk far outweighed the upside, and it was the potential for "ruinous damages", rather than the loss of the "prime mover advantage", that Apotex Canada fixed on in its decision-making.

142 **Fourthly**, to the extent that there is any real world analogy of what might have occurred in the counter-factual scenario where an interlocutory injunction was not ordered on 25 September 2007, that analogy is not with the entirely different circumstances of the litigation in Canada or the United States for the reasons given by the primary judge.¹³⁸ The closest analogy is with the events leading up to Gyles J's orders on 19 August 2008. At that time, and with the benefit of risk/reward analyses, there were serious doubts expressed by Mr Kay about whether to launch at risk, pending an appeal, if Apotex were successful in invalidating Sanofi's patent.

138 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 282-284 [201]-[218].

143 It would be enough to dismiss this appeal if these four reasons established only that the findings of the courts below were open and are free from clear error. But they do more than that. The concurrent findings are compelling.

Not open to the Commonwealth on a third challenge to revisit factual issues

144 Even if we were to hold the considerable doubt necessary to justify this Court entertaining a close examination of the concurrent findings of fact and counter-fact in circumstances that do not disclose any substantial injustice (and we do not), there is a further difficulty facing the Commonwealth. That further difficulty is that important aspects of the Commonwealth's counter-factual case on this appeal involved allegations of error by the Full Court and by the primary judge which were not part of the Commonwealth's notice of appeal either to this Court or to the Full Court and the consideration of which may have required a far more complete copy before this Court of the record (of evidence, transcript and submissions) showing how the Commonwealth ran its case in the courts below.

145 As explained above, although the Commonwealth's second ground of appeal was expressed broadly, it cannot properly be understood in its literal terms, which would require this Court to engage in a full retrial of the matter, albeit without witnesses. The central basis upon which special leave was sought before this Court was the issue concerning onus of proof addressed above.¹³⁹ The grant of special leave did not envisage that this Court would, or could, attempt to reconsider, and weigh, the basis for the many concurrent factual findings and inferences made by the courts below in the two days upon which the appeal was listed before this Court. To the contrary, the grant of special leave envisaged this matter could be resolved without the Court needing to have regard to voluminous amounts of material.¹⁴⁰

146 It is not appropriate or possible to address each of the concurrent findings that the Commonwealth sought to have this court reconsider, remake, and then overturn, whether at all or in the circumstances just described. Indeed, this Court would not merely be required to engage in an entire retrial without the benefit of the whole record, including submissions on many aspects of the trial. In some instances, the Court would be required to consider important matters which were neither the subject of submissions nor even addressed by the courts below. Examples of fact finding are illustrative.

139 See [13]-[16].

140 See [49] above.

147 One such fact is that on 14 August 2008, after the trial judge had delivered his final decision on injunctive relief, and after the risk/reward analysis for seeking PBS listing in July 2008 had been prepared and provided to Mr Kay, Dr Sherman chose *not* to seek a stay of the final orders in order to seek PBS listing and launch at risk. He chose instead to appeal the decision and seek orders preserving Apotex's position concerning compensation from Sanofi, should Apotex be successful on appeal.

148 Another example of factual findings that it is neither appropriate nor possible for this Court to revisit are the findings concerning the June 2007 correspondence. Senior counsel for the Commonwealth properly conceded that the June 2007 correspondence did not reveal an unconditional and absolute intention to launch at risk, no matter what happened in the meantime. But how conditional or tentative was any intention to launch at risk? The Commonwealth made such an assessment extremely difficult by failing to call Dr Sherman to give evidence. The compelling nature of the reasoning on this point in the courts below has already been explained.

149 This Court was, however, invited to comb through the nuances and sequence of the June 2007 emails in order to draw an inference that, contrary to the concurrent reasoning below, a final and almost unconditional decision had been reached at that time by Dr Sherman that Apotex would launch at risk. Submissions were made about ambiguities in sentences in the correspondence. What was meant by Mr Millichamp's statement in his email on 27 June 2007 that the plan to launch if Apotex was successful in obtaining an interlocutory injunction was "subject to [Dr Sherman]'s further advice/approval"? What did Mr Millichamp mean on 28 June 2007 when he described his outlined plan to launch at risk "as per instructions from [Dr Sherman]"? What were Dr Sherman's precise "instructions"? What did Mr Haas mean when he asked on 28 June 2007 whether Dr Sherman was "in the loop" in relation to the strategy to launch at risk? Could the emails in June 2007 be seen as a continuation, or re-confirmation, of any intention to launch in February 2007?

150 Some of these questions were the subject of detailed submissions at trial. But before this Court, only extracts of those submissions from trial were reproduced. Submissions were made in this Court that, despite the findings of the primary judge about Mr Millichamp's credibility as a witness, Mr Millichamp's evidence could be relied upon for the first time in this Court to support an interpretation of those emails that was favourable to the Commonwealth's submissions. Even if such a course were possible in this Court (which it is not) this Court was not taken, in oral submissions, to the detailed cross-examination of Mr Millichamp, and possibly other witnesses, about the meaning of the email correspondence. For instance, in a passage from the primary judge to which this Court was not referred in oral submissions, the primary judge set out some of the

lengthy cross-examination of Mr Millichamp about the meaning of his email on 27 June 2007, where Mr Millichamp said that "[i]f we are successful in avoiding an injunction we will plan to launch subject to [Dr Sherman's] further advice/approval". The primary judge said of Mr Millichamp's evidence that this email did not show his intention to confirm a launch at risk with Dr Sherman: "I found this evidence most unconvincing. In my view it was largely non-responsive and evasive."¹⁴¹

151 Further, the Commonwealth's contention in its oral submissions in this Court that "critical bits in the contemporaneous evidence were ignored by the primary judge and were either ignored or not addressed by the Full Court" was wrong or, at the very least, overstated. To take just one example, the Commonwealth submitted that the primary judge "made nothing" of the email of 27 June 2007 stating "FYI – Game on !!!". The Commonwealth ran the same argument in the Full Court and it failed. The Full Court stated, as was the fact, that the primary judge had addressed the email in context and then stated, as was the fact, that many of the 2007 emails from Dr Sherman before and after the "Game on" email were redacted for legal professional privilege, which begged the question of what the "game" was. Put in different terms, the primary judge, affirmed unanimously by the Full Court, did not find that the "game" was to launch at risk. What the "game" was referring to turned "on the contents of Dr Sherman's two emails which are unknown".¹⁴² That finding was open and is not clearly wrong.

152 A further example of factual findings that the Commonwealth sought to overturn but which cannot be re-opened is the findings of the primary judge that, in assessing the counter-factual question, the evidence of Apotex's launches of generic products on different occasions was not helpful.¹⁴³ The primary judge declined to make a finding that Apotex Canada was an aggressive drug company that had a strategy of identifying weak patents and launching generic medicines at risk so long as it was not restrained by an interlocutory injunction. The Commonwealth challenged that in the Full Court and was rejected comprehensively. There was no challenge to that finding in the notice of appeal to this Court.

141 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 290 [250].

142 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 411 ALR 315 at 345 [129].

143 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2020) [No 5] 151 IPR 237 at 283-284 [217]-[218], 301-303 [316]-[320].

153 At a level of substance, the primary judge rejected Mr Millichamp's comparison between the hypothetical launch "at risk" pending initial trial of the clopidogrel products, and the actual launch at risk pending initial trial, by Apotex Australia, of perindopril erbumine in 2006. The comparison was inapt because perindopril erbumine had already been the subject of a 12.5% price reduction by the time Apotex launched its own product, the patent for perindopril erbumine had expired by that time, and the relevant trial did not concern patent infringement but rather allegations of misleading or deceptive conduct.¹⁴⁴ Similarly, the primary judge also rejected Mr Millichamp's evidence that Apotex's "at risk" launch of carvedilol demonstrated Apotex's willingness to launch its clopidogrel products at risk. The application for an interlocutory injunction in relation to carvedilol was refused on the basis that it was "less than likely" that the launch would trigger a 12.5% price drop (and no evidence was produced that this price drop ever occurred in relation to carvedilol) thus making that launch a substantially different prospect than an at risk launch of clopidogrel.¹⁴⁵

154 It is not open to the Commonwealth now to challenge the unanimous confirmation by the Full Court¹⁴⁶ of the finding of the primary judge rejecting Mr Millichamp's evidence that Apotex always took the opportunity to launch where possible as unpersuasive.¹⁴⁷ Nor is it open to the Commonwealth, without any particular of appeal, to challenge the speculation by the Full Court, which was raised only as one speculative possibility of the meaning of the "Game on" email, that the "Game on" email might have concerned a game "to signal to the market that Apotex was going to launch in order to goad Sanofi into seeking an interlocutory injunction and proffering an undertaking as to damages".¹⁴⁸

155 Finally, the Commonwealth during the course of oral submissions placed particular significance on what it described as three critical facts which were

144 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 302-303 [316]-[319].

145 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 303 [320]-[321].

146 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 411 ALR 315 at 373-374 [260]-[267].

147 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 301-302 [316]-[317].

148 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 411 ALR 315 at 345 [129].

missed by the Full Court. First, the statement by Mr Catterns KC, senior counsel for Apotex, during the hearing on 18 September 2007, that Apotex would apply for PBS listing if there was no interlocutory injunction, supported by the sworn evidence of Mr Millichamp that it was Apotex's "intention to apply for listing of its clopidogrel ... tablets at the next available opportunity", and made in circumstances where counsel have a duty of candour before the courts. Secondly, that Apotex rejected an express offer of an undertaking as to damages that accompanied Sanofi's claim for interlocutory injunctive relief in its notice of motion. Senior counsel for the Commonwealth submitted that this evidence ruled out any possibility that Apotex may have been playing a "game ... to signal to the market that Apotex was going to launch in order to goad Sanofi into seeking an interlocutory injunction and proffering an undertaking as to damages" or that Apotex had no real intention to launch at risk. Thirdly, that, at the time these statements were made or actions taken: (i) Apotex knew that it had missed the application date for listing its clopidogrel products on the PBS in December and that the next available listing would not be until April 2008; and (ii) Apotex reasonably anticipated that the trial would be listed before Gyles J and, accordingly, that judgment on final relief would be delivered by 22 August 2008.

156 The first,¹⁴⁹ second¹⁵⁰ and third¹⁵¹ "facts" formed part of the Commonwealth's case before the Full Court and were expressly addressed, and unanimously rejected, by the Full Court. Those facts were not missed.

Notice of contention

157 Although it is strictly unnecessary to address the issues raised in Sanofi's notice of contention, it is important to do so because those issues reinforce two points upon which the appeal to this Court should be dismissed. First, the issues in the notice of contention reinforce the grave difficulty for this Court in attempting to revisit findings below without this Court being seized of the whole of the record or all of the matters in dispute. Indeed, in a number of instances the position of the Commonwealth itself was that this Court should not attempt to revisit any finding below. Secondly, the issues raised by the notice of contention emphasise that the assertions that the Commonwealth had suffered a loss of approximately

149 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 411 ALR 315 at 358 [176], 379-380 [296].

150 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 411 ALR 315 at 322 [18], 345 [129].

151 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 411 ALR 315 at 392 [354]-[355].

\$325 million are contrary to findings of the primary judge, which were not disturbed on appeal, and which are not before this Court. As explained at the outset of these reasons, on the basis of the findings of the primary judge, the most that any loss to the Commonwealth could be is approximately \$11 million.

158 Sanofi relied upon seven grounds of contention in their notice of contention.

(1) *Grounds without submissions*

159 Three grounds of their notice of contention — grounds 2, 5 and 6 — were said by Sanofi to be "not ripe for determination" by this Court. Although those three grounds of contention were raised in the Full Court, none of them needed to be, or was, decided by the Full Court. Those three grounds of contention were raised by Sanofi in this Court only so that those grounds could be remitted to the Full Court if the appeal were allowed. In the event that the appeal was dismissed Sanofi made no submissions concerning, and therefore did not press, those grounds.

160 Since we have concluded that the appeal should be dismissed, only one point need be made about grounds 2, 5 and 6. That point is that ground 2 of the notice of contention asserted that the Commonwealth had failed to prove that an application by Apotex to list its clopidogrel products on the PBS from 1 April 2008 would likely have been approved by the Minister or a delegate of the Minister. In other words, the Commonwealth did not prove that it suffered any loss. Hence, even if the Commonwealth had proved its counter-factual case, the amount of around \$11 million, as an asserted loss by the Commonwealth, would remain an unresolved matter of dispute between the parties.

(2) *Scope of the undertaking and remoteness*

161 The first ground of contention concerns the proper application of the test for the availability and quantification of compensation on an undertaking as to damages and, in particular, whether any of the Commonwealth's alleged losses could be said to flow "directly" from the operation of the interlocutory injunction granted on 25 September 2007.

162 Sanofi did not, and could not, dispute that the losses alleged to have been suffered by the Commonwealth were of a kind that could reasonably have been foreseen as sufficiently likely. Instead, Sanofi's first ground of contention asserted that the Commonwealth's alleged loss did not "flow directly" from the interlocutory injunction. The Commonwealth's alleged loss was said to be indirect because it required Apotex to apply for, and receive, listing of its clopidogrel products on the PBS.

163 Sanofi's undertaking as to damages was given in a form that has been relatively stable since 1842.¹⁵² The terms of the undertaking are open-textured. They require payment of compensation "as the Court may consider to be just" to any person "whether or not a party" who is "adversely affected" by the operation of the interlocutory injunction.

164 In its submission that any loss suffered by the Commonwealth was not compensation recoverable on an undertaking as to damages, Sanofi relied heavily upon the decision of the Court of Appeal of England and Wales in *Smith v Day*.¹⁵³ That nineteenth century case was the first detailed consideration of the scope of compensation available on an undertaking as to damages. The issue concerned whether there should be an inquiry into damages arising from an undertaking as to damages given by the plaintiff as a condition of an injunction that restrained the defendant from performing building work. The only damage alleged by the defendant was said to be the loss of a tenancy in the building, but the defendant did not prove that there was any binding agreement to lease. The Court of Appeal unanimously refused to order an inquiry as to damages on the basis that no compensation was payable under the undertaking. All members of the Court held that any damage was too remote, regardless of whether there had been a binding tenancy agreement.¹⁵⁴ Brett LJ, with whom Cotton LJ agreed on this point, applied the principles in *Hadley v Baxendale*,¹⁵⁵ by analogy, to conclude that the loss of the benefit of that agreement would not have been "proximate and natural" and was therefore too remote to be recoverable.¹⁵⁶

165 The law concerning the availability of compensation upon an undertaking as to damages has developed since the expression in *Smith v Day*¹⁵⁷ of the limit based on remoteness of damage. The most recent consideration by this Court of compensation on an undertaking as to damages was in *European Bank Ltd v Evans*.¹⁵⁸ In that case, this Court recognised that the calculation of damages in

152 Kremer, "The origin of the usual undertaking as to damages when obtaining interlocutory injunctive relief" (2024) 17 *Journal of Equity* 211 at 240.

153 (1882) 21 Ch D 421.

154 *Smith v Day* (1882) 21 Ch D 421 at 426-427, 428, 430.

155 (1854) 9 Ex 341 [156 ER 145].

156 *Smith v Day* (1882) 21 Ch D 421 at 428, 430.

157 (1882) 21 Ch D 421.

158 (2010) 240 CLR 432.

contract, and the remoteness of damage principles in *Hadley v Baxendale*,¹⁵⁹ are only an analogy.¹⁶⁰ An undertaking as to damages is given to the court. It is enforceable by the court, including with sanctions for contempt. It is not a contract between the parties.

166 In *European Bank Ltd v Evans*, this Court held that the varied circumstances in which compensation might be sought prevent the assessment of compensation being "constrained by a rigid formulation".¹⁶¹ Rather, the flexible formulation endorsed was that proposed by Aickin J in *Air Express Ltd v Ansett Transport Industries (Operations) Pty Ltd*:¹⁶² that in most cases it will be just and equitable to award compensation where the damages flow directly from the injunction and could reasonably be foreseen.¹⁶³ Two different questions therefore arose: (i) whether the loss flowed directly from the interlocutory injunction ordered; and (ii) whether "a loss of the kind actually sustained *could have been* foreseen"?¹⁶⁴ The first question concerns the scope of the undertaking. The second question concerns remoteness of damage including the extent of the liabilities that flow from the undertaking.

167 The concept of "directness" is not a verbal formula for a constraint upon the extent of liability akin to that of damage of a kind that is not sufficiently foreseeable and therefore too remote. Instead, the use of "directness" is an attempt to capture the requirement that, for damage to be recoverable under the undertaking, damage caused by the grant of the injunction must fall within the scope of the undertaking.¹⁶⁵

168 An example relied upon by Sanofi was *Ex parte Hall; In re Wood*¹⁶⁶ where Bowen LJ held that the scope of an undertaking as to damages arising from an

159 (1854) 9 Ex 341 at 354 [156 ER 145 at 151].

160 *European Bank Ltd v Evans* (2010) 240 CLR 432 at 438 [14].

161 (2010) 240 CLR 432 at 439 [17].

162 (1981) 146 CLR 249 at 266-267.

163 *European Bank Ltd v Evans* (2010) 240 CLR 432 at 439 [18].

164 *European Bank Ltd v Evans* (2010) 240 CLR 432 at 442 [29] (emphasis in original).

165 *Air Express Ltd v Ansett Transport Industries (Operations) Pty Ltd* (1981) 146 CLR 249 at 319.

166 (1883) 23 Ch D 644 at 653.

interlocutory injunction restraining the claimant on the undertaking from selling specified property did not extend to losses arising from unlawful acts that prevented the claimant obtaining possession of the property. Another example, very closely related to the circumstances of the present case, is the decision of the Privy Council in *Fenris Consulting Ltd v Ennismore Fund Management Ltd*.¹⁶⁷ In that case, one issue was the scope of an undertaking as to damages given in support of an interim freezing order where the interim order was subsequently replaced by a final order and the final order was overturned on appeal. The Privy Council held that, although the final judgment was later overturned on appeal, the final judgment had "totally eclipsed" the interim freezing order upon which the undertaking had been given.¹⁶⁸ Ultimately, in every case, as senior counsel for Sanofi properly accepted, in the assessment of the scope of a duty arising from an undertaking the fundamental considerations are the terms of the undertaking and the context in which it was given.

169 In this case, any losses suffered by the Commonwealth, during the currency of the interlocutory injunction, caused by the failure of Apotex's clopidogrel products to be listed on the PBS on 1 April 2008, were plainly within the scope of the undertaking as to damages. If, absent the interlocutory injunction, Apotex would have applied for listing of its clopidogrel products on the PBS (which the concurrent findings below were that it would not have) then it was common ground at the time of the hearing of the interlocutory injunction that it would have been inevitable that Apotex's products would have been listed and that, consequently, there would have been a 12.5% price reduction for clopidogrel products listed on the PBS and subsidised by the Commonwealth. As Sanofi accepted in this Court, Sanofi, Apotex and Gyles J knew that a loss that the Commonwealth might suffer as a result of the interlocutory injunction would be loss arising from this price reduction. This was therefore the very loss to third parties "adversely affected" that was reasonably contemplated at the time the interlocutory injunction was granted and therefore within the scope of the undertaking. The first ground of the notice of contention must be rejected.

170 On the other hand, the extent of the Commonwealth's alleged losses that would fall within the scope of the undertaking is quite another question. Although it is possible to conclude on this appeal that Sanofi's submissions on the first ground of the notice of contention misconstrued the legal principles concerning compensation on an undertaking as to damages, Sanofi's third ground of its notice of contention illustrates a further difficulty for this Court in re-assessing facts. That

¹⁶⁷ [2022] 2 CILR 1 (Privy Council).

¹⁶⁸ *Fenris Consulting Ltd v Ennismore Fund Management Ltd* [2022] 2 CILR 1 at 21 [50] (Privy Council).

further difficulty is the problems in assessing facts when only part of the issues in dispute are before this Court.

171 The third ground of contention was not decided by the Full Court, and is a particular factual application of the first ground concerning part of the Commonwealth's alleged losses that are said by Sanofi not to flow "directly" from the interlocutory injunction. The third ground asserts that approximately \$274 million of the Commonwealth's alleged \$325 million loss did not flow directly from the interlocutory injunction, being: (i) asserted loss of approximately \$216 million from price disclosure price reductions in relation to PBS listed clopidogrel products that the Commonwealth says would have occurred under the *National Health Act 1953* (Cth); and (ii) asserted loss of approximately \$58 million from the reduction in the price of combination products (clopidogrel with aspirin) that would have occurred due to the Pharmaceutical Benefits Advisory Committee recommendation that the price of the combination products be no higher than the price of PBS listed clopidogrel products.

172 As the Commonwealth succinctly expressed the point, the third ground of the notice of contention was a submission that "two portions of the Commonwealth's [alleged] loss" were too "factually attenuated" to permit recovery. The Commonwealth's alleged loss from these two portions were said to be: (i) the loss of price disclosure price reductions that would have occurred between 1 April 2010 and 31 December 2014; and (ii) payments made by the Commonwealth in respect of combination products between 1 December 2009 and 31 March 2016.¹⁶⁹ Sanofi's submissions on the "indirectness" of these two portions of alleged loss were sometimes expressed in terms that suggested that these portions of the alleged loss were too remote. But, however expressed, Sanofi's third ground of contention requires an anterior issue to be addressed. That anterior issue is whether the two portions of alleged loss were within the scope of the undertaking as to damages. If they were not within the scope of the undertaking, then the issue of whether they would involve a liability that is too remote from the undertaking would never be reached.

173 As the Commonwealth correctly accepted, the anterior issue concerning the scope of the undertaking as to damages is an issue that is not before this Court. The essence of the anterior issue is that the undertaking as to damages was given in support of the interlocutory injunction and expressed to be subject to "further order". The "further order" of Gyles J, which dissolved the interlocutory

169 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 246 [24].

injunction,¹⁷⁰ was made on 19 August 2008 based on reasons given on 12 August 2008. The scope of the undertaking as to damages could not extend beyond the scope of the interlocutory injunction that it supported. This point was resolved by the primary judge adversely to the Commonwealth and not addressed on appeal to the Full Court.

174 In reasoning which was echoed by that of the Privy Council in *Fenris Consulting Ltd v Ennismore Fund Management Ltd*,¹⁷¹ the primary judge concluded that these two portions of alleged loss (amounting to around \$274 million of the Commonwealth's alleged \$325 million loss) were outside the scope of the undertaking that supported the interlocutory injunction made on 25 September 2007 as those alleged losses occurred after Gyles J granted the final injunction on 19 August 2008. Indeed, even \$40 million of the remaining \$51 million of alleged loss by the Commonwealth arose after 19 August 2008. As the primary judge put this point, "the existence of the interlocutory injunction cannot account for the failure of Apotex Australia to obtain a PBS listing of its clopidogrel products at any time after 19 August 2008".¹⁷² The "adverse effects" of the interlocutory injunction which was the subject of the undertaking ceased when the interlocutory injunction was dissipated or overtaken by the final injunction.

175 In short, the third ground of the notice of contention cannot be resolved by this Court. It is inextricably entwined with the findings of the primary judge, the bases for which are not before this Court, to the effect that around \$314 million of the Commonwealth's \$325 million of alleged loss is beyond the scope of the undertaking as to damages because the scope of the undertaking did not extend beyond the period of operation of the interlocutory injunction which that undertaking supported, a period which concluded on 19 August 2008.

170 *Bolton v London School Board* (1878) 7 Ch D 766 at 771. See also Ingpen, Bloxam and Garrett, *Seton's Forms Judgments, and Orders in the High Court of Justice and Court of Appeal, Having Especial Reference to the Chancery Division, with Practical Notes*, 7th ed (1912) vol 1 at 508-509; Paterson, *Kerr's Treatise on the Law and Practice of Injunctions*, 6th ed (1927) at 642-643.

171 [2022] 2 CILR 1 (Privy Council).

172 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 344 [561]. See also at 344 [564].

(3) *Recoverability of losses to the Commonwealth*

176 The fourth ground of contention asserts that the body politic of the Commonwealth, by its executive, was not a person "adversely affected" by the interlocutory injunction and had suffered no compensable loss because the alleged loss arose from "the operation of a legislative scheme for social welfare". Alternatively, because the loss arose "by the operation of the Commonwealth's own laws". And, by further alternative, the body politic of the Commonwealth cannot be adversely affected, within the meaning of an undertaking as to damages, by the operation of an interlocutory injunction because it must be in the interests of the Commonwealth, as a polity, for the losses to be suffered because they reflect the impact upon a body politic of orders made by the judicial branch "in aid of rights asserted under the laws of the Commonwealth".

177 The fourth ground of contention would, if correct, be a simple answer to the whole of this appeal. But it is not correct. Each of the submissions that support the fourth ground of contention assumes that a loss to the body politic of the Commonwealth of Australia is to be treated differently from a loss to any other legal person because the alleged loss arises from "a legislative scheme for social welfare", from "the operation of the Commonwealth's own laws", or from actions of the judicial branch of the Commonwealth in enforcing those laws.

178 Each aspect of this argument involves a basic constitutional misconception. The Commonwealth of Australia, as a body politic, is a legal person with three "branches" or dimensions of power.¹⁷³ But as a legal person, the body politic generally falls to be treated in the same way as any other person. Section 64 of the *Judiciary Act 1903* (Cth) assumes that this equality of treatment with subjects of the Crown will apply not merely to duties imposed upon the public generally¹⁷⁴ but also to rights that are granted to the public generally.

179 That constitutional background informs the interpretation of Sanofi's undertaking as to damages. It is possible, although very unlikely, that an undertaking as to damages might be given in terms which, while extending to third parties, expressly or impliedly exclude the effect of the interlocutory injunction on the body politic of the Commonwealth of Australia as a third party. But, as

173 *Chief Executive Officer, Aboriginal Areas Protection Authority v Director of National Parks* (2024) 98 ALJR 655 at 673 [80], 684-685 [141]-[143]; 418 ALR 202 at 222, 237-238.

174 *Bropho v Western Australia* (1990) 171 CLR 1 at 20-21; *Chief Executive Officer, Aboriginal Areas Protection Authority v Director of National Parks* (2024) 98 ALJR 655 at 694 [182]; 418 ALR 202 at 250.

explained above in relation to the first ground of the notice of contention, the undertaking by Sanofi was plainly not of that nature. Nothing in the terms of Sanofi's undertaking suggested an exclusion of the Commonwealth of Australia from its scope. Rather, the context in which the undertaking was given involved express recognition that the Commonwealth of Australia was contemplated as within the scope of the undertaking.

(4) Therapeutic Goods Act 1989 (Cth)

180 The seventh ground of contention concerns an argument that was the subject of a stated case by the Commonwealth and Sanofi to a differently constituted Full Court.¹⁷⁵ That argument was rejected by that Full Court and two applications for special leave to appeal from that judgment to this Court were refused.¹⁷⁶ Sanofi now seeks to reagitate the point, arguing that the provisions of the *Therapeutic Goods Act 1989* (Cth) constitute a specific regime that is a code for the recovery of compensation for loss arising from the erroneous assertion of patent rights.

181 This ground of contention was unsuccessfully agitated by Sanofi as an interlocutory argument in a proceeding where the argument was fully ventilated and full reasoning was given for rejecting it on a case stated to the Full Court, and which is the very same proceeding from which this appeal lies.¹⁷⁷ Sanofi applied for special leave to appeal to this Court, from the Full Court's judgment on the stated case, and was refused on the basis that there was no reason to doubt the correctness of the conclusion of the Full Court.¹⁷⁸ Having obtained this decision, in the substantive determination of this proceeding concerning Sanofi's undertaking as to damages, this point was not raised again before the primary judge or before the Full Court. But Sanofi now seeks to relitigate the same point in this Court by its seventh ground of contention.

182 It can be accepted that a ground of contention can fall within r 42.08.5 of the *High Court Rules 2004* (Cth) as a matter that the court below "has failed to decide" even if the matter was not raised before the court below, provided that it

¹⁷⁵ *The Commonwealth v Sanofi* (2015) 237 FCR 483.

¹⁷⁶ *Sanofi (formerly Sanofi-Aventis) v The Commonwealth* [2016] HCASL 98; *Wyeth v The Commonwealth* [2016] HCASL 99.

¹⁷⁷ *The Commonwealth v Sanofi* (2015) 237 FCR 483.

¹⁷⁸ *Sanofi (formerly Sanofi-Aventis) v The Commonwealth* [2016] HCASL 98.

involves no new issue of fact.¹⁷⁹ But this issue was decided in these proceedings as a preliminary issue by the Full Court in 2015. In any event, depending upon the "way in which the case has been conducted", there are circumstances where a ground that is not raised in the court below will not be entertained.¹⁸⁰ The most obvious of those circumstances is where the ground of contention is an abuse of process. That is the case with ground 7 of Sanofi's notice of contention.

183 Although Sanofi's first special leave application was not *res judicata* and did not give rise to an issue estoppel, the long-standing authority of this Court has been that, other than in exceptional circumstances, a subsequent application for special leave that traverses substantially the same subject matter as an earlier application will be an abuse of process.¹⁸¹ This principle cannot be subverted by raising the special leave issue in a notice of contention between the same parties. Exceptional circumstances are likewise required. There are no exceptional circumstances in this case. The argument was not raised in the substantive hearing in the Full Court below because it had been fully disposed of in the previous case stated, from which special leave was sought. As senior counsel for Sanofi properly accepted, the arguments that Sanofi seeks to put in relation to ground 7 of the notice of contention differ from those previously put to the Full Court, and to this Court, only in matters of "nuance"; the substance of the argument is "exactly the same".

Conclusion

184 The appeal should be dismissed with costs.

179 *Suttor v Gundowda Pty Ltd* (1950) 81 CLR 418 at 438, quoting *Connecticut Fire Insurance Company v Kavanagh* [1892] AC 473 at 480.

180 *Owners "Shin Kobe Maru" v Empire Shipping Co Inc* (1994) 68 ALJR 311 at 313; 120 ALR 12 at 14. See also *Test Claimants in the FII Group Litigation v Revenue and Customs Comrs (formerly Inland Revenue Comrs)* [2022] AC 1 at 57 [90], citing *Notting Hill Finance Ltd v Sheikh* [2019] 4 WLR 146 at 6 [27]-[28].

181 *Re Golding* (2020) 94 ALJR 1014 at 1018 [11]; 384 ALR 204 at 207-208, citing numerous special leave dispositions.

JAGOT J.

The appeal

185 This appeal concerns decisions of the Federal Court of Australia (Nicholas J)¹⁸² and the Full Court of the Federal Court of Australia (Besanko, Perram and Yates JJ),¹⁸³ respectively: (a) dismissing the application of the Commonwealth to be paid compensation pursuant to an undertaking as to damages that Sanofi¹⁸⁴ gave to the Federal Court of Australia on 25 September 2007 as the price for obtaining an interlocutory injunction restraining a pharmaceutical company, Apotex Pty Ltd ("Apotex Australia"), from supplying a generic medicine in Australia alleged to infringe a patent of Sanofi that was subsequently declared invalid; and (b) dismissing the Commonwealth's appeal from that order.

186 The appeal should be allowed. As will be explained, this is not a case in which the principle of particular appellate restraint in the face of relevant concurrent findings of fact by the Courts below is engaged. Nor is it a case in which, in truth, there is a vast amount of conflicting evidence. Further, and in accordance with the common law adversarial system, both parties have put before this Court all evidence they contend is relevant to the resolution of the issues in the appeal and this Court is entitled to proceed on that basis. In any event, on the evidence adduced below, and as relied on by the parties in the appeal to this Court, the reasoning processes of both Courts below involved clear error productive of plain injustice, demanding this Court's intervention.¹⁸⁵ Importantly, these clear errors reflect that the Courts below did not directly confront the Commonwealth's case or the totality of the evidence the Commonwealth adduced in support of its case. This reinforces that, third hearing or not, a real injustice would be inflicted on the Commonwealth were this Court to repeat the errors of the Courts below. Once the Commonwealth's case and the totality of the evidence the Commonwealth adduced in support are considered, the unavoidable conclusion is that the Commonwealth proved that, but for the grant of the interlocutory injunction on 25 September 2007, Apotex Australia would have applied for (and obtained) listing of its generic medicine on the Pharmaceutical Benefits Scheme ("PBS")¹⁸⁶ and would have supplied its products to the market in Australia on and from 1 April 2008. As such, the Commonwealth is a person "adversely affected"

182 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237.

183 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66.

184 In these reasons "Sanofi", where applicable, includes Sanofi's licensees and related entities.

185 *Louth v Diprose* (1992) 175 CLR 621 at 634.

186 Under the *National Health Act 1953* (Cth), Pt VII.

by the interlocutory injunction and is entitled to claim compensation from Sanofi in accordance with the terms of Sanofi's undertaking as to damages.

Grounds of appeal and contention

187 The Commonwealth's appeal is brought on two grounds as follows:

- "1. The Full Court erred in failing to hold that:
 - (a) the Commonwealth's evidential burden was to establish a *prima facie* case that its loss flowed directly from the interlocutory injunction and that, once that was established, an evidential burden shifted to the respondents to establish their contention that Apotex would not have sought listing on the Pharmaceutical Benefits Scheme (**PBS**) even if not enjoined; and
 - (b) the Commonwealth discharged its evidential burden but the respondents did not.
2. The Full Court erred in failing to find, by inference from the evidence, that in the absence of the interlocutory injunction, it was likely that Dr Sherman would have reconfirmed the plan to seek PBS listing."

188 Ultimately, however, the Commonwealth accepted that the construct informing ground 1 of its appeal was merely an analytical tool and not determinative. Accordingly, the focus of these reasons for judgment is ground 2.

189 Sanofi's notice of contention is more extensive. Excluding particulars, the grounds raised in the notice of contention and pressed before this Court¹⁸⁷ are:

- "1. The Full Court of the Federal Court of Australia (**Full Court**) erred in failing to hold that the claimed loss of the appellant (**Commonwealth**) did not flow directly from the operation of the interlocutory injunction granted on 25 September 2007 (**Interlocutory Injunction**) against Apotex Pty Ltd (**Apotex**) and therefore that compensation for the Commonwealth's claimed loss is not recoverable pursuant to the undertakings as to damages given by the respondents in support of the Interlocutory Injunction.

¹⁸⁷ Sanofi submitted that grounds 2, 5 and 6 were not ripe for determination by this Court and should be remitted to the Federal Court of Australia if Apotex Australia's appeal were to be allowed. The Commonwealth did not submit otherwise.

...

3. The Full Court ought to have held that the Commonwealth's claimed loss in respect of price disclosure price reductions and the combination products did not directly flow from the granting of the Interlocutory Injunction by reason not only of the matters at J[441]-[451], but also by reason that such alleged loss was posited as the outcome of a number of suppliers having made, in the counterfactual, various commercial decisions, and the outcome of various regulatory changes, in the period of several years after the grant of the Interlocutory Injunction, as well as (in the case of the combination products of clopidogrel and aspirin) the course and outcome of hypothetical negotiations between the Commonwealth and the respondents.
4. The Full Court ought to have held that the primary judge erred in finding at J[574] and J[581] that the Commonwealth was a person 'adversely affected' by the Interlocutory Injunction and had suffered compensable loss ... [particulars (a)-(c)] ... and ought instead to have dismissed the Commonwealth's claim on the basis that it was not a person 'adversely affected' by the Interlocutory Injunction and in any event had suffered no compensable loss.

...

7. The Full Court ought to have held that the Commonwealth is precluded, as a matter of law, from recovering compensation pursuant to any of the undertakings as to damages given by the respondents in support of the Interlocutory Injunction by reason of Chapter 3, Part 3-2, Division 2 of the *Therapeutic Goods Act 1989* (Cth), and that the decision of the Full Court given on 7 December 2015 ... was wrong."

Basic facts

190 Sanofi, as patentee, had exclusive rights in Australia to the exploitation of a patent for a "blockbuster" drug, a blood platelet aggregation inhibitor, known as clopidogrel. A "blockbuster" drug is one that generates substantial global sales. Annual global sales of clopidogrel were equivalent to more than USD \$1 billion in revenue for Sanofi.

191 Sanofi's Australian clopidogrel patent was granted on 7 June 1990 and was due to expire on 4 February 2013. By reason of the patent, and since registration

of their products on the Australian Register of Therapeutic Goods ("ARTG")¹⁸⁸ on 2 December 1998 and listing of their products on the PBS on 1 November 1999, Sanofi was the exclusive supplier of clopidogrel in Australia (in hydrogen sulfate form under two different brand names).

192 Apotex Australia is a generic pharmaceutical company formerly known as GenRx Pty Ltd and Apotex Australia Pty Ltd. It is part of a larger company group, which is referred to as "Apotex" in these reasons.

193 On 16 August 2007 Apotex Australia filed an application in the Federal Court of Australia seeking an order revoking Sanofi's Australian clopidogrel patent on the ground the patent was invalid.

194 On 17 September 2007 Sanofi filed a cross-claim seeking final and interlocutory relief against Apotex Australia for threatened infringement of Sanofi's Australian clopidogrel patent and a notice of motion detailing the interlocutory relief claimed.

195 The notice of motion was heard before Gyles J on 18 September 2007. His Honour reserved his decision.

196 On 21 September 2007 Gyles J delivered oral reasons to the effect that he would grant the interlocutory injunction Sanofi sought other than in respect of the listing of the Apotex clopidogrel products on the PBS. On 25 September 2007 Gyles J published revised written reasons for the grant of the interlocutory injunction¹⁸⁹ and made orders. The orders of 25 September 2007 are in these terms:

"UPON the Respondent/Cross-Claimant [Sanofi] undertaking to the Court to:

- (a) submit to such order (if any) as the Court may consider to be just for the payment of compensation, to be assessed by the Court or as it may direct, to any person whether or not a party, adversely affected by the operation of Order 1 set out below or any continuation (with or without variation); and
- (b) pay the compensation referred to in (a) to the person or persons there referred to.

188 Under the *Therapeutic Goods Act 1989* (Cth), Ch 3.

189 *GenRx Pty Ltd v Sanofi-Aventis* (2007) 73 IPR 502.

THE COURT:

1. ORDERS that, pending the determination of the proceedings or further order, the Applicant/Cross-Respondent [Apotex Australia] ... be restrained from infringing Australian Letters Patent No 597784 (the **Patent**) and, in particular, from engaging in the following acts within the patent area (as that term is defined in *Patents Act* 1990 (Cth)), without the license or authority of the Respondent/Cross-Claimant:
 - (a) making, selling or otherwise disposing of the products known as [GenRx Clopidogrel Products] or any other pharmaceutical composition the active ingredient of which is clopidogrel bisulfate, a compound claimed in claims 1, 3, 10 and 11 of the Patent (collectively, the **GenRx Clopidogrel Products**);
 - (b) offering to make, sell or otherwise dispose of the GenRx Clopidogrel Products;
 - (c) using or importing the GenRx Clopidogrel Products;
 - (d) keeping the GenRx Clopidogrel Products for the purpose of doing any of the acts described in sub-paragraphs (a) to (c) above;
 - (e) authorising other people to engage in any of the acts described in sub-paragraphs (a) to (d) above.
2. NOTES that the Applicant/Cross-Respondent [Apotex Australia] undertakes to the Court that, pending the determination of the proceedings or further order, it will not, whether by itself, its directors, officers, servants or agents or otherwise, take any steps to obtain listing of any of the GenRx Clopidogrel products under the pharmaceutical benefits scheme maintained by the Commonwealth under the *National Health Act* 1953 (Cth).
3. ORDERS the Respondent/Cross-Claimant [Sanofi] to provide by 23 October 2007 to the Applicant/Cross-Respondent security in the sum of A\$40 million, either by way of a cash deposit into a joint account or by way of bank guarantee or irrevocable standby letter of credit or any combination of these, pending the determination of the amount of compensation, if any, that the Court may consider should be paid to the Applicant/Cross-Respondent [Apotex Australia] should it be found to have been adversely affected by Order 1.

...

12. DIRECTS the proceeding be fixed for final hearing for a period of two to three weeks commencing on 28 April 2008.

..."

197 Gyles J heard the substantive proceedings between 28 April and 15 May 2008. His Honour delivered judgment on 12 August 2008. Gyles J found claims 2-5 of Sanofi's Australian clopidogrel patent to be valid (which, if it had launched its products, Apotex Australia would have therefore infringed). Gyles J made final orders in the proceedings on 19 August 2008 in accordance with these findings.

198 Apotex Australia filed an appeal against Gyles J's orders on 19 August 2008. Sanofi filed a cross-appeal on 8 September 2008.

199 The Full Court of the Federal Court of Australia (Emmett, Bennett, and Middleton JJ) heard the appeal in February 2009. The Full Court delivered judgment on 29 September 2009.¹⁹⁰

200 On 13 October 2009 the Full Court made orders allowing Apotex Australia's appeal, setting aside the final injunction (order 2 of the orders of 19 August 2008), and revoking Sanofi's Australian clopidogrel patent.

201 On 12 March 2010 Sanofi was refused special leave to appeal to the High Court against the orders made on 13 October 2009.

202 On 4 May 2010 Apotex claimed compensation under the various undertakings Sanofi had given to the Court. These compensation claims were discontinued on 7 November 2014 pursuant to a settlement deed between Sanofi and Apotex executed on 4 November 2014.

203 On 11 April 2013 the Commonwealth filed an interlocutory application in the proceeding which Gyles J had heard. The Commonwealth claimed compensation for loss pursuant to Sanofi's undertaking as to damages given on 25 September 2007. The Commonwealth's case was (and is) that, but for the interlocutory injunction granted on 25 September 2007 on the basis of Sanofi's undertaking as to damages, Apotex Australia would have applied to list its clopidogrel products on the PBS and, as a matter of course, those products would have been so listed on 1 April 2008 and supplied in Australia thereafter. If that had occurred, by operation of provisions of the *National Health Act 1953* (Cth), the price paid by the Commonwealth for all clopidogrel products supplied in Australia would have decreased by 12.5% on and from 1 April 2008 (the PBS listing date), and by other amounts on several occasions thereafter also in accordance with the

190 *Apotex Pty Ltd (ACN 096 916 148) v Sanofi-Aventis* (2009) 82 IPR 416 at 451 [193].

National Health Act. The Commonwealth claims compensation for the difference between the price it paid for clopidogrel products supplied in Australia since 1 April 2008 and the price it would have paid for those products had Apotex Australia's clopidogrel products been listed on the PBS on 1 April 2008 in the amount of approximately \$325 million.

204 On 11 May 2015 the Federal Court of Australia (Nicholas J) stated a case to the Full Court of the Federal Court of Australia. The question of law stated was: "[i]s the Commonwealth of Australia precluded, as a matter of law, from recovering compensation pursuant to any of the Undertakings as to Damages by reason of Chapter 3, Part 3-2, Division 2 of the *Therapeutic Goods Act 1989* (Cth)?" The Full Court (Dowsett, Kenny and Nicholas JJ) delivered judgment and made orders on 7 December 2015 answering that question "[n]o".¹⁹¹

205 On 12 May 2016 Sanofi was refused special leave to appeal against the answer in the stated case.¹⁹²

206 The primary judge heard the Commonwealth's claim for compensation between 28 August and 29 September 2017. On 28 April 2020 the primary judge dismissed the Commonwealth's claim for compensation.¹⁹³

207 The Full Court of the Federal Court of Australia heard the Commonwealth's appeal between 16 and 24 February 2021 and dismissed that appeal on 26 June 2023.¹⁹⁴ The Commonwealth was granted special leave to appeal to this Court against the orders dismissing its appeal on 18 December 2023.

Legislative context

208 Apotex and Sanofi were sophisticated international pharmaceutical companies, the former a generic pharmaceutical company and the latter an originator pharmaceutical company. Both were advised nationally and internationally by experienced patent and intellectual property lawyers.

209 At all times both would have understood the relevant legislative context. That is, they would have understood that: (a) in order for Apotex Australia (or any other generic company) to market and supply clopidogrel products in Australia they needed to have their products registered on the ARTG; (b) registration on the

191 *The Commonwealth v Sanofi* (2015) 237 FCR 483.

192 *Sanofi (formerly Sanofi-Aventis) v The Commonwealth* [2016] HCASL 98.

193 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237.

194 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66.

ARTG was also necessary before any product could be listed on the PBS; and (c) while a product can be marketed and supplied in Australia without PBS listing (provided it is registered on the ARTG), the sale of a prescription medication product will be as a private prescription only, without the Commonwealth subsidising the price to be paid by the person prescribed the product by co-payment to the pharmacist (or approved medical practitioner) dispensing the product.¹⁹⁵ Further, they would have known that for any application to list generic medications on the PBS which would result in a change to the price subsidised by the Commonwealth for a drug there were, at the relevant time, three application deadlines (about four months before the listing date) and three listing dates (1 April, 1 August and 1 December) each year.¹⁹⁶

210 They also would have understood that from 1 August 2007, upon commencement of amendments to the *National Health Act*,¹⁹⁷ the listing of a "new brand of a pharmaceutical item (eg a generic version of the listed pharmaceutical item) triggers an automatic and immediate 12.5% price reduction"¹⁹⁸ for all versions of the medicine.¹⁹⁹ They further would have understood that from 1 August 2007, the listing of a generic bioequivalent pharmaceutical item on the PBS required the applicant to guarantee the supply of the item from the listing date for a period of 24 months. If unable to supply (or if a belief was formed to that effect), the applicant had to notify the Minister as soon as possible, failure to do so being a criminal offence.²⁰⁰ Failure to supply in accordance with the required

195 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 247-248 [36]-[42], 252 [59]-[60].

196 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 248 [41].

197 *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2007* (Cth).

198 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 249-50 [47].

199 *National Health Act 1953* (Cth), s 99ACH. On the evidence, the only uncertainty at the time, from Apotex Australia's perspective, was whether the 12.5% price reduction would be permanent or the product would revert to the previous (higher) price if the substitutable brand was no longer supplied.

200 *National Health Act 1953* (Cth), ss 99AEB-AEG; *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 250 [50].

guarantee could also have other serious consequences, including in respect of the PBS listing of other products sponsored by the same supplier.²⁰¹

Principal conclusions of the primary judge

211 The primary judge dismissed the Commonwealth's application for compensation. His Honour recorded that the first issue was whether "the evidence establishes that Apotex Australia would have applied for a PBS listing of its clopidogrel products by 1 December 2007 so that they would be listed on the PBS from 1 April 2008", it being common ground that this issue was to be determined on the balance of probabilities and, if answered in the negative, that the Commonwealth's application for compensation must be dismissed.²⁰² His Honour answered the question in the negative on several bases.

212 In coming to that negative answer, the primary judge made various factual findings. To understand these findings, it is necessary to explain the following. The Chief Executive Officer ("CEO") and Chairman of Apotex was Dr Bernard "Barry" Sherman (also its co-founder). Mr Andrew Kay, President of Apotex International Inc, reported to Mr Craig Baxter and Dr Sherman. Mr Baxter, of a related Apotex entity, reported directly to Dr Sherman. Mr Millichamp, as Managing Director of Apotex Australia, reported to Mr Michael Weingarten of Apotex Inc ("Apotex Canada") before June 2007 and to Mr Kay after June 2007. Ms Karen McTavish (National Sales and Marketing Director, Apotex Australia) reported to Mr Millichamp, as did Mr Paddy Smith (Chief Financial Officer, Apotex Australia). Apotex's supply and manufacturing arm involved a separate line of reporting in which Mr Stephen Haas (Corporate Project Manager, New Product Demand Planning, Apotex Canada) reported to Mr Gord Fahner (Vice President, Finance, Apotex Canada) and Mr Fahner reported directly to Dr Sherman. Dr Jeremy Desai was Apotex Canada's Executive Vice President of Research and Development and reported directly to Dr Sherman.

213 The primary judge's findings included that in an email of 20 February 2007 from Dr Sherman to Mr Millichamp ("[p]lan is as follows ... [i]f [Sanofi] do not give an undertaking for our damages and do not get an injunction, we will launch"), Dr Sherman was "intending to have Apotex Australia launch at risk in the event that Sanofi did not obtain any interlocutory injunction" and this "no longer

201 *National Health Act 1953* (Cth), s 99AEH; *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 251 [52].

202 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 246 [26]-[27]. The question whether the Commonwealth's claim should have been determined on the basis of a loss of opportunity was not argued.

depended on the outcome of the litigation in Canada or the United States".²⁰³ Further, that Apotex Australia launching its products depended on PBS listing as "there would have been no commercial benefit to Apotex Australia if it were to market its clopidogrel products in Australia in the absence of a PBS listing".²⁰⁴

214 The primary judge observed that "Mr Millichamp's email to Mr Haas [of 27 June 2007 at 1.59pm, saying "... If we are successful in avoiding an injunction we will plan to launch subject to Barry's further advice/approval"] suggests that at the time it was sent it was Mr Millichamp's understanding that even if Apotex Australia was successful in avoiding an interlocutory injunction, the launch of a generic clopidogrel was subject to Dr Sherman's further advice or approval", which was inconsistent with Mr Millichamp's evidence that Dr Sherman had approved the launch at risk on 20 February 2007. The primary judge said the email of 27 June 2007 at 1.59pm "reflects an understanding on Mr Millichamp's part that even if the application for the interlocutory injunction was successfully resisted by Apotex Australia, Mr Millichamp would still need to consult with Dr Sherman (either directly or more likely through Mr Kay or Mr Baxter) for the purpose of obtaining Dr Sherman's authority to proceed with a product launch".²⁰⁵

215 The primary judge found Mr Millichamp's evidence about the reference to "Barry's further advice/approval" in the email of 27 June 2007 at 1.59pm "most unconvincing" and "largely non-responsive and evasive".²⁰⁶ The primary judge concluded that "the terms of Mr Millichamp's email are more likely than not to be correct in so far as they suggest that Dr Sherman had not finally committed to a launch at risk in Australia and that it would be necessary for Mr Millichamp to obtain final approval to launch at risk in the event that no interlocutory injunction was granted".²⁰⁷

216 The primary judge also considered an email from Mr Kay to Mr Haas and others on 8 August 2007 ("[t]he current plan is to put Sanofi on notice of our intention to launch and so invite them to seek an interlocutory [injunction] against

203 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 286 [231]-[232].

204 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 288 [239].

205 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 289 [248].

206 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 290 [250].

207 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 290 [251].

us launching. We are assuming that this will be successful and are thus not planning to launch at this stage") to be significant as it indicated that "Mr Kay was not expecting that Apotex Australia would be successful in its efforts to resist an application for an interlocutory injunction".²⁰⁸ The primary judge referred to Dr Sherman's email in response ("[w]e should put Sanofi on notice ASAP") and said that on "the basis of the emails exchanged between Mr Kay and Dr Sherman on 8 August 2007, and in the absence of evidence to the contrary, I infer that neither Dr Sherman nor Mr Kay were expecting that Apotex Australia would be successful in resisting an application for an interlocutory injunction by Sanofi".²⁰⁹

217 The primary judge recorded that at the hearing of the interlocutory injunction application before Gyles J on 18 September 2007, Mr Catterns KC for Apotex Australia was "explicit and direct in stating that Apotex would apply for [PBS] listing as at 1 April 2008 if there was no interlocutory injunction".²¹⁰ According to the primary judge, however, there "were two related developments in September 2007 which could have led Dr Sherman to conclude that it might be preferable not to launch at risk even if Gyles J was to have refused the interlocutory injunction".²¹¹

218 The first development to which the primary judge referred was that "in early September ... Apotex Australia became aware that its application to list its clopidogrel products on the PBS on 1 December 2007 had been filed too late for that to occur, and that the earliest possible date for a PBS listing was 1 April 2008", as reported by Mr Millichamp to Mr Kay on 4 September 2007.²¹² The primary judge said this "information appears to have been conveyed to Dr Sherman by email from Mr Haas on 14 [sic – 15] September 2007".²¹³

208 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 291 [252].

209 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 291 [255].

210 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 294 [272].

211 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 295 [278].

212 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 295 [279].

213 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 295 [280].

219 The second development to which the primary judge referred was that when Gyles J said he would grant the interlocutory injunction on 21 September 2007, he also informed the parties that the final hearing would be before him commencing on 28 April 2008.²¹⁴ The primary judge said that since "the application for the relevant PBS listing did not need to be filed before 1 December 2007 to obtain a listing on 1 April 2008, there was no reason why Apotex Australia had to make any final decision in relation to PBS listing before 1 December 2007. Even then, it still would have been possible for Apotex Australia to withdraw any such application at any time up to 14 February 2008 or thereabouts."²¹⁵

220 The primary judge then said:²¹⁶

"Mr Millichamp's evidence based on the hypothetical proposition that there could be a final hearing in December 2007 to the effect that '... we would almost certainly ... launch at risk' seems to me to assume that this would be Dr Sherman's instruction to him in such circumstances. It does not explain why Dr Sherman would have wished to launch at risk before the final hearing in the event that it was scheduled to occur in the very near future, and in the same month as the next available PBS listing date. The risks of doing so were substantial if Apotex Australia were to launch at risk in such circumstances given the possibility that, in the event that it failed to persuade the trial judge that the Patent was invalid, it could find itself having to cease any further sales following the grant of a final injunction shortly after obtaining a PBS listing that triggered a price reduction that might not be reversed or, at least, might not be reversed for some significant period of time.

...

In the absence of evidence from Dr Sherman, I am not persuaded that he would have authorised a launch at risk in circumstances where an interlocutory injunction had been refused, but a final hearing was fixed to commence on 28 April 2008. The advice previously communicated by Mr Millichamp in his letter of 17 August 2007 was that a trial was to take place within approximately 12 to 18 months. In the absence of evidence to

214 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 296 [281].

215 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 296 [282].

216 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 297-298 [284]-[289].

the contrary I infer that Apotex Canada was also acting on this understanding until no earlier than 13 September 2007.

...

It is not possible to know how Dr Sherman would have reacted to news that the proceeding had been fixed for hearing on 28 April 2008 in the hypothetical situation in which no interlocutory injunction had been granted. He may well have wanted to know how long the final hearing would take and how long it may take for Gyles J to deliver his judgment. Had Dr Sherman asked, he would most likely have been told that his Honour would cease to hold his judicial office from 22 August 2008 (unless he retired sooner) and that he would need to deliver judgment before then."

221 In respect of events after the grant of the interlocutory injunction, the primary judge accepted that "[Apotex's] July 2008 and September 2009 risk/reward analyses addressed different circumstances from those that existed in August 2007. Nevertheless, those analyses and Apotex Canada's ultimate response to them [not to launch at risk at that time] tends to contradict the assertion made in Mr Millichamp's oral evidence that Apotex tries to get on the market as soon as possible."²¹⁷ The primary judge also said that "[a]nother important matter when assessing the veracity of Mr Millichamp's evidence on this topic is that the profit forecasts forwarded to Mr Kay by Mr Millichamp in his email of 22 June 2007 incorporated two scenarios that essentially mirrored the first two of the three scenarios included in the July 2008 analysis ... [and] in all three scenarios the potential exposure arising out of a claim for damages by Sanofi greatly exceeded the forecast profit".²¹⁸

222 The primary judge also said that:²¹⁹

"I do not accept that the 20 February 2007 email was an instruction on which Mr Millichamp would have considered himself 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. The suggestion that Mr Millichamp did not need to obtain any further approval from

217 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 303 [322].

218 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 303-304 [324].

219 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 307 [340]-[341].

Dr Sherman before launching at risk is, in my view, inconsistent with the email correspondence between Mr Kay and Dr Sherman and Mr Millichamp and Mr Haas.

Nor do I consider that the email sent by Dr Sherman on 20 February 2007 is persuasive evidence as to what Dr Sherman's thinking may have been eight or nine months later. The 20 February 2007 email was sent prior to any decision by the US District Court in relation to the US Patent. Some of the developments that subsequently occurred in 2007 were expected; the ARTG registration of Apotex's clopidogrel products was one of these. However, the coincidence of events that would have 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 (as actually occurred) later that month was a result of developments that could not have been anticipated until about the time the interlocutory application was determined."

223 The primary judge said further: (a) "[i]n this case I would have expected Dr Sherman to have been available to the Commonwealth rather than to Sanofi"; (b) "[i]n circumstances where Mr Fahner, a senior executive at Apotex Canada, was called by the Commonwealth, it seems to me it would be reasonable to expect it to have also called Dr Sherman to give direct evidence of his state of mind at relevant times"; (c) "[t]here was no evidence called by the Commonwealth that would provide any explanation as to why it did not call Dr Sherman or what attempts, if any, it made to call him"; and (d) "[i]n circumstances where the Commonwealth's decision not to call Dr Sherman was wholly unexplained, I infer that the Commonwealth chose not to call him because it considered that his evidence would not have assisted its case".²²⁰ The primary judge concluded that:²²¹

"I am not prepared to infer, based on the 20 February 2007 email, or any of the subsequent correspondence in evidence which was said to justify the drawing of such an inference, that Dr Sherman was likely to have instructed Mr Millichamp to procure the listing of Apotex's clopidogrel products with effect from 1 April 2008.

In my opinion, the Commonwealth's case suffers from an evidentiary deficiency which cannot be made good by drawing inferences from correspondence written by Dr Sherman in the lead up to the hearing of the interlocutory application. In particular, I do not think it can be inferred that

220 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 308 [344]-[347].

221 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 308-309 [348]-[351].

if Dr Sherman had known that the trial of the patent proceeding would commence in the same month that Apotex Australia obtained a PBS listing of its clopidogrel products (triggering a 12.5% statutory price reduction), that he would have, in those circumstances, authorised Apotex Australia 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).

...

In the result, I am not persuaded that Apotex Australia would have sought and obtained a PBS listing of its clopidogrel products from 1 April 2008 even if the interlocutory injunction had not been granted. It follows that the Commonwealth's claim for compensation must be dismissed."

224 The primary judge further concluded that if he were incorrect in this conclusion, the Commonwealth's loss did not flow directly from the interlocutory injunction.²²²

Principal conclusions of the Full Court

225 The Full Court, on appeal, disagreed with the primary judge's conclusion that the Commonwealth's loss did not flow directly from the interlocutory injunction.²²³

226 Otherwise, in respect of the question whether Apotex Australia would have launched its clopidogrel products at risk on 1 April 2008 but for the interlocutory injunction, the Full Court recorded that Sanofi's case included "first, 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, second, evidence that once it 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", the latter of which was said to be "actual evidence of what Apotex would have done in the counterfactual".²²⁴

222 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 324-325 [445]-[451].

223 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 76-78 [33]-[44], 86 [82]-[83].

224 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 88 [90].

227 The Full Court rejected the Commonwealth's contentions that the primary judge overlooked important evidence, finding various emails on which the Commonwealth had relied and to which the primary judge did not refer to be immaterial. The Full Court's conclusion of immateriality applied (expressly or inferentially) to: (a) two emails from Dr Sherman sent on 27 June 2007 at 4.44am and 5.12 am (copied to Mr Millichamp, but redacted on account of a claim for legal professional privilege);²²⁵ (b) Mr Millichamp's email on 27 June 2007 at 11.23am saying "FYI –Game on !!!" and forwarding Dr Sherman's emails;²²⁶ (c) Ms McTavish's email of 28 June 2007 in response asking if Sanofi had been notified;²²⁷ (d) an email from Mr Haas to Mr Millichamp of 28 June 2007 saying "please advise as to estimated launch date so that I can have forecasts shifted out accordingly. I will, however, initiate blister tooling activities to determine timing for providing you with pack count desired for AUS market";²²⁸ (e) Mr Millichamp's email to Mr Haas of 28 June 2007 at 10.28pm ("as per instructions from Barry the plan (in outline) for clopidogrel is as follows ... If we are successful in defending our position vs Sanofi and an injunction is not granted by the courts then we will launch");²²⁹ (f) Mr Haas's email in reply to Mr Millichamp on 28 June 2007 at 11.02pm ("[s]trategy from my side is to get everything in place so that we can proceed with commercial manufacture immediately once given the go-ahead");²³⁰ (g) Mr Haas's email of 28 June 2007 at 11.44pm ("[o]ne further question[.] Is Barry in the loop the strategy below (potentially launch end October but latest Mid November)?");²³¹ (h) Dr Desai's

225 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 96 [129].

226 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 96 [129].

227 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 97 [134].

228 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 97 [133].

229 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 92-93 [117], 98-101 [137]-[143], 134 [314].

230 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 101 [145].

231 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 101 [146].

email of 29 June 2007 ("I just want to clarify our position for Australia ...");²³² (i) Mr Haas's email of 29 June 2007 forwarding Dr Desai's email to Mr Millichamp;²³³ (j) Mr Millichamp's email of 29 June 2007 in response to Mr Haas ("I was probably not clear enough in my mail to you ... The scenario I referred to was in the event that we avoid the imposition of an injunction granted in favour of Sanofi. We will be free to sell until final trial, and after, if we are successful. In the instance that we are successful we will need stock ready for a December PBS listing ... Thus if we are successful we will go ahead and launch");²³⁴ (k) two emails of 10 August 2007 (responding to an email from Mr Millichamp on 9 August 2007 "[i]f we are successful and defend against an application for interlocutory relief from Sanofi we would like to launch as soon as possible") from Mr Kay ("[t]hanks for the comprehensive update[.] OK by me") and Mr Caccamo ("[w]e have aligned our launch plans accordingly") respectively;²³⁵ (l) Mr Kay's further email of 10 August 2007 to Mr Millichamp ("[t]his looks fine");²³⁶ (m) an email from Mr Haas to Mr Millichamp of 5 September 2007 ("[t]arget launch date and forecasts will now be shifted out to Mar '08 ...");²³⁷ and (n) Mr Haas's email of 15 September 2007, amongst other things, quoting Mr Millichamp.²³⁸

232 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 102 [149].

233 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 102-103 [150]-[151].

234 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 103-104 [154]-[155].

235 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 104 [160].

236 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 105 [163].

237 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 106 [166]-[167].

238 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 107 [170].

228 Overall, in respect of the contemporaneous evidence to which the primary judge did not refer in his reasoning process, the Full Court concluded that:²³⁹

"Much of the evidence which the Commonwealth submits was not referred to by the [primary] judge was in fact referred to. To the extent that some of it was not, none of it was material for the reasons we have given and we are unpersuaded that his Honour did not refer to it because he had overlooked it. The inference we would draw is that his Honour did consider it but, like us, did not regard it as material worth mentioning. We do not therefore accept that the five matters set out above made it 'abundantly clear' that Dr Sherman had reconfirmed the decision to launch at risk or that there was no evidence in the period from June to September 2007 (scil 'the all-important months in 2007' (AS [73])) that Dr Sherman had wavered from his desire to launch at risk: AS [73]. On the contrary, the evidence strongly points to the correctness of the [primary] judge's conclusion."

229 The Full Court also rejected the Commonwealth's reliance on the submissions of Mr Catterns KC to Gyles J on 18 September 2007 to the effect that, if not restrained by an interlocutory injunction, Apotex Australia would obtain PBS listing and launch its generic clopidogrel products onto the Australian market on 1 April 2008, to support the inference that Apotex Australia would have launched those products at risk on the basis that the primary judge had referred to those submissions.²⁴⁰

230 The Full Court further rejected the Commonwealth's reliance on Apotex Australia's conduct in arranging and offering \$50 million security to avoid the grant of the interlocutory injunction as evidence supporting the inference that Apotex had decided to and would launch at risk if not restrained by interlocutory injunction. The Full Court said this evidence went "nowhere" as "whilst we accept that this was not a minor step, it is not possible to say just what kind of financial commitment this was from Apotex Canada's perspective".²⁴¹ Further, according to the Full Court, "the proffering of an undertaking to provide security was consistent with Apotex keeping its options open" and it "is entirely possible as a matter of logic for Apotex to have been willing to proffer the undertaking to provide the

239 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 111-112 [189].

240 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 109 [176], referring to *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 294 [272].

241 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 114-115 [204].

security and, as yet, not to have made a final decision as to whether it was going to launch".²⁴²

231 The Full Court also said this:²⁴³

"Although the Commonwealth made much of this email [ie, Mr Millichamp's email forwarding Dr Sherman's emails to a number of other persons at 11.23 am on 27 June 2007 and saying 'FYI –Game on !!!'], it begs the question of what the game was. There are at least two possibilities. One 'game' was to seek to launch at risk. Another 'game' was to signal to the market that Apotex was going to launch in order to goad Sanofi into seeking an interlocutory injunction and proffering an undertaking as to damages. Which of these was the 'game' to which Mr Millichamp was referring rather turns on the contents of Dr Sherman's two emails which are unknown."

232 In rejecting the Commonwealth's submissions that the primary judge's process of reasoning involved error in respect of Dr Sherman not having been called to fill an "evidentiary deficiency", the Full Court said:²⁴⁴

"The [primary] judge did not accept that the inference sought by the Commonwealth should be drawn. The first step was that his Honour found that the coincidence of the PBS listing date of 1 April 2008 and the trial date of 28 April 2008 was not something which could have been anticipated until the time that the interlocutory injunction application was determined: J [341]. The second step was to observe that his Honour was not minded to draw the inference that Dr Sherman would have launched at risk in the counterfactual on the basis of [indirect evidence of Dr Sherman's likely disposition towards launching at risk on 1 April 2008, consisting of correspondence to which Dr Sherman was a party, statements made by persons who were dealing with Dr Sherman and other objectively available evidence]: J [348]. The third step was to identify as an evidentiary lacuna the fact that Dr Sherman had not given [direct evidence as to whether he would have decided to launch at risk on 1 April 2008 but for the interlocutory injunction]. Contrary to the Commonwealth's submissions, his Honour did not speculate about what Dr Sherman would, or would not have

242 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 115 [205].

243 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 96 [129]. See also at 97 [134].

244 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 118 [219]. See also at 117 [217].

done, once apprised of the 1 April 2008 launch date and 28 April 2008 trial date. Rather, what his Honour said at J [349] was that he was not going to draw any inference about it in the absence of evidence from Dr Sherman."

233 In respect of the Commonwealth's submissions that it had not been put to Mr Millichamp that paragraph 38 of his 17 September 2007 affidavit²⁴⁵ put before Gyles J was false, the Full Court considered that, because the primary judge had not found this evidence to be knowingly false, "there was no direct finding that the [primary] judge made that was required to be put to Mr Millichamp".²⁴⁶ Therefore, "his Honour found only that the Commonwealth had failed to prove that Dr Sherman would have directed Apotex to seek a PBS listing if the injunction were refused".²⁴⁷ As a result, "nothing the [primary] judge found required that it be put to Mr Millichamp that §38 of his affidavit was false".²⁴⁸

234 Given the Full Court's conclusions that the evidence to which the primary judge did not refer in his reasoning process was immaterial, the Commonwealth's submission that the oversights were a consequence of the inordinate delay between the hearing before the primary judge and the delivery of judgment (29 September 2017 until 28 April 2020) was also rejected as immaterial.²⁴⁹ In respect of the same submission of inordinate delay vitiating the credit findings made against Mr Millichamp, the Full Court said that the "Commonwealth's case became that Dr Sherman had decided in February 2007 that Apotex would launch at risk" but one "difficulty with this case was the absence of Dr Sherman to give any evidence as to what he would have done" and a "further problem with that case was the large amount of evidence which was only consistent with Dr Sherman having a continuing role in the decision making process". To the extent the primary judge did reject Mr Millichamp's evidence as lacking credit in respect of his 27 June 2007 email to Mr Haas ("... subject to Barry's further advice/approval"), the Full Court said that the primary judge's "criticisms were not related to the

245 In paragraph 38 Mr Millichamp said "... However, it is [Apotex Australia's] intention to apply for listing of its clopidogrel 75mg (as hydrogen sulfate) tablets at the next available opportunity, which is by 1 December 2007."

246 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 131 [297].

247 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 131 [298].

248 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 132 [302].

249 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 149 [378].

demeanour of Mr Millichamp. Rather, they were directed at the content of what he had said. The [primary] judge examined that content and found it wanting. This is not a case, therefore, where a trial judge has said that he did not accept a witness's evidence because he found it unconvincing. ... The basis for the credit finding is therefore entirely before this Court." As the primary judge's "reasons as a whole represent a most thorough and searching excavation of the very complicated factual questions which the case generated", the Full Court was "not satisfied that the delay provides any reason for reviewing his Honour's conclusion that this aspect of Mr Millichamp's evidence was unsatisfactory".²⁵⁰

Concurrent factual findings?

235 Sanofi submitted that, as there are concurrent or co-ordinate factual findings by the primary judge and the Full Court, the Commonwealth had to establish not merely error below but "special reasons such as plain injustice or clear error" for this Court to disturb those findings.²⁵¹

The practice in respect of concurrent factual findings

236 The requirement for "special reasons" to exist before this Court will overturn concurrent factual findings has been referred to as a "practice".²⁵² In *Louth v Diprose* the advantages of the primary judge in having seen and heard all the witnesses give evidence were "immeasurable".²⁵³ In that context, and where the intermediate appellate court said "that the evidence as a whole, the findings as to the reliability of the witnesses, as well as many undisputed facts clearly supported the conclusions" of the primary judge and upheld those findings, Deane J said that "the case is one in which there have been concurrent findings of fact by the primary court, and the intermediate appellate court. It is well settled that a second appellate court, such as this Court is in the present case, should not, in the absence of special reasons such as plain injustice or clear error, disturb such concurrent findings".²⁵⁴ Deane J considered the rationale for the practice to be "the overall interests of the administration of justice and of the preservation of at least some vestige of practical equality before the law that, in the absence of special circumstances, there should be an end to the litigation of an issue of fact at least

250 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 149-151 [380]-[388].

251 *Kozarov v Victoria* (2022) 273 CLR 115 at 134 [49]. See also at 140 [67].

252 *Kozarov v Victoria* (2022) 273 CLR 115 at 134 [49].

253 *Louth v Diprose* (1992) 175 CLR 621 at 633, referring to *Wilton v Farnworth* (1948) 76 CLR 646 at 654.

254 *Louth v Diprose* (1992) 175 CLR 621 at 633-634.

when the stage is reached that one party has succeeded upon it both on the hearing before the court of first instance and on a rehearing before the court of first appeal".²⁵⁵

237 The cases to which Deane J referred in support of the practice describe it in different ways. Mason J referred to Barwick CJ's statement (with which Stephen, Jacobs and Aickin JJ had also agreed) that "... where there have been concurrent findings of fact ... an appellant has in this Court at least a difficult task in persuading it that nonetheless it ought to set aside such findings or that exercise of discretion. This Court must necessarily give weight to such concurrent findings though, of course, in a proper case' [it is] 'able to depart from them.'"²⁵⁶ Gibbs CJ, Mason, Murphy, Wilson and Brennan JJ endorsed the practice on the basis that, in a case involving a vast body of conflicting evidence upon which concurrent factual findings were made, an appellant "naturally faces a difficult task" as the Court "will give the greatest respect to such concurrent findings, although free of course to depart from them if convinced that they are wrong".²⁵⁷ In the latter case, their Honours were so convinced and allowed the appeal.²⁵⁸

238 Gleeson CJ described the practice as a "principle of long standing", the importance of which "has not been diminished, but rather has been increased, in the circumstances of modern litigation".²⁵⁹ Gleeson CJ quoted versions of the threshold justifying the overturning of concurrent factual findings including "plain injustice or clear error", "clearly demonstrated" error, "a tolerably clear conviction" of error, and a "clear conviction" of error.²⁶⁰ In the same case, Kirby J considered that "a clear case of error is needed for interference in concurrent findings of fact made below".²⁶¹ Heydon J considered the practice to be unobjectionable if it was merely functional (that is, if "all that is meant is that if

255 *Louth v Diprose* (1992) 175 CLR 621 at 634, quoting *Waltons Stores (Interstate) Ltd v Maher* (1988) 164 CLR 387 at 434-435.

256 *Commonwealth v Introvigne* (1982) 150 CLR 258 at 274, quoting *Baffsky v Brewis* (1976) 51 ALJR 170 at 172; 12 ALR 435 at 438.

257 *South Australia v Johnson* (1982) 42 ALR 161 at 167.

258 *South Australia v Johnson* (1982) 42 ALR 161 at 174-176.

259 *Roads and Traffic Authority of New South Wales v Dederer* (2007) 234 CLR 330 at 334 [5].

260 *Roads and Traffic Authority of New South Wales v Dederer* (2007) 234 CLR 330 at 334-335 [5]-[7].

261 *Roads and Traffic Authority of New South Wales v Dederer* (2007) 234 CLR 330 at 379 [166].

four judges have agreed on what the facts are, it will be difficult in a practical sense to persuade three more to disagree"²⁶²), but otherwise problematic.²⁶³

239 In the present case, the precise nature of the practice and its content need not be resolved. The approach to concurrent factual findings of this Court assumes that the courts below have weighed the relevant evidence and come to the same conclusions about it. The approach cannot apply to a case where a principal plank of the appeal is that the courts below did not confront and weigh the relevant evidence. In those circumstances, the question whether the reasoning below miscarried (in that neither court below confronted and weighed the relevant evidence as required in order to make ultimate factual findings) must precede the question of relevance of any proposed concurrent factual findings.

The "concurrent" factual findings in this case

240 In any event, all but one of the "concurrent" factual findings on which Sanofi relied are either relatively insignificant or are based only on the interpretation of contemporaneous documents. The other "concurrent" factual finding is the ultimate factual finding that the Commonwealth did not discharge its onus of proof. To the extent interpretation of documents is involved, while in some cases the primary judge will have the advantage of "seeing the oral and documentary evidence unfold in a coherent manner, which cannot be replicated on appeal",²⁶⁴ that advantage was undermined in the present case by the period of 31 months between the hearing and the primary judge's delivery of judgment. As a result, this Court is as well-placed as either of the Courts below to undertake the required interpretative and inferential exercise. More importantly, in that exercise, the whole of the contemporaneous evidence on which the Commonwealth relied is important and neither Court below confronted the whole of that evidence in the context of the case as put by the Commonwealth. This is why the interests of justice demand that this Court perform that exercise.

Dr Sherman "bullish" based on US launch?

241 The primary judge did not accept that Apotex's launch of its clopidogrel products in the United States of America ("the US") was "genuinely 'at risk'"

262 *Roads and Traffic Authority of New South Wales v Dederer* (2007) 234 CLR 330 at 410-411 [287].

263 *Roads and Traffic Authority of New South Wales v Dederer* (2007) 234 CLR 330 at 409-415 [284]-[294].

264 *Expectation Pty Ltd v PRD Realty Pty Ltd* (2004) 140 FCR 17 at 32 [70], referring to *State Rail Authority (NSW) v Earthline Constructions Pty Ltd (In liq)* (1999) 73 ALJR 306 at 330 [90]; 160 ALR 588 at 619.

because, as Apotex knew, under a settlement agreement reached in the US with Sanofi on 26 May 2006, its liability was capped at a percentage of its profits on sales if, ultimately, the US equivalent clopidogrel patent was held to be valid and infringed by Apotex.²⁶⁵ The Commonwealth did not challenge this finding before the Full Court. The Full Court said that it would not have accepted such a challenge in any event. The Full Court therefore said that this evidence was "not available as an aid to the drawing of an inference that Dr Sherman was "bullish".²⁶⁶

242 The concurrent findings are that the evidence of the launch in the US does not support an inference that Dr Sherman was "bullish", meaning an aggressive risk-taker at any possible cost. That Dr Sherman was not an aggressive risk-taker at any possible cost accords with Dr Sherman being a rational commercial decision-maker. That, however, does not mean he was other than entrepreneurial and willing to take large, albeit calculated, risks. As the CEO of a generic pharmaceutical company such as Apotex, Dr Sherman could hardly have been otherwise.

Dr Sherman's February 2007 decision relating to Australian launch

243 The primary judge found that on 20 February 2007 Dr Sherman's plan was clear, being "to have Apotex Australia launch at risk in the event that Sanofi did not obtain any interlocutory injunction".²⁶⁷ The Full Court did not make this finding, but the finding is correct on the evidence.

Mr Millichamp's explanation of the 27 June 2007 email to Mr Haas

244 This email said "... If we are successful in avoiding an injunction we will plan to launch subject to Barry's further advice/approval." The primary judge did not accept Mr Millichamp's explanation of the reference to "subject to Barry's further advice/approval".²⁶⁸

245 The Full Court said that, as the primary judge's conclusion was based not on demeanour but the content of the evidence, the "basis for the credit finding is

265 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 283-284 [217]-[218]. See also at 283 [209]-[210].

266 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 114 [199]-[200]. See also at 124 [261], 126 [272].

267 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 286 [231].

268 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 290 [251].

therefore entirely before this Court".²⁶⁹ It is also clear that the Full Court agreed with the primary judge that this 27 June 2007 email, in effect, supported the inference that Dr Sherman had not made a final decision to launch at risk in Australia as at June 2007.²⁷⁰

Apotex's 17 August 2007 public statement

246 Mr Millichamp sent a letter to Apotex staff on 17 August 2007 on the basis that sales team members could provide it to customers. That letter said, amongst other things, "[w]e intend to launch this product into the Australian market in the near future" and "[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)".

247 The primary judge said that in this letter "Apotex Australia had not committed itself to launching in the event no interlocutory injunction was granted".²⁷¹ The Full Court agreed with the primary judge about the meaning of this letter.²⁷²

Apotex's potential liability

248 The primary judge considered Apotex's July 2008 risk/reward analysis to be "revealing" of "what Apotex Australia perceived its financial exposure to Sanofi could be if it successfully resisted Sanofi's application for an interlocutory injunction and then proceeded to launch its clopidogrel products in Australia with the benefit of PBS listing from 1 April 2008".²⁷³ The primary judge said that the "evidence does not suggest that the business case for Apotex Australia launching its clopidogrel products in August or September 2008 followed by PBS listing from 1 December 2008 would have been significantly less attractive to Apotex Australia than a launch at risk in February or March 2008 followed by a PBS listing

269 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 151 [386].

270 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 97-98 [135], 100 [142], 103-104 [155], 108-109 [174], 150-151 [385].

271 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 297 [288].

272 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 93 [118], 93-94 [120], 103-104 [155].

273 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 298 [292].

from 1 April 2008".²⁷⁴ In this context, the primary judge also said that, as at August 2008, "no other generic supplier (including Spirit [Pharmaceuticals Pty Ltd (Spirit), another generic pharmaceutical company]) had obtained ARTG registration for any clopidogrel product. The deadline for applying for a PBS listing on 1 December 2008 was 1 September 2008. In the circumstances, it is difficult to see how Apotex Australia's opportunity to secure the first mover advantage was significantly diminished and I do not think it was. It should also be recalled that according to Mr Millichamp's July 2008 email to Mr Kay, Apotex Australia's preferred position was to launch."²⁷⁵

249 The Full Court rejected the challenge to the primary judge's use of material from after the grant of the interlocutory injunction and said that "the contention that circumstances had changed because Apotex had been kept out of the market for a year falls away, for the 35% market share assumption remained" between 2007 and 2008. The Full Court agreed with the primary judge that the risk/reward analyses in June 2007 and July 2008 "showed that Apotex stood to lose much more than it stood to gain by launching" which "meant that Mr Millichamp's evidence that the business case had changed could not be correct".²⁷⁶

Events in 2007 after 20 February 2007

250 The primary judge said that the "coincidence of events that would have 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 (as actually occurred) later that month was a result of developments that could not have been anticipated until about the time the interlocutory application was determined".²⁷⁷ The Full Court found no error in this reasoning, describing the events as "unanticipated developments" about which Dr Sherman's reaction was unknown,²⁷⁸ and said that "[t]hese two matters were not

274 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 302 [317].

275 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 305 [330].

276 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 119-120 [224]-[229].

277 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 307 [341].

278 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 143 [354]-[355].

known at the time of any of the correspondence upon which the Commonwealth relied".²⁷⁹

Dr Sherman's reaction to early final hearing

251 The primary judge said that it is "not possible to know how Dr Sherman would have reacted to news that the proceeding had been fixed for hearing on 28 April 2008 in the hypothetical situation in which no interlocutory injunction had been granted" but, if he had asked, he would most likely have been told that Gyles J would be retiring by 22 August 2008 and would have to deliver judgment before then.²⁸⁰ The Full Court rejected the Commonwealth's contention that this involved impermissible speculation by the primary judge, saying that the primary judge "did not decline to draw inferences because Dr Sherman was not called. Rather, his Honour felt that the documents upon which the Commonwealth relied could not, in themselves, sustain any inference about what Dr Sherman would have done if the injunction were refused. The reason this was so was because by the time the injunction was granted, it was known that there would be an early trial in April 2008 and that this was the same month that Apotex would have obtained its PBS listing. These two matters were not known at the time of any of the correspondence upon which the Commonwealth relied."²⁸¹

PBS listing and launch at risk decision

252 The primary judge said that "[i]n the absence of evidence from Dr Sherman, I am not persuaded that he would have authorised a launch at risk in circumstances where an interlocutory injunction had been refused, but a final hearing was fixed to commence on 28 April 2008. The advice previously communicated by Mr Millichamp in his letter of 17 August 2007 was that a trial was to take place within approximately 12 to 18 months. In the absence of evidence to the contrary I infer that Apotex Canada was also acting on this understanding until no earlier than 13 September 2007."²⁸² The primary judge also said that "I am not prepared to infer, based on the 20 February 2007 email, or any of the subsequent correspondence in evidence which was said to justify the drawing of such an

279 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 143 [354]. See also at 117-118 [217]-[220], 120 [231].

280 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 298 [289].

281 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 143 [354]. See also at 117-118 [217]-[220], 120 [231].

282 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 297 [286]. See also at 308-309 [348]-[349], 309 [351].

inference, that Dr Sherman was likely to have instructed Mr Millichamp to procure the listing of Apotex's clopidogrel products with effect from 1 April 2008."²⁸³

253 The Full Court said that "[t]he premise upon which the Commonwealth's claim for damages rests is that but for the injunction, Apotex would have successfully launched its clopidogrel products on 1 April 2008 including by applying for and successfully securing listing on the PBS by that date. The [primary] judge was not persuaded of this as a matter of fact and we reject the challenge to that conclusion below"²⁸⁴ and that the primary judge "did not err in declining to draw an inference that Dr Sherman would have instructed Mr Millichamp to procure the PBS listing of Apotex's clopidogrel products from 1 April 2008".²⁸⁵

254 Parts of the Full Court's reasons on which Sanofi relied are expressed as mere rejections of error by the primary judge. As the Full Court elsewhere put it, however, "the evidence strongly points to the correctness of the [primary] judge's conclusion" that "Dr Sherman's decision to launch at risk was only provisional",²⁸⁶ and there "was abundant evidence from which it could be inferred that Apotex would not launch at risk on 1 April 2008. This included the facts that it had not launched at risk in the US, had not been proposing to launch at risk if it had succeeded before Gyles J and did not launch at risk once it fully succeeded in the Full Court."²⁸⁷

The two developments "unanticipated" before 18 September 2007

255 As noted, the primary judge considered it significant that there were two "developments" that Dr Sherman could not have anticipated "until about the time the interlocutory application was determined".²⁸⁸ The Full Court saw no error in

283 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 308 [348].

284 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 72 [14].

285 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 147 [373].

286 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 111-112 [189].

287 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 120 [230].

288 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 307 [341].

this description of the matters.²⁸⁹ As noted, the matters were that: (a) Apotex Australia had missed the deadline for PBS listing on 1 December 2007 and therefore could next apply for PBS listing by 1 December 2007, with PBS listing then occurring only on 1 April 2008; and (b) Apotex Australia's revocation proceeding would be heard in April-May 2008 and judgment had to be published by 22 August 2008 (being the date by which Gyles J had to retire).

256 The first problem with the reasoning of the Courts below is that timing matters in this case. It cannot be said that Dr Sherman could not have known about these events "until about the time the interlocutory application was determined". The second problem is that neither the primary judge nor the Full Court confronted the contemporaneous documentary evidence which indicated to the contrary of their reasoning. The third problem is that the two events occurred before the hearing of the interlocutory injunction application on 18 September 2007 – what occurred before that time in fact occurred and is not hypothetical. As such, the best evidence of what Dr Sherman could or would have done in response to these events, which he must have known about before 18 September 2007, is what he in fact did (which was to continue to pursue PBS listing and launch of Apotex Australia's clopidogrel products on 1 April 2008). There was no scope to treat these events as part of the hypothetical or "counterfactual" analysis as they occurred well before 18 September 2007.

Earliest PBS listing of 1 April 2008

257 Apotex Australia's application for PBS listing of its clopidogrel products was dated 1 September 2007. Apotex Australia knew by 4 September 2007 that it had missed the application date for PBS listing on 1 December 2007 and withdrew its application on that day, 4 September 2007. This was two weeks before the hearing of the interlocutory injunction.

258 The idea that Dr Sherman would not have known of this fact on or soon after 4 September 2007 should not be seriously entertained. That there is no evidence of Dr Sherman being so informed before 15 September 2007 is correct. But to infer that the email was the first time Dr Sherman knew of that fact defies reality and involves clear error.

259 It is plain from the evidence that: (a) Dr Sherman, as co-founder of Apotex Canada, its CEO and Chairman, and the ultimate controller of Apotex, was the ultimate decision-maker for Apotex Australia to obtain PBS listing and launch its clopidogrel products in Australia but, more than that, was involved in detailed aspects of the logistical and related arrangements for that purpose; and (b) while Mr Millichamp reported directly to Mr Kay from mid-2007, as would be expected

²⁸⁹ *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 117-118 [217]-[220], 120 [231], 143 [354]-[355].

in the ordinary course of a business, Mr Millichamp also had direct dealings with Dr Sherman (Mr Millichamp said, for example, that he had "pretty good direct contact with Dr Sherman").

260 Mr Millichamp informed Mr Kay, Mr Haas, and Mr Caccamo (of Apotex Canada), and others at Apotex Australia, of the earliest PBS listing date of 1 April 2008 on the same day (4 September 2007) that the Department of Health and Aged Care informed Apotex Australia that it had missed the deadline for 1 December 2007 listing. Mr Millichamp's email of 4 September 2007 was sent to, amongst others, Mr Kay, who reported directly to Dr Sherman, and Mr Haas, as the new listing date affected all logistical aspects for supply. It must be inferred that Mr Millichamp sent this email immediately because the information was important, and the kind of information Dr Sherman needed to be told promptly by Mr Kay. Further, Mr Haas's email of 15 September 2007 to Dr Sherman mentioning the April 2008 PBS listing date did not present that information as new or unexpected information. Mr Haas quoted the email from Mr Millichamp of 4 September 2007 (and described it as the "[l]ast communication" received from Mr Millichamp) only to answer questions from Dr Sherman about the possibility of re-packaging the US product for the Australian market. There is no hint in Mr Haas's email that the fact Apotex Australia could not launch before 1 April 2008 (as the next available PBS listing date) would have been a surprise to Dr Sherman. Nor is there any hint of Dr Sherman considering this to be new information on 15 September 2007. Had Dr Sherman believed that Apotex Australia could obtain PBS listing and launch its products on 1 December 2007, but was being told for the first time on 15 September 2007 that it could not do so until April 2008 (with the interlocutory injunction hearing scheduled for 18 September 2007, as had occurred at the 13 September 2007 directions hearing), some expression of at least surprise by Dr Sherman might be expected in the ordinary course. Instead, Dr Sherman continued to deal with the practicalities of having product with an adequate shelf life available for import to Australia.

261 In these circumstances, the only reasonably open inference on the evidence was that Dr Sherman knew about the earliest PBS listing date of 1 April 2008 on or soon after 4 September 2007. And, even if the significance of that had somehow escaped Dr Sherman until 15 September 2007 (which is frankly impossible to believe), that was still well before the hearing on 18 September 2007.

Final hearing in April-May 2008

262 The primary judge said that at the directions hearing on 13 September 2007 "Gyles J raised the possibility of fixing the proceeding for a final hearing to take place within the next six months. A trial in six months was much sooner than Mr Millichamp had until this time anticipated. He had previously understood that

the trial was likely to occur in somewhere between 12 and 18 months' time."²⁹⁰ The primary judge then said that it was only on 21 September 2007 that Gyles J said the final hearing would be commencing on 28 April 2008 before him.²⁹¹ According to the primary judge "[s]ince the application for the relevant PBS listing did not need to be filed before 1 December 2007 to obtain a listing on 1 April 2008, there was no reason why Apotex Australia had to make any final decision in relation to PBS listing before 1 December 2007. Even then, it still would have been possible for Apotex Australia to withdraw any such application at any time up to 14 February 2008 or thereabouts."²⁹²

263 The directions hearing on 13 September 2007 was five days before the interlocutory injunction hearing on 18 September 2007. The fact that Gyles J did not "confirm" that the final hearing would be before him commencing 28 April 2008 until 21 September 2007 does not mean that Apotex would not have had that prospect firmly in its mind after the directions hearing on 13 September 2007, where Gyles J indicated his intention for the final hearing to be held sooner rather than later and potentially within the next six months. The contemporaneous evidence is precisely to that effect.

264 Far from being disturbed by the prospect of a hearing within six months, Mr Millichamp was delighted. Mr Millichamp sent an email to Mr Kay on 13 September 2007 (the same day as the directions hearing, again, because the information was important) disclosing that Mr Millichamp considered that a final hearing occurring soon was very much in favour of Apotex's interests and against Sanofi's interests. Speed of final hearing was so important to Apotex that Mr Kay's response was still to express concern about other generic competitors having clopidogrel products registered on the ARTG and being able to obtain PBS listing to launch before or shortly after Apotex Australia had done so. Mr Millichamp's response was that "[o]ur strategy will be to launch ASAP, assuming no injunction, and ensure we sell in stock and lock in customers to optimize our revenues and block any potential competition for as long as we can". Similarly, Mr Smith emailed Mr Fahner on 13 September 2007 about the case moving quickly and attached Mr Millichamp's email to Mr Kay.

265 In other words, while the prospect of obtaining a final hearing in April 2008 was a surprise to Apotex on 13 September 2007, from a contemporaneous

290 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 293 [266].

291 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 296 [281].

292 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 296 [282].

objective perspective, it was nothing but important and good news for Apotex. Apotex rightly believed that, in 2007, it had the jump on its generic competitors in respect of clopidogrel. Under pain of criminal sanction for false or misleading statements, Mr Millichamp had certified on 14 August 2007 that, acting in good faith, Apotex Australia believed on reasonable grounds that it was not and did not propose to market its clopidogrel products in a manner or circumstance that would infringe a valid claim of a patent. That is, Apotex believed on reasonable grounds that the relevant claims of Sanofi's Australian clopidogrel patent were invalid. From Apotex's contemporaneous perspective, the sooner Apotex Australia could get a final judgment invalidating Sanofi's patent, the better. This is particularly so given: (a) Apotex's clear (rational and correct) belief that Sanofi would not be content to claim damages from Apotex later if the patent was found to be valid, but would seek to restrain Apotex Australia from launching its clopidogrel products; and (b) Apotex's undoubted appreciation (which it must have had from legal advice) that the *status quo*, a highly relevant factor in any interlocutory injunction application, would favour Sanofi being granted interlocutory relief.

266 The worst outcome from Apotex's contemporaneous perspective would have been to have had its clopidogrel products listed on the PBS and then be subject to an interlocutory injunction (consistently with the submissions of Mr Catterns KC to Gyles J on 18 September 2007). The second worst outcome from Apotex's contemporaneous perspective, however, would have been to be subject to an interlocutory injunction and a delayed final hearing and judgment (as then Apotex Australia's commercial advantage over its generic competitors would have been lost).

267 The primary judge's proposition that Gyles J confirming the early hearing date commencing 28 April 2008 before him was a significant new development on 21 September 2007, which "could" have led Dr Sherman to conclude that it "might" be preferable not to launch at risk, even if Gyles J was to have refused the interlocutory injunction, is speculation contrary to: (a) the incontrovertible fact that Gyles J had raised a hearing within this timeframe with the parties on 13 September 2007; and (b) Apotex's contemporaneous records between 13 and 18 September 2007, which incontrovertibly expose how important and desirable this was from Apotex's perspective.

268 Three matters follow. First, and for the same reasons given above about Dr Sherman's "hands on" role, the only reasonably open inference on the evidence was that Dr Sherman knew about the real prospect of an April-May 2008 hearing before Gyles J (with judgment by no later than 22 August 2008) on or shortly after 13 September 2007. Second, Dr Sherman therefore had plenty of time to change strategy if he wished before the interlocutory hearing on 18 September 2007. Third, there is no hint in any contemporaneous Apotex document that these new circumstances on 13 September 2007 meant that there should be or was any change of Apotex's strategy of PBS listing and launching on 1 April 2008 if Sanofi did not

obtain an interlocutory injunction; the contemporaneous Apotex documents in fact confirm that the early hearing date did not cause any change to Apotex's strategy.

Consequences

269 These clear errors in the reasoning process of the Courts below are significant. In terms of the primary judge's reasoning process, the errors occurred at the outset and before consideration of the so-called "counterfactual" of what Apotex would have done had it not been subject to the interlocutory injunction. These errors must be inferred to have influenced the primary judge's assessment of all factors relevant to his Honour's subsequent analysis.

270 Before the Full Court the Commonwealth contended that the primary judge had erred in this regard as: (a) "there was not a single document from Dr Sherman in evidence from the all-important months in 2007 which indicated any wavering in his desire to launch at risk in Australia if not restrained"; (b) the "possible change of position based on the first fact [the 1 April 2008 PBS listing] was unsubstantiated speculation directly contradicted by the contemporaneous records and actions"; (c) the "possible change of position based on the second fact was mere speculation that – if it was to be entertained – had to be set against all of the compelling reasons why Dr Sherman had made the decision to launch in the first place, and the interlocking steps which had since been taken by Apotex to launch at risk. The [primary] judge did not engage in that analysis"; and (d) had the primary judge "properly brought all of the Commonwealth's submissions and evidence to bear, ... Sanofi's speculation that an early trial might have made a difference to Dr Sherman would have gone nowhere".

271 The Full Court rejected any error by the primary judge in this regard on the basis that the primary judge had in fact declined to speculate about what Dr Sherman would have done if confronted with these facts in the absence of evidence from Dr Sherman.²⁹³ The Full Court's characterisation of the primary judge's reasons, however, does not confront the substance of those reasons or of the Commonwealth's submissions. The primary judge said in terms that the "two related developments in September 2007 ... *could* have led Dr Sherman to conclude that it *might* be preferable not to launch at risk even if Gyles J was to have refused the interlocutory injunction".²⁹⁴ This speculation led the primary judge directly to the view that "there was no reason why Apotex Australia had to

293 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 118 [220], 120 [231], 143 [354]-[355].

294 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 295 [278] (emphasis added).

make any final decision in relation to PBS listing before 1 December 2007".²⁹⁵ This in turn led the primary judge to characterise Mr Millichamp's evidence as not explaining "why Dr Sherman would have wished to launch at risk before the final hearing in the event that it was scheduled to occur in the very near future, and in the same month as the next available PBS listing date".²⁹⁶ And that fed directly into the primary judge's critical conclusion that "[i]n the absence of evidence from Dr Sherman, I am not persuaded that he would have authorised a launch at risk in circumstances where an interlocutory injunction had been refused, but a final hearing was fixed to commence on 28 April 2008".²⁹⁷

272 The Full Court's further conclusion that the Commonwealth's submissions in this regard were not within the scope of its notice of appeal as they were "not a contention that the trial judge overlooked evidence or submissions"²⁹⁸ reinforces that the Full Court did not confront the substance of the Commonwealth's case on appeal. Part of the problem is that, as the Commonwealth submitted, the Full Court took an atomised approach to the materiality of the errors the Commonwealth alleged in the primary judge's reasoning. For example, in dismissing the Commonwealth's contention that the primary judge had not grappled with the significance of what Mr Catterns KC said to Gyles J on 18 September 2007, the Full Court said that "this lacks merit since the trial judge expressly dealt with it at J [272]",²⁹⁹ but did not identify that the references which the primary judge made to the submissions of Mr Catterns KC to Gyles J on 18 September 2007 occurred only in the context of his Honour's description of events.³⁰⁰ There is no such reference by the primary judge in the context of his Honour's weighing the possibilities and probabilities of what would have occurred if Gyles J had not granted the interlocutory injunction on 25 September 2007.

295 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 296 [282].

296 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 297 [284].

297 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 297 [286].

298 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 117 [217].

299 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 109 [176].

300 eg *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 256 [84], 294 [272].

273 Given these clear errors it would be plainly unjust if this Court declined to consider for itself the whole of the evidence the parties put before it to determine the Commonwealth's appeal to this Court. As noted, the rationale for this Court's reticence in respect of interfering with concurrent factual findings by courts below, bringing an ultimate end to disputation about factual findings where two courts have examined the same evidence, assumes that the courts below have confronted the evidence and reached a conclusion informed by that confrontation. This case is different. The very basis of complaint to the Full Court was that the primary judge had not confronted the whole of the relevant evidence, which then led to the primary judge engaging in an impermissible chain of reasoning. The Full Court itself did not confront the whole of the relevant evidence when it evaluated the primary judge's chain of reasoning and mischaracterised that chain of reasoning. In these circumstances, the importance and value of finality in the administration of justice cannot outweigh that it is justice that is being administered.

"Counterfactual" analysis

274 The "so-called 'counter-factual' approach is merely a tool to assess whether the operation of [an interlocutory injunction] has caused loss".³⁰¹ The ultimate question in this appeal is would Apotex Australia have sought to list its clopidogrel products on the PBS to achieve a listing date of 1 April 2008 and, on listing, launched its products onto the Australian market if it had not been the subject of an interlocutory injunction as ordered on 25 September 2007. This is the relevant question because Sanofi's undertaking, being the basis for the grant of that interlocutory injunction, requires Sanofi to submit to such order (if any) for the payment of compensation to any person "adversely affected by the operation of Order 1 set out below". Order 1 is the interlocutory injunction restraining Apotex Australia from "making, selling or otherwise disposing of" or "offering to make, sell or otherwise dispose of" Apotex's clopidogrel products. Order 1 operated from 25 September 2007. No person could be adversely affected by order 1 until it commenced operating on 25 September 2007 (despite the making of such an order being inevitable from 21 September 2007, given Gyles J's oral reasons delivered on that date). A party who wishes for an undertaking to apply to adverse effects that might have occurred before the restraining order is made has to ask for it.

275 There is nothing hypothetical or "counterfactual" about what occurred up to the making of the interlocutory order on 25 September 2007. The first hypothetical or "counterfactual" event is that it is to be assumed that Gyles J did not grant the interlocutory injunction on 25 September 2007. Speculation about why Gyles J hypothetically did not grant the interlocutory injunction on 25 September 2007 is impermissible. It is not permissible to speculate, for example, that Gyles J hypothetically did not grant the interlocutory injunction because he considered it highly likely Sanofi's Australian clopidogrel patent would be found invalid. Nor is

301 *Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth* (2018) 136 IPR 8 at 79 [301].

it permissible to speculate that Sanofi did not apply for an interlocutory injunction, because it did in fact apply for an interlocutory injunction. It is permissible to consider everything that did in fact occur up to 25 September 2007, including, for example, that Gyles J's oral reasons were given on 21 September 2007. It is also permissible to consider everything that did in fact occur after 25 September 2007 but, in answering the ultimate question, the relevance and significance of everything that occurred after that date is to be evaluated assuming that no interlocutory injunction had been granted. No more complexity should be permitted to intrude into the so-called "counterfactual" or hypothetical analysis than this.

Reconstructive hypothetical evidence

The problems with this kind of evidence

276 The fundamental problem with any witness giving hypothetical evidence of what they would have done in a past hypothetical situation is the human condition. In the ordinary course witnesses give evidence of what they in fact perceived or thought in the past. They also routinely give evidence of the intentions they held in the past. Giving hypothetical evidence of what they say they would have done in a past hypothetical situation is different. In such a case, the mere state of being human has significant consequences because the witness is not being asked to *recollect* anything, they are being asked to *reconstruct* something. It is impossible for the witness to unknow what has happened or undo the life experiences they have had between the time in the past and the time of giving evidence. If the time in the past is many years ago, the witness is unlikely to be able to recall all (or even most of) the things they knew then that would have been relevant to their actions or understandings at that time, nor to accurately reconstruct the significance of each of those things in the actual circumstances at that time (particularly if those circumstances were complex and rapidly evolving), let alone in an hypothesised circumstance.

277 These problems exist even before the unconscious or conscious pull of self-interest is considered. Self-interest is not merely confined to a party who stands to gain some benefit from a particular event or circumstance. To be interested in appearing to be the best version of oneself is to be human. This kind of interest is likely to affect reconstructive evidence a witness gives in ways as various as human nature itself.

278 These issues do not mean that the party bearing the onus of proof in a complex case, even one involving past hypothetical reconstruction, must be unsuccessful. Rather, they mean that contemporaneous documentary and circumstantial evidence relating to actual circumstances before the critical event (in this case, the grant of the interlocutory injunction) that must be hypothesised out of existence is far more likely to be a reliable source of evidence upon which a court may determine the probabilities or possibilities of the reconstructive

hypothetical past. This is why close attention to that contemporaneous documentary evidence is essential.

279 Judges also need to be mindful of these issues when considering whether any witness could or should have been called to give reconstructive hypothetical evidence. The past in question in this case was a decade before the hearing and was complex. Further, ample contemporaneous documentary and other contextual evidence was available in this case to inform the assessment of the possibilities and the probabilities relevant to the ultimate question. Finally, Mr Millichamp, the person responsible for implementing Dr Sherman's decisions in Australia, was called. Having called Mr Millichamp to give evidence, there would be no expectation of the relevant kind that the Commonwealth also must call Dr Sherman to give evidence, which would thereby engage the kind of inference considered in *Jones v Dunkel*.

This case exposes the problems

280 The most important piece of evidence Mr Millichamp gave occurred in this exchange:

"Now, in this email [Mr Millichamp's email to Mr Haas sent at 10.28pm on 28 June 2007] you say to Mr [Haas] that:

As per instructions from Barry, the plan [(in outline)] –

just pausing there. Do you say those instructions from Barry are the ones that we saw in February 2007 [Dr Sherman's email of 20 February 2007] earlier this morning?---Unless there were any interim instructions, which I can't remember, I would be referring to the original ones, yes.

281 That is, Mr Millichamp was expressly allowing for the possibility that there was an instruction from Dr Sherman after 20 February 2007 and before 18 September 2007 to PBS list and launch at risk but saying that he could not recall any such instruction. Mr Millichamp therefore believed that the only instruction he had from Dr Sherman to PBS list and launch at risk was the email of 20 February 2007. He gave all his evidence based on this belief. In giving that evidence, however, he was never taken to any of Apotex's contemporaneous documentary records indicating that this recollection might well be wrong. This is in circumstances where Mr Millichamp was giving evidence in August-September 2017 about events that occurred in June 2007, a decade earlier.

282 The significance of Mr Millichamp's recollection that he was acting based on Dr Sherman's instructions of 20 February 2007 to the reasoning of the primary judge and Full Court cannot be overstated. The primary judge considered, for example: Mr Millichamp's email to Mr Haas on 27 June 2007 at 1.59pm to be "not consistent with the understanding that Mr Millichamp claimed to have held at this

time based on Dr Sherman's email of 20 February 2007";³⁰² that Mr Millichamp's recollection made the two new and unanticipated developments about the PBS listing date deferral and the final hearing in April 2008 even more important;³⁰³ that Dr Sherman's email of 20 February 2007 was not "persuasive evidence as to what Dr Sherman's thinking may have been eight or nine months later";³⁰⁴ and that he was "not prepared to infer, based on the 20 February 2007 email, or any of the subsequent correspondence in evidence which was said to justify the drawing of such an inference, that Dr Sherman was likely to have instructed Mr Millichamp to procure the listing of Apotex's clopidogrel products with effect from 1 April 2008".³⁰⁵

283 The case the Commonwealth put to the primary judge in closing submissions, however, was that it had to be inferred from the email correspondence in and from June 2007 that Dr Sherman had, at that time, "re-confirmed" his instructions of 20 February 2007. This is the evidence to which the primary judge made only selective reference.

284 Mr Millichamp's evidence about the 20 February 2007 email took on even greater significance before the Full Court than before the primary judge. The Commonwealth submitted to the Full Court that Dr Sherman had decided to PBS list and launch at risk on 20 February 2007 and had thereafter maintained that decision up to and throughout the hearing of Sanofi's interlocutory application. As the Commonwealth put to the Full Court, the 20 February 2007 email was Dr Sherman's "[i]nitial decision to launch" whereas the emails of late June 2007 and thereafter evidenced Dr Sherman's "[r]econfirmation" of the decision to launch. The Full Court, however, focused on Mr Millichamp's evidence about the 20 February 2007 email being the decision which he believed instructed him to PBS list and launch and on the inconsistency of that evidence with the emails in and from late June 2007 onwards. The Full Court found no error in the fact that the primary judge did not refer to many of the key emails in reaching his conclusions, particularly his conclusion that "the 20 February 2007 email was [not] an instruction on which Mr Millichamp would have considered himself entitled to act in late 2007 without reverting, either directly or indirectly, to Dr Sherman for

302 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 289 [248]. See also at 307 [340].

303 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 307 [341].

304 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 307 [341].

305 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 308 [348].

the purpose of obtaining confirmation of that instruction and the necessary final approval from him authorising a launch at risk".³⁰⁶

285 Once it is recognised that Mr Millichamp was giving evidence of his recollection of events from 10 years in the past, Mr Millichamp's repeated insistence that the instruction he had in mind was the 20 February 2007 email from Dr Sherman is of no great moment. It says nothing about Mr Millichamp's credit or reliability as a witness. It creates no "evidentiary gap" that only Dr Sherman could fill. Mr Millichamp referred in his evidence to the possibility of an instruction from Dr Sherman after 20 February 2007 and before 18 September 2007 but said he could not recall any such instruction. He was never taken to any of the June 2007 emails (redacted in this proceeding, but which Mr Millichamp would have seen at the time) which the Commonwealth argued contained the "reconfirmation" of Dr Sherman's instructions to PBS list and launch.

286 Nor is it apparent why it would be expected that the Commonwealth would call Dr Sherman when the Commonwealth had called Mr Millichamp and had adduced the supporting contemporaneous documentary evidence. After all, it was Sanofi who was asserting Mr Millichamp to be dishonest (rather than merely mistaken about Dr Sherman's only relevant instruction being on 20 February 2007 and not later in June 2007). Further, Apotex (not the Commonwealth) had claimed legal professional privilege over the later emails from Dr Sherman on which the Commonwealth relied as giving rise to the inevitable inference of Dr Sherman's "re-confirmed" instruction to Mr Millichamp to PBS list and launch if not subject to an interlocutory injunction. In these circumstances it is not apparent that it would be "natural"³⁰⁷ for the Commonwealth to have called Dr Sherman and for Sanofi not to have called Dr Sherman. The fact that Apotex and Sanofi were competitors who had engaged in significant litigation with each other is immaterial given the relevant issue concerns a hypothetical past from a decade before the hearing.³⁰⁸ That other Apotex witnesses were called by and co-operated with the Commonwealth in the proceeding is not to the point. The fact is either party could have called Dr Sherman (if he was willing to give evidence) or sought an order (if possible) to require him to give evidence. Neither party did. There was no scope

306 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 307 [340], quoted in *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 91 [108].

307 *Payne v Parker* [1976] 1 NSWLR 191 at 201E-202C.

308 cf *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 308 [344]-[347]; *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 145-146 [366].

or support for any inference in Sanofi's favour or against the Commonwealth from that fact in the circumstances.

Did the Commonwealth discharge its legal onus of proof?

287 The question in the Commonwealth's appeal remains whether the Commonwealth discharged its legal onus to prove that Apotex Australia would have applied for (and obtained) PBS listing of its clopidogrel products on 1 April 2008 and on that date launched those products onto the Australian market at risk of ultimately being found to have infringed Sanofi's Australian clopidogrel patent (if Apotex Australia's challenge to the validity of that patent failed). Insofar as this question includes the obtaining of PBS listing, the issue is not part of the appeal as the primary judge found that "an application made by Apotex Australia to list its clopidogrel products on the PBS from 1 April 2008 would most likely have been approved by the Minister or Delegate"³⁰⁹ and Sanofi's challenge to that conclusion has not yet been determined. Suffice to say, however, Sanofi's contention that Apotex Australia would not have obtained PBS listing for its clopidogrel products on 1 April 2008 if it had applied to do so by 1 December 2007 directly contradicts the common assumed position before Gyles J on the hearing of the interlocutory injunction application. In this regard it remains the case that when a party who has obtained the benefit of an interlocutory injunction on one assumed factual basis later asserts to the contrary to avoid liability under that party's undertaking as to damages, "close scrutiny and a degree of scepticism" are required "because inconsistency may involve permitting a party who has obtained equity not to do equity".³¹⁰

288 It is also relevant to note at the outset the basic wisdom informing the observation of Mason J that:³¹¹

"Unless the circumstances indicate otherwise, when it appears that damage flows from the non-performance of an act and the performance of that act has been restrained by an interim injunction, the inference will generally be drawn that the damage has been occasioned by the injunction."

289 Contrary to Sanofi's submissions, Gibbs and Stephen JJ in *Air Express* did not express any general principle that a party claiming on an undertaking must fail if they do not call the decision-maker in the face of any potential countervailing

309 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 320 [421].

310 *Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth* (2018) 136 IPR 8 at 83 [319].

311 *Air Express Ltd v Ansett Transport Industries (Operations) Pty Ltd* (1981) 146 CLR 249 at 332.

consideration. The problem in *Air Express* was the lack of any evidence about the grant of the required permission, which meant that no inference about the probability of such permission being granted (in contrast to mere speculation) was possible.³¹² The present case bears no resemblance to that factual context.

290 The evidence establishes that the basic business of Apotex, as a generic pharmaceutical company, was to make and sell drugs that other pharmaceutical companies had developed and, most likely, patented. As Mr Millichamp's contemporaneous emails and evidence disclosed, getting on the market with a generic version of a "blockbuster" drug is a generic pharmaceutical company's ideal, not just because of the money it could make but because of the broader and long-term commercial relationships it could facilitate with large pharmacy chains. Patents and related litigation, and related sophisticated legal advice and representation and the associated costs, are part of the business. Generic pharmaceuticals must be bioequivalent to the original drug in Australia, meaning it is very important for a generic pharmaceutical company to have the first generic version of the original drug on the market, because that generic pharmaceutical company can then lock both the pharmacy, and the patient as the ultimate buyer of that brand of the drug, into a long-term supply arrangement.

291 Therefore, while no commercially rational generic pharmaceutical company would act without undertaking an analysis of all the possible risks and rewards of potentially infringing a patent by exploiting a molecule or formula the subject of the patent, the risks for the generic pharmaceutical company are not confined to the liability to pay damages to the registered owner of the patent and the rewards are not confined to the profits the generic pharmaceutical company could make by its exploitation of the molecule or formula. This context is exposed in Mr Millichamp's email to Mr Kay of 22 June 2007 identifying Apotex's business model and the importance of the incremental benefits that launching at risk involved in the form of acquiring major new customers (that is, pharmacy chains). That email reflects the reality that a generic pharmaceutical company like Apotex (which was not a developer of new drugs) had to be entrepreneurial and willing to take large, albeit calculated, risks to improve its market position.

292 Rational commercial entities of complex businesses, like Apotex, plan their future actions well in advance of implementing them. They must do so because their businesses involve interrelated components. If they did not do so, they could not be sure that they would be able to act when they wanted to. In planning, responsible people must make decisions. In this case, the responsible person for making the decisions was Dr Sherman and the responsible person for implementing Dr Sherman's decisions in Australia was Mr Millichamp. The idea that a person such as Dr Sherman decides, and that any decision having been made

312 *Air Express Ltd v Ansett Transport Industries (Operations) Pty Ltd* (1981) 146 CLR 249 at 314, 317-318, 332-334.

is irrevocable, is one unrealistic extreme. The other unrealistic extreme is that a person such as Dr Sherman would never make a decision until the last possible moment or that every decision he made was purely provisional. The reality of Apotex's business is that Dr Sherman would have had to make decisions about important strategic matters well in advance of the implementation of those decisions. Having so decided, no decision would be irrevocable unless it had in fact been implemented. In the ordinary and usual course of Apotex's business, it would be expected that Dr Sherman would keep all important commercial decisions under review so that he could respond to circumstances as and when they arose. Keeping decisions under review does not mean that no decision was made or that any such decision was merely provisional. For these reasons, the Full Court's conclusion that Dr Sherman would have had a continuing role in all major decisions,³¹³ including keeping all important decisions under review, does not mean that: (a) Dr Sherman had not decided to PBS list and launch in late June 2007; (b) Dr Sherman had not maintained that decision at 18 September 2007 (when Gyles J heard the interlocutory injunction application); or (c) Dr Sherman, inconsistently with all his decisions to 18 September 2007, would have changed his mind after that time merely because another decision-maker (not Dr Sherman) could rationally consider that it might be preferable to defer deciding until after Gyles J had given judgment on the interlocutory injunction application.

293 The contemporaneous documentary evidence exposes that Apotex's business decision-making processes operated in exactly this manner. Dr Sherman wanted to get Apotex's clopidogrel products on the market in Australia. In June 2006, he decided that if Apotex entities succeeded in the litigation in the US and Canada, Apotex would launch its clopidogrel products on the market in Australia (which means that it also would have obtained PBS listing for its products). Mr Millichamp understood this to be Dr Sherman's instruction to him, as Mr Millichamp's email of 15 February 2007 makes clear. By that time, however, it was also clear that the litigation in the US and Canada would not be resolved quickly. Dr Sherman therefore decided that Apotex would launch its clopidogrel products on the market in Australia without waiting for the results of that litigation. This is recorded in the email of 20 February 2007.

294 It is obvious from later emails of 22 and 25 June 2007 that Mr Kay wanted more up to date information. Mr Millichamp explained to Mr Kay why he remained of the view that Apotex should launch its clopidogrel products on the market in Australia, as Dr Sherman had instructed in February 2007. This does not mean that Dr Sherman had changed his mind about the decision communicated on 20 February 2007. It means only that Mr Kay and Mr Millichamp were doing exactly what they should have been doing in ensuring that Dr Sherman could be made aware of current circumstances relevant to his prior decision. This is why

313 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 149 [382].

Mr Kay emailed Dr Sherman on 25 June 2007 with the then current information asking that he "re-confirm or otherwise our approach in Australia". The approach, which Mr Millichamp was implementing, was to PBS list and launch at risk if Sanofi did not obtain an interlocutory injunction.

295 Not unexpectedly, the next round of emails within Apotex included emails to and from Apotex's lawyers in Australia which are subject to claims for legal professional privilege. One email from Dr Sherman not entirely subject to such a claim is that of 26 June 2007 saying "[w]e will stay with bisulfate in Australia", with wholly redacted emails from Dr Sherman following on 27 June 2007, leading to Mr Millichamp's 27 June 2007 "FYI –Game on !!!" email. "FYI –Game on !!!" on its own is ambiguous. In context, however, its meaning is clear. Put to one side, for the moment, Mr Millichamp's later email on 27 June 2007 at 1.59pm saying "... If we are successful in avoiding an injunction we will plan to launch subject to Barry's further advice/approval." What else does the contemporaneous evidence disclose? The answers are unavoidable.

296 Why would Dr Sherman have said "[w]e will stay with bisulfate in Australia" on 26 June 2007 if his decision was not to seek PBS listing and launch at risk in Australia? He did not need to do so to "goad" Sanofi into applying for an interlocutory injunction. It was said in an internal Apotex email. Dr Sherman only needed to do so if he was re-confirming the 20 February 2007 decision.

297 Why would Mr Haas need to know the estimated launch date to "initiate blister tooling activities to determine timing for providing you with pack count desired for AUS market", as he asked on 28 June 2007? Again, none of these internal documents were for Sanofi's benefit to "goad" Sanofi into applying for an interlocutory injunction. They are internal Apotex emails enabling Apotex to be ready to apply for PBS listing and launch of its clopidogrel products onto the Australian market on 1 April 2008 if not subject to an interlocutory injunction.

298 Similarly, Mr Millichamp telling Mr Haas at 10.28pm on 28 June 2007 that "as per instructions from Barry the plan (in outline) for clopidogrel is as follows"; "[i]f we are successful in defending our position vs Sanofi and an injunction is not granted by the courts then we will launch"; and "[t]herefore 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" also makes no sense if Dr Sherman had not confirmed his decision to PBS list and launch at risk if Sanofi did not obtain an interlocutory injunction.

299 The ambiguities in the contemporaneous documentary evidence, when considered in context, are insignificant and readily resolved. The meaning of Mr Millichamp's email on 27 June 2007 at 1.59pm saying "... If we are successful in avoiding an injunction we will plan to launch subject to Barry's further advice/approval", understood in context, is sufficiently clear. It is not that Dr Sherman had not re-confirmed his decision to PBS list and launch at risk on or

about 26 or 27 June 2007. The inference from the evidence that he had done so cannot be avoided; it was the only reasonably open inference on the evidence. It is that Dr Sherman was a rational commercial decision-maker and would always keep his important decisions under review until (and no doubt after) implementation. That is, Mr Millichamp would have expected that, in the ordinary course, Dr Sherman would continue to be provided with up-to-date information as and when required to enable Dr Sherman to confirm or review his decisions from time to time.

300 Mr Haas's email of 28 June 2007, "[o]ne further question[.] Is Barry in the loop the strategy below (potentially launch end October but latest Mid November)?" is also readily explicable. In context, Mr Haas was asking about the details, including timing, of the specific implementation strategy that Mr Millichamp had provided. He was not seeking to ensure that Mr Millichamp was not off on some frolic of his own in arranging to PBS list and launch if Apotex Australia was not subject to an interlocutory injunction.

301 Apotex not making launch stocks (when it could probably re-deploy stock from the US) and Dr Sherman having made it clear that he did not want to waste money on launch activities until Apotex knew if it could launch or not discloses good commercial sense and no more. Nothing can change the fact that Apotex expected Sanofi to apply for an interlocutory injunction and recognised that Sanofi had a case for interlocutory relief. In these circumstances it was commercially sensible for Apotex not to spend more money than necessary to ensure that it could PBS list and launch on PBS listing once it knew whether Sanofi had obtained an interlocutory injunction or not. It is not evidence that Apotex might not PBS list and launch if Sanofi did not obtain an interlocutory injunction. This is exactly the explanation Mr Millichamp gave Mr Haas in his email of 29 June 2007. That email, consistent with the other contemporaneous documentary evidence, said that "if we are successful [in defending the interlocutory injunction application] we will go ahead and launch".

302 For the same reasons, Mr Kay's email to Mr Haas and others on 8 August 2007, indicating that Apotex was assuming that Sanofi's interlocutory injunction application would succeed and that Apotex was "thus not planning to launch at this stage", must be understood in the context of the fact that Apotex did think it most likely that Sanofi would obtain an interlocutory injunction. Again, this did not mean that Dr Sherman had not decided in late June 2007 to confirm his 20 February 2007 decision to PBS list and launch if Sanofi did not obtain an interlocutory injunction. It meant only that Apotex believed that it would likely (but by no means certainly) be subject to an interlocutory injunction, in which event, it could not launch. Even if there was any doubt as to what Mr Kay meant, Mr Millichamp sought to clarify this in his email of 9 August 2007 to Mr Kay, Dr Sherman and Mr Haas saying "[i]f we are successful and defend against an application for interlocutory relief from Sanofi we would like to launch as soon as possible. The earliest date that we can get PBS (Government reimbursement)

listing is Dec 07." Mr Kay's response, "OK by me", into which Dr Sherman was copied, leaves no room for doubt. Dr Sherman wanted Apotex to obtain PBS listing and launch as soon as possible, believed to be 1 December 2007 at that time, if Sanofi did not obtain an interlocutory injunction. Mr Caccamo's email "[w]e have aligned our launch plans accordingly" confirms that position.

303 This explains why Apotex Australia then applied for registration of its clopidogrel products on the ARTG; commenced the proceeding; notified Sanofi that it was preparing to launch; and instructed its lawyers to defend the interlocutory injunction application. Mr Millichamp's letter to Apotex Australia employees of 17 August 2007, in this context and given that it says "[w]e intend to launch this product into the Australian market in the near future", cannot be understood as saying that Apotex had made no decision to PBS list and launch if Sanofi did not obtain an interlocutory injunction. Again, in context, the statement in that letter ("[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") accorded with Mr Millichamp's understanding that Dr Sherman kept all his important commercial decisions under review and would expect to be updated about all relevant circumstances should Sanofi apply for an interlocutory injunction and on the determination of that application.

304 It is also relevant that, at all times, Apotex and Sanofi both had sophisticated and experienced lawyers, including senior and junior counsel with specialist patent law expertise. This is why, for example, Mr Millichamp knew that Apotex Australia would have to both provide substantial security (\$50 million to \$70 million) to have a real chance of avoiding Sanofi obtaining the interlocutory injunction and give undertakings of its own about record keeping and the like. To entertain as a real possibility that Apotex had wanted to "goad" Sanofi into applying for an interlocutory injunction to obtain an undertaking as to damages without in fact intending to PBS list and launch its own clopidogrel products onto the Australian market (as the Full Court did³¹⁴) required several matters to be directly confronted.

305 First, it was never put to Mr Millichamp that Apotex had wanted to "goad" Sanofi into applying for an interlocutory injunction to obtain an undertaking as to damages without in fact intending to PBS list and launch its own clopidogrel products onto the Australian market. The closest the cross-examination came (and it was not close) was the question to Mr Millichamp that the point of him notifying Sanofi of Apotex's intentions on 17 August 2007 was to goad Sanofi into applying for an interlocutory injunction. What was not put to Mr Millichamp is that this goading was dishonest in that, in fact, Apotex wanted Sanofi to believe it would

314 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 96 [129]. See also at 97 [134].

PBS list and launch if not subject to an interlocutory injunction when it did not have any such intention. Mr Millichamp denied the goading but was given no opportunity at any time to deny the further imputation of dishonesty.

306 Second, the seriousness of the dishonesty that would have been involved in Apotex misleading Sanofi into believing it intended to PBS list and launch if not subject to an interlocutory injunction if it had no intention of doing so is not to be underestimated. That conduct would not have been a mere litigious "game" or "sharp" commercial practice. It would have been misleading and deceptive conduct and perhaps a fraud. It could have amounted to attempting to obtain a financial advantage by deception, which is a crime. Moreover, it would have been a plan that Apotex could never have shared with its lawyers or counsel. Apotex Australia's lawyers and counsel could not have adduced Mr Millichamp's evidence before Gyles J that "it is [Apotex's] intention to apply for listing of its clopidogrel 75mg (as hydrogen sulfate) tablets at the next available opportunity, which is by 1 December 2007" or informed Gyles J, as Mr Catterns KC did, that Apotex would apply for PBS listing on 1 December 2007, obtain it as a matter of course on 1 April 2008, and launch its clopidogrel products onto the market then (having taken orders in advance), unless they had been instructed that this was Apotex Australia's intention.

307 Third, if this deception was Apotex's secret plan, Apotex appears to have undertaken no risk assessment of any kind of the chance that its plan might be foiled by Sanofi ultimately proving that it had been deceived by Apotex into providing the undertaking as to damages. Further, no hint or suggestion of this secret plan emerges from any of Apotex's documents. This is in circumstances where subsequently, after the final hearing before Gyles J and before his Honour delivered judgment, Mr Kay emailed Mr Millichamp saying "I wonder if the best outcome would be that we win at first instance, [Sanofi] appeal and the injunction remains in place pending appeal. That way, 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. What do you think?" Mr Kay followed this up with this musing: "my view is that in the event of our success and should [Sanofi] decide to appeal we should in some way allow the injunction to continue, and seek damages should any appeal fail to go [Sanofi's] way". The key words here are "in some way". Mr Kay obviously did not know how this could be achieved. If it had already been achieved on 18 September 2007 (at the hearing of the interlocutory injunction application), however, Mr Kay's musings to this effect in August 2008 make no sense. Had Mr Kay or anyone else in Apotex had the same thoughts before 18 September 2007, it would be expected that some hint of them might appear in the documents leading up to that date. But there is no such hint.

308 Fourth, had anyone in Apotex communicated any such idea to their lawyers, the response would have had to include advice that: (a) Apotex Australia could not mislead the Court to obtain the potential financial advantage of Sanofi's

undertaking as to damages; and (b) accordingly, if Apotex Australia did not intend to PBS list and launch on 1 April 2008, then Sanofi could not obtain an interlocutory injunction (as there would be no real threat of infringement of the patent) and Apotex Australia could not obtain the benefit of Sanofi's undertaking as to damages (as it would bear the onus of proving actual loss). That is, either Apotex had to decide before 18 September 2007 that it was going to PBS list and launch on 1 April 2008 or it was involved in a sophisticated deception of not only Sanofi and Gyles J but also of its own lawyers.

309 Fifth, the idea is difficult to reconcile with Apotex's actual conduct of the defence of Sanofi's interlocutory application, including the arrangements it made to offer security for Sanofi's losses of \$50 million. As to the security, the important point is not what it would have cost Apotex to obtain the letter of credit,³¹⁵ but that it formed part of Apotex determinedly and seriously defending against the grant of an interlocutory injunction because it thought it had a genuine (even if not a probable) chance of succeeding – a chance which was well worth trying to achieve given that clopidogrel was a "blockbuster" drug. If Apotex Australia had preferred to be enjoined and obtain an undertaking as to damages on the fundamental (and, given its sophisticated legal advice, inexplicable) misunderstanding that it did not ultimately have to prove actual loss to be compensated under the undertaking (which meant that it had to prove that but for the interlocutory injunction it would have obtained PBS listing and launched, in order to satisfy the requirement of causation), then Apotex Australia had no reason to run a comprehensive defence of Sanofi's application and offer serious security to avoid being enjoined.

310 Sixth, the Full Court's conclusion that the offering of the security was "consistent with Apotex keeping its options open"³¹⁶ is perplexing. Had Apotex Australia's defence of Sanofi's application been successful it would have had to provide the security within 28 days as it offered. If, after 18 September 2007, and having succeeded in defending against the application for an interlocutory injunction so that no such interlocutory order was made, Apotex Australia informed Gyles J that it had changed its mind and did not want to PBS list and launch on 1 April 2008 and therefore would not be providing the security, there would have been potentially serious consequences for Apotex Australia if it could not also identify a material change of circumstances justifying its changed position (which it would not have been able to do). At the least, Apotex Australia would have been ordered to pay indemnity costs in respect of Sanofi's application and would have lost any chance of an early final hearing, which would have been to its substantial commercial detriment. The prospect of the desired commercial

315 cf *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 114-115 [204]-[205].

316 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 115 [205].

consequence of Apotex Australia being taken seriously in the market in Australia, as referred to in Mr Millichamp's email of 22 June 2007, also would have been seriously damaged.

311 Seventh, Sanofi had access to equally sophisticated legal advice as Apotex did. For example, the lawyers for both parties in Australia would have known what was occurring in the US and Canada, including the settlement agreement reached in the US on 26 May 2006. They would have been advising their respective clients of the potential classes of recoverable loss in Australia. In applying for the interlocutory injunction at the price of the undertaking as to damages, offering any amount of security for Apotex Australia's losses Gyles J might require, and giving security for Apotex Australia's potential losses of \$40 million, Sanofi proved that on 18 September 2007 it believed that Apotex Australia would PBS list and launch on 1 April 2008 if not restrained by interlocutory injunction. Had Sanofi believed on 18 September 2007 that Apotex Australia was bluffing, it need not have applied for the interlocutory injunction. Had Sanofi come to believe after 25 September 2007 that Apotex Australia was bluffing, it could have approached the Court on that basis to dissolve the interlocutory injunction and withdraw the security and undertaking as to damages.

312 The Courts below did not directly confront these matters in the weighing of the possibilities and probabilities of Apotex's conduct had it not been subject to the interlocutory injunction. In that process of weighing, the Courts below instead focused on five matters. First, that the delayed PBS listing date of 1 April 2008 coincided with the early hearing in April-May 2008, two events which were said not to be known "until about the time the interlocutory application was determined"³¹⁷ and could have led Dr Sherman to change his mind or not commit to PBS listing and launch until the final hearing had concluded.³¹⁸ Second, that the risk/reward calculations from July 2008 exposed the substantial risk to Apotex Australia of it having PBS listed and launched at risk, as did the subsequent calculations in September 2009, and that these calculations would have also been reflective of the risk/reward position immediately before September 2007 (that is, that in all cases, Apotex Australia's potential liability to Sanofi greatly exceeded its potential profits). Third, that Apotex Australia did not launch at risk when it could have done so after it succeeded before the Full Court in September-October 2009. Fourth, the inconsistency of part of Mr Millichamp's evidence with the contemporaneous documentary evidence. Fifth, the fact that Dr Sherman was not called by the Commonwealth.

317 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 307 [341].

318 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 309 [349].

313 The fourth and fifth matters have been considered above and, for the reasons given, cannot sustain the conclusions of the primary judge and the Full Court. The first matter has also largely been dealt with and found to involve clear error. The first matter is also inconsistent with the discussion above to the effect that: (a) Dr Sherman had to make an effective decision before 18 September 2007 to PBS list and launch Apotex's clopidogrel products onto the Australian market; (b) the evidence demands an inference that Dr Sherman so decided in late June 2007 and maintained that decision until 18 September 2007; (c) the early final hearing was in Apotex's interests and the shorter period of selling at risk was preferred by Apotex; (d) while Dr Sherman's decision would not have been irrevocable before 1 April 2008, in the sense that it should be inferred that Dr Sherman would maintain his key commercial decisions under review, there is no basis to infer that Dr Sherman would have changed his mind after 18 September 2007 and before 1 April 2008 unless some material change of circumstances occurred making it effectively impractical for Apotex Australia to supply its clopidogrel products to the market; and (e) there is no evidence of any such change of circumstances.

314 The second and third matters, understood in context, do not undermine the conclusion that, but for the grant of the interlocutory injunction on 25 September 2007, Apotex Australia would have applied for (and obtained) PBS listing on 1 April 2008 and launched its clopidogrel products onto the Australian market on that day (having taken orders from pharmacists before 1 April 2008 in anticipation of PBS listing). There were fundamental differences in circumstances between September 2007 and the subsequent periods.

315 One fundamental difference in circumstance is that in September 2007 Apotex knew that it would be the first generic supplier of clopidogrel in Australia if it obtained PBS listing on 1 April 2008. Being the first generic onto the market, or first mover, was critically important to Apotex, as the evidence exposes (and as is consistent with commercial common sense for a generic pharmaceutical company which needs to lock in pharmacies to buy its products). Mr Millichamp gave evidence that, once Apotex Australia started the proceeding, he expected other generic companies to accelerate their plans to have their generic clopidogrel products available for sale in Australia. As it turns out, Mr Millichamp was right. Two other generic pharmaceutical companies were able to apply for registration of their clopidogrel products on the ARTG in September 2008, within about 12 months of the litigation starting.

316 The primary judge considered that Apotex Australia's first mover advantage was not diminished by August 2008 as "no other generic supplier ... had obtained ARTG registration for any clopidogrel product".³¹⁹ His Honour also concluded that

319 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 305 [330].

the July 2008 and September 2009 risk/reward analyses and Apotex Canada's response to them "tends to contradict the assertion made in Mr Millichamp's oral evidence that Apotex tries to get on the market as soon as possible".³²⁰ The Full Court agreed.³²¹

317 These conclusions, however, overlook Apotex's anticipation that from the moment the litigation commenced, other generic companies would be accelerating their plans to have their generic clopidogrel products on the Australian market. For Apotex the issue was being the first to the market and being the supplier of the only PBS listed generic version of clopidogrel for as long as possible. In that circumstance, Apotex's only competition would be Sanofi. Apotex would not necessarily know when any other generic company applied for ARTG registration of a clopidogrel product (as an application was kept confidential), but its anticipation was correct (as the fact of ARTG registration applications by Sandoz Pty Ltd and Spirit in September 2008 show). By the time it did the July 2008 calculations, moreover, Apotex allowed for the possibility that up to two other generic companies would have clopidogrel products on the market, which would cut Apotex's market share from an estimated 35% to 8.5%. It must be inferred that Apotex knew the longer it was not on the market, the greater the likelihood that when it did make it to market, that market would be split with other generic competitors. That this likelihood is not reflected in the September 2009 calculations does not mean that, by that time, Apotex no longer had a concern about generic competition. The September 2009 document merely *assumes* no other generic competition.

318 The prospect of other generic competition soon after Apotex Australia obtaining PBS listing and launching its products is fundamental because of its consequences. It is not just that Apotex Australia would lose market share to other generics (but that is important). It is that Apotex Australia alone would be responsible for the 12.5% price drop of Sanofi's products. Other generic competitors would be able to enter the market knowing that they had no potential liability for the 12.5% price drop of Sanofi's clopidogrel products. It is one thing to be potentially liable for a 12.5% price drop when the market will be divided between one generic and one originator. It is another to pave the way for other generics to be protected from potential liability for the 12.5% price drop and share the market with them in addition to the originator.

319 Apotex Australia manifestly lost its clear run as first mover by being subject to the interlocutory injunction on 25 September 2007. That clear run had

320 *The Commonwealth v Sanofi (formerly Sanofi-Aventis) [No 5]* (2020) 151 IPR 237 at 303 [322].

321 *The Commonwealth v Sanofi (formerly Sanofi-Aventis)* (2023) 174 IPR 66 at 118-120 [222]-[229].

substantial value to Apotex Australia over and above the profits it would make. While Apotex Australia's profits could never match Sanofi's potential losses (because of the 12.5% price drop and generic discounting to which Sanofi would respond by discounting its own prices below the 12.5% price drop level), Sanofi's potential losses and Apotex's risk of liability for those losses both depended on the validity of Sanofi's Australian clopidogrel patent. In contrast, Apotex Australia's potential profits and other gains would be in its hand immediately on PBS listing and launching on 1 April 2008.

320 This leads to the other fundamental change in circumstance after September 2007. The inference that should be drawn from the evidence is that up to and in September 2007 Apotex was confident that it would succeed in having Sanofi's Australian clopidogrel patent declared invalid. This is apparent from several facts: (a) Dr Sherman decided to PBS list and launch at risk on 20 February 2007 despite not then knowing the outcome of the litigation in the US and Canada, and confirmed that decision in late June 2007; (b) on 14 August 2007 Mr Millichamp and Mr Smith certified that Apotex Australia believed on reasonable grounds that it was not marketing and did not propose to market its Apotex clopidogrel products "in a manner or circumstance that would infringe a valid claim of a patent", under pain of criminal sanction for false or misleading statements; (c) Apotex Australia wanted a final hearing soon; and (d) Apotex Australia offered the \$50 million security when it did not have to do so. Moreover, any doubt in this regard is dispelled by Mr Millichamp's email of 19 September 2007 saying "[e]ven if we get an injunction imposed I am very confident that we will win at final [trial]. In that case we will obviously seek damages (a large amount)."

321 Mr Millichamp was not challenged about the veracity of his email of 19 September 2007 accurately reflecting his (and Apotex's) state of mind in 2007. Nor was he challenged about the veracity of his oral evidence that "we always believed that all of the claims of the patent were invalid". If Apotex was confident it was going to succeed in having Sanofi's Australian clopidogrel patent declared invalid and revoked, the potentially ruinous damages to which it might be subject if it failed would have had a different, and far less significant, complexion to Apotex in 2007-2008 than is apparent in the reasoning of the Courts below. As Mr Millichamp put it, "[i]f we launched at risk, yes. It's a large exposure. But only if we were found to infringe the patent. The launch at risk I'm not found to infringe, though. The risk is nothing." In its actual commercial context at the time, it must be inferred that Apotex was committed to take what it considered to be a low risk of potentially ruinous damages for what it considered to be a high likelihood of a very large potential reward.

322 Further, Apotex Australia's arguments to defeat the interlocutory application included that the relevant compound claimed in Sanofi's Australian clopidogrel patent had been disclosed in the equivalent Canadian patent published in Australia on 7 November 1985, so there was a "very substantial issue" as to the

novelty of Sanofi's Australian clopidogrel patent. In the hearing before Gyles J on 18 September 2007, Mr Catterns KC explained that Apotex Australia had a "strong case" on lack of novelty because of the disclosure in the Canadian patent of the racemic mixture. While nothing is certain in litigation, novelty is the kind of issue on which a party is able to receive meaningful advice before a hearing starts (even if subject to the usual caveats about litigation uncertainty). It must be inferred that Apotex received advice on its prospects of having Sanofi's Australian clopidogrel patent revoked for invalidity and that such advice provided a basis for Mr Millichamp's view that he was "very confident" Apotex would succeed.

323 In contrast, by the time the final hearing before Gyles J was completed in May 2008, Apotex had experienced either having seen or having had reported to it a day-by-day account of the hearing – including the cross-examination of their expert witnesses, the competing submissions of the parties, and the reactions of Gyles J (in circumstances where events show that Gyles J concluded, albeit in the event wrongly, that the key claims of Sanofi's Australian clopidogrel patent should not be revoked for invalidity). Whatever Apotex did after the final hearing before Gyles J concluded in May 2008 it did knowing what occurred in that hearing. That makes Apotex's deliberations from that time onwards incomparable to its actual deliberations before 25 September 2007 and to its "counterfactual" or hypothetical deliberations after 25 September 2007. As to the former, the two circumstances are entirely different. As to the latter, if Apotex Australia had not been restrained on 25 September 2007, the required inference is that it would have PBS listed and launched on 1 April 2008, also creating an entirely different set of circumstances from those which in fact existed after 25 September 2007.

324 Accordingly, the inescapable actual (non-hypothetical) facts are that Dr Sherman decided to PBS list and launch Apotex's generic clopidogrel products in Australia on three occasions: in June 2006 (on the condition that Apotex succeeded in the litigation in the US and Canada); on 20 February 2007 (irrespective of the position in the litigation in the US and Canada); and again in late June 2007. On each occasion Dr Sherman must be inferred to have known that Apotex's potential profits could never exceed or be remotely close to Sanofi's potential losses. Unless Dr Sherman was willing to have Apotex Australia take the risk of liability for such losses based on the view that Apotex Australia was ultimately likely to succeed in having Sanofi's Australian clopidogrel patent declared invalid and revoked, he was wasting a lot of time and money in taking all necessary steps to do so. In fact, if not so willing, Dr Sherman's instructions to Apotex Canada and Apotex Australia are nonsensical and irrational.

325 In this context, the potentially ruinous damages to which Apotex Australia would be subjected if it ultimately failed in having Sanofi's Australian clopidogrel patent declared invalid and revoked depended on that contingency which, it should be inferred from the evidence, Dr Sherman considered was most unlikely. Against that low risk of Apotex Australia failing to have Sanofi's Australian clopidogrel patent declared invalid and revoked, there was an enormous upside for Apotex if

it obtained PBS listing for and launched its clopidogrel products on the Australian market. Had Sanofi not succeeded in obtaining the interlocutory injunction and had Apotex Australia obtained PBS listing and launched its clopidogrel products on the Australian market on 1 April 2008, Apotex Australia anticipated that it could be the sole generic provider of that product for up to 12 months. As noted, it is not only the profit that Apotex Australia would have made as a result of PBS listing and launching at risk which is relevant. Equally relevant are the benefits it would have obtained in potential long-term deals and commercial relationships with pharmacists across Australia by supplying the only generic blockbuster drug of this kind. These were the opportunities that it must be inferred Dr Sherman perceived at the time (from 2007 to 1 April 2008). In these circumstances it was commercially rational for Dr Sherman to have sought to exploit these opportunities by seeking to PBS list Apotex's clopidogrel products and launch those products onto the Australian market on 1 April 2008. As Mr Millichamp put it, Apotex was "absolutely prepared to take the risk and knew what the risk was" at the relevant time between 2007 and 1 April 2008. Properly placed in context, the evidence amply supported this conclusion, meaning the Commonwealth discharged its onus of proof.

326 Another important observation should now be made. It is that a party such as Sanofi which comes to a court seeking an interlocutory injunction on the basis that it will give the usual undertaking as to damages must be taken to be acting in good faith on a reasonable belief that: (a) if not restrained, the party that it seeks to enjoin will carry out the threatened act; and (b) if it is ultimately wrong about its legal right to prevent that act, it will be liable to not only the restrained parties but also to adversely affected third parties. Where, as here, Sanofi knew that the relevant third party was the Commonwealth, and the financial position that Sanofi was seeking to preserve was the Commonwealth paying substantially more than would otherwise be the case if Apotex Australia did what it said it was going to do (obtain PBS listing and launch its clopidogrel products on 1 April 2008), it would be one thing for Sanofi to prove a material and unanticipated change of circumstances after the grant of interlocutory injunction making it practically impossible for Apotex Australia to do that which it had been restrained from doing (in which event a sophisticated litigator like Sanofi would, it must be inferred, approach the Court to dissolve the interlocutory injunction and withdraw the undertaking as to damages and the security). It is another thing altogether for such a party instead to contend that the very thing which it obtained the interlocutory injunction to prevent would not have occurred in any event. Such a contention demands the closest scrutiny because it could bring the administration of justice into disrepute for one judge to be persuaded that there is a real threat of potentially unlawful action requiring restraint, only for another judge years later to conclude there was no such threat at all.

327 Further, in circumstances where the only person other than Apotex Australia to have been at a real risk of loss from the (ultimately) wrongful grant of the interlocutory injunction is the Commonwealth, the potential injustice is all the

greater. In 2019, in the Second Reading Speech for the *National Health Amendment (Pharmaceutical Benefits) Bill 2019* (Cth), the Minister for Health said that the PBS provides Australians with "access to vital medicines" and "is rightly respected and valued for the high-quality, cost-effective services it delivers". According to the Second Reading Speech the PBS "covers more than 5,000 clinically proven products across a broad range of conditions" and, since 2013, the Commonwealth had "made over 2,100 new or amended PBS listings, at an investment of over \$10.6 billion".³²²

328 The Commonwealth (and the taxpayer) has a real interest in ensuring that the Commonwealth is not paying more for medicines than it ought to be paying. Given the interlocutory injunction wrongfully granted on 25 September 2007, the Commonwealth was paying more for Sanofi's clopidogrel products in Australia than it ought to have been paying since 1 April 2008 (even if that amounted to a fraction of the sums involved in operating the PBS). Sanofi took the benefit of the interlocutory injunction which had the effect of the Commonwealth paying the higher price for two years after 1 April 2008. Sanofi also took the benefit of that higher price in the commercial arrangements it made with pharmacists during that period. Having done so, it would be fundamentally unjust for Sanofi to retain the benefits it has been permitted to retain by the clearly erroneous judgments below.

Sanofi's notice of contention

329 The grounds of Sanofi's notice of contention which are ripe for determination by this Court can be dismissed within a short compass.

Ground 1

330 Sanofi undertook to "submit to such order (if any) as the Court may consider to be just for the payment of compensation, to be assessed by the Court or as it may direct, to any person whether or not a party, adversely affected by the operation of Order 1 ...". The relevant question posed by ground 1 of Sanofi's notice of contention is whether the Commonwealth has been "adversely affected" by order 1, which restrained Apotex Australia from "making, selling or otherwise disposing of" or "offering to make, sell or otherwise dispose of" its clopidogrel products. The relevant controls on the potential liability of a party giving the usual undertaking as to damages are twofold. First, the person must be adversely affected by the interlocutory injunction, not the mere fact of the litigation. That is, the interlocutory injunction must be the cause of the claimed loss. Second, the loss claimed by that person must be sufficiently connected to the substance of the interlocutory injunction to justify the characterisation of that loss as the person having been "adversely affected" by the interlocutory injunction. While that

322 Australia, House of Representatives, *Parliamentary Debates* (Hansard), 4 July 2019 at 291-292.

sufficiency of connection has been identified in various ways, including that the loss flow directly from the interlocutory order, that means nothing more than that the loss must be the natural consequence of the interlocutory order which could have been foreseen when the interlocutory order was granted.³²³ This best reflects the object of the undertaking as to damages, which is to ensure that persons are protected from loss sustained "by reason of the grant of the interim injunction in the event that it emerges that the plaintiff is not entitled to relief".³²⁴

331 The Commonwealth's loss was a natural consequence of the interlocutory injunction granted on 25 September 2007. Nothing more should be necessary to reach this conclusion other than to point to the reasons for judgment of Gyles J in granting the interlocutory injunction, in which his Honour said "I am much influenced by the effects of disturbing the status quo, particularly as it relates to the operation of the PBS".³²⁵

332 In any event, the evidence discloses that unless it could supply its generic clopidogrel products to the market, Apotex Australia had no reason to seek PBS listing of those products. Sanofi knew this at all material times. Sanofi gave the undertaking contemplating that the Commonwealth would continue to pay higher prices for Sanofi's clopidogrel products for so long as Apotex Australia did not obtain PBS listing of its generic clopidogrel products, and that Apotex Australia would not do so for so long as it could not supply its generic clopidogrel products in Australia. The Commonwealth's loss was a natural and specifically foreseen kind of consequence of the granting of the interlocutory injunction.

Ground 3

333 Ground 3 is not able to be determined by this Court. Neither the primary judge nor the Full Court dealt with this issue, and it depends on factual considerations.

Ground 4

334 The contention in ground 4 is that the Commonwealth is not a person who could be "adversely affected" by the interlocutory injunction through the suffering of compensable loss because: (a) the consequential impact on the level of costs

323 eg, *Air Express Ltd v Ansett Transport Industries (Operations) Pty Ltd* (1981) 146 CLR 249 at 266-267, 312-313; *European Bank Ltd v Evans* (2010) 240 CLR 432 at 439 [18].

324 *Air Express Ltd v Ansett Transport Industries (Operations) Pty Ltd* (1981) 146 CLR 249 at 325.

325 *GenRx Pty Ltd v Sanofi-Aventis* (2007) 73 IPR 502 at 506 [15].

incurred in the operation of a legislative scheme for social welfare is not a compensable loss; (b) the alleged loss was caused by the operation of the Commonwealth's own laws governing the PBS; and (c) it must be in the interests of the Commonwealth for orders made by a superior court of the Commonwealth, in aid of rights asserted under the laws of the Commonwealth, to operate, and be complied with, according to their terms.

335 The contention is without merit. The Commonwealth is a "person" within Sanofi's undertaking. It is a person, moreover, specifically contemplated in the hearing before Gyles J as being within the scope of the undertaking. There is no principled basis which would lead to the Commonwealth's claim as a person adversely affected by the interlocutory injunction being assessed differently from the claim of any other person. As the Commonwealth noted, s 64 of the *Judiciary Act 1903* (Cth) provides that in "[i]n any suit to which the Commonwealth ... is a party, the rights of parties shall as nearly as possible be the same, and judgment may be given ... as in a suit between subject and subject". No reason to apply s 64 other than in accordance with its terms is apparent. As the Commonwealth submitted:

"The result of the interlocutory injunction was a real and substantial overpayment by the Commonwealth of PBS subsidies, the primary beneficiary of which was Sanofi. Such effects are within the concept of adverse effect. They were within Sanofi's contemplation when it approached the Court for an injunction. Its evidence before Gyles J concerned the operation of the PBS and the effect it would have on Sanofi should Apotex's clopidogrel products be listed on the PBS. That evidence was a key reason for his Honour making the injunction that he did ..."

Ground 7

336 Ground 7 is opportunistic at best and approaching an abuse of process at worst.³²⁶ Sanofi has already argued and lost the same point in the same proceeding in circumstances where it was refused special leave to appeal against that fully reasoned loss in the Full Court of the Federal Court of Australia and where there has been no material change in circumstances to justify the re-litigation of the point.³²⁷

337 Repetition does not improve the point. Chapter 3, Pt 3-2, Div 2 of the *Therapeutic Goods Act* is not a code. As the Full Court observed in dismissing

326 See, by analogy, *Re Golding* (2020) 94 ALJR 1014 at 1018 [11]; 384 ALR 204 at 207-208.

327 *The Commonwealth v Sanofi* (2015) 237 FCR 483; *Sanofi (formerly Sanofi-Aventis) v The Commonwealth* [2016] HCASL 98.

Sanofi's arguments the first time around: (a) "Div 2 of Pt 3-2 of Ch 3 of the [*Therapeutic Goods Act*] does not include any express restriction which prevents the Commonwealth, or any other person, from recovering under the usual undertaking as to damages in the ordinary way in circumstances where the patentee fails to obtain a final injunction but is not shown to have engaged in any relevant misconduct";³²⁸ (b) "the notion that Div 2 might operate as an exhaustive code in respect of the Commonwealth's claim but not the claim of the applicant for registration, does not reflect a rational legislative choice";³²⁹ (c) the "contrary view of Div 2 is likely to produce results that are inconvenient and unjust";³³⁰ (d) s 26C "has nothing to say about the entitlement of the Commonwealth to recover under the usual undertaking as to damages. In particular, s 26C(5) to (8) are essentially concerned with ... permitting the Commonwealth ... to recover damages where a false or misleading certificate is given by the patentee prior to commencing proceedings in which an interlocutory injunction is obtained";³³¹ and (e) there "is nothing in the ... relevant legislative history to suggest that ss 26B, 26C and 26D were intended to curtail the right of any person, including ... the Commonwealth ... to recover on a usual undertaking as to damages given by a patentee as a condition of obtaining an interlocutory injunction".³³²

Conclusion and orders

338 The Commonwealth's appeal on ground 2 should succeed. Sanofi's notice of contention should fail. The orders of the Full Court made on 26 June 2023 and order 1 of the orders of the Federal Court of Australia made on 28 April 2020 should be set aside. The matter should be remitted to a newly constituted Full Court for determination of grounds 2, 3, 5 and 6 of Sanofi's notice of contention. The respondents should pay the appellant's costs of the proceedings below to date and of the appeal to this Court.

328 *The Commonwealth v Sanofi* (2015) 237 FCR 483 at 506 [91].

329 *The Commonwealth v Sanofi* (2015) 237 FCR 483 at 507 [93].

330 *The Commonwealth v Sanofi* (2015) 237 FCR 483 at 507 [96].

331 *The Commonwealth v Sanofi* (2015) 237 FCR 483 at 508 [98].

332 *The Commonwealth v Sanofi* (2015) 237 FCR 483 at 511 [113].

339 BEECH-JONES J. When a well-resourced and sophisticated litigant, such as a pharmaceutical company, approaches a court seeking an injunction to restrain another well-resourced and sophisticated litigant from launching a competing drug, both litigants should be held to the unqualified statements each make to the court as to their intentions and the risks each assumes in seeking and resisting the injunction.

340 The premise of the reasoning of the courts below is that if one of those litigants informed a court that, absent an injunction restraining them from doing so, they intended to launch a product on the market when that was not their intention, then that would not be deceitful conduct attracting severe consequences. That premise should not be countenanced. When the unequivocal statements made on behalf of Apotex Australia Pty Ltd (formerly known as GenRx Pty Ltd) ("Apotex Australia") to the Federal Court of Australia on 18 September 2007 about its intention to launch its range of clopidogrel pharmaceutical products are understood in that context, then the findings of the courts below cannot be sustained and the appellant, the Commonwealth of Australia, should succeed.

341 The full circumstances and issues arising in this appeal, including the notice of contention, are set out in the judgment of Jagot J. Subject to what follows I agree with her Honour's reasoning on all issues.

Background

342 On 7 June 1990, the first respondent, Sanofi (formerly Sanofi-Aventis), was granted an Australian patent for the drug "clopidogrel". In August 2007, Apotex Australia commenced proceedings in the Federal Court seeking the revocation of the patent ("the revocation proceedings"). On 17 September 2007, Sanofi filed a cross-claim seeking final relief in respect of a threatened infringement of the patent by Apotex Australia. Sanofi also filed an application for an interlocutory injunction restraining any infringement by Apotex Australia pending a final hearing of its cross-claim. The hearing of the application for the interlocutory injunction took place before Gyles J on 18 September 2007. On 21 September 2007, his Honour delivered ex tempore reasons for granting the injunction. On 25 September 2007, his Honour published revised reasons for granting the interlocutory injunction,³³³ noted Sanofi's undertaking as to damages and made injunctive orders restraining Apotex Australia from, inter alia, making, selling, importing or otherwise disposing of clopidogrel products.

343 On 20 February 2008, another pharmaceutical company, Spirit Pharmaceuticals Pty Ltd, filed an application seeking revocation of Sanofi's patent.

333 *GenRx Pty Ltd v Sanofi-Aventis* (2007) 73 IPR 502.

The final hearing of that proceeding and the revocation proceedings commenced before Gyles J on 28 April 2008. On 12 August 2008, judgment was delivered.³³⁴ Apotex Australia was only partly successful in seeking to have the patent revoked.³³⁵ Apotex Australia appealed the judgment of Gyles J to the Full Court of the Federal Court. On 29 September 2009, the Full Court upheld Apotex Australia's appeal.³³⁶ On 13 October 2009, the Full Court made orders revoking the entirety of Sanofi's patent. Sanofi sought special leave to appeal from those orders to this Court. The application for special leave to appeal from the decision of the Full Court to this Court was refused on 12 March 2010.

344 The undertaking as to damages proffered by Sanofi to the Federal Court on 25 September 2007 in support of the interlocutory injunction against Apotex Australia obliged Sanofi to pay compensation to any person adversely affected by the injunction, whether or not that person was a party to the litigation.³³⁷ In 2013, the Commonwealth applied for payment of compensation by Sanofi pursuant to that undertaking.

345 The Commonwealth's application for compensation was heard in 2017. The Commonwealth sought recovery of an amount representing the difference between the price subsidies it paid for the supply of clopidogrel under the Pharmaceutical Benefits Scheme ("the PBS") on and from 1 April 2008, and the reduced amount of price subsidies it would have paid had Apotex Australia obtained a listing on the PBS for its clopidogrel products from that date. It was common ground that one of the effects of the legislative provisions governing the PBS was that,³³⁸ if Apotex Australia obtained a listing on 1 April 2008, it would have triggered a 12.5% reduction in the price of supply of clopidogrel with a consequential reduction in the subsidy paid by the Commonwealth. The Commonwealth also contended that other aspects of the legislative scheme would have resulted in further price reductions.

334 *Apotex Pty Ltd (formerly GenRx Pty Ltd) (ACN 096 916 148) v Sanofi-Aventis* (2008) 78 IPR 485.

335 *Apotex Pty Ltd (formerly GenRx Pty Ltd) (ACN 096 916 148) v Sanofi-Aventis* (2008) 78 IPR 485 at 536 [134].

336 *Apotex Pty Ltd v Sanofi-Aventis* (2009) 82 IPR 416 at 451 [193].

337 See *Patrick Stevedores Operations No 2 Pty Ltd v Maritime Union of Australia* (1998) 195 CLR 1 at 41-43.

338 *National Health Act 1953* (Cth), s 99ACB.

346 The Commonwealth's claim for compensation rested on the contention that, if Sanofi's claim for an interlocutory injunction had been refused, Apotex Australia would have sought and obtained a PBS listing for its clopidogrel products with effect from 1 April 2008 and would have sold its clopidogrel products from that date even though, if the validity of Sanofi's patent was upheld, Apotex Australia would have been exposed to a damages claim ("a launch at risk"). The injunctive relief granted by Gyles J against Apotex Australia did not specifically restrain it from having its products listed on the PBS. In fact, Apotex Australia gave an undertaking that it would not seek such a listing and that undertaking was not supported by Sanofi's undertaking as to damages. However, for the reasons given by Jagot J,³³⁹ the injunction granted by Gyles J had the practical effect of preventing Apotex Australia from seeking a PBS listing and any loss to the Commonwealth that flows from that failure was caused by the injunction. Further, it was common ground during the hearing before Gyles J that, had Apotex Australia applied for a listing on the PBS, its application would have been granted.

347 It follows that the critical factual issue on which the Commonwealth's claim depended was whether, had the injunction been refused, Apotex Australia would have sought to have its clopidogrel products listed on the PBS with effect from 1 April 2008 and would have launched its clopidogrel products at risk. The primary judge did not accept that the Commonwealth proved that on the balance of probabilities³⁴⁰ and the Full Court upheld the primary judge's finding.³⁴¹

The appeal in this Court

348 By a grant of special leave to appeal, the Commonwealth appealed the decision of the Full Court to this Court. The Commonwealth's notice of appeal contained two grounds of appeal. The first ground sought to raise an issue of principle about shifting evidential burdens in respect of applications for compensation pursuant to an undertaking as to damages contingent, as they are, upon the demonstration of the counterfactual of what would have happened had the injunction been refused.

349 It is not necessary to address the first ground of the Commonwealth's appeal in any detail. It suffices to state that the Commonwealth bore the legal onus of

339 See reasons of Jagot J at [330]-[331].

340 *The Commonwealth v Sanofi (formerly Sanofi-aventis) [No 5]* ("Sanofi (No 5)") (2020) 151 IPR 237 at 246 [26]-[27], 309 [349]-[351].

341 *The Commonwealth v Sanofi (formerly Sanofi-aventis) ("Sanofi FFC")* (2023) 411 ALR 315 at 321 [14].

proof³⁴² and had to establish that, but for the injunction, damage would have been suffered,³⁴³ although that should not be taken as excluding the award of compensation for the loss of a valuable commercial opportunity. In considering whether that burden has been discharged, regard must be had to the distinction between damage flowing from the injunction and damage flowing from the litigation itself.³⁴⁴ Otherwise, questions of shifting evidential onuses or burdens fall to be determined by reference to established principles, the application of which are case dependent on the evidence each party adduces and what each party contends.³⁴⁵

350 The balance of these reasons concern the Commonwealth's second ground of appeal. That ground contends that "[t]he Full Court erred in failing to find, by inference from the evidence, that in the absence of the interlocutory injunction, it was likely that Dr Sherman would have reconfirmed the plan to seek PBS listing". The reference to "Dr Sherman" is to Dr Bernard ("Barry") Sherman who was the ultimate controller of Apotex Australia. The reference to "inference" in this ground of appeal needs to be treated with caution. The Commonwealth's case concerned the establishment of a counterfactual, namely whether Apotex Australia would have listed its clopidogrel products and launched at risk from 1 April 2008 had the injunction been refused. However, as explained below, the Commonwealth sought to prove that "inference" by principally relying on direct evidence as to Apotex Australia's intentions up to and including the time the injunction was granted.

351 During the appeal there was debate about the point in time at which the counterfactual inquiry commenced for the purpose of determining the Commonwealth's claim on the undertaking as to damages. On one view, it commenced when Gyles J gave ex tempore reasons for granting the injunction (21 September 2007) and on another, it only commenced when the injunctive orders were made (25 September 2007). According to Sanofi it did not commence until 28 days after the injunction was granted because, had the injunction been refused, that was the time when Apotex Australia would have been obliged to provide \$50 million in security for Sanofi's claim for damages.³⁴⁶

342 *Air Express Ltd v Ansett Transport Industries (Operations) Pty Ltd* (1981) 146 CLR 249 at 313, 320, 324-325.

343 *Air Express* (1981) 146 CLR 249 at 318, 320, 325.

344 *Air Express* (1981) 146 CLR 249 at 268, 310, 312, 315, 324.

345 *Purkess v Crittenden* (1965) 114 CLR 164 at 168.

346 See below at [366].

352 Sanofi's contention as to the time when the counterfactual commences should be rejected. On any view, had the injunction been refused by Gyles J, then any further consideration by Apotex Australia of whether to list and launch and, if so, when, would have commenced immediately upon learning that there was no restriction on it doing so. Otherwise, it is not necessary to resolve precisely when the counterfactual inquiry commences, although, as noted by Jagot J,³⁴⁷ that inquiry must exclude any consideration of the reasons why Gyles J might have refused the injunction. It also must exclude consideration of the actual reasons given by Gyles J for granting the injunction (and most likely any views expressed by his Honour during the course of the interlocutory hearing about the strength of each party's case). However, the parties did not contend that it excluded consideration of any statement made to Gyles J during the hearing of the application for the interlocutory injunction.

353 Regardless of whether the analysis changed from ascertaining past actual events to counterfactual events on 21 September 2007 or 25 September 2007, the outcome is the same, namely that the Commonwealth overwhelmingly proved that, but for the grant of the injunction, Apotex Australia would have had its clopidogrel products listed on the PBS from 1 April 2008 and launched those products at risk. The primary judge and the Full Court were in error in finding otherwise.

The events of 2017

354 Before the primary judge, the Commonwealth tendered numerous internal documents that it obtained from Apotex Australia about its decision making and planning from 2006 to 2007, as well as documents concerning the proceedings before Gyles J. Parts of the internal documents were redacted by Apotex Australia on the basis of legal professional privilege; a claim that was accepted by all parties.³⁴⁸ These documents were admitted without limitation³⁴⁹ and were evidence of the matters they asserted.

355 The Commonwealth also adduced evidence from Mr Roger Millichamp, who was the managing director of Apotex Australia throughout the relevant period. Apotex Australia's ultimate holding company was Sherfam Inc. One of the companies in the Apotex group was Apotex Inc ("Apotex Canada"). As noted, the principal and directing mind of Apotex Australia and the corporate structure which it formed part of was Dr Sherman. In his oral evidence, Mr Millichamp said that

347 See reasons of Jagot J at [275].

348 *Sanofi (No 5)* (2020) 151 IPR 237 at 275 [174]-[175].

349 See *Evidence Act 1995* (Cth), s 136.

the strategic decisions in relation to litigation were made at the Apotex group's "HQ" in Canada and that he executed those instructions in Australia.

356 Leaving aside two documents, the documents admitted into evidence concerning Apotex Australia's intentions in the period from February 2007 leading up to the application for the injunction filed on 17 September 2007 were unequivocal in stating its intention to list and launch its clopidogrel products at risk unless it was restrained by injunction. On 20 February 2007, Dr Sherman emailed Mr Millichamp confirming that, if no injunction was granted, then Apotex Australia would launch its clopidogrel products. This intention was reiterated in subsequent emails sent throughout 2007 between Mr Millichamp and other executives of the Apotex group located in Canada and Australia.

357 The documents tendered by the Commonwealth revealed that Apotex Australia analysed the financial risk of launching in terms of its exposure to Sanofi for damages at around \$50 million if it was unsuccessful in seeking to revoke the patent. The documents adduced also demonstrate that Apotex Australia addressed the logistics of manufacturing and distributing its clopidogrel products.

358 One document that the primary judge accepted raised a doubt about Apotex Australia's intentions, at least in the period from February 2007 to September 2007, was a partly redacted email sent by Mr Millichamp to Apotex Canada's Corporate Project Manager, Mr Stephen Haas, on 27 June 2007 at 1.59 pm.³⁵⁰ The email stated, inter alia, that "[i]f we are successful in avoiding an injunction we will plan to launch *subject to Barry's further advice / approval*" (emphasis added). The primary judge's treatment of this email is addressed below.³⁵¹ At this point, it is important to place this email in context.

359 On 25 June 2007, Mr Millichamp sent an email to Mr Andrew Kay, the President of Apotex Canada. Mr Kay reported to Dr Sherman. The email was copied to Mr Paddy Smith, the Chief Financial Officer of Apotex Australia and Ms Karen McTavish, the National Sales and Marketing Director of Apotex Australia. The email set out a detailed timeline for the PBS listing and launch at risk of Apotex Australia's clopidogrel products. On the same day, Mr Kay sent an email to Dr Sherman asking that he "re-confirm" the decision to launch. At 11.44 am on 26 June 2007, Dr Sherman sent an email to Mr Kay that was redacted, except for the words "[w]e will stay with bisulfate in Australia", that being a reference to an ingredient of clopidogrel. At 11.54 am on 26 June 2007, Mr Kay sent an email to Dr Sherman stating, "[p]lease advise when you have decided

350 In these reasons, all time references are references to Sydney time.

351 See below at [374].

whether to pursue revocation ... and if you wish us to move to launch at risk". Dr Sherman responded to that email at 4.44 am on 27 June 2007. At 5.12 am on 27 June 2007, Dr Sherman sent another email to Mr Kay. Both of the emails sent by Dr Sherman were copied to Mr Millichamp and their entire contents were redacted. At 11.23 am, Mr Millichamp forwarded that email to various executives of Apotex Australia with the comment "[g]ame on". As discussed above, at 1.59 pm on 27 June 2007, Mr Millichamp sent an email to Mr Haas which stated, "we will plan to launch subject to Barry's further advice / approval". Around ten hours later, Mr Haas responded seeking an estimated launch date.

360 At 10.28 pm on 28 June 2007, Mr Millichamp sent an email to Mr Haas which was copied to several executives of Apotex Australia. The email, which was partially redacted, stated:

"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 ...
- 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.*

...

We are not sure that we can launch yet so need to know if we should place orders in anticipation or should wait." (emphasis added)

361 Another document that the primary judge treated as evidence of a lack of firm intention on the part of Apotex Australia was a circular sent to Apotex Australia's staff on 17 August 2007, under Mr Millichamp's name, on the basis that staff could provide the circular to customers. The circular stated, "[w]e intend to launch [a clopidogrel] product into the Australian market in the near future". The circular outlined the potential for that launch to be affected by legal proceedings. It noted that, if Sanofi were to apply for an injunction, then such an application would be "vigorously defend[ed]", although Apotex Australia would refrain from seeking "PBS listing for clopidogrel or take orders from pharmacists until the application has been determined". The circular added, "[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".

362 The primary judge treated this circular as evidence that "Apotex Australia
had not committed itself to launching in the event no interlocutory injunction was
granted".³⁵² The Full Court agreed with the primary judge's characterisation of its
effect.³⁵³

363 On 16 August 2007, Apotex Australia commenced the revocation
proceedings. The next day, it notified Sanofi of its intention to market and sell its
clopidogrel products in the near future. From that time until early September 2007,
there was an exchange of correspondence between the parties' respective solicitors
seeking and denying undertakings.

364 On 1 September 2007, Apotex Australia lodged its application for a PBS
listing. However, it withdrew the application soon after because it was advised that
it was too late to secure a listing in December 2007. Apotex Australia then
recalibrated its timetable with a view to securing a listing from 1 April 2008.

365 On 6 September 2007, Apotex Australia advised Sanofi that it was prepared
to undertake to not have its clopidogrel products listed on the PBS and to not take
orders from pharmacists for its supply until 11 October 2007, provided that any
interlocutory injunction brought by Sanofi had been commenced and determined
by that date.

366 On 14 September 2007, Apotex Australia offered undertakings to keep
accounting records of, inter alia, units of clopidogrel product sold and to provide
security of \$50 million within 28 days for any damages and costs that may be
ultimately awarded against it if Sanofi's patent was not revoked.

367 In the meantime, the revocation proceedings were listed for directions on
13 September 2007. After the directions hearing, Mr Millichamp enthusiastically
reported to Mr Kay that, "the court wants our case to move quickly" with a possible
date for a final hearing within "the next six months". Mr Millichamp reiterated that
"[o]ur plan is to launch to customers (take orders) immediately, assuming that we
are free to sell, and then supply product in early 2008 for an April PBS listing".

368 As noted, on 17 September 2007, Sanofi filed its cross-claim and
application for an interlocutory injunction. It also proffered an undertaking as to
damages to support its application. On the same day, Mr Millichamp swore an
affidavit in which he reiterated Apotex Australia's intention to "apply for listing of
its clopidogrel ... tablets at the next available opportunity, which is by 1 December

352 *Sanofi (No 5)* (2020) 151 IPR 237 at 297 [288].

353 *Sanofi FFC* (2023) 411 ALR 315 at 342 [118].

2007". He noted that listing the clopidogrel products would trigger a 12.5% reduction in price for all clopidogrel brands and that Apotex Australia offered \$50 million as security for damages and costs that may be awarded in favour of Sanofi if it succeeded at a final hearing.

369 Mr Millichamp's affidavit was read during the interlocutory hearing before Gyles J on 18 September 2007. During that hearing, the following exchange occurred:

"[Gyles J]: No, but it is said that you will not get your PBS listing until April.

MR CATTERNS [senior counsel for Apotex Australia]: Yes. We agree, your Honour. We apply on 1 December and we get it [ie, PBS listing] on 1 April.

[Gyles J]: And being practical about it, *that's the time you'll launch is that right?*

MR CATTERNS: *Yes, your Honour.*" (emphasis added)

370 Mr Catterns then described the pre-launch activities that Apotex Australia would undertake prior to 1 April 2008, including "taking orders now, even before we apply for PBS listing and unless restrained we would do so". Mr Catterns informed the Court that it was "virtually impossible" for Apotex Australia not to obtain a listing on the PBS effective from 1 April 2008 and that "both sides" regarded listing on 1 April and the consequential 12.5% price reduction as "inevitable". Senior counsel for Sanofi, Mr Bannon, was not overawed by the occasion before Gyles J. He did not demur to any of these statements. He noted that the Commonwealth had not applied to be a party to the proceedings but observed that his client's undertaking as to damages was "not limited to the parties".

371 The next day, being 19 September 2007, Mr Millichamp reported on the hearing to an executive of Apotex Canada. He observed that, even if Apotex Australia was enjoined, he expected to win at trial but added, "[w]e are of course hoping that we get some great news on Friday that we are free to sell".

372 The course of the litigation from the time of the grant of the injunction is set out above.³⁵⁴ In the immediate period prior to the handing down of judgment in the revocation proceedings (ie, 12 August 2008), emails passing between

354 See above at [343]-[345].

Mr Millichamp, Mr Kay, Mr Smith and another executive of Apotex Canada reveal they were hesitant at that time to list and launch the clopidogrel products at risk if Apotex Australia was successful in having the patent revoked.³⁵⁵ Further, after Apotex Australia succeeded on appeal to the Full Court, it applied for a PBS listing of its clopidogrel products on 10 November 2009, but withdrew that application on 21 December 2009 as the special leave application filed by Sanofi in this Court was unlikely to be heard before the last day that it could withdraw its application. On 15 February 2010, Apotex Australia relodged its PBS listing application, but requested the approval be made conditional on the outcome of Sanofi's application for special leave to appeal.

373 After Sanofi's application for special leave to appeal was refused on 12 March 2010, Apotex Australia notified the Department of Health that its PBS listing application was now unconditional. It secured a listing of its clopidogrel products on the PBS on 1 May 2010, triggering the 12.5% price reduction.

The primary judge's reasoning

374 The primary judge set out the effect of some of this material concerning the events up to the granting of the injunction by Gyles J. His Honour construed the email from Mr Millichamp of 27 June 2007 that stated "we will plan to launch subject to Barry's further advice / approval" as suggesting that "Dr Sherman had not finally committed to a launch at risk in Australia and that it would be necessary for Mr Millichamp to obtain final approval to launch at risk in the event that no interlocutory injunction was granted".³⁵⁶ His Honour did not accept Mr Millichamp's oral evidence to the effect that the comment in his email of 27 June 2007 did not reflect any requirement to obtain further approval from Dr Sherman.³⁵⁷

375 Having construed the email as evidence demonstrating that any intention on the part of Dr Sherman to list and launch was provisional, the primary judge discounted the events that occurred during the course of the revocation proceedings as demonstrating any firmer intention on Dr Sherman's or Apotex Australia's part. In particular, the primary judge identified "two related developments" in September 2007 as affecting whether Dr Sherman would have decided that it was preferable not to launch at risk even if Gyles J refused the

355 See reasons of Jagot J at [307].

356 *Sanofi (No 5)* (2020) 151 IPR 237 at 290 [251].

357 *Sanofi (No 5)* (2020) 151 IPR 237 at 289-290 [249]-[251].

interlocutory injunction.³⁵⁸ The first development was the notification on 4 September 2007 that Apotex Australia could not achieve a PBS listing until 1 April 2008.³⁵⁹ The second development occurred on 21 September 2007 when Gyles J published his reasons for granting the interlocutory injunction and confirmed that a final hearing in the revocation proceedings would commence on 28 April 2008.³⁶⁰

376 Ultimately, the primary judge concluded that "[i]n the absence of evidence from Dr Sherman, I am not persuaded that he would have authorised a launch at risk in circumstances where an interlocutory injunction had been refused, but a final hearing was fixed to commence on 28 April 2008".³⁶¹

377 The primary judge also made reference to the circumstance that in 2008 and 2009 Apotex Australia did not seek to list and launch at risk,³⁶² as bearing on whether it would have done so in September 2007 had the application for an injunction been refused by Gyles J. His Honour noted that Apotex Australia had prepared revised financial risk and reward analyses in July 2008 and September 2009 that showed a much-reduced potential upside and substantially increased financial downside from a launch at risk.³⁶³ In particular, the revised estimate of Apotex Australia's financial exposure to Sanofi if it launched at risk and the patent was held valid was around \$166 million in July 2008³⁶⁴ and \$650 million in September 2009.³⁶⁵

378 However, in the end result, the primary judge drew little support from the events of 2008 and 2009 for the overall conclusion that the Commonwealth failed to discharge its onus of proof. His Honour merely concluded that the financial analyses and "Apotex Canada's ultimate response to them tend[ed] to contradict the assertion made in Mr Millichamp's oral evidence that Apotex [Australia] trie[d]

358 *Sanofi (No 5)* (2020) 151 IPR 237 at 295 [278].

359 *Sanofi (No 5)* (2020) 151 IPR 237 at 295 [279].

360 *Sanofi (No 5)* (2020) 151 IPR 237 at 296 [281].

361 *Sanofi (No 5)* (2020) 151 IPR 237 at 297 [286].

362 *Sanofi (No 5)* (2020) 151 IPR 237 at 304 [325].

363 *Sanofi (No 5)* (2020) 151 IPR 237 at 299 [294]-[296], 301 [310].

364 *Sanofi (No 5)* (2020) 151 IPR 237 at 299 [296].

365 *Sanofi (No 5)* (2020) 151 IPR 237 at 301 [311].

to get on the market as soon as possible".³⁶⁶ In any event, I agree with Jagot J's analysis of the lack of utility of the events of 2008 and 2009 to an assessment as to what Apotex Australia would have done had the injunction been refused.³⁶⁷

The statements made to Gyles J in 2007

379 It is necessary to address the evidential effect of the statements made on behalf of Apotex Australia to Gyles J in 2007. Both the primary judge and the Full Court failed to address their significance.

380 Before the primary judge the Commonwealth relied on Mr Catterns' exchange with Gyles J in which he unequivocally stated that, if not restrained by an injunction, Apotex Australia intended to list and launch its clopidogrel products at risk from 1 April 2008.³⁶⁸ That statement was supported by Mr Millichamp's affidavit sworn on 17 September 2007.

381 Both the primary judge and the Full Court dealt with that reliance in part by pointing out that, while Mr Millichamp wished to launch at risk if the injunction application by Sanofi was refused, the real question was whether Dr Sherman would have decided to launch at risk after that refusal.³⁶⁹ On that basis, the Full Court rejected the Commonwealth's submission that the primary judge's reasoning was flawed because it was never put to Mr Millichamp that the assertion in his affidavit sworn on 17 September 2007 that Apotex Australia would launch at risk if the injunction was refused was false.³⁷⁰

382 The reasoning of the primary judge and the Full Court concerning the statements made during the injunction hearing before Gyles J rests in part on the edifice created from Mr Millichamp's email of 27 June 2007 to the effect that Dr Sherman's further approval was required to list and launch. Even so, the reasoning of the primary judge and the Full Court did not address how, in the face of the unequivocal statements that were made to Gyles J and the offer to provide

366 *Sanofi (No 5)* (2020) 151 IPR 237 at 303 [322].

367 See reasons of Jagot J at [316]-[325].

368 *Sanofi (No 5)* (2020) 151 IPR 237 at 256 [84]-[85].

369 *Sanofi (No 5)* (2020) 151 IPR 237 at 290 [251]; *Sanofi FFC* (2023) 411 ALR 315 at 380-381 [301].

370 *Sanofi FFC* (2023) 411 ALR 315 at 379-381 [296]-[302].

security, Dr Sherman could have decided not to launch (or not approve a launch) if an injunction was not granted.

383 The hypothetical context in which Dr Sherman would have had to make any decision about whether or not to launch at risk if the application for an interlocutory injunction had been refused was one in which Apotex Australia, via its managing director and senior counsel, would have already told Gyles J in emphatic terms that it would list and launch at risk. If the injunction was refused, and then for some reason Dr Sherman decided not to launch, what would have been the fate of Apotex Australia's undertaking to the Federal Court to provide security of \$50 million for Sanofi's damages claim (and costs)? Apotex Australia could not have assumed that it would be relieved of that undertaking simply because Sanofi would no longer incur losses from Apotex Australia having launched its clopidogrel products on the market. Instead, Apotex Australia would have had to apply to the Court to be relieved from its undertaking. Absent a compelling change of circumstances justifying a change of intention, on that application, Apotex Australia would have had to embark on the potentially excruciating and perilous task of explaining why its earlier statements about its intentions were "overstated" (if not outright false).

384 The Full Court were dismissive of the Commonwealth's reliance on Apotex Australia's proffering of the undertaking to provide security of \$50 million. Their Honours noted that there was no evidence about the level of financial commitment required of Apotex Australia to provide the security and observed that it was "entirely possible as a matter of logic for Apotex [Australia] to have been willing to proffer the undertaking to provide the security and, as yet, not to have made a final decision as to whether it was going to launch".³⁷¹

385 If the Full Court's reference to a "matter of logic" means consideration in isolation, then that may be correct, although whatever the cost of the security to Apotex Australia, it was, as the Full Court conceded, "not a small step".³⁷² However, Apotex Australia's offer of security is not to be considered in isolation. If Apotex Australia had abandoned its stated intention to launch at risk, but proffered the security, the company and its managing director would still have been exposed to an allegation that they had mislead Gyles J about the company's intentions. No doubt Gyles J conducted directions hearings in the lead up to the final hearing of the revocation proceedings in April 2008. It is inevitable that his

371 *Sanofi FFC* (2023) 411 ALR 315 at 364 [205].

372 *Sanofi FFC* (2023) 411 ALR 315 at 364 [204].

Honour would have been informed if Apotex Australia had not sought PBS listing or launched at risk as it said it would.

386 Further, any attempt by Dr Sherman to cause Apotex Australia to abandon the stated intention to launch at risk in the event that the injunction was refused without some compelling change of circumstances justifying that course would have most likely required Mr Catterns and the rest of Apotex Australia's legal representatives to cease acting on Apotex Australia's behalf. On that scenario, it might have appeared that they had been party to misleading statements made to Gyles J as to their client's intentions. Any attempt by Apotex Australia to recant could have invited scrutiny as to the instructions that had previously been given to its legal representatives and the advice the legal representatives had provided.

387 If an injunction had been refused, then Apotex Australia and its managing director, Mr Millichamp, would have already committed to listing its clopidogrel products on the PBS and launching at risk. If, absent some change in circumstances justifying an abandoning of that intention, Dr Sherman had decided to cause Apotex Australia not to list and launch at risk, he would have placed his Australian operations team including Mr Millichamp in significant peril and severely disrupted the application to revoke Sanofi's patent.

388 Otherwise, when considered in light of the emphatic statements made to Gyles J on behalf of Apotex Australia about its intention to list and launch, neither of the two points identified by the primary judge as leading to Dr Sherman concluding that it was preferable not to launch if an injunction was refused have any force. As noted, by no later than 14 September 2007, Dr Sherman had been advised of the revised date of the proposed PBS listing.³⁷³ The entire premise of the hearing before Gyles J was that the revised proposed list and launch date was 1 April 2008. Further, the early hearing date that his Honour announced when granting the injunction had already been foreshadowed in Mr Millichamp's email of 13 September 2007 to Mr Kay. Any suggestion that Mr Kay would not have passed that information onto Dr Sherman is risible.

389 For the sake of completeness, it should be noted that there is no evidence that Mr Millichamp's evidence did not represent his understanding of Apotex Australia's intentions or that Mr Catterns' statements to Gyles J did not genuinely represent his instructions.

373 *Sanofi (No 5)* (2020) 151 IPR 237 at 295 [279]-[280].

The email of 26 June 2007 and *Jones v Dunkel*

390 In addressing the effect of the documents concerning Apotex Australia's intentions up to the time the injunction was sought by Sanofi, the primary judge did not accept that the email of 20 February 2007 was an instruction that provided Mr Millichamp with sufficient authority to launch at risk in late 2007 without reverting to Dr Sherman, or that the email was "persuasive evidence" of what Dr Sherman's thought process would have been "eight or nine months later" if the injunction was refused.³⁷⁴ This latter finding built on the primary judge's interpretation of the email of 26 June 2007 noted above.³⁷⁵

391 From that premise, the primary judge concluded that Dr Sherman was a witness whom it was expected that the Commonwealth would have called and that justified drawing an inference of the kind referred to in *Jones v Dunkel*,³⁷⁶ namely "that the Commonwealth chose not to call [Dr Sherman] because it considered that his evidence would not have assisted its case".³⁷⁷ The primary judge then reasoned as follows:³⁷⁸

"I am not prepared to infer, based on the 20 February 2007 email, or any of the subsequent correspondence in evidence which was said to justify the drawing of such an inference, that Dr Sherman was likely to have instructed Mr Millichamp to procure the listing of Apotex [Australia's] clopidogrel products with effect from 1 April 2008.

In my opinion, the Commonwealth's case suffers from an evidentiary deficiency which cannot be made good by drawing inferences from correspondence written by Dr Sherman in the lead up to the hearing of the interlocutory application. In particular, I do not think it can be inferred that if Dr Sherman had known that the trial of the patent proceeding would commence in the same month that Apotex Australia obtained a PBS listing of its clopidogrel products (triggering a 12.5% statutory price reduction), that he would have, in those circumstances, authorised Apotex Australia to obtain such a listing before judgment was delivered or, at least, until the

374 *Sanofi (No 5)* (2020) 151 IPR 237 at 307 [340]-[341].

375 See above at [374].

376 (1959) 101 CLR 298.

377 *Sanofi No 5* (2020) 151 IPR 237 at 308 [345]-[347].

378 *Sanofi No 5* (2020) 151 IPR 237 at 308-309 [348]-[349].

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)."

392 The difficulty with the second paragraph of the above extract has already been identified, namely that, prior to the hearing of the application for an interlocutory injunction, Dr Sherman was apprised of both the likely date of the final hearing of the revocation proceedings and the revised likely PBS listing date, yet Apotex Australia proceeded to fight the injunction and tell Gyles J of its intention to list and launch at risk regardless. There was no "evidentiary deficiency" as described. Both the primary judge and the Full Court erred in concluding otherwise.³⁷⁹

393 Further, these paragraphs purport to apply *Jones v Dunkel* in the manner explained by Glass JA in *Payne v Parker*,³⁸⁰ namely that the failure by a party who bears the legal onus of proof to call a witness whom it is expected they would have called may result in the inferences for which they contend being treated with greater reserve.³⁸¹ The Commonwealth carried the legal onus of proof and, as noted, the primary judge found that it was expected that it would have called Dr Sherman.³⁸²

394 However, the approach of the primary judge as seen in the above passage, and that of the Full Court, misstated the Commonwealth's case. The Commonwealth did not seek to prove that, had the injunction been refused, Dr Sherman was likely to have given *fresh instructions* to Mr Millichamp to procure the listing of Apotex Australia's clopidogrel products with effect from 1 April 2008. Instead, the Commonwealth's case was that, prior to the hearing before Gyles J, Apotex Australia was unequivocally committed to listing and launching at risk and, to the extent that depended on a decision by Dr Sherman, he *had already* made it. To the extent that the Commonwealth's case involved the drawing of an inference about what Dr Sherman would have decided if the application for an interlocutory injunction had been refused, it was only that there was no proper basis for concluding that he would have caused Apotex Australia to

379 *Sanofi FFC* (2023) 411 ALR 315 at 392 [355].

380 (1976) 1 NSWLR 191.

381 *Payne v Parker* (1976) 1 NSWLR 191 at 200-201.

382 *Sanofi (No 5)* (2020) 151 IPR 237 at 308 [345]-[347].

recant what it told Gyles J. The constraints on him doing so have already been addressed.³⁸³

395 As noted, the Commonwealth's case deployed direct evidence of Apotex Australia's intentions immediately prior to the grant of the interlocutory injunction, being the statement made to Gyles J by Mr Catterns and Mr Millichamp's affidavit. In submissions before the primary judge, the only specific inference that the Commonwealth submitted should be drawn was that, in the emails sent by Dr Sherman at 4.44 am and at 5.12 am on 27 June 2007, he reiterated the instructions he gave on 20 February 2007 to launch at risk unless restrained. The absence of Dr Sherman from the witness box could not justify refusing to draw that inference because the undisputed claim for privilege over the redacted portion of Dr Sherman's emails meant that no witness could be asked to give direct evidence of their contents; ie, there was no (admissible) evidence about those emails that Dr Sherman could elucidate.³⁸⁴

396 The Commonwealth's submission about the contents of Dr Sherman's emails sent on 27 June 2007 was never expressly addressed by the primary judge. The Full Court rejected the Commonwealth's complaint about that failure by reasoning that the submission was just a recitation of the Commonwealth's case that Dr Sherman had instructed Apotex Australia to launch at risk and that the primary judge had addressed that submission below.³⁸⁵ However, that reasoning mischaracterises the Commonwealth's submission which, as noted, concerned the drawing of a particular inference about the contents of certain emails. Thus, in the end result, an important submission made by the Commonwealth was not addressed at first instance or on appeal.

397 In fact, the Commonwealth's submission had great force. In particular, the Commonwealth contended that an inference about the contents of Dr Sherman's emails sent on 27 June 2007 should be drawn from three of the emails sent in the immediate period afterwards, which have been described above,³⁸⁶ namely: the email from Mr Millichamp to Mr Haas at 1.59 pm on 27 June 2007 that said "we will plan to launch subject to Barry's further advice / approval"; the email from Mr Millichamp to executives of Apotex Australia at 11.23 am on 27 June 2007 that passed on Dr Sherman's redacted email, and which said "[g]ame on"; and the

383 See above at [379]-[387].

384 cf *Payne v Parker* (1976) 1 NSWLR 191 at 202.

385 *Sanofi FFC* (2023) 411 ALR 315 at 383 [316].

386 See above at [359]-[360].

email sent by Mr Millichamp to Mr Haas and copied to others at 10.28 pm on 28 June 2007 which said "as per instructions from Barry" and provided a list of objectives detailing the "plan" for Apotex Australia's clopidogrel products, with the third point stating "[i]f we are successful in defending our position vs Sanofi and an injunction is not granted by the courts then we will launch".

398 The second email in which Mr Millichamp said "[g]ame on" was noted by the primary judge, but its contents were not engaged with.³⁸⁷ The Full Court addressed that email by identifying two possibilities as to what was meant by the "game". The first possibility identified by the Full Court was to launch at risk. The second possibility identified by the Full Court was "to signal to the market that Apotex [Australia] was going to launch in order to goad Sanofi into seeking an interlocutory injunction and proffering an undertaking as to damages". The Full Court added that "[w]hich of these was the 'game' to which Mr Millichamp was referring rather turns on the contents of Dr Sherman's two emails which are unknown".³⁸⁸

399 There are three difficulties with the Full Court's analysis of the reference to "game" in Mr Millichamp's email. First, the word "game" was coined by Mr Millichamp and his email was not redacted. It was never suggested to Mr Millichamp that his intention was to "goad" Sanofi into proffering an undertaking as to damages without genuinely intending to resist the injunction and launch at risk if an injunction was not granted.³⁸⁹ Second, if the "game" was to "goad" Sanofi into proffering an undertaking as to damages, then that object was achieved by no later than 17 September 2007 when such an undertaking was proffered by Sanofi (although no doubt from the outset, all the parties envisaged it would be required as the price of Sanofi obtaining an injunction). Despite that offer, Apotex Australia continued to vigorously resist Sanofi's application for an injunction. Third, the possibility that Sanofi was being goaded disregards the unequivocal statements made by Apotex Australia to Gyles J as to its intentions. Goading a commercial rival in correspondence is one thing. Deliberately misleading a court is a very different thing. Once that possibility of goading is removed, as it must be, the Full Court's reasoning bolsters the drawing of the particular inference sought by the Commonwealth at trial.

400 Despite being set out verbatim in the Commonwealth's written submissions, the third email it relied on, being the email from Mr Millichamp in which he

387 *Sanofi (No 5)* (2020) 151 IPR 237 at 289 [245].

388 *Sanofi FFC* (2023) 411 ALR 315 at 345 [129].

389 See reasons of Jagot J at [305].

referred to "as per instructions from Barry", was not referred to at all by the primary judge. The Full Court found it was not necessary for the primary judge to do so "once the full scope of the trial judge's reasoning [was] grasped".³⁹⁰ This was a reference to the primary judge's reasoning that, while Mr Millichamp was enthusiastic to launch, that was no answer to the "proposition that Dr Sherman's final approval before a launch would be necessary".³⁹¹ However, that reasoning failed to address the point being made by the Commonwealth in its submission, namely that, when considered in context, the opening words to Mr Millichamp's email suggested that he was passing on an instruction from Dr Sherman that was contained in the redacted emails sent on 27 June 2007.

401 Instead, as noted, from the first of the emails that the Commonwealth relied, the primary judge extracted the suggestion that any approval given by Dr Sherman was provisional and had to be confirmed. That conclusion failed to address the context in which the email was sent. As the Commonwealth's submission suggested, that context strongly supported the contention that Dr Sherman had reiterated the intention to launch ("[g]ame on") and had not qualified the intention to launch.

402 Lastly, the inference sought to be drawn by the Commonwealth about those emails was not undermined by Mr Millichamp's oral evidence before the primary judge when he was asked about the source of his instructions for the "plan" referred to in his email to Mr Haas on 28 June 2007 ("as per instructions from Barry the plan"). In response to this question, Mr Millichamp said that "[u]nless there were any interim instructions, which I can't remember, I would be referring to the original ones [from 20 Feb 2007], yes". As explained by Jagot J,³⁹² much was made of this by the primary judge³⁹³ and the Full Court.³⁹⁴ However, this evidence could not detract from the Commonwealth's case, and that is not just because Mr Millichamp was giving evidence in 2017 about events that took place in 2007.³⁹⁵ The redactions for privilege meant Mr Millichamp could not be shown the very emails the Commonwealth contended contained the instructions given by Dr Sherman. As already noted, neither Mr Millichamp nor anyone else, including

390 *Sanofi FFC* (2023) 411 ALR 315 at 383 [314].

391 *Sanofi FFC* (2023) 411 ALR 315 at 349 [141].

392 See reasons of Jagot J at [282]-[284].

393 *Sanofi (No 5)* (2020) 151 IPR 237 at 289 [248], 295 [277], 308 [348].

394 *Sanofi FFC* (2023) 411 ALR 315 at 388 [340].

395 See reasons of Jagot J at [285].

Dr Sherman, could give direct evidence of their contents (unless privilege was waived by Apotex Australia).

403 Thus, in addressing the period up to the hearing of the injunction, the primary judge failed to properly address the Commonwealth's case and overlooked cogent evidence concerning Apotex Australia's intention to list and launch at risk if not restrained. The Full Court similarly erred in dismissing the Commonwealth's complaints about his Honour's fact finding concerning this period.

404 Compounding this failure was the approach adopted by both the primary judge³⁹⁶ and the Full Court³⁹⁷ to the circular of 17 August 2007. When the reference to "the decision whether to launch ... will be delayed until the outcome" of the injunction application is known is read with the balance of the document, especially the early statement of, "[w]e intend to launch", then the circular is not evidence of a lack of a firm intention to launch at risk. It simply reflects the commercial reality that the outcome of the injunction application and what occurred during the application would, or at least could, affect Apotex Australia's launch of its clopidogrel products.

405 In the end result, the inference sought by the Commonwealth about the instructions given by Dr Sherman in his emails of 27 June 2007 should be drawn. The formation of that intention at that time did not exclude Dr Sherman revisiting the issue or later confirming it. However, by late June 2007 and throughout July and August 2007, it was "[g]ame on" as far as Apotex Australia was concerned.

406 Further, even if the particular inference the Commonwealth contended about the contents of Dr Sherman's emails of 27 June 2007 was not drawn, and even if Mr Millichamp's email of 27 June 2007 was capable of raising some doubt at that time about the firmness of Apotex Australia's intention to seek listing and launch if an injunction was refused, then that did not obviate the necessity to consider what was demonstrated by the totality of the Commonwealth's evidence concerning Apotex Australia's intentions up until the grant of the interlocutory injunction by Gyles J. That evidence demonstrated that throughout 2007 Apotex Australia formed an intention to list its clopidogrel products on the PBS and launch those products at risk unless restrained by an injunction. It culminated in Apotex Australia unequivocally communicating that intention to Gyles J. Until that occurred, it was undoubtedly open to Dr Sherman to change course. However, for

396 *Sanofi (No 5)* (2020) 151 IPR 237 at 297 [288].

397 *Sanofi FFC* (2023) 411 ALR 315 at 342 [118].

the reasons set out above, his scope to do so after the statements were made to Gyles J was very much narrowed, if not removed entirely.

No inference adverse to the Commonwealth can be drawn

407 As noted, relying on *Jones v Dunkel* and *Payne v Parker*, the primary judge declined to draw an inference that the Commonwealth did not seek, namely that, had no injunction been granted, Dr Sherman was likely to have instructed Mr Millichamp to procure the listing of Apotex Australia's clopidogrel products with effect from 1 April 2008.³⁹⁸ The Full Court adopted the same approach in rejecting the Commonwealth's criticism of the primary judge's reliance on *Jones v Dunkel*. The Full Court observed that "Dr Sherman's evidence would have undoubtedly elucidated the central issue in this case: what would Dr Sherman have done if the injunction had been refused?".³⁹⁹

408 However, that was not the central issue. The central issue was whether Apotex Australia would have listed and launched its clopidogrel products at risk if the injunction had been refused? It is true that Dr Sherman was its directing mind, but Apotex Australia had already committed itself to listing and launching at risk by telling Gyles J that it would do so. Even though the statements made concerned Apotex Australia's future intentions, the fact they were made to a court meant that they could not be withdrawn without good reason. Like the company minutes considered in *Australia Securities and Investments Commission v Hellicar* ("*Hellicar*"), the evidence of the statements made to Gyles J were an "exact proof",⁴⁰⁰ and, save for the specific inference sought about the contents of the email from Dr Sherman of 27 June 2007, so much of the Commonwealth's case that contended that Apotex Australia had the requisite intention just prior to the grant of the injunction did not depend on inferences, "let alone on 'uncertain inferences'".⁴⁰¹ There was no scope for any application of *Jones v Dunkel* or any analogous principle to detract from the evidentiary force of the evidence of the statements made to Gyles J.

409 As for the counterfactual period after the injunction was hypothetically refused, even if the preconditions to the drawing of a *Jones v Dunkel* inference by

³⁹⁸ *Sanofi (No 5)* (2020) 151 IPR 237 at 308 [348].

³⁹⁹ *Sanofi FFC* (2023) 411 ALR 315 at 394 [364].

⁴⁰⁰ (2012) 247 CLR 345 at 445 [257].

⁴⁰¹ *Australian Securities and Investments Commission v Hellicar* ("*Hellicar*") (2012) 247 CLR 345 at 413 [169].

reason of the Commonwealth's failure to call Dr Sherman were otherwise established, the only inference that could have been drawn was that his evidence would not have assisted the Commonwealth.⁴⁰² In light of what Gyles J was told about Apotex Australia's intentions, the passage of time between 2007 and the hearing before the primary judge and the counterfactual nature of the evidence sought to be elicited, such an inference would take the matter nowhere. It would be no different to Dr Sherman giving evidence to the effect that, without the benefit of hindsight, he could not remember or reconstruct what he would have done.⁴⁰³

410 In any event, the absence of Dr Sherman could not found an inference that was *adverse* to the Commonwealth's case.⁴⁰⁴ In particular, his absence could not be used to support a finding that he would have instructed Apotex Australia to recant what it told Gyles J and abandon its stated intention to launch. Like the absent witness, Mr Robb, considered in *Hellicar*, there is no basis for concluding that it was likely that, if called, Dr Sherman might have either disowned Mr Millichamp's and Mr Catterns' statements to Gyles J or provided some plausible basis upon which Apotex Australia could have abandoned its stated intention to launch at risk without attracting any sanction for doing so.⁴⁰⁵ Without evidence of that kind, the Commonwealth was entitled to succeed on this part of its case.

Conclusion

411 Neither the primary judge nor the Full Court properly addressed the Commonwealth's case. To the extent that "concurrent" factual findings were made that were materially adverse to the Commonwealth's case, the standard of review for each has been emphatically met in that there was both "clear error" as well as a "plain injustice"⁴⁰⁶ to the Commonwealth in that its case was not addressed on its merits. The Commonwealth overwhelmingly demonstrated that, had the injunction been refused, Apotex Australia would have sought and obtained a PBS listing of its clopidogrel products with effect from 1 April 2008 and launched at risk.

402 *Hellicar* (2012) 247 CLR 345 at 432 [232]; *Jones v Dunkel* (1959) 101 CLR 298 at 308.

403 See *Hellicar* (2012) 247 CLR 345 at 440-441 [249].

404 *Hellicar* (2012) 247 CLR 345 at 413 [168], 432 [232].

405 *Hellicar* (2012) 247 CLR 345 at 413 [168].

406 *Louth v Diprose* (1992) 175 CLR 621 at 633-634.

Ground 2 of the Commonwealth's appeal should be upheld. For the reasons given by Jagot J, Sanofi's notice of contention should be rejected.

412 The orders proposed by Jagot J should be made.

