



HIGH COURT OF AUSTRALIA

NOTICE OF FILING

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Details of Filing

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Important Information

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

IN THE HIGH COURT OF AUSTRALIA
SYDNEY REGISTRY

BETWEEN:

Commonwealth of Australia

Appellant

and

Sanofi (formerly Sanofi-Aventis)

First Respondent

Sanofi-Aventis US LLC

Second Respondent

Bristol-Myers Squibb Investco LLC

Third Respondent

JOINT CHRONOLOGY

Part I: This chronology is in a form suitable for publication on the internet.

Part II: List of principal events leading to the litigation.

Note: The parties have jointly prepared a longer chronology, which is in the joint book of further materials. The parties are of the view that the longer chronology will be of greater assistance to the Court than this compressed version since it places the key documents within the broader context of the background to these proceedings. The longer chronology is also in the same form as the chronology which was before the Full Court and which is referred to extensively in its judgment, but it has been updated to include references to the Full Court's judgment and the Appeal Book, as well as some new items (as to which see footnote 1 below).

Item ¹	Date	Event	Reference
Part A – Pre 2007: In 2006 GenRx begins considering a possible launch of clopidogrel in Australia, while its parent company (Apotex Canada) litigates with Sanofi in respect of clopidogrel in the United States and Canada.			
0*	7 June 1990	Australian Patent 597784 (Patent) is granted.	
1	1 November 1999	Sanofi-Aventis Australia Pty Ltd's brand of clopidogrel, PLAVIX , together with Bristol-Myers Squibb Australia Pty Ltd's brand of clopidogrel, ISCOVER , are listed on the Pharmaceutical Benefits Scheme (PBS). The brands are co-marketed.	PJ [2] AB 15 PJ [36] AB 21 FC [2] AB 202
1A	21 November 2001	Apotex Inc (Apotex Canada), through Apotex Corporation (Apotex US), files an Abbreviated New Drug Application (ANDA) with the United States (US) Food and Drug Administration (FDA) seeking approval to sell generic clopidogrel bisulfate in the US.	PJ [206] AB 66
1B	21 March 2002	Sanofi (formerly Sanofi-Aventis), Sanofi-Synthelabo Inc. and Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership (collectively, the Sanofi entities) file a claim in the District Court (US) against Apotex Canada and Apotex US (together, Apotex entities) for infringement of Sanofi's US patent for clopidogrel (US Patent) (US Patent Litigation). The Apotex entities file a counterclaim alleging the patent is invalid and unenforceable.	PJ [207] AB 66-67
1C	10 March 2003	Apotex Canada serves a Notice of Allegation on Canadian Sanofi entities for the purpose of obtaining a Notice of Compliance (NOC) for a generic clopidogrel bisulfate product.	PJ [201] AB 65
1D	28 April 2003	Canadian Sanofi entities seek an order prohibiting the Canadian Minister of Health from issuing a NOC to Apotex Canada until expiry of the Canadian patent for clopidogrel (Canadian Patent).	PJ [201] AB 65-66
2A	21 March 2005	The Federal Court (Canada) grants an order of prohibition preventing issuance of a NOC to Apotex Canada in respect of its clopidogrel bisulfate tablets.	PJ [202] AB 66
3E	20 January 2006	The FDA gives final approval to the Apotex entities' ANDA for generic clopidogrel bisulfate.	PJ [208] AB 67
4	1 March 2006	R Millichamp becomes Managing Director of GenRx Pty Ltd, the Australian subsidiary of the Apotex Group which also includes Apotex Canada, Apotex International Inc and Apotex US. R Millichamp instructs his senior	PJ [198] AB 65 PJ [220] AB 68

¹ The item numbers recorded here are the same as the item numbers that were in the chronology before the Full Court and which the Full Court adopted in its reasons: *Commonwealth of Australia v Sanofi (formerly Sanofi-Aventis)* [2023] FCAFC 97; (2023) 411 ALR 315 at [99], save that:

- (a) only those items relevant to the Appellant's grounds of appeal and the Respondents' notice of contention have been reproduced, and some new items have been added (marked with *); and
- (b) the material to which those items relate was either before the Full Court but not the subject of a discrete item number in the Full Court's chronology or concern matters relating to the procedural history of these proceedings.

Item ¹	Date	Event	Reference
		management team to prepare regular launch forecasts and plans for all key generic product launches, including clopidogrel.	
4A	17 March 2006	The parties reach an agreement to resolve the US Patent Litigation (US Settlement Agreement), which is subject to regulatory approvals.	PJ [209] AB 67
4B	Early May 2006	The parties to the US Settlement Agreement are informed that the US Settlement Agreement will not be approved.	PJ [209] AB 67
7A	26 May 2006	The parties to the US Settlement Agreement reach an amended settlement agreement (Amended US Settlement Agreement), which is also subject to regulatory approvals.	PJ [210]-[211] AB 67 PJ [217] AB 68 PJ [301] AB 89 FC [200] AB 262 FC [272] AB 278
8	19-20 June 2006	M Weingarten (Vice President of Sales, Apotex Canada) sends B Sherman (CEO and Chairman, Apotex Canada) an email providing forecasts for supplying clopidogrel in Australia and asking for his advice on how to proceed. B Sherman replies that, if Apotex Canada wins in the US and Canada, it will launch at risk in Australia on approval, but if it loses in the US and Canada, it will not launch in Australia.	PJ [223]-[224] AB 69
9	27 June 2006	GenRx submits to the Therapeutic Goods Administration (TGA) a dossier containing bioequivalence and bioavailability data for its generic clopidogrel 75mg (as hydrogen sulfate) showing equivalence to PLAVIX and ISCOVER.	PJ [226] AB 69
9A	28 July 2006	The parties to the Amended US Settlement Agreement are informed that the Amended US Settlement Agreement will not be approved.	PJ [210] AB 67
11	8 August 2006	Apotex entities launch generic clopidogrel products in the US having followed the process to declare “regulatory denial” under the Amended US Settlement Agreement and the District Court (US) having refused to grant a temporary order restraining the Apotex entities from launching in the US.	PJ [201]-[213] AB 65-67 PJ [218] AB 68 PJ [301] AB 89 FC [198]-[200] AB 261-262
12	15 August 2006	Sanofi entities file a motion in the District Court (US) seeking an order preliminarily restraining the Apotex entities from infringing the US Patent and recalling all of the generic clopidogrel products that had been manufactured and distributed since the 8 August 2006 launch by the Apotex entities.	PJ [213] AB 67
13	31 August 2006	District Court (US) grants a preliminary injunction restraining the Apotex entities from further distribution of their clopidogrel products but declines to order the recall sought by the Sanofi entities.	PJ [214] AB 67 PJ [232] AB 71
13A	21 September 2006	The Apotex entities seek a stay of the preliminary injunction in the US but this is denied by the Court of Appeals (US).	PJ [214] AB 67
13B	8 December 2006	The Court of Appeals (US) affirms the preliminary injunction in the US.	PJ [214] AB 67

Item ¹	Date	Event	Reference
13C	22 December 2006	Federal Court of Appeal (Canada) dismisses Apotex Canada's appeal of the 21 March 2005 NOC decision.	PJ [202] AB 66
14A	22 January-15 February 2007	Trial in the US Patent Litigation before District Court (US) with judgment reserved.	
Part B – GenRx/Apotex Canada communicate about a possible launch of clopidogrel in Australia.			
14B	15 February 2007	R Millichamp sends a (heavily redacted) email to M Weingarten and P Smith (Chief Financial Officer, GenRx) stating " <i>our current understanding</i> " of launch plans for Australia dependent on the outcome of the Canadian and US litigation.	PJ [228] AB 70
15	20 February 2007	B Sherman sends a (redacted) email to M Weingarten, I Hughes (legal practitioner) and R Millichamp setting out a plan to file suit in Australia to invalidate the Patent, to " <i>advise Sanofi that we will launch unless they move for and obtain an injunction, in which case they will have to give an undertaking for our damages</i> ", and to launch " <i>[i]f they do not give an undertaking for our damages and do not get an injunction</i> ".	PJ [229]-[232] AB 70-71 PJ [248] AB 75 PJ [276]-[277] AB 83 PJ [339]-[341] AB 98-99 PJ [348] AB 100 FC [108]-[110] AB 232 FC [121] AB 236 FC [125] AB 237-238 FC [131]-[133] AB 239-240 FC [142] AB 243-244 FC [212] AB 265 FC [214] AB 265 FC [234] AB 270-271 FC [259] AB 275-276 FC [332]-[333] AB 292-293 FC [352] AB 299 FC [381] AB 307 FC [383] AB 308
16	13 April 2007	A Kay (President, Apotex International) writes to S Lydeamore (Vice President Business Development, Apotex Canada) noting B Sherman's instructions " <i>to attempt to launch at risk and then invalidate</i> " (item 15).	PJ [233] AB 71
17	19 June 2007	District Court (US) declares that the US Patent was not invalid or unenforceable and grants permanent injunction against the Apotex entities restraining them from further infringement of the US Patent.	PJ [215] AB 68 PJ [234] AB 71
18	22 June 2007	R Millichamp sends a (heavily redacted) email to A Kay attaching GenRx's financial scenarios and stating " <i>[o]ur recommendation is that we should launch</i> ". A Kay responds requesting a timetable scenario of events.	PJ [234]-[237] AB 71-72 PJ [324] AB 94 PJ [326] AB 95 FC [226]-[229] AB 268-269 FC [279]-[285] AB 280-281
19	25 June 2007	R Millichamp responds to the request from A Kay (item 18) for a timetable scenario of events.	PJ [237]-[240] AB 72-74 PJ [312]-[313] AB 91 FC [140]-[141] AB 242-243 FC [283] AB 281 FC [334]-[335] AB 293-294
20	25 June 2007	A Kay sends an email to B Sherman asking him to " <i>re-confirm or otherwise</i> " the approach to launching clopidogrel in Australia.	PJ [241]-[242] AB 74 FC [114] AB 233-234

Item ¹	Date	Event	Reference
			FC [127]-[128] AB 238 FC [236] AB 271 FC [382] AB 307
20A to 24	26-27 June 2007	B Sherman, A Kay, R Millichamp and others exchange emails (some of which are partly or wholly redacted) and in one email (item 24) R Millichamp forwards an email from B Sherman (which is redacted) and states “FYI – Game on !!!”. Note: these emails are itemized and sequenced in the joint long form chronology.	PJ [242]-[245] AB 74-75 PJ [247] AB 75 FC [114] AB 233-234 FC [128]-[129] AB 238-239 FC [236]-[237] AB 271 FC [311]-[312] AB 287 FC [382] AB 307
25 to 26, 29, 29AA to 29A, 30 to 31	27-29 June 2007	R Millichamp and S Haas (Corporate Project Manager, New Product Demand Planning, Apotex Canada) exchange emails about plans to launch clopidogrel in Australia. Note: these emails are itemized and sequenced in the joint long form chronology.	PJ [246]-[251] AB 75-77 FC [117] AB 234 FC [124]-[125] AB 236-238 FC [130]-[133] AB 239-240 FC [135] AB 240-241 FC [137]-[138] AB 241-242 FC [141]-[146] AB 243-245 FC [149]-[150] AB 246-247 FC [152]-[156] AB 247-249 FC [167] AB 252 FC [172(a)-(d)] 254 FC [173]-[175] AB 254-255 FC [193] AB 260 FC [239(c)] AB 272 FC [240]-[241] AB 272 FC [313]-[314] AB 287-288 FC [317]-[320] AB 289-290 FC [382]-[383] AB 307-308
31A	5 July 2007	Apotex Canada is granted leave to appeal the 22 December 2006 judgment of the Federal Court of Appeal (Canada) (item 13C) to the Supreme Court of Canada.	PJ [203] AB 66
33	1 August 2007	Reforms to the PBS take effect which include a minimum statutory price reduction of 12.5% on the listing of a second brand of a drug on the PBS, and the introduction of “price disclosure price reductions” which may lead to further reductions of the listing price of brands of a drug on the PBS.	PJ [21] AB 18 PJ [45]-[53] AB 23-26 FC [23] AB 209
34 to 40	8-10 August 2007	B Sherman, S Haas, A Kay, R Millichamp and others exchange emails setting out the plans for GenRx’s clopidogrel products if not enjoined (some of which are partly or wholly redacted). Note: these emails are itemized and sequenced in the joint long form chronology.	PJ [252]-[255] AB 77-78 FC [124]-[125] AB 236-238 FC [134] AB 240 FC [157]-[163] AB 249-250 FC [178]-[188] AB 256-259 FC [239(d)]-[241] AB 272 FC [241] AB 272 FC [321]-[322] AB 290 FC [324]-[329] AB 291-292
Part C – GenRx communicates with the TGA, Sanofi and its customers about a possible launch of clopidogrel and commences patent revocation proceedings against Sanofi.			
41	15 August 2007	GenRx sends a letter to the TGA requesting bioequivalence statement for its clopidogrel products and provides a certificate pursuant to	PJ [257] AB 78

Item ¹	Date	Event	Reference
		s 26B(1) of the <i>Therapeutic Goods Act 1989</i> (Cth) (TG Act).	
42	16 August 2007	GenRx commences proceeding NSD1639/2007 in the Federal Court of Australia (Federal Court) against the present respondents (collectively, Sanofi) to revoke the Patent (Patent Proceeding).	PJ [7] AB 16 PJ [80] AB 32 PJ [258] AB 78 FC [6] AB 203
43	17 August 2007	GenRx receives letters from the TGA confirming approval and registration of its 75 mg clopidogrel products (Apotex Clopidogrel Products) on the Australian Register of Therapeutic Goods (ARTG), effective 21 August 2007.	PJ [259] AB 78
44	17 August 2007	R Millichamp writes to Sanofi-Aventis Australia Pty Ltd (R Allsopp , Director of Legal) to inform it that GenRx has obtained ARTG registration for the Apotex Clopidogrel Products, has applied to the Federal Court for an order revoking the Patent, and that it is preparing to launch the product into the Australian market in the near future.	PJ [259] AB 78 FC [338]-[339] AB 294-295
45	17 August 2007	R Millichamp provides a letter to the sales team at GenRx suggesting that it could be circulated by them to customers (as later done). The letter notes that GenRx has commenced the Patent Proceeding and has signaled its intention to launch clopidogrel in Australia to Sanofi, and that if Sanofi applies for an interim injunction " <i>the decision whether to launch these products will be delayed until the outcome of that application has been determined</i> ".	PJ [260] AB 78-79 PJ [286] AB 86 PJ [288] AB 86 FC [118] AB 234-235 FC [120] AB 235-236 FC [135] AB 240-241 FC [142] AB 243-244 FC [336] AB 294 FC [338]-[339] AB 294-295
47	21 August 2007	The Apotex Clopidogrel Products are registered on the ARTG.	PJ [5] AB 15 PJ [259] AB 78
48	21 August 2007	Email chain between various people at Sanofi-Aventis Australia Pty Ltd including R Allsopp, A Dick (Retail Business Unit Director) and J Moulding (General Manager) regarding GenRx's announcement of a potential launch in Australia of a generic clopidogrel product.	FC [119]-[121] AB 235-236 FC [202] AB 262-263 FC [244] AB 272 FC [330]-[331] AB 292
48A	24 August 2007	Allens Arthur Robinson (Sanofi) writes to Blake Dawson Waldron (GenRx) requesting certain undertakings.	FC [202] AB 262-263 FC [336]-[339] AB 294-295
48B	28 August 2007	Blake Dawson Waldron (GenRx) responds to Allens Arthur Robinson (Sanofi) (item 48A) declining to give the undertakings sought.	FC [202] AB 262-263 FC [336]-[337] AB 294 FC [338]-[339] AB 294-295
49	28 August 2007	R Millichamp forwards to P Smith, B Sherman's email dated 20 February 2007 (item 15).	FC [202] AB 262-263
50, 50B, 50C	29-30 August 2007	R Millichamp, A Kay and P Smith exchange emails in relation to a bank guarantee for \$50M. Note: these emails are itemized and sequenced in the joint long form chronology.	FC [202] AB 262-263 FC [204] AB 263 FC [208]-[209] AB 264
50A	29 August 2007	Sanofi signs notification under s 26C of the TG Act to the TGA (which was submitted to the	PJ [454(e)] AB 124 PJ [598] AB 158

Item ¹	Date	Event	Reference
		TGA on 5 September 2007, and received by the TGA on 7 September 2007).	
Part D – PBS listing application: GenRx takes steps to list clopidogrel on the PBS; the application is expressed to be conditional but, in any event, GenRx misses the deadline for a 1 December 2007 PBS listing and withdraws its application.			
51	1 September 2007	GenRx and Symbion Pharmacy Services submit hard copy applications to list the Apotex Clopidogrel Products on the PBS with effect from 1 December 2007, and seek confirmation that the applications can be deferred or withdrawn without triggering the 12.5% price decrease if notification is provided in writing by 12 October 2007. GenRx provides an assurance of supply.	PJ [261]-[263] AB 79 PJ [365] AB 104 FC [122]-[123] AB 236
52A	3 September 2007	Allens Arthur Robinson (Sanofi) writes to Blake Dawson Waldron (GenRx) in response to the letter dated 28 August 2007 (item 48B) demanding certain undertakings.	FC [338]-[339] AB 294-295
53	3/4 September 2007	The Department of Health and Ageing (Department) first receives GenRx's PBS listing applications. The Department informs GenRx that its applications had been received after the 1 September 2007 deadline and could not be accepted for a 1 December 2007 listing.	PJ [10] AB 16 PJ [261] AB 79 PJ [264] AB 79-80 FC [122] AB 236
54	4 September 2007	R Millichamp writes to A Kay confirming that the earliest possible date for the PBS listing of the Apotex Clopidogrel Products is 1 April 2008.	PJ [279] AB 83 FC [164]-[166] AB 250-252 FC [232(b)] AB 270 FC [245] AB 273 FC [248] AB 273
55	4/5 September 2007	GenRx withdraws its PBS listing applications (item 53) by letter dated 4 September 2007, emailed 5 September 2007.	PJ [10] AB 16 PJ [264] AB 79-80
56	5 September 2007	S Haas responds to R Millichamp's 4 September email (item 54) to A Kay and says, among other things, that the target launch date has changed.	FC [124] AB 236-237 FC [124(i)] AB 237 FC [125] AB 237-238 FC [164]-[167] AB 250-252 FC [172(e)] AB 254 FC [175] AB 255 FC [232(c)] AB 270 FC [241] AB 272 FC [245] AB 273 FC [249] AB 273
57	6 September 2007	Blake Dawson Waldron (GenRx) responds to the Allens Arthur Robinson (Sanofi) letter of 3 September 2007 (item 52A). GenRx agrees to provide Sanofi with an undertaking not to have its clopidogrel products listed on the PBS until the outcome of Sanofi's application for interlocutory relief has been determined, provided that any such application is determined by 11 October 2007.	PJ [265] AB 80
Part E – Response to interlocutory injunction application: GenRx prepares to respond to an application for an interlocutory injunction by Sanofi.			
59	13 September 2007	First directions hearing in the Patent Proceeding.	PJ [266] AB 80 PJ [281] AB 84

Item ¹	Date	Event	Reference
			FC [140] AB 242
59A	13 September 2007	R Millichamp informs A Kay by email of the outcome of the first directions hearing and the possibility of a hearing date in the Patent Proceeding in the next six months.	PJ [267] AB 80 FC [140]-[141] AB 242-243
60, 60A 63, 63A	13-14 September 2007	P Smith and G Fahner (Vice President of Business Operations & Finance, Apotex Canada) exchange emails about a \$50M bank guarantee. P Smith and the National Australia Bank exchange emails about a \$50M bank guarantee. Note: these emails are itemized and sequenced in the joint long form chronology.	PJ [269]-[271] AB 81-82 FC [204] AB 263 FC [286]-[288] AB 281-282
60B, 60C	13-14 September 2007	A Kay and R Millichamp exchange emails about the possibility of another generic company obtaining a PBS listing for clopidogrel on 1 April 2008. Note: these emails are itemized and sequenced in the joint long form chronology.	PJ [267]-[268] AB 80 FC [232(d)] AB 270 FC [250] AB 273 FC [291]-[293] AB 282
61	14 September 2007	B Sherman emails various people (including V Lesch (Global Manager, New Products Demand Planning, Apotex Canada) and S Haas asking various questions about Apotex Canada's US clopidogrel tablets.	PJ [270] AB 81 FC [168] AB 252 FC [232(e)] AB 270 FC [251]-[254] AB 273-275
64A	14 September 2007	Letter from Blake Dawson Waldron (GenRx) to Allens Arthur Robinson (Sanofi) providing undertakings, on behalf of GenRx, in relation to sales or other distribution of the Apotex Clopidogrel Products.	FC [303]-[305] AB 285-286
65-66	15-16 September 2007	S Haas, B Sherman, R Millichamp and others exchange emails about expiry dating for Apotex Canada's US clopidogrel tablets. Note: these emails are itemized and sequenced in the joint long form chronology.	PJ [270] AB 81 PJ [280] AB 83 FC [124] AB 236-237 FC [124(j)] AB 237 FC [125] AB 237-238 FC [168]-[170] AB 252-253 FC [172(f)] AB 254 FC [173] AB 255 FC [175] AB 255 FC [241] AB 272 FC [253] AB 274
Part F – Interlocutory hearing: Sanofi files a cross-claim for patent infringement and makes an application for interlocutory injunctions, and one is granted by Gyles J; the final hearing of the patent revocation proceedings is listed to commence on 28 April 2008.			
67	17 September 2007	Sanofi files and serves: (a) a defence in the Patent Proceeding; (b) a cross-claim against GenRx alleging infringement of the Patent; (c) an interlocutory motion seeking, upon Sanofi giving the usual undertaking as to damages, interlocutory injunctions restraining (i) manufacture and supply of the Apotex Clopidogrel Products, and (ii)	PJ [7] AB 16 PJ [80]-[81] AB 32 PJ [272] AB 82 FC [6] AB 203 FC [18] AB 208

Item ¹	Date	Event	Reference
		GenRx taking steps to obtain PBS listing of the Apotex Clopidogrel Products (Sanofi's application).	
69	18 September 2007	The Federal Court (Gyles J) hears Sanofi's application. Gyles J indicates that he did not see any proper basis on which the Court could prevent Apotex from taking steps to list its clopidogrel products on the PBS in response to which Apotex informs the Court that if an injunction on supply was ordered it would undertake not to apply for PBS listing during the period of that restraint.	PJ [82] AB 32 PJ [84]-[85] AB 32-33 PJ [272] AB 82 FC [7] AB 203-204 FC [19] AB 208-209 FC [21] AB 209 FC [28]-[30] AB 210-211 FC [38] AB 214 FC [176]-[177] AB 255-256 FC [201] AB 262 FC [341] AB 295-296
70	19 September 2007	R Millichamp emails J Desai (Executive Vice President of Research and Development, Apotex Canada) giving information about the interlocutory hearing.	PJ [273] AB 82 FC [204] AB 263
71	19-21 September 2007	Email correspondence between P Smith, G Fahner and others as to security, the timing of Gyles J's anticipated decision on Sanofi's application and timing for putting the security in place (if required) and the taking of orders.	PJ [274] AB 82 FC [204] AB 263 FC [289] AB 282
72	20 September 2007	GenRx becomes known as Apotex Pty Ltd.	PJ [7] AB 16 PJ [198] AB 65 FC [5] AB 203
73	21 September 2007	Gyles J delivers reasons orally as to why an interlocutory injunction should be granted and informs the parties that the proceeding will be fixed for a final hearing before him commencing on 28 April 2008. <i>Note:</i> Gyles J's retirement date was 22 August 2008, such that judgment needed to be delivered by then.	PJ [86] AB 33-34 PJ [275] AB 82 PJ [281] AB 84 PJ [289] AB 86 PJ [565] AB 148 FC [7] AB 203-204 FC [31] AB 211-212 FC [211] AB 265
74	25 September 2007	The Federal Court (Gyles J) makes orders granting an interlocutory injunction upon Sanofi giving the usual undertaking as to damages (First Sanofi Undertaking). Apotex gives an undertaking not to seek PBS listing (First Apotex Undertaking).	PJ [11] AB 16 PJ [12] AB 17 PJ [82] AB 32 PJ [89]-[99] AB 34-37 PJ [275] AB 82 PJ [565] AB 148 FC [3] AB 202 FC [7] AB 203-204 FC [31] AB 211-212
74AA	25 September 2007	Gyles J publishes his revised reasons for judgment (<i>GenRx Pty Ltd v Sanofi-Aventis</i> [2007] FCA 1485; (2007) 73 IPR 502) which he had delivered orally on 21 September 2007.	PJ [89] AB 34 FC [7] AB 203-204 FC [31] AB 211-212
Part 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.			
75	1 December 2007	The date by which an applicant intending to have a first generic brand listed on the PBS from 1 April 2008 was required to submit its application to the Department.	PJ [10] AB 16 PJ [264] AB 79-80 PJ [282] AB 84

Item ¹	Date	Event	Reference
77A	1 April 2008	PBS listing date in the counterfactual world in which Gyles J did not grant the interlocutory injunction on 25 September 2007.	FC [9] AB 204-205 FC [14] AB 207
77B	28-30 April 2008, 1-2 May 2008, 5-7 May 2008, 13-15 May 2008	Hearing of the Patent Proceeding before Gyles J.	PJ [14] AB 17
80-84	28 July-12 August 2008	Email correspondence between R Millichamp, A Kay, P Smith and C Baxter (President, Apotex Holdings Inc, and CEO, Sherfam Inc) as to anticipated judgment delivery and decisions required in response as to whether to appeal (if unsuccessful at trial) or launch (if successful) (some of which are wholly or partly redacted). Note: these emails are itemized and sequenced in the joint long form chronology.	PJ [292]-[297] AB 87-88 PJ [299]-[302] AB 88-89 PJ [304] AB 89-90 PJ [306]-[309] AB 90 PJ [310] AB 90 PJ [313] AB 91 PJ [316]-[317] AB 91-92 PJ [321]-[324] AB 93-94 PJ [326] AB 95 PJ [330] AB 96 PJ [550] AB 145 FC [222] AB 267-268 FC [226]-[229] AB 268-269
Part H – Judgment and appeal: Sanofi succeeds at first instance in the patent revocation proceedings but is unsuccessful on appeal; another generic company, Sandoz, is the first to list its clopidogrel products on the PBS on 1 April 2010.			
85	12 August 2008	Gyles J delivers judgment on Apotex’s claim for revocation of the Patent and Sanofi’s claim for infringement of it in Sanofi’s favour: <i>Apotex Pty Ltd (formerly GenRx Pty Ltd) v Sanofi-Aventis</i> [2008] FCA 1194; (2008) 78 IPR 485.	PJ [14] AB 17 PJ [101] AB 37 PJ [306] AB 90 PJ [327] AB 95-96
86	19 August 2008	The Federal Court (Gyles J) makes orders following the decision on 12 August 2008 (item 85). The orders restrain Apotex from, among other things, supplying certain clopidogrel products. The orders also release Apotex from the First Apotex Undertaking.	PJ [14] AB 17 PJ [105]-[108] AB 38-39 PJ [482]-[490] AB 129-130
87	19 August 2008	Apotex files a Notice of Appeal against certain orders made on 19 August 2008 (Appeal Proceeding).	PJ [14] AB 17 PJ [109] AB 39
87C*	8 September 2008	Sanofi files a cross-appeal from certain orders made on 19 August 2008.	PJ [109] AB 39
88	15 September 2008	The Federal Court (Moore J) makes orders by consent, recording undertakings given by the parties (Second Sanofi Undertaking).	PJ [15] AB 17 [110]-[120] AB 39-42
88A	6 November 2008	Supreme Court of Canada dismisses Apotex Canada’s appeal regarding the 21 March 2005 NOC decision.	PJ [203] AB 66
88B	12 December 2008	The Court of Appeals (US) affirms the 19 June 2007 decision of the District Court (US).	PJ [215] AB 68
88D	22 April 2009	Apotex Canada commences impeachment action against the Canadian Sanofi entities seeking declarations that the Canadian Patent was invalid and that its generic clopidogrel products did not infringe that patent (Impeachment Action).	
88E	8 June 2009	Canadian Sanofi entities commence infringement action against Apotex Canada and Apotex Pharmachem Inc. (the Canadian Apotex entities) seeking a declaration that	PJ [204] AB 66

Item ¹	Date	Event	Reference
		they had infringed the Canadian Patent by manufacturing clopidogrel products in Canada for export to other countries, and injunctive relief and an account of profits or damages (Infringement Action).	
88F	24 July 2009	The Apotex entities file a petition for a writ of certiorari in the Supreme Court of the US.	PJ [216] AB 68
89	29 September 2009	The Full Court determines the Appeal Proceeding in Apotex's favour: <i>Apotex Pty Ltd v Sanofi-Aventis</i> [2009] FCAFC 134; (2009) 82 IPR 416.	PJ [15] AB 17
90	13 October 2009	The Full Court makes orders and stays the operation of a number of those orders upon Sanofi giving another undertaking as to damages (Third Sanofi Undertaking).	PJ [15] AB 17 PJ [121]-[130] AB 42-44
90A	2 November 2009	The Supreme Court of the US issues a Memorandum Decision denying the Apotex entities' petition for a writ of certiorari.	PJ [216] AB 68
91	3 November 2009	Sanofi files an application to the High Court for special leave to appeal the decision of the Full Court in the Appeal Proceeding (S295/2009).	PJ [16] AB 17 FC [10] AB 205-206
97	15 February 2010	Apotex submits an application to list the Apotex Clopidogrel Products on the PBS with effect from 1 May 2010, conditional on the outcome of Sanofi's special leave application in the High Court of Australia.	
98	12 March 2010	The High Court refuses Sanofi's application for special leave (S295/2009).	PJ [16] AB 17 PJ [131] AB 144 PJ [485] AB 129 FC [10] AB 205-206
100	12 March 2010	On R Millichamp's instructions, J Keast (Regional Scientific & Regulatory Affairs Director, Apotex) emails the First Assistant Secretary of the Pharmaceutical Benefits Division of the Department, and confirms Apotex's PBS listing application was " <i>no longer conditional but absolute and we will be launching 1 May 2010.</i> "	
101	1 April 2010	Sandoz becomes the first generic pharmaceutical company to list its clopidogrel product (CLOPIDOGREL SANDOZ) on the PBS triggering 12.5% statutory price reduction pursuant to s 99ACB of the <i>National Health Act 1953</i> (Cth) (NHA), movement of clopidogrel from F1 to F2A formulary and price disclosure with a May to April reporting period under the price disclosure regime.	PJ [16] AB 17
Part I – Apotex's PBS listing and claims: Apotex's clopidogrel products are listed on the PBS on 1 May 2010; Apotex and related entities, and the Commonwealth make claims on Sanofi's undertakings.			
102	1 May 2010	The Apotex Clopidogrel Products are listed on the PBS.	PJ [16] AB 17 PJ [132] AB 44-45
103	4 May 2010	Apotex and two related entities (Apotex Canada and Apotex Research Private Limited) file a notice of motion applying for orders requiring the payment of damages by Sanofi	PJ [17] AB 18 PJ [133] AB 45

Item ¹	Date	Event	Reference
		pursuant to the First, Second and Third Sanofi Undertakings.	
103A	19 October 2010	The District Court (US) awards the Sanofi entities US \$442,209,362 in damages, plus interest and costs.	PJ [217] AB 68 FC [200] AB 262
103B	1 December 2010	The price disclosure price reduction regime provided in the NHA and Regulations is amended to provide for Expanded and Accelerated Price Disclosure including: (1) a third price reduction date is added, 1 December; and (2) a “Guaranteed Adjustment Proportion” (GAP) price reduction is set for 1 April 2012.	
103C	18 October 2011	Court of Appeals (US) upholds the District Court’s finding that Apotex Canada was jointly and severally liable for the Sanofi entities’ damages but reversed the grant of pre-judgment interest.	
103D	6 December 2011	The Federal Court (Canada) holds each of the claims of the Canadian Patent invalid. Accordingly, the Impeachment Action is allowed and the Infringement Action is dismissed.	PJ [204] AB 66
105A	1 October 2012	The price disclosure price reduction calculation provisions in the NHA and Regulations are amended to make the “approved ex-manufacturer price” the base price, rather than the “approved price to pharmacists”, and the GAP price reduction is repealed.	
108	11 April 2013	The Commonwealth commences its claim for compensation from Sanofi by filing an interlocutory application (Commonwealth Compensation Proceeding).	PJ [19] AB 18 PJ [139] AB 46 FC [10] AB 205
108A	24 July 2013	Canadian Federal Court judgment is set aside by the Federal Court of Appeal, which holds the Canadian patent is valid and has been infringed. The matter is returned to the Federal Court to deal with remedies.	PJ [205] AB 66
108B	September 2013	The Apotex entities file special leave to appeal application in the Supreme Court of Canada.	PJ [205] AB 66
108C	30 January 2014	Supreme Court of Canada grants the Canadian Apotex entities special leave to appeal the Canadian Infringement Action and Impeachment Action decisions.	PJ [205] AB 66
108D	13 March-3 June 2014	The price disclosure price reduction regime provided in the NHA and Regulations is amended to provide for Simplified Price Disclosure.	
108E	3 November 2014	Appeal to the Supreme Court of Canada is discontinued by the Canadian Apotex entities, and the appeal is closed on the same date.	PJ [205] AB 66
109	4 November 2014	Sanofi and Apotex enter into a settlement agreement in respect of Apotex’s claim for compensation against Sanofi (Australian Settlement Agreement).	PJ [18] AB 18 PJ [134] AB 45
110	4 November 2014	The Sanofi entities and Apotex entities enter into a settlement agreement in respect of	PJ [205] AB 66

Item ¹	Date	Event	Reference
		Canadian Court proceedings (Canadian Settlement Agreement).	
111	7 November 2014	Apotex discontinues its compensation claim against Sanofi.	PJ [18] AB 18 PJ [134] AB 45
112	24 December 2014	Sanofi files its second application for special leave to appeal from the Full Court's decision in the Appeal Proceeding.	
112A AA*	11 May 2015	The Federal Court (Nicholas J) orders that there be a case stated in respect of the Commonwealth Compensation Proceeding and similar compensation claims against Wyeth and Wyeth Australia (Wyeth Parties) (Stated Case).	
112A	27 June 2015- 1 May 2016	The price disclosure price reduction regime provided in the NHA and Regulations is amended to introduce flow-on price reductions for combination items on the F2 formulary, and provide for originator brand information to be excluded from the price calculations.	
113	13 November 2015	The High Court refuses Sanofi's second application for special leave to appeal from the decision in the Appeal Proceeding: <i>Sanofi-Aventis v Apotex Pty Ltd</i> [2015] HCATrans 300.	
114	7 December 2015	The Full Court (Dowsett, Kenny and Nicholas JJ) determines the Stated Case: <i>Commonwealth of Australia v Sanofi (formerly Sanofi-Aventis)</i> [2015] FCAFC 172; (2015) 237 FCR 483.	
114A* 114B*	4 January 2016	Sanofi and the Wyeth Parties file applications for special leave to appeal from the Full Court's decision in the Stated Case (High Court, S1 of 2016, S2 of 2016, S3 of 2016 and M5 of 2016).	
115 115A*	12 May 2016	The High Court refuses Sanofi's and the Wyeth Parties' applications for special leave to appeal from the Full Court's decision in the Stated Case: <i>Sanofi (formerly Sanofi-Aventis) v Commonwealth of Australia</i> [2016] HCASL 98; <i>Wyeth & Anor (3 Applications) v Commonwealth of Australia</i> [2016] HCASL 99.	
116	19 April 2017	The Federal Court (Nicholas J) declares that clause 6 of the Australian Settlement Agreement was, in part, unenforceable: <i>Commonwealth of Australia v Sanofi (formerly Sanofi-Aventis)</i> [2017] FCA 382.	PJ [135]-[138] AB 45-46
127*	28 April 2020	Primary Judgment. The Federal Court (Nicholas J) dismisses the Commonwealth's interlocutory application in the Commonwealth Compensation Proceeding: <i>Commonwealth of Australia v Sanofi (formerly Sanofi-Aventis) (No 5)</i> [2020] FCA 543; (2020) 151 IPR 237.	Orders at AB 179-181 FC [10] AB 205
136	26 June 2023	Full Court Judgment. The Full Court of the Federal Court (Besanko, Yates and Perram JJ) dismisses the Commonwealth's appeal from the decision of Nicholas J in the Commonwealth Compensation Proceeding: <i>Commonwealth of Australia v Sanofi (formerly</i>	Orders at AB 312-313

Item ¹	Date	Event	Reference
		Sanofi-Aventis) [2023] FCAFC 97; (2023) 411 ALR 315.	

Dated: 22 April 2024



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