

HIGH COURT OF AUSTRALIA

KIEFEL CJ,
GAGELER, EDELMAN, STEWARD AND GLEESON JJ

Matter No S22/2021

H. LUNDBECK A/S & ANOR

APPELLANTS

AND

SANDOZ PTY LTD

RESPONDENT

Matter No S23/2021

CNS PHARMA PTY LTD

APPELLANT

AND

SANDOZ PTY LTD

RESPONDENT

H. Lundbeck A/S v Sandoz Pty Ltd
CNS Pharma Pty Ltd v Sandoz Pty Ltd
[2022] HCA 4
Date of Hearing: 8 October 2021
Date of Judgment: 9 March 2022
S22/2021 & S23/2021

ORDER

In Matter No S22/2021:

- 1. Appeal allowed with costs.*
- 2. Set aside orders 1, 2 and 3 made on 4 August 2020 and orders 1 and 2 made on 30 March 2021 of the Full Court of the Federal Court of Australia and, in their place, order that:*

- (a) *the appeal and cross-appeal from the orders of the primary judge made on 19 February 2019 each be allowed in part;*
- (b) *declare that the second respondent did not have rights to bring proceedings under s 79 of the Patents Act 1990 (Cth);*
- (c) *orders 2 and 3 made by the primary judge on 19 February 2019 be set aside;*
- (d) *declare that the first respondent is entitled to damages and pre-judgment interest calculated thereon;*
- (e) *the matter be remitted to the primary judge for the recalculation of damages and pre-judgment interest payable to the first respondent;*
- (f) *the parties be given liberty to apply to the primary judge for a stay of the remitted proceedings pending the determination of the proceedings relating to the licence granted to the appellant by the Commissioner of Patents on 11 April 2019 under s 223(9) of the Patents Act 1990 (Cth);*
- (g) *the appellant pay the respondents' costs to date in the proceedings before the primary judge, and costs of the appeal and cross-appeal to the Full Court of the Federal Court of Australia; and*
- (h) *the appeal and cross-appeal be otherwise dismissed.*

In Matter No S23/2021:

Appeal dismissed with costs.

On appeal from the Federal Court of Australia

Representation

A J L Bannon SC with L Merrick and C I Cunliffe for the appellants in each matter (instructed by Corrs Chambers Westgarth)

C Dimitriadis SC and A R Lang SC for the respondent in each matter
(instructed by Clayton Utz)

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

CATCHWORDS

H. Lundbeck A/S v Sandoz Pty Ltd CNS Pharma Pty Ltd v Sandoz Pty Ltd

Contract – Construction – Where clause in settlement agreement entered into between appellants and respondent prior to expiry of original term of patent granted respondent non-exclusive licence to exploit patent – Where clause in settlement agreement did not specify end date of non-exclusive licence – Whether non-exclusive licence applied to acts during extended term of patent.

Patents – Infringement – Where term of patent extended under *Patents Act 1990* (Cth) ("Act") – Where patentee and exclusive licensee brought infringement proceedings for acts done during extended term of patent – Whether exclusive licensee had rights to bring infringement proceedings under s 79 of Act for acts done during extended term of patent – Whether respondent engaged in misleading or deceptive conduct by not disclosing to customers possibility that term of patent might be extended – Construction and effect of s 79 of Act – When patentee's cause of action accrued under s 79 of Act for the purposes of s 51A(1)(a) of *Federal Court of Australia Act 1976* (Cth).

Words and phrases – "acts of infringement", "cause of action accrued", "commercial benefit", "exclusive licensee", "extension", "extension of the term of the patent", "grant of an extension", "infringement proceedings", "irrevocable non-exclusive licence", "misleading or deceptive conduct", "patent", "patentee's rights", "pharmaceutical substance", "term of the patent".

Federal Court of Australia Act 1976 (Cth), s 51A(1)(a).
Patents Act 1990 (Cth), s 79.

1 KIEFEL CJ, GAGELER, STEWARD AND GLEESON JJ. These two appeals from decisions of the Full Court of the Federal Court (Nicholas, Yates and Beach JJ)¹, each on appeal from a judgment of a single judge of that Court (Jagot J)², constitute another instalment in long-running serial litigation concerning the extension under the *Patents Act 1990* (Cth) ("the Act") of the term of a standard patent relating to a pharmaceutical substance known as escitalopram ("the Patent").

2 Escitalopram is used as a treatment for depression. Two pharmaceutical products containing escitalopram are included in the Australian Register of Therapeutic Goods ("ARTG"). One is known as "Cipramil", the other as "Lexapro".

3 The appellants in one appeal ("the Lundbeck Appeal") are H Lundbeck A/S ("Lundbeck Denmark") and Lundbeck Australia Pty Ltd ("Lundbeck Australia"). Lundbeck Denmark, a Danish pharmaceutical company, is the owner of the Patent. Lundbeck Australia, its Australian subsidiary, holds an exclusive licence of the Patent from Lundbeck Denmark. The appellant in the other appeal ("the Pharma Appeal"), CNS Pharma Pty Ltd ("Pharma"), is a subsidiary of Lundbeck Australia which sells a generic version of Lexapro in Australia which is also manufactured by and purchased from Lundbeck Denmark.

4 The Patent as granted to Lundbeck Denmark was dated 13 June 1989. Having a standard term of 20 years, it expired on Saturday 13 June 2009. However, on 25 June 2014 Lundbeck Denmark was granted an extension of the term to 9 December 2012.

5 The respondent in both appeals, Sandoz Pty Ltd ("Sandoz"), is a supplier of generic pharmaceutical products. During the extended term, from Monday 15 June 2009 to 9 December 2012, Sandoz sold generic escitalopram products.

6 On 26 June 2014, the day after the grant of the extension of the term, Lundbeck Denmark and Lundbeck Australia commenced proceedings against Sandoz in the Federal Court. Lundbeck Denmark and Lundbeck Australia claimed declaratory relief, damages and pre-judgment interest on the basis that, by selling generic escitalopram products between 15 June 2009 and 9 December 2012,

1 *Sandoz Pty Ltd v H Lundbeck A/S* (2020) 384 ALR 35; *Sandoz Pty Ltd v H Lundbeck A/S [No 2]* [2021] FCAFC 47.

2 *H Lundbeck A/S v Sandoz Pty Ltd* (2018) 137 IPR 408; *H Lundbeck A/S v Sandoz Pty Ltd [No 2]* [2019] FCA 46.

Kiefel CJ
Gageler J
Steward J
Gleeson J

2.

Sandoz infringed the Patent. Pharma also commenced proceedings against Sandoz in the Federal Court. Being neither the patentee nor an exclusive licensee, Pharma could not commence proceedings for patent infringement. Rather, Pharma put its separate claim to declaratory relief, damages and pre-judgment interest on the basis that Sandoz also engaged in misleading or deceptive conduct within the meaning of s 52 of the *Trade Practices Act 1974* (Cth) and s 18 of the *Australian Consumer Law* in Sch 2 to the *Competition and Consumer Act 2010* (Cth), by failing to warn customers and potential customers to whom it sold its generic escitalopram products that their supply of those products might infringe the Patent if and when an extension of the term was granted.

7 The primary judge found against Sandoz in both proceedings. Her Honour accordingly made declarations and awarded damages and pre-judgment interest to Lundbeck Denmark and Lundbeck Australia (for loss found to have been occasioned to each of them by Sandoz's infringement of the Patent) and to Pharma (for loss found to have been occasioned to it by the conduct on the part of Sandoz that her Honour found to be misleading or deceptive).

8 The Full Court allowed Sandoz's appeals, setting aside the declarations and awards of damages and pre-judgment interest made by the primary judge, and in their place ordering the dismissal of both proceedings. The principal ground on which the Full Court allowed the appeals was that the Full Court found³, contrary to a finding of the primary judge⁴, that Sandoz held a non-exclusive licence from Lundbeck Australia from 31 May 2009 to 9 December 2012 through the operation of a clause ("the settlement clause") in a "Settlement Agreement" which Sandoz had entered into with Lundbeck Denmark and Lundbeck Australia in February 2007. The holding of that non-exclusive licence meant that none of Sandoz's sales between 15 June 2009 and 9 December 2012 amounted to acts of infringement.

9 The principal ground of each appeal to this Court is that the Full Court was wrong, and the primary judge was right, in their competing constructions of the settlement clause. If that ground is upheld, as we think it should be, two further grounds arise in the Lundbeck Appeal and a further issue is raised by notice of contention in the Pharma Appeal.

3 *Sandoz Pty Ltd v H Lundbeck A/S* (2020) 384 ALR 35 at 48-51 [55]-[69].

4 *H Lundbeck A/S v Sandoz Pty Ltd* (2018) 137 IPR 408 at 480-485 [275]-[303].

3.

10 The first of the further grounds in the Lundbeck Appeal concerns whether Lundbeck Australia (as distinct from Lundbeck Denmark) had rights to bring proceedings in respect of acts of infringement during the extended term: the primary judge held that it did⁵; the Full Court considered that it did not⁶. The second concerns when a cause of action for damages for infringement during the extended term arose against Sandoz for the purpose of calculating pre-judgment interest: the primary judge held that the cause of action for Lundbeck Denmark arose annually from 15 June 2009 and for Lundbeck Australia arose at the time of each infringing sale⁷; the Full Court considered that no cause of action arose until the later grant of the extension of the term of the Patent⁸. In respect of both grounds, we think that the Full Court was correct.

11 The further issue which arises by notice of contention in the Pharma Appeal is whether Sandoz's failure to warn the pharmacists to whom it sold that supply of its generic escitalopram products might infringe the Patent if and when an extension of the term was granted constituted misleading or deceptive conduct. The primary judge, as already noted, found that it did⁹. The Full Court did not need to address that finding given that, on its construction of the settlement clause, none of Sandoz's sales between 15 June 2009 and 9 December 2012 infringed the Patent¹⁰. Disagreeing with the primary judge, we do not consider that Sandoz's failure to warn amounted to misleading or deceptive conduct.

12 Though the issue raised by the notice of contention in the Pharma Appeal is discrete, resolution of each of the other issues in the appeals, including the construction of the settlement clause, turns substantially on the construction and operation of provisions of the Act governing the extension of the terms of standard patents relating to pharmaceutical substances. Those provisions are best expounded, and the facts relating to the Settlement Agreement recorded, before

5 *H Lundbeck A/S v Sandoz Pty Ltd* (2018) 137 IPR 408 at 453-458 [173]-[195].

6 *Sandoz Pty Ltd v H Lundbeck A/S* (2020) 384 ALR 35 at 56-63 [83]-[110].

7 *H Lundbeck A/S v Sandoz Pty Ltd* (2018) 137 IPR 408 at 523 [467]-[468], 524 [472], 540 [532].

8 *Sandoz Pty Ltd v H Lundbeck A/S* (2020) 384 ALR 35 at 69-73 [135]-[147].

9 *H Lundbeck A/S v Sandoz Pty Ltd* (2018) 137 IPR 408 at 540-544 [534]-[548].

10 *Sandoz Pty Ltd v H Lundbeck A/S* (2020) 384 ALR 35 at 73 [151].

Kiefel CJ
Gageler J
Steward J
Gleeson J

4.

explaining in turn: the proper construction of the settlement clause; why Lundbeck Australia had no right to bring proceedings for infringement during the extended term; why Lundbeck Denmark had no cause of action against Sandoz until the grant of the extension of the term; and why Sandoz's failure to warn did not constitute misleading or deceptive conduct.

The term and extension of the term of a standard patent

13 The Commissioner of Patents grants a standard patent for an invention by registering prescribed particulars of the patent in the Register of Patents¹¹. The patent once granted gives to the patentee exclusive rights, during the term of the patent, both to exploit the invention (including by sale¹²) and to authorise another person to exploit the invention¹³.

14 The term of a standard patent is 20 years from the date of the patent¹⁴. The date of the patent is the date of filing of the complete specification, which must contain a clear disclosure of the invention¹⁵, or such other date as might be provided for in regulations made under the Act¹⁶.

15 The Act makes no provision for the extension of the term of a standard patent other than provision for the extension of the term of a standard patent relating to a pharmaceutical substance that is contained in goods included in the ARTG. Provision in that respect is made in Pt 3 of Ch 6, which was inserted by amendment in 1998 ("the 1998 Act")¹⁷, but which was relevantly modelled in part on provisions inserted into the *Patents Act 1952* (Cth) ("the 1952 Act") in 1989

11 Section 61 of the Act.

12 Section 3 of the Act and Sch 1 (definition of "exploit") to the Act.

13 Section 13 of the Act.

14 Section 67 of the Act.

15 Section 40(2), (3) and (4) of the Act.

16 Section 65 of the Act.

17 *Intellectual Property Laws Amendment Act 1998* (Cth).

5.

("the 1989 Act")¹⁸ which were carried over into the Act as enacted¹⁹ but repealed in 1994²⁰.

16 The second reading speech for the Bill for the 1998 Act described the objective of Pt 3 of Ch 6 as being "to provide an 'effective patent life' more in line with that available to inventions in other fields of technology"²¹. In *Alphapharm Pty Ltd v H Lundbeck A/S*²², Crennan, Bell and Gageler JJ noted:

"The purposes of the extension of term scheme are to balance the competing interests of a patentee of a pharmaceutical substance whose exploitation of monopoly has been delayed (because of regulatory delay) and the public interest in the unrestricted use of the pharmaceutical invention (including by a competitor) after the expiration of the monopoly (that is, the term)."

17 Section 70 allows the patentee of a standard patent relating to a pharmaceutical substance contained in goods included in the ARTG to apply to the Commissioner for a one-off extension of the term of the patent if the period between the date of the patent and the date of commencement of the first inclusion of goods containing the substance in the ARTG is five years or more²³.

18 Section 71 provides that the patentee must apply for the extension during the term of the patent and within six months after the latest of three specified dates, here within six months after the first inclusion of goods containing the substance

18 *Patents Amendment Act 1989* (Cth).

19 See Div 2 of Pt 3 of Ch 6 of the Act as enacted.

20 *Patents (World Trade Organization Amendments) Act 1994* (Cth).

21 Australia, House of Representatives, *Parliamentary Debates* (Hansard), 26 November 1997 at 11275.

22 (2014) 254 CLR 247 at 271 [60].

23 Section 70(1), (2)(a), (3), (4) and (5)(a) of the Act.

Kiefel CJ
Gageler J
Steward J
Gleeson J

6.

in the ARTG²⁴. However, in specified circumstances²⁵, the Commissioner has discretion to extend the time for the patentee to apply for the extension²⁶. The application must be advertised²⁷, must be accepted by the Commissioner if satisfied that the requirements of ss 70 and 71 are met²⁸, and may be opposed by any person on the ground that one or more of the requirements of ss 70 and 71 are not met²⁹.

19 Section 76 provides that the Commissioner must grant an extension of the term if there is no opposition to the grant or if, in spite of opposition, the Commissioner's decision or the decision on any appeal is that the extension should be granted³⁰. The term of the extension so granted is spelt out in s 77 by reference to a formula (equating to how much longer than five years the first inclusion of goods containing the substance in the ARTG was after the date of the patent)³¹ but is capped at five years³².

20 During the term of the extension, the exclusive rights given by the patent are limited by operation of s 78. In particular, the exclusive rights of the patentee are not infringed by a person exploiting the pharmaceutical substance for a purpose other than a therapeutic use³³. The explanatory memorandum for the Bill for the 1998 Act referred to these amendments as "spring-boarding" provisions designed

24 Section 71(2)(b) of the Act.

25 Section 223(2) of the Act.

26 See *Alphapharm Pty Ltd v H Lundbeck A/S* (2014) 254 CLR 247.

27 Section 72 of the Act.

28 Section 74 of the Act.

29 Section 75 of the Act.

30 Section 76(1) of the Act.

31 Section 77(1) of the Act.

32 Section 77(2) of the Act.

33 Section 78(a)(i) of the Act.

7.

to allow suppliers of generic pharmaceutical products to take steps necessary to meet pre-marketing regulatory requirements³⁴.

21 Section 79, the construction and operation of which lies at the heart of the appeals, provides:

"If:

- (a) a patentee applies for an extension of the term of a standard patent; and
- (b) the term of the patent expires before the application is determined; and
- (c) the extension is granted;

the patentee has, after the extension is granted, the same rights to start proceedings in respect of the doing of an act during the period:

- (d) commencing on the expiration of the term of the patent; and
- (e) ending on the day on which the extension was granted;

as if the extension had been granted at the time when the act was done."

22 The reference in s 79 to "rights to start proceedings in respect of the doing of an act" needs to be understood against the background of s 120 of the Act.

23 Section 120 provides that "infringement proceedings" may be started in a prescribed court, or in another court having jurisdiction to hear and determine the matter, by the patentee or an exclusive licensee³⁵. The section goes on to require the patentee to be a party in the proceedings³⁶, to shield the patentee against costs

34 Australia, House of Representatives, *Intellectual Property Laws Amendment Bill 1997*, Explanatory Memorandum at 2.

35 Section 120(1) of the Act.

36 Section 120(2) of the Act.

Kiefel CJ
 Gageler J
 Steward J
 Gleeson J

8.

unless the patentee chooses to participate³⁷, and to prescribe the period within which "[i]nfringement proceedings must be started"³⁸.

24 "Infringement proceedings" are defined in the Act to mean "proceedings for infringement of a patent"³⁹. Yet, as noted by Kiefel CJ, Bell and Keane JJ in *Calidad Pty Ltd v Seiko Epson Corporation*⁴⁰ and by Gummow A-CJ and Kirby J in *Northern Territory v Collins*⁴¹, "infringement" is left undefined, the scheme of the Act being instead to fix attention on the exclusive rights given by the patent. That is because proceedings for infringement of a patent – though regulated, augmented and explicated by Ch 11 of the Act, including through the provision of statutory remedies⁴² – are proceedings in tort for the doing of an act in violation of one or more legal rights in rem⁴³ the contours of which are defined by the exclusive rights given by the patent.

25 Section 120 assumes tortious liability on the part of a person who does an act that infringes an exclusive right to exploit the invention during the term of a patent and addresses itself to proceedings to enforce that liability. The stipulations set out in the section, including as to the court in which infringement proceedings

37 Section 120(3) of the Act.

38 Section 120(4) of the Act.

39 Section 3 of the Act and Sch 1 (definition of "infringement proceedings") to the Act.

40 (2020) 94 ALJR 1044 at 1054 [26]; 384 ALR 577 at 584.

41 (2008) 235 CLR 619 at 624 [20].

42 Sections 122 and 123 of the Act.

43 Ricketson, *The Law of Intellectual Property* (1984) at 992 [50.37]; *Independent Oil Industries Ltd v The Shell Co of Australia Ltd* (1937) 37 SR (NSW) 394 at 414; *General Tire and Rubber Co v Firestone Tyre and Rubber Co Ltd* [1976] RPC 197 at 211-212; *Collins v Northern Territory* (2007) 161 FCR 549 at 559-562 [24]-[28] (a decision overturned on appeal on different grounds in *Northern Territory v Collins* (2008) 235 CLR 619). See also *Clarke v Adie* (1877) 2 App Cas 315 at 333-334.

9.

can be started⁴⁴ and as to the period within which infringement proceedings can be started⁴⁵, are procedural.

26 Section 79, in contrast, assumes absence of tortious liability on the part of a person who has done an act of the same nature during the period between the expiration of the term of a standard patent and the grant of an extension of the term of the patent. On that assumption, the section confers on the patentee rights to start proceedings against the person in respect of the doing of the act by creating the statutory fiction – connoted by the words "as if"⁴⁶ – that the extension had been granted at the time when the act was done.

27 The rights to proceed conferred by s 79 through the operation of that statutory fiction are inherently substantive. That is because, to be equivalent to the rights to proceed that the patentee would have had in tort had the extension been granted when the act was done, the rights to proceed conferred by the section necessarily impose liability on the person by whom the act was done equivalent to the liability the person would have had in tort had the extension been granted when the act was done. The fiction created by the section enables the patentee to enforce the statutory liability created by the section by starting infringement proceedings against the person, to which s 120 then applies.

28 As will be explained, legislative perception of the need to create that statutory fiction must be taken to reflect legislative acceptance that the grant of an extension under s 76 after the expiration of the term of the patent does not itself operate to give rise to liability in tort for an act that occurred between the date of the expiration and the date of the grant.

29 Legislative acceptance of that limitation can be seen as an acknowledgement of the application to the power conferred by s 76 of the standard common law presumption "that a statute changing the law ought not, unless the intention appears with reasonable certainty, to be understood as applying to facts or events that have already occurred in such a way as to confer or impose or otherwise affect rights or liabilities which the law had defined by reference to the

44 cf *R v Ward* (1978) 140 CLR 584 at 588-589; *Kodak (Aust) Pty Ltd v The Commonwealth* (1988) 22 FCR 197 at 201-202.

45 cf *Minister for Home Affairs v DMA18* (2020) 95 ALJR 14 at 23-24 [31]; 385 ALR 16 at 27.

46 cf *Re Macks; Ex parte Saint* (2000) 204 CLR 158 at 203 [115].

Kiefel CJ
Gageler J
Steward J
Gleeson J

10.

past events"⁴⁷. The presumption, in other words, is "that prima facie a statute must not be construed so as to change the legal character, or the legal consequences, of past events and transactions"⁴⁸. The presumption applies to the interpretation of a statute conferring power to affect rights and liabilities in the same way as it applies to the interpretation of a statute operating directly to affect rights and liabilities⁴⁹.

30 Understanding an exercise of the power conferred by s 76 to have an operation consistent with the application to the section of the standard common law presumption does no violence to the word "extension". The word is not defined in the Act and has been acknowledged in the context of patent law to have a meaning which "may well vary with the nature of the subject matter"⁵⁰.

31 Once it is accepted that "extension" in the context of Pt 3 of Ch 6 is not to be read according to its usual connotation to imply "that what is to be extended must be current or existing"⁵¹, there is no reason to regard the grant of the extension to which s 76 refers as necessarily operating to give exclusive rights that are contiguous with those given by the original grant. The construction of the section rather lends itself to being analogised to what has been said to be "trite law"⁵² in respect of the grant of a lease expressed to take effect from a date earlier than the date on which the lease is in fact granted: that "[t]he 'term' ... only designates the time for which it is to run, by way of calculation"⁵³ and that "its operation as a grant [of an interest in property] is merely prospective"⁵⁴. The date of expiration

47 *Chang Jeeng v Nuffield (Australia) Pty Ltd* (1959) 101 CLR 629 at 637-638.

48 *Ku-Ring-Gai Municipal Council v Attorney-General for the State of New South Wales* (1957) 99 CLR 251 at 269.

49 *ADCO Constructions Pty Ltd v Goudappel* (2014) 254 CLR 1 at 21 [51].

50 *Sanofi v Parke Davis Pty Ltd [No 2]* (1983) 152 CLR 1 at 7.

51 *Parke Davis Pty Ltd v Sanofi* (1982) 43 ALR 487 at 503.

52 *Perpetual Trustee Co Ltd v Morley* (1968) 121 CLR 659 at 662-663.

53 *Perpetual Trustee Co Ltd v Morley* (1968) 121 CLR 659 at 663, quoting *Cooper v Robinson* (1842) 10 M & W 694 at 696 [152 ER 651 at 652].

54 *Perpetual Trustee Co Ltd v Morley* (1968) 121 CLR 659 at 662, quoting *Wyburd v Tuck* (1799) 1 B & P 458 at 464 [126 ER 1009 at 1012].

of the term of the original grant can be understood as marking the commencement of the extension the duration of which is calculated in accordance with s 77. The grant of further exclusive rights to exploit the invention is prospective only from the date that the grant is in fact made under s 76.

32 Legislative history supports that understanding of an exercise of the power conferred by s 76 operating to give to the patentee further exclusive rights to exploit the invention only during the period (if any) from the date of the grant of the extension to the date of the expiration of the term of the extension calculated in accordance with s 77.

33 Under s 84(5) of the *Patents Act 1903* (Cth), and under s 94(1) of the 1952 Act until the 1989 Act, power was conferred on a court either to order an extension of the term of any patent or to order the grant of a new patent. The power was exercisable where the court was of the opinion that the patentee had been inadequately remunerated by the patent. An extension of the term of a patent and the grant of a new patent were each understood to be a "graft" onto the original grant so as to have "no existence apart from the parent grant"⁵⁵.

34 Where the order of the court was made before the expiration of the original term, the practice was normally to extend the term. Where the original term had expired, the practice was normally to order a new grant. Irrespective of whether the order was to extend the term of the patent or to grant a new patent, however, an order made after the expiration of the patent would be made subject to a condition that no proceeding could be commenced or prosecuted in respect of acts of infringement which occurred after the date of expiration of the original term and before the date of the order⁵⁶.

55 *In re Robinson's Patent* (1918) 25 CLR 116 at 137 and *Sanofi v Parke Davis Pty Ltd [No 2]* (1983) 152 CLR 1 at 11, each quoting *Bovill v Finch* (1870) LR 5 CP 523 at 532. See also *Ex parte Celotex Corporation*; *In re Shaw's Patents* (1937) 57 CLR 19 at 25.

56 *Ex parte Celotex Corporation*; *In re Shaw's Patents* (1937) 57 CLR 19 at 25. See eg *In re Robinson's Patent* (1918) 25 CLR 116 at 139; *Gillette Industries Ltd v Commissioner of Patents* (1943) 67 CLR 529 at 535; *In re Usines de Melle's Patent* (1954) 91 CLR 42 at 52.

Kiefel CJ
Gageler J
Steward J
Gleeson J

12.

35 In *Sanofi v Parke Davis Pty Ltd [No 2]*⁵⁷, Mason A-CJ, Wilson and Dawson JJ referred to the imposition of a condition in those terms as "appropriate to protect the interests of those members of the public who might otherwise be prejudiced by the extension of the term of the patent"⁵⁸. Brennan J, who concurred in the result, went further. His Honour explained the imposition of a condition in those terms to be necessary to ensure that the order that was made was within the power conferred by s 94(1) of the 1952 Act. Focusing specifically on the power to order the grant of a new patent conferred by s 94(1)(b) of the 1952 Act, Brennan J explained⁵⁹:

"The general terms of a statute are not construed as affecting retrospectively a person's freedom to act in a way which was lawful at the time for it manifestly shocks one's sense of justice that an act legal at the time of doing it should be made unlawful by some new enactment. By parity of reasoning, if a statute confers a power to affect another person's freedom to act, the statute is not construed as conferring a power to impose a liability retrospectively for doing what was lawful at the time unless the terms of the statute clearly require that construction. It follows that, if the grant of a new patent without conditions in extension of a term which has expired would confer rights upon the patentee against a person who had made, used or sold the subject matter of the patent when it was in the public domain, such a grant would exceed the power conferred by s 94(1)(b). There is a strong general presumption that a legislature does not intend to impose a new liability in respect of something that has already happened. There is no indication that the [1952] Act intends a retrospective alteration of the rights of the patentee so as to permit him to treat as an infringer a person who lawfully made, used or sold the subject matter of the patent when it was in the public domain. However, if such an innocent infringer can be protected and is protected by appropriate ... conditions ... contained in the new patent exempting him from liability for acts done while the invention was in the public domain, an order for the grant of such a new patent is within the power conferred by s 94(1)(b). A new patent containing such conditions does not retrospectively destroy the legal immunity of an innocent infringer for acts done prior to the grant of the new patent."

57 (1983) 152 CLR 1.

58 (1983) 152 CLR 1 at 15.

59 (1983) 152 CLR 1 at 20-21 (cleaned up).

36 The explanation given by Brennan J in *Sanofi* of the proper construction of s 94(1) of the 1952 Act involved an application to that provision of the standard common law presumption to which reference has already been made. When the 1989 Act replaced s 94(1) of the 1952 Act with the regime for the administrative grant of an extension of the term of a standard patent relating to a pharmaceutical substance on which Pt 3 of Ch 6 of the Act came to be modelled, the approach taken by Brennan J to the proper construction of a power to extend the term of a patent must be taken to have been heeded.

37 Of the numerous respects in which the regime for the administrative grant of an extension of the term of a standard patent relating to a pharmaceutical substance introduced by the 1989 Act differed from the earlier regime for the curial extension of a patent or grant of a new patent, two are of present significance. The first was abandonment of the former provision for a grant of a new patent in favour of an extension of the term of a patent in every case. The second was abandonment of the former curial discretion as to the period of an extension and as to the conditions of an extension in favour of what the explanatory memorandum for the Bill for the 1989 Act referred to as "more straightforward administrative procedures"⁶⁰.

38 The approach adopted in the 1989 Act, as later carried through into Pt 3 of Ch 6 of the Act as amended by the 1998 Act, was to make automatic and exhaustive legislative prescription as to: the period of the extension; the limitation of the exclusive rights of the patentee during the period of the extension; and the rights of the patentee in respect of acts of infringement which occurred after the date of expiration of the original term and before the grant of the extension.

39 Within that context, the provision of the 1952 Act as amended by the 1989 Act which was the progenitor of s 79 of the Act⁶¹ was explained in the explanatory memorandum for the Bill for the 1989 Act to have had "the effect that, where a patent's term is extended after the original term expired, the patentee's rights will backdate to the date of expiry"⁶². It was the equivalent to s 79 (s 96A) that was explained as having that backdating effect on the patentee's rights, not the equivalent of s 76 (s 90). The same approach was taken in the 1998 Act. The

60 Australia, Senate, *Patents Amendment Bill 1989*, Explanatory Memorandum at 2 [1].

61 Section 96A of the 1952 Act.

62 Australia, Senate, *Patents Amendment Bill 1989*, Explanatory Memorandum at 6 [27].

Kiefel CJ
Gageler J
Steward J
Gleeson J

14.

legislature's approach both in 1989 and in 1998 was consistent with an appreciation of the application of Brennan J's reasoning in *Sanofi*.

40 The position, in short, is that the power conferred by s 76 to extend the term of a standard patent relating to a pharmaceutical substance contained in goods included in the ARTG is a power to grant further exclusive rights to the patentee to exploit the invention from the date of the grant of the extension to the date of the expiration of the period that commences with the date of the expiration of the term of the original grant and that ends on the date determined in accordance with s 77. Where the power conferred by s 76 is exercised *after* the expiration of the term of the original grant, there is a temporal gap in the conferral of exclusive rights on the patentee. The function of s 79 is to fill that gap. In conferring rights to start proceedings in respect of acts that occurred between the expiration of the term of the original grant and the subsequent grant of an extension, s 79 operates to impose a substantive liability for those acts which does not arise merely by force of the exercise of the power conferred by s 76. In respect of acts that occurred between the expiration of the term of the original grant and the subsequent grant of an extension of the term, the rights to start proceedings conferred by s 79 (as qualified by s 78) are substantive and exhaustive.

The Settlement Agreement

41 The background to Sandoz having entered into the Settlement Agreement with Lundbeck Denmark and Lundbeck Australia in February 2007 had as its genesis the inclusion of Cipramil in the ARTG in December 1997. Lexapro was not included in the ARTG until September 2003.

42 In December 2003, Lundbeck Denmark applied for an extension of the term of the Patent based on the inclusion of Lexapro in the ARTG. Based on the inclusion of Lexapro in the ARTG, the Commissioner in 2004 granted an extension of the term of the Patent to end on 13 June 2014. However, the Commissioner in 2006 corrected the grant of the extension so as to result in it ending on 9 December 2012. The correction was based on the earlier inclusion of Cipramil in the ARTG.

43 Four separate proceedings were then commenced in the Federal Court. Lundbeck Denmark appealed the decision of the Commissioner to correct the extension of the term of the Patent from 13 June 2014 to 9 December 2012. Sandoz and two other suppliers of generic pharmaceutical products each commenced separate proceedings against Lundbeck Denmark challenging the validity of the Patent. The Settlement Agreement resolved Sandoz's challenge to the validity of the Patent, following which Sandoz's proceeding against Lundbeck Denmark was discontinued by consent.

15.

44 The Settlement Agreement defined "Patent" to mean the Patent and defined "Proceeding" to mean Sandoz's proceeding against Lundbeck Denmark for revocation of the Patent. Under the Settlement Agreement, Lundbeck Denmark and Lundbeck Australia jointly and severally released Sandoz "from all claims, actions and causes of actions ... present and future, relating to the Proceeding". By the settlement clause, cl 3 of the Settlement Agreement, Lundbeck Denmark and Lundbeck Australia jointly and severally granted Sandoz what was described as "an irrevocable non-exclusive licence to the Patent".

45 The settlement clause was expressed as follows:

- "(1) Lundbeck Denmark and Lundbeck Australia jointly and severally grant Sandoz an irrevocable non-exclusive licence to the Patent effective from:
 - (a) 31 May 2009 if the Patent expires on 13 June 2009;
 - (b) 26 November 2012 if the Patent expires on 9 December 2012;
 - (c) 31 May 2014 if the Patent expires on 13 June 2014; or
 - (d) 2 weeks prior to the expiry of the Patent if the Patent expires on a date other than a date described in clause 3(a) to (c).
- (2) In addition to the licence granted under clause 3(1), Lundbeck Denmark and Lundbeck Australia jointly and severally grant Sandoz an irrevocable non-exclusive licence to the Patent, effective from the beginning of the calendar month in which the licence granted under clause 3(1) becomes effective, for the sole purpose of manufacturing, importing, marketing and offering to sell (but not selling or supplying) pharmaceutical products containing escitalopram.
- (3) For the avoidance of doubt, nothing in this Agreement is to be taken as granting a licence of, or authorisation to exploit, any patent other than the Patent."

46 The inspiration for each of the first three of the dates specified in the settlement clause as a possible date for the expiration of the Patent is not difficult to discern. 13 June 2009 was the prospective date for the expiration of the Patent if there were no extension of its term. 9 December 2012 was the prospective date for the expiration of the Patent if there were an extension of its term based on the inclusion of Cipramil in the ARTG. 13 June 2014 was the prospective date for the

Kiefel CJ
Gageler J
Steward J
Gleeson J

16.

expiration of the Patent if there were an extension of its term based on the inclusion of Lexapro in the ARTG.

47 The challenges to the validity of the Patent by the other suppliers of generic pharmaceutical products continued afterwards in the Federal Court. These challenges were largely unsuccessful at first instance⁶³ and on appeal to the Full Court⁶⁴, save importantly that the extension of the term was held to have been wholly invalid. That is to say, the Patent was held not to have been extended either to 9 December 2012 or to 13 June 2014. The outcome was accordingly that the Patent remained due to expire at the end of the term of its original grant, being 13 June 2009.

48 On 12 June 2009, the day after the decision of the Full Court confirming that the extension of the term was invalid and the day before the expiration of the term of the original grant of the Patent, Lundbeck Denmark applied to the Commissioner for an extension of time to apply for an extension of the term based on the inclusion of Cipramil in the ARTG. The Commissioner granted that application⁶⁵ in a decision which was later upheld on appeal by the Administrative Appeals Tribunal⁶⁶ and on further appeal to the Full Court of the Federal Court⁶⁷ and to this Court⁶⁸.

49 The extension of time for the making of the application having been upheld, the Commissioner on 25 June 2014 granted the extension of the term to 9 December 2012 based on the inclusion of Cipramil in the ARTG. The grant of

63 *Alphapharm Pty Ltd v H Lundbeck A/S* (2008) 76 IPR 618.

64 *H Lundbeck A/S v Alphapharm Pty Ltd* (2009) 177 FCR 151.

65 *Alphapharm Pty Ltd v H Lundbeck A/S* (2011) 92 IPR 628.

66 *Re Aspen Pharma Pty Ltd and Commissioner of Patents* (2012) 132 ALD 648.

67 *Aspen Pharma Pty Ltd v H Lundbeck A/S* (2013) 216 FCR 508.

68 *Alphapharm Pty Ltd v H Lundbeck A/S* (2014) 254 CLR 247.

the extension was challenged by Sandoz and others in the Federal Court. The challenge was unsuccessful at first instance⁶⁹ and on appeal to the Full Court⁷⁰.

50 From the standpoint of the parties entering into the Settlement Agreement in February 2007, the prospect of the Patent being extended so as to end on 9 December 2012 after its term had expired on 13 June 2009 was found by the primary judge⁷¹ and accepted by the Full Court⁷² to have been a "possibility" but one which was "objectively remote". Her Honour found⁷³, and the Full Court accepted⁷⁴, that the parties in entering into the Settlement Agreement can be taken to have expected that they would know by 1 May 2009 when the Patent would expire.

Construction of the settlement clause

51 Parties to a written contract by which they contract in respect of statutory rights can ordinarily be taken to use statutory language according to its statutory meaning. To recognise as much is to recognise no more than that the statute is central to the matrix of fact within the context of which the common intention of the parties falls to be objectively determined⁷⁵. Absent reason to consider that the parties together intend language used in a statute to have some other meaning, there is no reason not to attribute to them a common intention to use that language according to its statutory meaning.

52 All parties to the appeals implicitly recognised that principle. But only the appellants applied it consistently.

69 *Alphapharm Pty Ltd v H Lundbeck A/S* (2014) 110 IPR 59.

70 *Alphapharm Pty Ltd v H Lundbeck A/S* (2015) 234 FCR 306.

71 *H Lundbeck A/S v Sandoz Pty Ltd* (2018) 137 IPR 408 at 483 [291].

72 *Sandoz Pty Ltd v H Lundbeck A/S* (2020) 384 ALR 35 at 51 [69].

73 *H Lundbeck A/S v Sandoz Pty Ltd* (2018) 137 IPR 408 at 484 [294].

74 *Sandoz Pty Ltd v H Lundbeck A/S* (2020) 384 ALR 35 at 49 [59].

75 *Phoenix Commercial Enterprises Pty Ltd v City of Canada Bay Council* [2010] NSWCA 64 at [176]. See also *Royal Botanic Gardens and Domain Trust v South Sydney City Council* (2002) 240 CLR 45 at 53 [12]; Carter, *The Construction of Commercial Contracts* (2012) at 202-203 [6-29].

Kiefel CJ
Gageler J
Steward J
Gleeson J

18.

53 The parties were agreed on the hearing of the appeals that the words "Patent" and "expire" in the settlement clause took their content from the Act. One consequence was that they were agreed that the "irrevocable non-exclusive licence to the Patent" granted to Sandoz by the settlement clause amounted to a grant of permission to exploit the invention including by selling pharmaceutical products containing escitalopram. Another consequence was that they were agreed that (notwithstanding the later grant on 25 June 2014 of the extension to 9 December 2012) the Patent in fact expired with the expiration of its original term on 13 June 2009. Accordingly, they were agreed that cl 3(1)(a), and not cl 3(1)(b), was triggered with the result that the licence was effective from 31 May 2009.

54 But only the appellants applied the word "Patent" consistently to conclude that the licence "to the Patent" granted to Sandoz by cl 3(1)(a) was for a term which commenced on 31 May 2009 and which expired with the expiration of the original term of the Patent on 13 June 2009. The argument for Sandoz was that the licence granted was for a term which commenced on 31 May 2009 but which had no fixed end date. The licence, according to Sandoz, was not only irrevocable but indefinite.

55 The argument for Sandoz failed to give temporal effect to the licence granted to Sandoz by cl 3(1)(a) being expressed to be "to the Patent" which was expressed to "expire" on 13 June 2009 and failed also to be attentive to the internal logic of the settlement clause.

56 When cl 3(1)(a) is read in context with cl 3(1)(b), cl 3(1)(c) and cl 3(1)(d), it is apparent that each of those paragraphs of the settlement clause was consistent in treating the date of the expiration of the licence as the date of the expiration of the Patent and that each paragraph of the settlement clause was consistent in specifying as the date of the commencement of the licence a date two weeks before expiration. The overall effect was that, no matter what the date of the expiration of the term of the Patent might end up being, the irrevocable non-exclusive licence to the Patent granted was to commence two weeks before that date and was to expire on the date of that expiration.

57 The "commercial result" which the parties can be inferred to have intended to produce by the settlement clause structured in that way⁷⁶ was to allow Sandoz to sell generic pharmaceutical products containing escitalopram during the final two weeks of the term of the Patent. During that period other suppliers of generic pharmaceutical products would still be excluded from selling products containing escitalopram through the continuing operation of the exclusive rights to exploit the

76 *Electricity Generation Corporation v Woodside Energy Ltd* (2014) 251 CLR 640 at 656-657 [35], quoting *Re Golden Key Ltd* [2009] EWCA Civ 636 at [28].

invention conferred on Lundbeck Denmark for the term of the Patent. The benefit of being able to sell generic pharmaceutical products containing escitalopram during the final two weeks of the term of the Patent through the operation of the licence conferred by cl 3(1) was enhanced by the more limited licence conferred through the operation of cl 3(2), which allowed Sandoz to start manufacturing, importing, marketing and offering to sell (but not yet to sell) its generic pharmaceutical products containing escitalopram at the beginning of the calendar month in which the two week licence enabling it to sell was to become effective.

58 Through the settlement clause Sandoz accordingly got the modest but valuable commercial benefit of a two week head-start over competing suppliers of generic pharmaceutical products containing escitalopram, who would not be able to start selling until after the Patent expired. That is what Lundbeck Denmark and Lundbeck Australia were conceding to Sandoz in exchange for Sandoz giving up its challenge to the validity of the Patent.

59 True it is that the parties cannot be taken to have foreseen the grant of an extension of the term after the original term of the Patent had expired as anything more than a remote possibility, that Sandoz by entering into the Settlement Agreement was giving up for the future as well as for the present any right to challenge the validity of the Patent, and that the parties can be taken to have recognised the commercial importance to Sandoz of being able to continue to sell its generic pharmaceutical products containing escitalopram once it had started. But equally, it is not easy to regard the parties as having bargained away substantially the whole of the commercial benefit to Lundbeck Denmark of obtaining a grant of an extension of the term after the original term had expired in the event that what seemed to be a remote possibility became a reality.

60 Objectively construed in the context within which the parties entered into the Settlement Agreement, the language of the settlement clause cannot be interpreted as saying anything about any right to bring proceedings against Sandoz that Lundbeck Denmark or Lundbeck Australia might have under s 79 of the Act in the event of an extension of the term of the Patent being granted after the original term of the Patent expired. In the events that subsequently occurred, the settlement clause relevantly operated to confer on Sandoz no more than permission to sell pharmaceutical products containing escitalopram during the period which commenced on 31 May 2009 and which expired with the expiration of the original term of the Patent on 13 June 2009.

Kiefel CJ
Gageler J
Steward J
Gleeson J

20.

Lundbeck Australia had no rights to bring infringement proceedings against Sandoz

61 Once it is recognised that the only rights to bring proceedings in respect of acts occurring between the date of the expiration of the original term of a patent and the date of the grant of an extension of the term of that patent are those conferred by s 79 of the Act, it is apparent on the face of the section that the rights to bring proceedings in respect of those acts are limited to the patentee.

62 Whether s 79's non-conferral of rights to bring proceedings on an exclusive licensee can be explained, as the Full Court surmised⁷⁷, by reference to the patentee alone having a right to apply for an extension of the term, or whether the potential position of an exclusive licensee was simply overlooked in the framing of the section, does not emerge from the legislative history or extrinsic material and does not ultimately matter.

63 The province of statutory construction is the attribution of meaning to the enacted statutory text, not the remediation of perceived legislative oversight⁷⁸. Here, the text is intractable and unambiguous.

64 Lundbeck Denmark, as patentee, had rights to bring proceedings against Sandoz under s 79 of the Act. Lundbeck Australia, as exclusive licensee, did not.

Lundbeck Denmark's cause of action against Sandoz accrued only on the grant of the extension

65 Section 51A(1)(a) of the *Federal Court of Australia Act 1976* (Cth) empowers the Federal Court in "any proceedings for the recovery of any money" to "order that there be included in the sum for which judgment is given interest ... on the whole or any part of the money for the whole or any part of the period between the date when the cause of action arose and the date as of which judgment is entered". A cause of action does not arise within the meaning of the provision until all of the facts which the applicant must prove to obtain judgment for the recovery of the money have come into existence⁷⁹.

77 *Sandoz Pty Ltd v H Lundbeck A/S* (2020) 384 ALR 35 at 62-63 [109].

78 *Taylor v Owners – Strata Plan No 11564* (2014) 253 CLR 531 at 556-557 [65].

79 *Do Carmo v Ford Excavations Pty Ltd* (1984) 154 CLR 234 at 245. See also *Ferrier v Civil Aviation Authority* (1994) 55 FCR 28 at 92.

66 When it is again recognised that the only rights Lundbeck Denmark had to recover damages against Sandoz in respect of acts which occurred between 13 June 2009 and 25 June 2014 were the rights conferred by s 79 of the Act, it is apparent that all of the facts that Lundbeck Denmark needed to prove to establish those rights did not come into existence until the grant of the extension of the term on 25 June 2014.

67 The fact that "the extension is granted" is a precondition to the rights to bring proceedings which s 79 of the Act confers on a patentee coming into existence.

68 Not for nothing did Lundbeck Denmark wait until 26 June 2014 to commence proceedings against Sandoz for infringement of the Patent. Only on 25 June 2014 did its cause of action arise under s 79 of the Act. And only from then could it obtain interest under s 51A(1)(a) of the *Federal Court of Australia Act* on the damages to which it is entitled through the operation of s 79 of the Act.

Sandoz did not engage in misleading or deceptive conduct

69 Resolution of the issue about misleading or deceptive conduct raised by the notice of contention in the Pharma Appeal does not call for revisitation of the principles pertaining to the characterisation of conduct as misleading or deceptive considered in *Campomar Sociedad Limitada v Nike International Ltd*⁸⁰ and in *Miller & Associates Insurance Broking Pty Ltd v BMW Australia Finance Ltd*⁸¹. It is enough to highlight two of those principles. One is the need, where the conduct is not said to be directed to identified individuals, "to isolate by some criterion" a representative member of the class of persons to whom the conduct is directed⁸². The other is the need, where the misleading or deceptive character of the conduct is said to lie in non-disclosure of some circumstance, ordinarily to establish that the representative member of the class to whom the conduct is directed would hold

80 (2000) 202 CLR 45 at 81-88 [92]-[107].

81 (2010) 241 CLR 357 at 368-371 [14]-[23].

82 *Campomar Sociedad Limitada v Nike International Ltd* (2000) 202 CLR 45 at 85 [103].

Kiefel CJ
Gageler J
Steward J
Gleeson J

22.

a reasonable expectation that the circumstance would be disclosed if the circumstance exists⁸³.

70 Pharma's pleaded case was that, in supplying its generic escitalopram products, Sandoz engaged in misleading or deceptive conduct on one or other of two bases. The first was that it failed, refused or neglected to warn its customers or potential customers (including distributors, pharmacies, medical practitioners, end users and others) that the exploitation of its generic products could infringe the Patent. The other was that it impliedly represented to those customers and potential customers that they could use its products without infringing the Patent.

71 The primary judge's finding of misleading or deceptive conduct was something of an amalgam of Pharma's pleaded alternatives. Her Honour said⁸⁴:

"It is not necessary to go so far as to say that there is a general principle that a failure to warn of a potential patent infringement by the supply of a product is likely to involve misleading and deceptive conduct. It may be accepted that each case turns on its own facts."

Her Honour continued⁸⁵:

"Sandoz achieved its sales to pharmacists on the basis of an implied misrepresentation that its products did not infringe any patent, but the products would infringe if and when the extension of term was granted. The extension of term was granted and thus the products infringed. This is sufficient to constitute misleading and deceptive conduct in the circumstances."

72 No exception is taken by Sandoz to the primary judge's finding that it achieved its sales on the basis of an implied misrepresentation that its products did not infringe any patent. The finding accords with findings of misleading or deceptive conduct having been implicit in the sale of infringing products in a

83 *Miller & Associates Insurance Broking Pty Ltd v BMW Australia Finance Ltd* (2010) 241 CLR 357 at 369-370 [18]-[21].

84 *H Lundbeck A/S v Sandoz Pty Ltd* (2018) 137 IPR 408 at 543 [545].

85 *H Lundbeck A/S v Sandoz Pty Ltd* (2018) 137 IPR 408 at 543 [545].

number of other patent infringement cases⁸⁶ to which her Honour had earlier referred⁸⁷.

73 The problem with the balance of the primary judge's finding to which Sandoz points lies in the absence of a foundation in the evidence for considering pharmacists to have held a reasonable expectation that Sandoz would inform them, not of an existing fact, but of the possibility that they might be exposed to proceedings for infringement (through the operation of s 79 of the Act) if and when an extension of the term of the Patent came to be granted in the future. That pharmacists would have held an expectation of being informed about a possibility of that nature is not self-evident. Their holding of such an expectation was not the subject of admission on the part of Sandoz and was not the subject of evidence adduced by Pharma.

74 The finding that Sandoz engaged in misleading or deceptive conduct in supplying its generic escitalopram products between 15 June 2009 and 9 December 2012 cannot be sustained.

Disposition of the appeals

75 The Pharma Appeal must be dismissed with costs.

76 The Lundbeck Appeal must be allowed. The orders of the Full Court allowing the appeal and dismissing the cross-appeal from the decision of the primary judge, setting aside the substantive orders made by the primary judge, and dismissing the proceedings, must each be set aside. In their place, the appeal and the cross-appeal from the decision of the primary judge must each be allowed in part, the orders made by the primary judge for damages and pre-judgment interest payable to each of Lundbeck Denmark and Lundbeck Australia must be set aside, and the matter must be remitted to the primary judge for recalculation of damages and pre-judgment interest payable to Lundbeck Denmark alone.

86 *Advanced Building Systems Pty Ltd v Ramset Fasteners (Aust) Pty Ltd* (1995) AIPC ¶91-129; *Ramset Fasteners (Aust) Pty Ltd v Advanced Building Systems Pty Ltd* (1999) 164 ALR 239; *Sanofi-Aventis Australia Pty Ltd v Apotex Pty Ltd [No 3]* (2011) 196 FCR 1 at 81-83 [275]-[282]; *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd [No 2]* (2012) 204 FCR 494 at 518 [91]; *Sandvik Intellectual Property AB v Quarry Mining & Construction Equipment Pty Ltd* (2016) 118 IPR 421 at 496-497 [272]-[277].

87 *H Lundbeck A/S v Sandoz Pty Ltd* (2018) 137 IPR 408 at 541-543 [538]-[544].

Kiefel CJ
Gageler J
Steward J
Gleeson J

24.

77 There is no dispute between the parties that the recalculation of damages must be undertaken in accordance with an adjustment made by the Full Court to the primary judge's discount of the damages from 25% to 2 to 3%. The recalculation of pre-judgment interest on those damages must be undertaken in accordance with the holding of this Court that Lundbeck Denmark's cause of action arose only on the grant of the extension of the term of the Patent on 25 June 2014.

78 There is also no dispute between the parties that the order remitting the matter to the primary judge for the recalculation of damages should be framed to ensure that it does not prejudice the outcome of a pending review by the Administrative Appeals Tribunal sought by Lundbeck Denmark of the decision by the Commissioner, after the decision of the primary judge but before the decision of the Full Court, to grant a licence under s 223(9) of the Act and reg 22.21 of the *Patents Regulations 1991* (Cth)⁸⁸.

79 As Lundbeck Denmark has had a substantial measure of success in the Lundbeck Appeal, Lundbeck Denmark and Lundbeck Australia are to have their costs to date of the proceedings before the primary judge, of the appeal and cross-appeal to the Full Court and of the appeal to this Court.

88 *H Lundbeck A/S v Sandoz Pty Ltd* (2019) 153 IPR 170.

EDELMAN J.

The issue of contractual implication and the consequential issues

80 The appellants in one of the appeals before this Court are H Lundbeck A/S ("Lundbeck Denmark") and its subsidiary and exclusive licensee, Lundbeck Australia Pty Ltd ("Lundbeck Australia"), collectively described below as the "Lundbeck entities". In February 2007, the Lundbeck entities entered into a settlement agreement with the respondent in both appeals, Sandoz Pty Ltd ("Sandoz"). By cl 5 of the settlement agreement, Sandoz agreed to discontinue proceedings that it had brought against the Lundbeck entities which had sought revocation of a patent that Lundbeck Denmark held in relation to a pharmaceutical substance called escitalopram, which is a treatment for depression ("the Patent").

81 The principal issue on these appeals concerns the interpretation of a bespoke clause in the settlement agreement and its application to remote circumstances which were not expected by either party to occur. By the bespoke clause, cl 3, the Lundbeck entities granted to Sandoz irrevocable non-exclusive licences "to the Patent". Clause 3 carefully provided for a commencement date for the licences based on various contingencies concerning when the term of the Patent might expire. The commencement date for the primary licence was set to be a date that was two weeks before the expiry of the term of the Patent. The principal interpretation issue arises because there was no express provision of an end date to the licences.

82 The appellants in both appeals submitted that the licences came to an end when the term of the Patent expired. This would have the effect that, if an extension of the term of the Patent were granted after expiry of the Patent term⁸⁹, Sandoz's licence would have expired and proceedings could be brought against Sandoz for post-expiry acts that would have infringed the Patent "as if the [Patent] extension had been granted"⁹⁰ at the time of those acts. The primary judge accepted this submission⁹¹. By contrast, Sandoz submitted that there was an absence of any expressed or implied end date in the licences which meant that the licences must be perpetual. Hence, Sandoz would have a defence to an action against it for infringement of the Patent on the basis that it acted under a licence. The Full Court of the Federal Court of Australia accepted this submission⁹². For the reasons below, and gratefully relying upon the comprehensive background and legislative history

89 See *Patents Act 1990* (Cth), s 76.

90 *Patents Act*, s 79.

91 *H Lundbeck A/S v Sandoz Pty Ltd* (2018) 137 IPR 408 at 484-485 [296]-[303].

92 *Sandoz Pty Ltd v H Lundbeck A/S* (2020) 384 ALR 35 at 51 [67]-[69].

set out in the joint judgment, the proper approach to recognition of implications means that the conclusion of the primary judge best reflects the implications in cl 3 that would be recognised by a reasonable person in the position of the parties. This conclusion gives rise to three consequential issues.

83 The first consequential issue concerns whether, in addition to the claim by Lundbeck Denmark as patentee, a claim can be brought against Sandoz for infringement of the Patent by Lundbeck Australia, as an exclusive licensee. Under s 79 of the *Patents Act 1990* (Cth), a patentee has the "same rights to start proceedings" for infringement following an extension of the term of a standard patent "as if the extension had been granted at the time when the act was done". The Full Court correctly concluded that this right to start proceedings under s 79 is conferred only upon a patentee and not upon an exclusive licensee⁹³. Lundbeck Australia had no "right" to start proceedings under s 79 of the *Patents Act*.

84 The second consequential issue is the date from which pre-judgment interest runs pursuant to s 51A(1)(a) of the *Federal Court of Australia Act 1976* (Cth) for Lundbeck Denmark's claim under s 79 of the *Patents Act*. Although it was unnecessary for the Full Court to address this issue, the Full Court correctly reasoned that the power to award interest to Lundbeck Denmark arose from the time at which its cause of action accrued, being the date when the term of the Patent was extended⁹⁴. Prior to this date, Lundbeck Denmark had no legal rights that were enforceable by legal action, and therefore no "cause of action" within the meaning of s 51A(1)(a).

85 The third consequential issue arises by a notice of contention in the second appeal, which is brought by a subsidiary of Lundbeck Australia, CNS Pharma Pty Ltd ("Pharma"). Pharma purchases from Lundbeck Denmark, and then sells, a generic product containing escitalopram. Pharma joined with the Lundbeck entities in support of the finding of the primary judge that the licences ended when the term of the Patent expired. Pharma then claimed that when Sandoz entered the market to sell products containing escitalopram Sandoz engaged in misleading or deceptive conduct within s 52 of the *Trade Practices Act 1974* (Cth) and s 18 of the *Australian Consumer Law*⁹⁵.

86 The primary judge found that Sandoz engaged in misleading or deceptive conduct by an implied misrepresentation from Sandoz that the products sold did not infringe any patent without the qualification that the products would infringe a

93 *Sandoz Pty Ltd v H Lundbeck A/S* (2020) 384 ALR 35 at 62-63 [105]-[110].

94 *Sandoz Pty Ltd v H Lundbeck A/S* (2020) 384 ALR 35 at 71-73 [140]-[147].

95 *Competition and Consumer Act 2010* (Cth), Sch 2.

patent if and when an extension of the term were granted to Lundbeck Denmark⁹⁶. The Full Court did not need to address this issue since its conclusion that Sandoz's licences were perpetual meant that the products did not infringe any patent. Ultimately, this third consequential issue reduces to whether Pharma established that the existence of the remote possibility of an extension of the term of the Patent was sufficiently material that Sandoz should have qualified its implied representation that its products did not infringe any patent in order to have the effect that the non-disclosure of that qualification could be misleading or deceptive. That remote possibility was not material.

The express and implied meaning of the terms of the primary licence

No express provision for an end date to the primary licence

87 Clause 3 of the settlement agreement provides as follows:

"Licence to exploit the Patent

- (1) Lundbeck Denmark and Lundbeck Australia jointly and severally grant Sandoz an irrevocable non-exclusive licence to the Patent effective from:
 - (a) 31 May 2009 if the Patent expires on 13 June 2009;
 - (b) 26 November 2012 if the Patent expires on 9 December 2012;
 - (c) 31 May 2014 if the Patent expires on 13 June 2014; or
 - (d) 2 weeks prior to the expiry of the Patent if the Patent expires on a date other than a date described in clause 3(a) to (c).
- (2) In addition to the licence granted under clause 3(1), Lundbeck Denmark and Lundbeck Australia jointly and severally grant Sandoz an irrevocable non-exclusive licence to the Patent, effective from the beginning of the calendar month in which the licence granted under clause 3(1) becomes effective, for the sole purpose of manufacturing, importing, marketing and offering to sell (but not selling or supplying) pharmaceutical products containing escitalopram.
- (3) For the avoidance of doubt, nothing in this Agreement is to be taken as granting a licence of, or authorisation to exploit, any patent other than the Patent."

⁹⁶ *H Lundbeck A/S v Sandoz Pty Ltd* (2018) 137 IPR 408 at 543 [545].

88 The licence in cl 3(1) is described in these reasons as the "primary licence" and the licence in cl 3(2) is described as the "supplementary licence". The possible commencement dates for the primary licence, and their objective, shared rationale, were clear. The first date, 31 May 2009, represented two weeks before the expected expiry date of the term of the Patent, 13 June 2009, if no extension were granted. The second and third dates represented two weeks before the expected expiry dates of the term of the Patent if there were an extension of the term of the Patent based on the inclusion of one or other of two pharmaceutical products containing escitalopram in the Australian Register of Therapeutic Goods⁹⁷.

89 One of the problems with the drafting of the primary licence and the supplementary licence is the expression "an irrevocable non-exclusive licence to the Patent". The best that can be said of that expression is that it is ambiguous. The primary judge took one view of what it meant. The Full Court took another.

90 In its literal terms, the expression "licence to the Patent" is nonsense. A licence is a freedom from a duty: it is "an authority to do something which would otherwise be wrongful or illegal or inoperative"⁹⁸. A patent over an invention is a grant of "the exclusive rights, during the term of the patent, to exploit the invention and to authorise another person to exploit the invention"⁹⁹. It makes no more sense to speak of a person having a "licence to the Patent" than it does to speak of an invitee to a leased property having a "licence to the lease".

91 It appears that the expression "licence to the Patent" was used interchangeably with the notion, as expressed in the heading to the clause and in cl 3(3), of a licence to exploit the Patent. But even then the expression is nonsensical. A patent is not something that is exploited. The subject matter of exploitation is the invention with which the patent is concerned. The only sensible meanings that can be given to the expression "licence to the Patent" are either: (i) a freedom to exploit the invention that is the subject matter of the Patent; or (ii) a freedom to exploit the invention that is the subject matter of the Patent during the term of the Patent. Consistently with the meaning of "exploit" in the *Patents Act*¹⁰⁰, the freedom to exploit the invention includes making, selling, or otherwise disposing of pharmaceutical products containing escitalopram.

97 See *Patents Act*, ss 70, 77.

98 *Federal Commissioner of Taxation v United Aircraft Corporation* (1943) 68 CLR 525 at 533.

99 *Patents Act*, s 13(1).

100 *Patents Act*, s 3 read with Sch 1 definition of "exploit".

92 Sandoz's essential submissions in this Court were simple and clear. First, it was submitted that cl 3 expressly provides for a commencement date but does not expressly provide for any end date for the licences. Hence, any end date for the licences required an implication to be recognised in cl 3. Sandoz submitted that the interpretation of the primary judge that limited the primary licence to a two-week period "had the same effect ... as implying a term for an end date". Secondly, it was submitted that the strictness of the test for recognition of an implied term, requiring satisfaction of five factors¹⁰¹, was not met.

Expressions and implications

93 There are ephemeral borders, to which lawyers sometimes cling, between three categories of interpretation of words in legal instruments: (i) interpretation of the meaning of express words in a clause; (ii) drawing inferences that recognise implications within a clause; and (iii) drawing inferences that recognise the implication of a new "term". All three are "an exercise in interpretation"¹⁰². All three are concerned with "what the [instrument] actually means"¹⁰³. And all three involve drawing inferences and recognising matters that are implied in the sense that they are not confined to the semantics of literally expressed meaning. For instance, like the latter two categories, even the first category will often involve drawing inferences from context by recognising explicatures from the express text¹⁰⁴. In all three categories, context and purpose supply additional information for the meaning that combines with the literal text. By this means, the "implication is included in [the meaning of] what is expressed"¹⁰⁵.

101 See *BP Refinery (Westernport) Pty Ltd v Shire of Hastings* (1977) 180 CLR 266 at 283.

102 *Codelfa Construction Pty Ltd v State Rail Authority of NSW* (1982) 149 CLR 337 at 345; *Commonwealth Bank of Australia v Barker* (2014) 253 CLR 169 at 186 [22].

103 *Attorney General of Belize v Belize Telecom Ltd* [2009] 1 WLR 1988 at 1994 [22]; [2009] 2 All ER 1127 at 1134; *Commonwealth Bank of Australia v Barker* (2014) 253 CLR 169 at 186 [22].

104 Sperber and Wilson, *Relevance: Communication and Cognition*, 2nd ed (1995) at 182; Carston, *Thoughts and Utterances: The Pragmatics of Explicit Communication* (2002) at 116-125. And see Haugh, "The Intuitive Basis of Implicature: Relevance Theoretic *Implicitness* versus Gricean *Implying*" (2002) 12 *Pragmatics* 117 at 123-130.

105 *Merchant Service Guild of Australasia v Newcastle and Hunter River Steamship Co Ltd [No 1]* (1913) 16 CLR 591 at 624. See also *Lubrano v Gollin & Co Pty Ltd*

94 The distinction between the three categories can be so fine that in the same case some members of this Court have treated the interpretation exercise as falling within one category while others have treated it as falling within another category¹⁰⁶. A decision that can illustrate the fine distinction is *Prenn v Simmonds*¹⁰⁷, which was considered by Mason J in *Codelfa Construction Pty Ltd v State Rail Authority of NSW*¹⁰⁸. As Mason J explained, the expression considered in that case, "profits of RTT", was held to mean "the consolidated profits of the group of companies consisting of RTT and its subsidiaries" by interpretation of the meaning of an express word – profits – having regard to surrounding circumstances. But the reasoning in *Prenn v Simmonds* might equally have been expressed as recognising an implication as though the word "consolidated" appeared before "profits" or as recognising an implied term that "profits of the RTT group shall be treated as profits of RTT".

95 Despite the close, perhaps inseparable, association between these three categories of interpretation, it can sometimes appear as though courts are applying a different test for interpretation in each different category. Putting to one side any issue concerning whether ambiguity is required before extrinsic circumstances and context can be considered¹⁰⁹, a constraint which does not arise in relation to the meaning of written documents or instruments generally¹¹⁰, a simple approach is generally taken in the category where the meaning of express words is concerned. In that category, the task of interpretation is commonly said simply to be a matter of ascertaining what would have been intended by a reasonable person in the position of the parties, with inferences about that meaning to be drawn from the

(1919) 27 CLR 113 at 118; *R v Rigby* (1956) 100 CLR 146 at 151; *Wurridjal v The Commonwealth* (2009) 237 CLR 309 at 368 [120].

106 Compare, for instance, the approaches in *Lewis Construction (Engineering) Pty Ltd v Southern Electric Authority of Queensland* (1976) 50 ALJR 769 at 770-771 (Barwick CJ in dissent), 773-775 (Gibbs J), with 777 (Stephen and Murphy JJ); 11 ALR 305 at 309, 314-318, 321-323.

107 [1971] 1 WLR 1381 at 1388; [1971] 3 All ER 237 at 243.

108 (1982) 149 CLR 337 at 348.

109 *Codelfa Construction Pty Ltd v State Rail Authority of NSW* (1982) 149 CLR 337 at 352, considered in *Franklins Pty Ltd v Metcash Trading Ltd* (2009) 76 NSWLR 603 at 617 [17(b)]; *Mainteck Services Pty Ltd v Stein Heurtey SA* (2014) 89 NSWLR 633 at 654-655 [78]-[79]; *Mount Bruce Mining Pty Ltd v Wright Prospecting Pty Ltd* (2015) 256 CLR 104 at 132 [110].

110 *Rinehart v Hancock Prospecting Pty Ltd* (2019) 267 CLR 514 at 548 [83].

information reasonably available to the parties¹¹¹. In *Chartbrook Ltd v Persimmon Homes Ltd*¹¹², Lord Hoffmann said that "there is not, so to speak, a limit to the amount of red ink or verbal rearrangement or correction which the court is allowed. All that is required is that it should be clear that something has gone wrong with the language and that it should be clear what a reasonable person would have understood the parties to have meant."

96 By contrast, the task of interpretation is sometimes expressed as a more rigid test, requiring much greater restraint, where the meaning of a clause requires an inference that is said to involve the addition or removal of words in the instrument. So, for drawing inferences that recognise an unexpressed implication within a clause, in *Fitzgerald v Masters*¹¹³, Dixon CJ and Fullagar J said that "[w]ords may generally be supplied, omitted or corrected, in an instrument, where it is clearly necessary in order to avoid absurdity or inconsistency". And an even stricter approach to drawing inferences that recognise an entire implied term in a contract appears from the famous passage in *Codelfa*¹¹⁴, where Mason J (with whom Stephen and Wilson JJ agreed) said that "courts have been at pains to emphasize that it is not enough that it is reasonable to imply a term" and that there are five "conditions necessary to ground the implication of a term". The proposed implied term: (1) must be reasonable and equitable; (2) must be necessary to give business efficacy to the contract, so that no term will be implied if the contract is effective without it; (3) must be so obvious that "it goes without saying"; (4) must be capable of clear expression; and (5) must not contradict any express term of the contract.

97 The ephemeral nature of the borders between the three categories of interpretation makes it difficult to justify any sharp distinctions between them. It has thus, albeit controversially, been suggested that the categories be entirely

111 *Maggbury Pty Ltd v Hafele Australia Pty Ltd* (2001) 210 CLR 181 at 188 [11], quoting *Investors Compensation Scheme Ltd v West Bromwich Building Society* [1998] 1 WLR 896 at 912; [1998] 1 All ER 98 at 114. See also *Attorney General of Belize v Belize Telecom Ltd* [2009] 1 WLR 1988 at 1993 [16]; [2009] 2 All ER 1127 at 1132.

112 [2009] AC 1101 at 1114 [25].

113 (1956) 95 CLR 420 at 426-427.

114 (1982) 149 CLR 337 at 346-347, approving *BP Refinery (Westernport) Pty Ltd v Shire of Hastings* (1977) 180 CLR 266 at 283. See also *Secured Income Real Estate (Australia) Ltd v St Martins Investments Pty Ltd* (1979) 144 CLR 596 at 605-606.

collapsed¹¹⁵. The best approach is to recognise that implications fall on a continuum that depends upon the extent of the contribution that the general or particular circumstances of context or purpose must make to the required inference beyond the language of the provision¹¹⁶. In contracts that are entirely in writing, like other entirely written instruments such as legislation, the larger the contribution from surrounding circumstances beyond the text that is required to recognise the implication the greater must be the relevance of those circumstances¹¹⁷ and the greater the "force as to carry conviction to the mind"¹¹⁸ that is needed before the implication can be recognised as one that would have been intended by a reasonable person in the position of the parties.

98 At one end of the continuum, an implication beyond the literal meaning of express words might be slight and in contractual interpretation the inference of that implied meaning can be readily drawn if that was the meaning that would have been intended by a reasonable person in the position of the parties. It does not matter if the inference is described as inserting new words. As Lord Eldon LC said in *Wight v Dicksons*¹¹⁹, "[i]t had been said that it was too strong to insert a word; but the answer was, that the other words in the [contract] could not have their proper effect without it".

99 At the other end of the continuum, a contractual implication beyond the literal meaning of the express words might be large, requiring a high level of satisfaction by the court that the implication would have been intended by a reasonable person in the position of the parties. Hence, if the implication is properly characterised as a new, and separate, term of the contract, the present state of the law is that a court will require satisfaction of all five of the factors endorsed in *Codelfa* before the implication is recognised.

115 See *Attorney General of Belize v Belize Telecom Ltd* [2009] 1 WLR 1988 at 1993-1995 [16]-[27]; [2009] 2 All ER 1127 at 1132-1135.

116 See Sternau et al, "Levels of interpretation: New tools for characterizing intended meanings" (2015) 84 *Journal of Pragmatics* 86 at 88.

117 Sperber and Wilson, *Relevance: Communication and Cognition*, 2nd ed (1995) at 123-132.

118 *Butt v Long* (1953) 88 CLR 476 at 488.

119 (1813) 1 Dow 141 at 147 [3 ER 651 at 653].

An implied end date?

100 These principles concerning implication arise on the interpretation of cl 3, and in particular the resolution of whether the expression "licence to the Patent" means only a freedom to exploit the invention that is the subject matter of the Patent or whether the meaning of that expression also includes the implication that the freedom is limited to the initial term of the Patent without regard to any extension. Neither of the competing interpretations, either that of Sandoz (perpetual licences) or that of the appellants (licences until the initial expiry of the Patent), treated the term of the licences as the term of the Patent with any extensions. Such an interpretation would not have been contemplated by a reasonable person in the position of the parties since it would leave the licences in a form of suspended animation between the expiry of the initial term of the Patent and any subsequent post-expiry extension of the term.

101 A licence to exploit the subject matter of a patent does not always terminate when the term of the patent expires; indeed, without a condition to the contrary, the licence will be valid even if the patent is invalid¹²⁰. Section 145 of the *Patents Act* assumes that there will be instances where the licence continues after the expiry of the term of the patent. In circumstances where "the instrument does not expressly provide for what is to happen when some event occurs", such as where there is no express provision that the licence is to come to an end when the term of the patent expires, the "most usual inference ... is that nothing is to happen"¹²¹. The licence does not terminate. That was the central, and powerful, plank of the reasoning of the Full Court¹²².

102 On the other hand, as explained above, it is clear that something went wrong with the manner in which the parties expressed themselves in cl 3. It requires only a slight inference beyond the literal meaning of the words to conclude that the reference in cll 3(1) and 3(2) to a "licence to the Patent", like the equally nonsensical words in cl 3(3) "licence of ... the Patent", carries the implication that the freedom to exploit the invention is limited to the term of the Patent. With the ease by which the implied meaning can be derived from the garbled words used, it is not necessary for background facts and reasonable assumptions to provide a high

120 As to consequences of this see, eg, *Taylor v Hare* (1805) 1 B & P (NR) 260 [127 ER 461]; *Lawes v Purser* (1856) 6 E & B 930 at 935 [119 ER 1110 at 1112]. Compare Mitchell, Mitchell and Watterson (eds), *Goff and Jones: The Law of Unjust Enrichment*, 9th ed (2016) at 468 [13-23].

121 *Attorney General of Belize v Belize Telecom Ltd* [2009] 1 WLR 1988 at 1993 [17]; [2009] 2 All ER 1127 at 1132.

122 *Sandoz Pty Ltd v H Lundbeck A/S* (2020) 384 ALR 35 at 50-51 [66]-[67].

level of satisfaction that this implication would have been intended by a reasonable person in the position of the parties. The background facts in this case provide sufficient satisfaction that a reasonable person in the position of the parties would have intended to limit the term of the licences to the initial term of the Patent.

103 One background fact is that the parties were aware that there was a "remote possibility that the term of the Patent might be extended sometime after it had expired"¹²³. On the first of the proposed dates, in cl 3(1)(a), which turned out to be the commencement of the primary licence, the period of extension would be approximately three and a half years. The appellants relied upon the remote possibility of this extension as a matter of commercial context that was said to favour their interpretation. If the primary and supplementary licences ended when the term of the Patent expired, then they would preserve the exclusivity of the Lundbeck entities' rights upon an extension of the term of the Patent.

104 Whilst it will always be an important matter of context for the interpretation of a commercial agreement if an interpretation would be "commercial nonsense"¹²⁴, it will rarely assist for the interpretation of an agreement that the court considers that, from the perspective of one party, one or more clauses are not commercially wise or convenient. As Neuberger LJ said in *Skanska Rashleigh Weatherfoil Ltd v Somerfield Stores Ltd*¹²⁵:

"[T]he court must be careful before departing from the natural meaning of the provision in the contract merely because it may conflict with its notions of commercial common sense of what the parties may must or should have thought or intended. Judges are not always the most commercially-minded, let alone the most commercially experienced, of people, and should, I think, avoid arrogating to themselves overconfidently the role of arbiter of commercial reasonableness or likelihood."

105 Perhaps with this principle in mind, but not without a flourish of comic hyperbole, the appellants submitted that Sandoz's interpretation was "madness" and "commercially incomprehensible" because Sandoz's interpretation suggested that the Lundbeck entities would have given up a right to exclude others from

123 *Sandoz Pty Ltd v H Lundbeck A/S* (2020) 384 ALR 35 at 51 [69].

124 *Simic v New South Wales Land and Housing Corporation* (2016) 260 CLR 85 at 111 [78]; *Electricity Generation Corporation v Woodside Energy Ltd* (2014) 251 CLR 640 at 656-657 [35]; *Mount Bruce Mining Pty Ltd v Wright Prospecting Pty Ltd* (2015) 256 CLR 104 at 117 [51].

125 [2006] EWCA Civ 1732 at [22]. See also Thomson, Warnick and Martin, *Commercial Contract Clauses: Principles and Interpretation*, 3rd ed (2019) at 19-21 [1350].

exploiting escitalopram products for three and a half years, without any royalties in return. This submission cannot be accepted. At the time of the settlement agreement, on any interpretation of cl 3 no reasonable person in the position of the parties would have considered that the Lundbeck entities were giving up such valuable rights.

106 On Sandoz's interpretation of cl 3, all that the Lundbeck entities were giving up was possible rights against one legal person, Sandoz, in circumstances where the rights would only exist on the remote possibility of an extension. Moreover, even if that remote possibility were to be treated as a certainty, it would equally be "madness" for Sandoz to discontinue its litigation in exchange for primary and supplementary licences that would enable it to sell escitalopram products when those licences were worthless because they expired within a very short period. If Sandoz knew that its primary licence would only be for two weeks, it would be unlawful to sell to pharmacists without disclosing that fact¹²⁶ and no reasonable pharmacist would purchase escitalopram products at short notice, knowing that even with instantaneous distribution the products could only be sold to customers for a small number of days from the date of purchase by the pharmacist.

107 Ultimately, therefore, the background fact that the parties were aware of the remote possibility that the term of the Patent might be extended after the initial expiry, to apply retrospectively, does not assist either interpretation of cl 3. Other background facts and circumstances are much more useful in interpreting the meaning of cl 3, and any implications contained in it.

108 Another objective background fact relevant to the interpretation of the settlement agreement¹²⁷ is the expressed purpose of the licences in pre-contractual communications between the parties. The purpose was expressed in each case as an "early entry licence" with a period from the start of the month "to stockpile and offer for sale (but not actually supply)" in order to take immediate advantage of the early entry licence. A further background fact at the time of the settlement agreement, which the primary judge also found would have been reasonably ascertainable by a reasonable person in the position of the parties, was that "various generic entities ... were keen to launch their own escitalopram products"¹²⁸.

126 See, eg, *Miller & Associates Insurance Broking Pty Ltd v BMW Australia Finance Ltd* (2010) 241 CLR 357 at 371 [23].

127 See *Codelfa Construction Pty Ltd v State Rail Authority of NSW* (1982) 149 CLR 337 at 352.

128 *H Lundbeck A/S v Sandoz Pty Ltd* (2018) 137 IPR 408 at 477-478 [264].

109 In short, the purpose of the licences was to enable Sandoz to get a head start over other entities seeking to enter the market to sell generic pharmaceutical products on the expiry of the term of the Patent. Even a short, two-week head start could enable Sandoz to establish itself as a preferred supplier, especially with the supplementary licence period from the start of the month for manufacturing, importing, marketing, and offering to sell. As the primary judge correctly explained¹²⁹:

"The parties also would have appreciated that, for generic entities, every day counted for entry into a market to maximise the opportunity to take market share and so any early entry Sandoz could negotiate in exchange for discontinuing its proceedings would have value to Sandoz."

110 In light of this purpose, a reasonable person in the position of the parties would have expected the primary licence to be for the two weeks until the expiry of the term of the Patent, with the earlier commencement of the supplementary licence. The purpose was effectively to give a head start to Sandoz shortly before the expiry of the term of the Patent, albeit that once that term had expired Sandoz would be placed in the same position as its competitors. The primary judge was therefore correct to conclude that, in effect, the licences "to the Patent" carried the implication that the freedom to exploit the invention was limited to the term of the Patent.

The consequential issues

Can Lundbeck Australia bring infringement proceedings?

111 The first issue that is consequential upon the conclusion that Sandoz's licences ended upon the expiry of the term of the Patent is whether Lundbeck Australia, as exclusive licensee, could bring infringement proceedings against Sandoz or whether the only party entitled to bring proceedings in such circumstances is Lundbeck Denmark, as patentee.

112 Section 79 of the *Patents Act* confers upon a patentee the "same rights to start proceedings" for the doing of an act, including an infringement, where an extension of the term of a standard patent is granted after the expiry of the initial term of the patent as if the extension had been granted when the act was done. The appellants submitted that the absence of an express conferral of the same "right" for an exclusive licensee to start proceedings was anomalous for three reasons: (i) the statutory scheme of the *Patents Act* contemplates that exclusive licences might be granted (for example, in s 13(1)), so it would be anomalous if the exclusive licensee did not have the "right" to pursue infringement proceedings; (ii) if an extension of the term were granted immediately before the expiry of the

129 *H Lundbeck A/S v Sandoz Pty Ltd* (2018) 137 IPR 408 at 478 [269].

term of a patent, then the patentee or exclusive licensee could bring proceedings, so it would be anomalous if only the patentee could do so immediately after the extension of the term were granted; and (iii) if the extension of the term is granted either during or after the term of the patent, then s 78 limits the exclusive rights of the patentee during the period of the extension but, since Parliament could not have contemplated freedom from those limits for the exclusive licensee, both ss 78 and 79 must impliedly extend also to exclusive licensees.

113 In effect, the submission of the appellants – that s 79 applies to an exclusive licensee – is that these anomalies combine to require that s 79 be read with the implication expressed in italics: "the patentee *or exclusive licensee* has, after the extension is granted, the same rights to start proceedings". The appellants' submission is effectively that this is an occasion of an error or infelicity in the drafting of legislation. Such errors, by inclusion or omission of only a few words, can radically change statutory meaning. But the correction of drafting errors, even substantial errors, does not defeat the intention of Parliament. To the contrary, such correction respects that intention. As with written contracts¹³⁰, an implication might exist that gives a statutory provision a meaning that would directly contradict, or would substantially change the effect of, the literal meaning of the provision¹³¹. But the more that an implication "departs from the natural and ordinary meaning of the terms of the provision in the context in which they appear", the more plain it must be that the meaning is one that "Parliament intended it to have"¹³².

114 The implication for which the appellants contended involves a large addition to the language of the provision, akin to the creation of a new term by applying s 79 also to exclusive licensees. Like implications in contractual instruments, a statutory implication that has effect as if the provision "contained additional words or omitted words involves a judgment of matters of degree" which is readily answered against "an insertion which is 'too big, or too much at variance with the language in fact used by the legislature'"¹³³. To the extent that

130 *Fitzgerald v Masters* (1956) 95 CLR 420 at 426-427.

131 *Associated Newspapers Ltd v Wavish* (1956) 96 CLR 526 at 528; *Director of Public Prosecutions (Nauru) v Fowler* (1984) 154 CLR 627 at 630; *Burrage v Queensland* (2015) 236 FCR 160 at 164 [18].

132 *Esso Australia Pty Ltd v Australian Workers' Union* (2017) 263 CLR 551 at 582 [52].

133 *Taylor v Owners – Strata Plan No 11564* (2014) 253 CLR 531 at 548 [38], citing *Western Bank Ltd v Schindler* [1977] Ch 1 at 18 and *Inco Europe Ltd v First Choice Distribution* [2000] 1 WLR 586 at 592; [2000] 2 All ER 109 at 115.

they are anomalies at all, the alleged three anomalies identified by the appellants are insufficient to justify recognition of such a large implication. The first two anomalies depend upon an assumption that Parliament intended to treat the position of an extension of the term before the expiry of the term of a patent in the same way as the position after expiry. As the Full Court observed, that assumption may not be correct¹³⁴. The third and final asserted anomaly is based on a misconception. No implication is needed in s 78 because, by limiting the rights of the patentee, s 78 also limits the derivative rights¹³⁵ of the exclusive licensee to commence infringement proceedings conferred by s 120 of the *Patents Act*.

115 The Full Court was therefore correct to conclude that Lundbeck Australia has no power to commence a proceeding for infringement of the Patent in respect of conduct which occurred during the extended term of the Patent. This ground of appeal in each of the appeals should be dismissed.

Interest

116 The second consequential issue concerns the date from which Lundbeck Denmark can claim interest under s 51A(1)(a) of the *Federal Court of Australia Act* on its claim under s 79 of the *Patents Act*. Section 51A(1)(a) empowers the Federal Court, in any proceedings for the recovery of any money, to include in the judgment sum an amount of interest on the whole or any part of the money due. The interest is to be awarded for the whole or any part of the period "between the date when the cause of action arose and the date as of which judgment is entered".

117 The issue reduces to the time at which the "cause of action arose". The expression "cause of action" is slippery. It can mean different things in different contexts. Sometimes the expression is taken to mean a right¹³⁶. The most common use of "cause of action", however, is in the sense set out in *Letang v Cooper*¹³⁷, where, in a passage relied upon on many occasions in Australia¹³⁸, Diplock LJ

134 *Sandoz Pty Ltd v H Lundbeck A/S* (2020) 384 ALR 35 at 62-63 [109]-[110].

135 See, especially, *Patents Act*, s 120(2).

136 See *Port of Melbourne Authority v Anshun Pty Ltd* (1981) 147 CLR 589 at 611.

137 [1965] 1 QB 232 at 242-243. See also the similar expositions in *Carter v Egg and Egg Pulp Marketing Board (Vic)* (1942) 66 CLR 557 at 600; *Port of Melbourne Authority v Anshun Pty Ltd* (1981) 147 CLR 589 at 611.

138 See, eg, *Wardley Australia Ltd v Western Australia* (1992) 175 CLR 514 at 539; *Permanent Building Society v Wheeler [No 2]* (1993) 10 WAR 569 at 572;

commenced his reasons with the description of a cause of action as "simply a factual situation the existence of which entitles one person to obtain from the court a remedy against another person". This common sense of a cause of action is the sense in which it is used in s 51A(1)(a) of the *Federal Court of Australia Act*. As Gaudron J described the reference to "cause of action" in that provision in *The Commonwealth v SCI Operations Pty Ltd*¹³⁹, it is a "legal right enforceable by legal action".

118 Section 79 of the *Patents Act* operates on past facts in that it creates a power for a patentee to "start proceedings" in respect of acts done after the expiry of the term of the patent and prior to the extension of the patent "as if the extension had been granted at the time when the act was done". The retroactive operation relies on a fiction that the extension was granted at the earlier date when the act was done. But s 79 does not create a further fiction to deem a patentee to have had the ability to obtain a remedy from the court at that earlier date.

119 In other words, s 79 creates a new cause of action from the date of the grant of the extension, with that cause of action operating on past facts. It does not deem a cause of action to have arisen at that earlier date. The Full Court was therefore correct that interest under s 51A(1)(a) of the *Federal Court of Australia Act* could only accrue for Lundbeck Denmark's claim from 25 June 2014, being the date on which the Commissioner of Patents granted the extension to the term of the Patent. This ground of appeal in each of the appeals should be dismissed.

Misleading or deceptive conduct

120 The issue raised by Sandoz's notice of contention in the Pharma appeal is whether Sandoz engaged in misleading or deceptive conduct by its non-disclosure of the existing fact or circumstance that there was a possibility that the term of the Patent might be extended, thus exposing pharmacists to potential liability for infringement. Sandoz submitted that its conduct was not misleading or deceptive.

121 Sandoz submitted that the primary judge erred by concluding that Sandoz made an implied representation that its products sold to pharmacists did not infringe any patent since, it was submitted, "a vendor would not normally be taken merely by selling a product to be warranting that the product does not infringe any patent". There is force in that submission, just as a licensor will not generally be

Macquarie Bank Ltd v National Mutual Life Association of Australia Ltd (1996) 40 NSWLR 543 at 558; *Keet v Ward* [2011] WASCA 139 at [24].

¹³⁹ (1998) 192 CLR 285 at 303 [35].

taken to have impliedly warranted to the licensee that the patent is valid¹⁴⁰. But this issue was not thoroughly argued in this Court, is arguably outside the terms of the notice of contention, and is not necessary to decide.

122 The notice of contention must succeed on a different point. It is possible for an implied representation of fact to be misleading or deceptive if the representation, whilst true, is subject to a qualification which is not disclosed. If the qualification is material, then the non-disclosure of that qualification can be misleading¹⁴¹. In this case, any implied representation by Sandoz that the products it sold did not infringe any patent was true at the time the representation was made. But a qualification to such a representation, that there was a remote possibility that a future extension to the term of a patent might permit proceedings to be brought against the purchaser, was not material. That is, there was no material qualification to which any implied representation by Sandoz should have been subject.

123 The primary judge found that the possibility that the term of the Patent might be extended was remote at the time of the settlement agreement in February 2007¹⁴². Her Honour did not suggest that this possibility was any more likely at the time of Sandoz's sales to pharmacists in June 2009. For this reason, Pharma did not establish at trial that the existence of the remote possibility was a sufficiently material qualification to any implied representation that Sandoz's products did not infringe any patent to have the effect that the non-disclosure of that qualification could be misleading or deceptive. There is a distinction between (i) an implied representation that medical practitioners, pharmacists, and patients are legally entitled to prescribe, dispense, or use a pharmaceutical product when they may not presently be so entitled¹⁴³, and (ii) an implied representation that such persons are so entitled but that there is a remote possibility that a future extension to the term of a patent might permit proceedings to be brought against them. Any implied representation to pharmacists by Sandoz would fall within the second category. The remoteness of the possibility is such that the sales by Sandoz did not involve any misleading or deceptive conduct by Sandoz.

140 *Suhr v Crofts (Engineers) Ltd* (1932) 49 RPC 359 at 366. See also Johnson, Roughton and Cook, *The Modern Law of Patents*, 3rd ed (2014) at 568 [10.79]; *Terrell on the Law of Patents*, 19th ed (2020) at 564 [16-82].

141 *Miller & Associates Insurance Broking Pty Ltd v BMW Australia Finance Ltd* (2010) 241 CLR 357 at 371 [23].

142 *H Lundbeck A/S v Sandoz Pty Ltd* (2018) 137 IPR 408 at 483 [290]-[291].

143 See, eg, *Sanofi-Aventis Australia Pty Ltd v Apotex Pty Ltd [No 3]* (2011) 196 FCR 1 at 81 [276], 83 [281].

41.

Conclusion

124

Orders should be made as proposed in the joint judgment.