Form 33

Rule 16.32

Defence to the Second Further Amended Statement of Claim

No. VID1395 of 2024

Federal Court of Australia

District Registry: Victoria

Division: General

BADEN GREEN

Applicant

JOHNSON & JOHNSON PTY LIMITED (ACN 001 121 446)

Respondent

A. PARTIES **3**

A.1 Applicant **3**

A.2 Group Members **3**

A.3 Respondent **3**

B. J&J PACIFIC ORAL PE PRODUCTS **3**

B.1 Product Range **3**

Benadryl Mucus Relief Plus Decongestant Oral Liquid 3
Benadryl PE Chesty Cough & Nasal Congestion Oral Liquid 5
Benadryl PE Dry Cough & Nasal Congestion Oral Liquid 5
Codral Cold & Flu 6
Codral Cold & Flu (Reformulation 2) 7
Codral Cold & Flu Oral Powder 8
Codral Cold & Flu + Dry Cough 9
Codral Cold & Flu + Mucus Cough 10
Codral Cold & Flu + Mucus Cough Oral Powder 12

Filed on behalf of (name & role of party) Johnson & Johnson Pacific Pty Limited (ACN 001 121 446)
Prepared by (name of person/lawyer) Herbert Smith Freehills Kramer and counsel
Law firm (if applicable) Herbert Smith Freehills Kramer
Tel +61 2 9225 5000 Fax +61 2 9322 4000
Email Jason.Betts@hsfkramer.com
Address for service (include state and postcode) Level 33, 161 Castlereagh Street SYDNEY NSW 2000

Codral Day & Night 13
Codral Day & Night Cold & Flu (New Formula) 14
Codral Day & Night + Dry Cough 15
Codral Decongestant 16
Codral Dry Cough + Cold Oral Liquid 17
Codral Mucus Cough + Cold Oral Liquid 18
Codral Multi Action 19
Codral Night 20
Codral Plus 21
Codral Plus Mucus Cough + Cold & Flu 22
Codral Relief Cold & Flu + Decongestant 24
Sinutab PE Sinus, Allergy & Pain Relief 25
Sudafed PE Nasal Decongestant 25
Sudafed PE Night 26
Sudafed PE Sinus + Allergy & Pain Relief 27
Sudafed PE Sinus + Anti Inflammatory Pain Relief 28
Sudafed PE Sinus + Pain Relief 29
Sudafed PE Sinus + Pain Relief Day & Night 30

B.2 Common characteristics of the J&J Pacific Oral PE Products 31

B.3 J&J Pacific's Packaging, Distribution, and Marketing 32

B.4 Consumer Guarantees 35
Nasal Decongestant Acceptable Quality Guarantee 36
Nasal Decongestant Description Guarantee 36
Nasal Decongestant Express Warranty Guarantee 36

C. APPLICANT AND GROUP MEMBERS PURCHASE J&J PACIFIC ORAL PE PRODUCTS 37

D. ALLEGED INEFFICACY OF PHENYLEPHRINE (AND THE J&J PACIFIC ORAL PE PRODUCTS) 37

E. ALLEGED ACL CONTRAVENTIONS 38

E.1 J&J Pacific's Alleged Consumer Guarantee Failures 38

F. ALLEGED LOSS AND DAMAGE AND DIMINUTION IN VALUE 38

F.1 J&J Pacific's Alleged Consumer Guarantee Failures Diminution in Value and Loss and Damage 38

G. RELIEF 39

H. LIMITATION PERIODS 39

A. PARTIES

A.1 Applicant

1. The Respondent does not know and therefore cannot admit paragraph 1 of the Second Further Amended Statement of Claim (**Claim**).

A.2 Group Members

2. In respect of paragraph 2 of the Claim, the Respondent:

   (a) refers to and repeats paragraph 1 above; and

   (b) otherwise admits paragraph 2 of the Claim.

3. The Respondent does not know and therefore cannot admit paragraph 3 of the Claim.

A.3 Respondent

4. In respect of paragraph 4 of the Claim, the Respondent:

   (a) says that its registered business name is Johnson & Johnson Pacific Pty Ltd (ACN 001 121 446); and

   (b) otherwise admits paragraph 4 of the Claim.

5. In respect of paragraph 5 of the Claim, the Respondent:

   (a) says that Johnson & Johnson Pty Ltd was first registered on 11 February 1931;

   (b) says further that in the period from 2001, Johnson & Johnson Pty Ltd has been a corporation within the meaning of the Corporations Act; and

   (c) otherwise denies paragraph 5 of the Claim.

B. J&J PACIFIC ORAL PE PRODUCTS

B.1 Product Range

6. In respect of paragraph 6 of the Claim, the Respondent:

   (a) admits the definition as adopted;

   (b) repeats paragraphs 7, 11, 15, 19, 23, 27, 31, 35, 39, 43, 47, 51, 55, 59, 63, 67, 71, 75, 80, 84, 88, 92, 96, 100, 104, 108 and 112 below; and

   (c) otherwise denies paragraph 6 of the Claim.

Benadryl Mucus Relief Plus Decongestant Oral Liquid

7. In respect of paragraph 7 of the Claim, the Respondent:

(a) says 21 September 2010 is the Australian Register of Therapeutic Goods (**ARTG**) Start Date of Benadryl Mucus Relief Plus Decongestant Oral Liquid;

(b) says that it was the distributor of Benadryl Mucus Relief Plus Decongestant Oral Liquid from when it first distributed that product to a wholesaler or retailer in or from approximately the second quarter of the 2011 calendar year;

(c) says that it caused or permitted its trading name to be applied to the covering labels and boxes by which Benadryl Mucus Relief Plus Decongestant Oral Liquid is supplied from when it first distributed the product to a wholesaler or retailer from approximately the second quarter of the 2011 calendar year;

(d) says it marketed Benadryl Mucus Relief Plus Decongestant Oral Liquid through its marketing channels from when it first distributed the product to a wholesaler or retailer in or from approximately the second quarter of the 2011 calendar year;

(e) says that sometime prior to December 2019, the Respondent stopped distributing Benadryl Mucus Relief Plus Decongestant Oral Liquid and in approximately December 2019, it was removed from sale by retailers;

(f) denies that it produced Benadryl Mucus Relief Plus Decongestant Oral Liquid;

(g) denies that it imported Benadryl Mucus Relief Plus Decongestant Oral Liquid; and

(h) otherwise denies paragraph 7 of the Claim.

8. In respect of paragraph 8 of the Claim, the Respondent:

(a) refers to and repeats paragraph 7 above;

(b) admits that in or from approximately the second quarter of the 2011 calendar year, it was the manufacturer of Benadryl Mucus Relief Plus Decongestant Oral Liquid within the meaning of section 7 of the *Competition and Consumer Act 2010* (Cth), Sch 2, Australian Consumer Law (**ACL**);

(c) denies that in the period on and from 1 January 2011 up until approximately the second quarter of the 2011 calendar year, being before the product was distributed, it was the manufacturer of Benadryl Mucus Relief Plus Decongestant Oral Liquid within the meaning of section 7 of the ACL; and

(d) otherwise does not know and therefore cannot admit paragraph 8 of the Claim.

9. The Respondent admits paragraph 9 of the Claim.

10. The Respondent admits paragraph 10 of the Claim.

Benadryl PE Chesty Cough & Nasal Congestion Oral Liquid

11. In respect of paragraph 11 of the Claim, the Respondent:

    (a) says that the product is called Benadryl PE Chesty Cough & Nasal Congestion Oral Liquid;

    (b) says 16 April 2008 is the ARTG Start Date of Benadryl PE Chesty Cough & Nasal Congestion Oral Liquid;

    (c) says that it was the distributor of Benadryl PE Chesty Cough & Nasal Congestion Oral Liquid from when it first distributed that product to a wholesaler or retailer in or from approximately the third quarter of the 2008 calendar year;

    (d) says that it caused or permitted its trading name to be applied to the covering labels and boxes by which Benadryl PE Chesty Cough & Nasal Congestion Oral Liquid is supplied from when it first distributed the product to a wholesaler or retailer from approximately the third quarter of the 2008 calendar year;

    (e) says it marketed Benadryl PE Chesty Cough & Nasal Congestion Oral Liquid through its marketing channels from when it first distributed the product to a wholesaler or retailer in or from approximately the third quarter of the 2008 calendar year;

    (f) denies that it produced Benadryl PE Chesty Cough & Nasal Congestion Oral Liquid;

    (g) denies that it imported Benadryl PE Chesty Cough & Nasal Congestion Oral Liquid; and otherwise denies paragraph 11 of the Claim.

12. In respect of paragraph 12 of the Claim, the Respondent:

    (a) refers to and repeats paragraph 11 above;

    (b) admits that on and after 1 January 2011, it was the manufacturer of Benadryl PE Chesty Cough & Nasal Congestion Oral Liquid within the meaning of section 7 of the ACL; and

    (c) otherwise does not know and therefore cannot admit paragraph 12 of the Claim.

13. The Respondent admits paragraph 13 of the Claim.

14. The Respondent admits paragraph 14 of the Claim.

Benadryl PE Dry Cough & Nasal Congestion Oral Liquid

15. In respect of paragraph 15 of the Claim, the Respondent:

    (a) says 4 March 2008 is the ARTG Start Date of Benadryl PE Dry Cough & Nasal Congestion Oral Liquid;

(b) says that it was the distributor of Benadryl PE Dry Cough & Nasal Congestion Oral Liquid from when it first distributed that product to a wholesaler or retailer in or from approximately the fourth quarter of the 2008 calendar year;

(c) says that it caused or permitted its trading name to be applied to the covering labels and boxes by which Benadryl PE Dry Cough & Nasal Congestion Oral Liquid is supplied from when it first distributed the product to a wholesaler or retailer from approximately the fourth quarter of the 2008 calendar year;

(d) says it marketed Benadryl PE Dry Cough & Nasal Congestion Oral Liquid through its marketing channels from when it first distributed the product to a wholesaler or retailer in or from approximately the fourth quarter of the 2008 calendar year;

(e) denies that it produced Benadryl PE Dry Cough & Nasal Congestion Oral Liquid;

(f) denies that it imported Benadryl PE Dry Cough & Nasal Congestion Oral Liquid; and

(g) otherwise denies paragraph 15 of the Claim.

16. In respect of paragraph 16 of the Claim, the Respondent:

(a) refers to and repeats paragraph 15 above;

(b) admits that on and after 1 January 2011, it was the manufacturer of Benadryl PE Dry Cough & Nasal Congestion Oral Liquid within the meaning of section 7 of the ACL; and

(c) otherwise does not know and therefore cannot admit paragraph 16 of the Claim.

17. The Respondent admits paragraph 17 of the Claim.

18. The Respondent admits paragraph 18 of the Claim.

Codral Cold & Flu

19. In respect of paragraph 19 of the Claim, the Respondent:

(a) says 11 May 2016 is the ARTG Start Date of Codral Cold & Flu;

(b) says that it was the distributor of Codral Cold & Flu from when it first distributed that product to a wholesaler or retailer in or from approximately the third quarter of the 2017 calendar year;

(c) says that it caused or permitted its trading name to be applied to the covering labels and boxes by which Codral Cold & Flu is supplied from when it first distributed the product to a wholesaler or retailer from approximately the third quarter of the 2017 calendar year;

(d) says it marketed Codral Cold & Flu through its marketing channels from when it first distributed the product to a wholesaler or retailer in or from approximately the third quarter of the 2017 calendar year;

(e) denies that it produced Codral Cold & Flu;

(f) denies that it imported Codral Cold & Flu;

(g) and otherwise denies paragraph 19 of the Claim.

20. In respect of paragraph 20 of the Claim, the Respondent:

(a) refers to and repeats paragraph 19 above;

(b) admits that in or from approximately the third quarter of the 2017 calendar year, it was the manufacturer of Codral Cold & Flu within the meaning of section 7 of the ACL;

(c) denies that in the period on and from 1 January 2011 up until approximately the third quarter of the 2017 calendar year, being before the product was distributed, it was the manufacturer of Codral Cold & Flu within the meaning of section 7 of the ACL; and

(d) otherwise does not know and therefore cannot admit paragraph 20 of the Claim.

21. The Respondent admits paragraph 21 of the Claim.

22. The Respondent admits paragraph 22 of the Claim.

Codral Cold & Flu (Reformulation 2)

23. In respect of paragraph 23 of the Claim, the Respondent:

(a) says that the name of this product:

(i) recorded on the ARTG was Codral Cold & Flu tablet blister pack (reformulation 2); and

(ii) recorded on the product's packaging was Codral Cold & Flu New Formula, and is referred to, for the purposes of the Claim, as **Codral Cold & Flu** (**Reformulation 2**);

(b) says 12 October 2005 is the ARTG Start Date of Codral Cold & Flu (Reformulation 2);

(c) says that it was the distributor of Codral Cold & Flu (Reformulation 2) from when it first distributed that product to a wholesaler or retailer in or from approximately the third quarter of the 2007 calendar year;

(d) says that it caused or permitted its trading name to be applied to the covering labels and boxes by which Codral Cold & Flu (Reformulation 2) is supplied from when it first distributed the product to a wholesaler or retailer from approximately the third quarter of the 2007 calendar year;

(e) says it marketed Codral Cold & Flu (Reformulation 2) through its marketing channels from when it first distributed the product to a wholesaler or retailer in or from approximately the third quarter of the 2007 calendar year;

(f) says that sometime prior to April 2018, the Respondent stopped distributing Codral Cold & Flu (Reformulation 2) and in approximately April 2018 it was removed from sale by retailers;

(g) denies that it produced Codral Cold & Flu (Reformulation 2);

(h) denies that it imported Codral Cold & Flu (Reformulation 2); and

(i) otherwise denies paragraph 23 of the Claim.

24. In respect of paragraph 24 of the Claim, the Respondent:

(a) refers to and repeats paragraph 23 above;

(b) admits that on and after 1 January 2011, it was the manufacturer of Codral Cold & Flu (Reformulation 2) within the meaning of section 7 of the ACL; and

(c) otherwise does not know and therefore cannot admit paragraph 24 of the Claim.

25. The Respondent admits paragraph 25 of the Claim.

26. The Respondent admits paragraph 26 of the Claim.

Codral Cold & Flu Oral Powder

27. In respect of paragraph 27 of the Claim, the Respondent:

(a) says that prior to around 4 April 2019 the product was known as Codral Relief Max Cold & Flu + Decongestant;

(b) says 25 March 2011 is the ARTG Start Date of Codral Cold & Flu Oral Powder (then called Codral Relief Max Cold & Flu + Decongestant);

(c) says that it was the distributor of Codral Cold & Flu Oral Powder from when it first distributed that product (then called Codral Relief Max Cold & Flu + Decongestant) to a wholesaler or retailer in or from approximately the first quarter of the 2012 calendar year;

(d) says that it caused or permitted its trading name to be applied to the covering labels and boxes by which Codral Cold & Flu Oral Powder is supplied from when it first distributed the product (then called Codral Relief Max Cold & Flu +

Decongestant) to a wholesaler or retailer from approximately the first quarter of the 2012 calendar year;

(e) says it marketed Codral Cold & Flu Oral Powder through its marketing channels from when it first distributed the product (then called Codral Relief Max Cold & Flu + Decongestant) to a wholesaler or retailer in or from approximately the first quarter of the 2012 calendar year;

(f) denies that it produced Codral Cold & Flu Oral Powder (previously called Codral Relief Max Cold & Flu + Decongestant);

(g) denies that it imported Codral Cold & Flu Oral Powder (previously called Codral Relief Max Cold & Flu + Decongestant); and

(h) otherwise denies paragraph 27 of the Claim.

28. In respect of paragraph 28 of the Claim, the Respondent:

(a) refers to and repeats paragraph 27 above;

(b) admits that in or from approximately the first quarter of the 2012 calendar year, it was the manufacturer of Codral Cold & Flu Oral Powder (then called Codral Relief Max Cold & Flu + Decongestant) within the meaning of section 7 of the ACL;

(c) denies that in the period on and from 1 January 2011 up until approximately the first quarter of the 2012 calendar year, being before the product was distributed, it was the manufacturer of Codral Cold & Flu Oral Powder (previously called Codral Relief Max Cold & Flu + Decongestant) within the meaning of section 7 of the ACL; and

(d) otherwise does not know and therefore cannot admit paragraph 28 of the Claim.

29. In respect of paragraph 29 of the Claim, the Respondent:

(a) identifies that each sachet contains 12.2mg of phenylephrine hydrochloride; and

(b) otherwise admits paragraph 29 of the Claim.

30. The Respondent admits paragraph 30 of the Claim.

Codral Cold & Flu + Dry Cough

31. In respect of paragraph 31 of the Claim, the Respondent:

(a) says that prior to around 17 July 2019 the product was known as Codral Multi Action + Cough;

(b) says 26 April 2017 is the ARTG Start Date of Codral Cold & Flu + Dry Cough (then called Codral Multi Action + Cough);

(c) says that it was the distributor of Codral Cold & Flu + Dry Cough from when it first distributed that product (then called Codral Multi Action + Cough) to a wholesaler or retailer in or from approximately the fourth quarter of the 2017 calendar year;

(d) says that it caused or permitted its trading name to be applied to the covering labels and boxes by which Codral Cold & Flu + Dry Cough is supplied from when it first distributed the product (then called Codral Multi Action + Cough) to a wholesaler or retailer from approximately the fourth quarter of the 2017 calendar year;

(e) says it marketed Codral Cold & Flu + Dry Cough through its marketing channels from when it first distributed the product (then called Codral Multi Action + Cough) to a wholesaler or retailer in or from approximately the fourth quarter of the 2017 calendar year;

(f) denies that it produced Codral Cold & Flu + Dry Cough (previously called Codral Multi Action + Cough);

(g) denies that it imported Codral Cold & Flu + Dry Cough (previously called Codral Multi Action + Cough); and

(h) otherwise denies paragraph 31 of the Claim.

32. In respect of paragraph 32 of the Claim, the Respondent:

(a) refers to and repeats paragraph 31 above;

(b) admits that in or from approximately the fourth quarter of the 2017 calendar year, it was the manufacturer of Codral Cold & Flu + Dry Cough (then called Codral Multi Action + Cough) within the meaning of section 7 of the ACL;

(c) denies that in the period on and from 1 January 2011 up until approximately the fourth quarter of the 2017 calendar year, being before the product was distributed, it was the manufacturer of Codral Cold & Flu + Dry Cough (previously called Codral Multi Action + Cough) within the meaning of section 7 of the ACL; and

(d) otherwise does not know and therefore cannot admit paragraph 28 of the Claim.

33. The Respondent admits paragraph 33 of the Claim.

34. The Respondent admits paragraph 34 of the Claim.

Codral Cold & Flu + Mucus Cough

35. In respect of paragraph 35 of the Claim, the Respondent:

(a) says that prior to around 4 April 2019 the product was known as Codral Relief 6 Signs Cold & Flu;

(b) says 31 October 2011 is the ARTG Start Date of Codral Cold & Flu + Mucus Cough (then called Codral Relief 6 Signs Cold & Flu);

(c) says that it was the distributor of Codral Cold & Flu + Mucus Cough from when it first distributed that product (then called Codral Relief 6 Signs Cold & Flu) to a wholesaler or retailer in or from approximately the first quarter of the 2013 calendar year;

(d) says that it caused or permitted its trading name to be applied to the covering labels and boxes by which Codral Cold & Flu + Mucus Cough is supplied from when it first distributed the product (then called Codral Relief 6 Signs Cold & Flu) to a wholesaler or retailer from approximately the first quarter of the 2013 calendar year;

(e) says it marketed Codral Cold & Flu + Mucus Cough through its marketing channels from when it first distributed the product (then called Codral Relief 6 Signs Cold & Flu) to a wholesaler or retailer in or from approximately the first quarter of the 2013 calendar year;

(f) denies that it produced Codral Cold & Flu + Mucus Cough (previously called Codral Relief 6 Signs Cold & Flu);

(g) denies that it imported Codral Cold & Flu + Mucus Cough (previously called Codral Relief 6 Signs Cold & Flu); and

(h) otherwise denies paragraph 35 of the Claim.

36. In respect of paragraph 36 of the Claim, the Respondent:

(a) refers to and repeats paragraph 35 above;

(b) admits that in or from approximately the first quarter of the 2013 calendar year, it was the manufacturer of Codral Cold & Flu + Mucus Cough (then called Codral Relief 6 Signs Cold & Flu) within the meaning of section 7 of the ACL;

(c) denies that in the period on and from 1 January 2011 up until approximately the first quarter of the 2013 calendar year, being before the product was distributed, it was the manufacturer of Codral Cold & Flu + Mucus Cough (previously called Codral Relief 6 Signs Cold & Flu) within the meaning of section 7 of the ACL; and

(d) otherwise does not know and therefore cannot admit paragraph 36 of the Claim.

37. The Respondent admits paragraph 37 of the Claim.

38. The Respondent admits paragraph 38 of the Claim.

Codral Cold & Flu + Mucus Cough Oral Powder

39. In respect of paragraph 39 of the Claim, the Respondent:

    (a) says prior to around 4 April 2019 the product was known as Codral Relief Max Strength 6 Signs Cold & Flu Hot Drink;

    (b) says 31 October 2011 is the ARTG Start Date of Codral Cold & Flu + Mucus Cough Oral Powder (then called Codral Relief Max Strength 6 Signs Cold & Flu Hot Drink);

    (c) says that it was the distributor of Codral Cold & Flu + Mucus Cough Oral Powder from when it first distributed that product (then called Codral Relief Max Strength 6 Signs Cold & Flu Hot Drink) to a wholesaler or retailer in or from approximately the first quarter of the 2013 calendar year;

    (d) says that it caused or permitted its trading name to be applied to the covering labels and boxes by which Codral Cold & Flu + Mucus Cough Oral Powder is supplied from when it first distributed the product (then called Codral Relief Max Strength 6 Signs Cold & Flu Hot Drink) to a wholesaler or retailer from approximately the first quarter of the 2013 calendar year;

    (e) says it marketed Codral Cold & Flu + Mucus Cough Oral Powder through its marketing channels from when it first distributed the product (then called Codral Relief Max Strength 6 Signs Cold & Flu Hot Drink) to a wholesaler or retailer in or from approximately the first quarter of the 2013 calendar year;

    (f) denies that it produced Codral Cold & Flu + Mucus Cough Oral Powder (previously called Codral Relief Max Strength 6 Signs Cold & Flu Hot Drink);

    (g) denies that it imported Codral Cold & Flu + Mucus Cough Oral Powder (previously called Codral Relief Max Strength 6 Signs Cold & Flu Hot Drink); and

    (h) otherwise denies paragraph 39 of the Claim.

40. In respect of paragraph 40 of the Claim, the Respondent:

    (a) refers to and repeats paragraph 39 above;

    (b) admits that in or from approximately the first quarter of the 2013 calendar year, it was the manufacturer of Codral Cold & Flu + Mucus Cough Oral Powder (then called Codral Relief Max Strength 6 Signs Cold & Flu Hot Drink) within the meaning of section 7 of the ACL;

    (c) denies that in the period on and from 1 January 2011 up until approximately the first quarter of the 2013 calendar year, being before the product was distributed, it was the manufacturer of Codral Cold & Flu + Mucus Cough Oral Powder

(previously called Codral Relief Max Strength 6 Signs Cold & Flu Hot Drink) within the meaning of section 7 of the ACL; and

(d) otherwise does not know and therefore cannot admit paragraph 40 of the Claim.

41. In respect of paragraph 41 of the Claim, the Respondent:

(a) says that at all material times, the Codral Cold & Flu + Mucus Cough Oral Powder packaging identifies that each sachet contains 12.2mg of phenylephrine hydrochloride; and

(b) otherwise admits paragraph 41 of the Claim.

42. The Respondent admits paragraph 42 of the Claim.

Codral Day & Night

43. In respect of paragraph 43 of the Claim, the Respondent:

(a) says 11 May 2016 is the ARTG Start Date of Codral Day & Night;

(b) says that it was the distributor of Codral Day & Night from when it first distributed that product to a wholesaler or retailer in or from approximately the third quarter of the 2017 calendar year;

(c) says that it caused or permitted its trading name to be applied to the covering labels and boxes by which Codral Day & Night is supplied from when it first distributed the product to a wholesaler or retailer from approximately the third quarter of the 2017 calendar year;

(d) says it marketed Codral Day & Night through its marketing channels from when it first distributed the product to a wholesaler or retailer in or from approximately the third quarter of the 2017 calendar year;

(e) denies that it produced Codral Day & Night;

(f) denies that it imported Codral Day & Night; and

(g) otherwise denies paragraph 43 of the Claim.

44. In respect of paragraph 44 of the Claim, the Respondent:

(a) refers to and repeats paragraph 43 above;

(b) admits that in or from approximately the third quarter of the 2017 calendar year, it was the manufacturer of Codral Day & Night within the meaning of section 7 of the ACL;

(c) denies that in the period on and from 1 January 2011 up until approximately the third quarter of the 2017 calendar year, being before the product was distributed,

it was the manufacturer of Codral Day & Night within the meaning of section 7 of the ACL; and

(d) otherwise does not know and therefore cannot admit paragraph 44 of the Claim.

45. The Respondent admits paragraph 45 of the Claim.

46. The Respondent admits paragraph 46 of the Claim.

Codral Day & Night Cold & Flu (New Formula)

47. In respect of paragraph 47 of the Claim, the Respondent:

(a) says that the product is called Codral Day & Night Cold & Flu (New formula);

(b) says 15 August 2005 is the ARTG Start Date of Codral Day & Night Cold & Flu (New formula);

(c) says that it was the distributor of Codral Day & Night Cold & Flu (New formula) from when it first distributed that product to a wholesaler or retailer in or from approximately the third quarter of the 2007 calendar year;

(d) says that it caused or permitted its trading name to be applied to the covering labels and boxes by which Codral Day & Night Cold & Flu (New formula) is supplied from when it first distributed the product to a wholesaler or retailer from approximately the third quarter of the 2007 calendar year;

(e) says it marketed Codral Day & Night Cold & Flu (New formula) through its marketing channels from when it first distributed the product to a wholesaler or retailer in or from approximately the third quarter of the 2007 calendar year;

(f) says that sometime prior to February 2018, the Respondent stopped distributing Codral Day & Night Cold & Flu (New formula) and in approximately February 2018 it was removed from sale by retailers;

(g) denies that it produced Codral Day & Night Cold & Flu (New formula);

(h) denies that it imported Codral Day & Night Cold & Flu (New formula); and

(i) otherwise denies paragraph 47 of the Claim.

48. In respect of paragraph 48 of the Claim, the Respondent:

(a) refers to and repeats paragraph 47 above;

(b) admits that on and after 1 January 2011, it was the manufacturer of Codral Day & Night Cold & Flu (New formula) within the meaning of section 7 of the ACL; and

(c) otherwise does not know and therefore cannot admit paragraph 48 of the Claim.

49. The Respondent admits paragraph 49 of the Claim.

50. The Respondent admits paragraph 50 of the Claim.

Codral Day & Night + Dry Cough

51. In respect of paragraph 51 of the Claim, the Respondent:

    (a) says that prior to around 17 July 2019 the product was known as Codral Cold & Flu + Cough Day & Night;

    (b) says 5 October 2005 is the ARTG Start Date of Codral Day & Night + Dry Cough (then called Codral Cold & Flu + Cough Day & Night);

    (c) says that it was the distributor of Codral Day & Night + Dry Cough from when it first distributed that product (then called Codral Cold & Flu + Cough Day & Night) to a wholesaler or retailer in or from approximately the third quarter of the 2007 calendar year;

    (d) says that it caused or permitted its trading name to be applied to the covering labels and boxes by which Codral Day & Night + Dry Cough is supplied from when it first distributed the product (then called Codral Cold & Flu + Cough Day & Night) to a wholesaler or retailer from approximately the third quarter of the 2007 calendar year;

    (e) says it marketed Codral Day & Night + Dry Cough through its marketing channels from when it first distributed the product (then called Codral Cold & Flu + Cough Day & Night) to a wholesaler or retailer in or from approximately the third quarter of the 2007 calendar year;

    (f) denies that it produced Codral Day & Night + Dry Cough (previously called Codral Cold & Flu + Cough Day & Night);

    (g) denies that it imported Codral Day & Night + Dry Cough (previously called Codral Cold & Flu + Cough Day & Night); and

    (h) otherwise denies paragraph 51 of the Claim.

52. In respect of paragraph 52 of the Claim, the Respondent:

    (a) refers to and repeats paragraph 51 above;

    (b) admits that on and after 1 January 2011, it was the manufacturer of Codral Day & Night + Dry Cough (previously called Codral Cold & Flu + Cough Day & Night) within the meaning of section 7 of the ACL; and

    (c) otherwise does not know and therefore cannot admit paragraph 52 of the Claim.

53. The Respondent admits paragraph 53 of the Claim.

54. The Respondent admits paragraph 54 of the Claim.

Codral Decongestant

55. In respect of paragraph 55 of the Claim, the Respondent:

(a) says prior to around 29 March 2019 the product was known as Codral Relief Decongestant;

(b) says 1 June 2011 is the ARTG Start Date of Codral Decongestant (then called Codral Relief Decongestant);

(c) says that it was the distributor of Codral Decongestant from when it first distributed that product (then called Codral Relief Decongestant) to a wholesaler or retailer in or from approximately the first quarter of the 2012 calendar year;

(d) says that it caused or permitted its trading name to be applied to the covering labels and boxes by which Codral Decongestant is supplied from when it first distributed the product (then called Codral Relief Decongestant) to a wholesaler or retailer from approximately the first quarter of the 2012 calendar year;

(e) says it marketed Codral Decongestant through its marketing channels from when it first distributed the product (then called Codral Relief Decongestant) to a wholesaler or retailer in or from approximately the first quarter of the 2012 calendar year;

(f) says that sometime prior to December 2021, the Respondent stopped distributing Codral Decongestant (previously called Codral Relief Decongestant) and in approximately December 2021 it was removed from sale by retailers (with a small number of residual sales continuing after this time);

(g) denies that it produced Codral Decongestant (previously called Codral Relief Decongestant);

(h) denies that it imported Codral Decongestant (previously called Codral Relief Decongestant); and

(i) otherwise denies paragraph 55 of the Claim.

56. In respect of paragraph 56 of the Claim, the Respondent:

(a) refers to and repeats paragraph 55 above;

(b) admits that in or from approximately the first quarter of the 2012 calendar year, it was the manufacturer of Codral Decongestant (then called Codral Relief Decongestant) within the meaning of section 7 of the ACL;

(c) denies that in the period on and from 1 January 2011 up until approximately the first quarter of the 2012 calendar year, being before the product was distributed, it

was the manufacturer of Codral Decongestant (previously called Codral Relief Decongestant) within the meaning of section 7 of the ACL; and

(d) otherwise does not know and therefore cannot admit paragraph 56 of the Claim.

57. The Respondent admits paragraph 57 of the Claim.

58. The Respondent admits paragraph 58 of the Claim.

Codral Dry Cough + Cold Oral Liquid

59. In respect of paragraph 59 of the Claim, the Respondent:

(a) says 19 August 2020 is the ARTG Start Date of Codral Dry Cough + Cold Oral Liquid;

(b) says that it was the distributor of Codral Dry Cough + Cold Oral Liquid from when it first distributed that product to a wholesaler or retailer in or from approximately the first quarter of the 2021 calendar year;

(c) says that it caused or permitted its trading name to be applied to the covering labels and boxes by which Codral Dry Cough + Cold Oral Liquid is supplied from when it first distributed the product to a wholesaler or retailer from approximately the first quarter of the 2021 calendar year;

(d) says it marketed Codral Dry Cough + Cold Oral Liquid through its marketing channels from when it first distributed the product to a wholesaler or retailer in or from approximately the first quarter of the 2021 calendar year;

(e) denies that it produced Codral Dry Cough + Cold Oral Liquid;

(f) denies that it imported Codral Dry Cough + Cold Oral Liquid; and

(g) otherwise denies paragraph 59 of the Claim.

60. In respect of paragraph 60 of the Claim, the Respondent:

(a) refers to and repeats paragraph 59 above;

(b) admits that in or from approximately the first quarter of the 2021 calendar year, it was the manufacturer of Codral Dry Cough + Cold Oral Liquid within the meaning of section 7 of the ACL;

(c) denies that in the period on and from 1 January 2011 up until approximately the first quarter of the 2021 calendar year, being before the product was distributed, it was the manufacturer of Codral Dry Cough + Cold Oral Liquid within the meaning of section 7 of the ACL; and

(d) otherwise does not know and therefore cannot admit paragraph 60 of the Claim.

61. The Respondent admits paragraph 61 of the Claim.

62. The Respondent admits paragraph 62 of the Claim.

Codral Mucus Cough + Cold Oral Liquid

63. In respect of paragraph 63 of the Claim, the Respondent:

    (a) says prior to around 24 October 2019 the product was known as Codral Relief Mucus Cough & Cold;

    (b) says 10 August 2011 is the ARTG Start Date of Codral Mucus Cough + Cold Oral Liquid (then called Codral Relief Mucus Cough & Cold);

    (c) says that it was the distributor of Codral Mucus Cough + Cold Oral Liquid from when it first distributed that product (then called Codral Relief Mucus Cough & Cold) to a wholesaler or retailer in or from approximately the first quarter of the 2012 calendar year;

    (d) says that it caused or permitted its trading name to be applied to the covering labels and boxes by which Codral Mucus Cough + Cold Oral Liquid is supplied from when it first distributed the product (then called Codral Relief Mucus Cough & Cold) to a wholesaler or retailer from approximately the first quarter of the 2012 calendar year;

    (e) says it marketed Codral Mucus Cough + Cold Oral Liquid through its marketing channels from when it first distributed the product (then called Codral Relief Mucus Cough & Cold) to a wholesaler or retailer in or from approximately the first quarter of the 2012 calendar year;

    (f) denies that it produced Codral Mucus Cough + Cold Oral Liquid (previously called Codral Relief Mucus Cough & Cold);

    (g) denies that it imported Codral Mucus Cough + Cold Oral Liquid (previously called Codral Relief Mucus Cough & Cold); and

    (h) otherwise denies paragraph 63 of the Claim.

64. In respect of paragraph 64 of the Claim, the Respondent:

    (a) refers to and repeats paragraph 63 above;

    (b) admits that in or from approximately the first quarter of the 2012 calendar year, it was the manufacturer of Codral Mucus Cough + Cold Oral Liquid (then called Codral Relief Mucus Cough & Cold) within the meaning of section 7 of the ACL;

    (c) denies that in the period on and from 1 January 2011 up until approximately the first quarter of the 2012 calendar year, being before the product was distributed, it

was the manufacturer of Codral Mucus Cough + Cold Oral Liquid (previously called Codral Relief Mucus Cough & Cold) within the meaning of section 7 of the ACL; and

(d) otherwise does not know and therefore cannot admit paragraph 64 of the Claim.

65. The Respondent admits paragraph 65 of the Claim.

66. The Respondent admits paragraph 66 of the Claim.

Codral Multi Action

67. In respect of paragraph 67 of the Claim, the Respondent:

(a) says that prior to around July 2013, the product was known as Codral 4 Flu;

(b) says 8 April 2010 is the ARTG Start Date of Codral Multi Action (then called Codral 4 Flu);

(c) says that it was the distributor of Codral Multi Action from when it first distributed that product (then called Codral 4 Flu) to a wholesaler or retailer in or from approximately the fourth quarter of the 2010 calendar year;

(d) says that it caused or permitted its trading name to be applied to the covering labels and boxes by which Codral Multi Action is supplied from when it first distributed the product (then called Codral 4 Flu) to a wholesaler or retailer from approximately the fourth quarter of the 2010 calendar year;

(e) says it marketed Codral Multi Action through its marketing channels from when it first distributed the product (then called Codral 4 Flu) to a wholesaler or retailer in or from approximately the fourth quarter of the 2010 calendar year;

(f) says that the product was available for sale in the following periods:

(i) between the fourth quarter of the 2010 calendar year and approximately August 2014 (with a small number of residual sales from retailers continuing after this time) as Codral 4 Flu; and

(ii) from approximately the first quarter of the 2017 calendar year onwards as Codral Multi Action;

(g) denies that it produced Codral Multi Action (previously called Codral 4 Flu);

(h) denies that it imported Codral Multi Action (previously called Codral 4 Flu); and

(i) otherwise denies paragraph 67 of the Claim.

68. In respect of paragraph 68 of the Claim, the Respondent:

(a) refers to and repeats paragraph 67 above;

(b) admits that on and after 1 January 2011, in the periods when the Respondent distributed the product set out in paragraph 67(f) above, it was the manufacturer of Codral Multi Action (at times called Codral 4 Flu) within the meaning of section 7 of the ACL;

(c) denies that in the periods on and from 1 January 2011 when the product was not distributed, that it was the manufacturer of Codral Multi Action (at times called Codral 4 Flu) within the meaning of section 7 of the ACL; and

(d) otherwise does not know and therefore cannot admit paragraph 68 of the Claim.

69. The Respondent admits paragraph 69 of the Claim.

70. The Respondent admits paragraph 70 of the Claim.

Codral Night

71. In respect of paragraph 71 of the Claim, the Respondent:

(a) says that prior to around 3 August 2017 the product was known as Codral Nightime Cold and Flu;

(b) says 4 November 2005 is the ARTG Start Date of Codral Night (then called Codral Nightime Cold and Flu);

(c) says that it was the distributor of Codral Night from when it first distributed that product (then called Codral Nightime Cold and Flu) to a wholesaler or retailer in or from approximately the third quarter of the 2007 calendar year;

(d) says that it caused or permitted its trading name to be applied to the covering labels and boxes by which Codral Night is supplied from when it first distributed the product (then called Codral Nightime Cold and Flu) to a wholesaler or retailer from approximately the third quarter of the 2007 calendar year;

(e) says it marketed Codral Night through its marketing channels from when it first distributed the product (then called Codral Nightime Cold and Flu) to a wholesaler or retailer in or from approximately the third quarter of the 2007 calendar year;

(f) denies that it produced Codral Night (previously called Codral Nightime Cold and Flu);

(g) denies that it imported Codral Night (previously called Codral Nightime Cold and Flu); and

(h) otherwise denies paragraph 71 of the Claim.

72. In respect of paragraph 72 of the Claim, the Respondent:

(a) refers to and repeats paragraph 71 above;

(b) admits that on and after 1 January 2011, it was the manufacturer of Codral Night (then called Codral Nightime Cold and Flu) within the meaning of section 7 of the ACL; and

(c) otherwise does not know and therefore cannot admit paragraph 72 of the Claim.

73. The Respondent admits paragraph 73 of the Claim.

74. The Respondent admits paragraph 74 of the Claim.

Codral Plus

75. In respect of paragraph 75 of the Claim, the Respondent:

(a) says 12 October 2018 is the ARTG Start Date of Codral Plus;

(b) says that it was the distributor of Codral Plus from when it first distributed that product to a wholesaler or retailer in or from approximately the first quarter of the 2019 calendar year;

(c) says that it caused or permitted its trading name to be applied to the covering labels and boxes by which Codral Plus is supplied from when it first distributed the product to a wholesaler or retailer from approximately the first quarter of the 2019 calendar year;

(d) says it marketed Codral Plus through its marketing channels from when it first distributed the product to a wholesaler or retailer in or from approximately the first quarter of the 2019 calendar year;

(e) says that sometime prior to second quarter of 2025, the Respondent stopped distributing Codral Plus (ARTG 310338) and in approximately the second quarter of 2025 it was removed from sale by retailers;

(f) denies that it produced Codral Plus;

(g) denies that it imported Codral Plus; and

(h) otherwise denies paragraph 75 of the Claim.

76. In respect of paragraph 76 of the Claim, the Respondent:

(a) refers to and repeats paragraph 75 above;

(b) admits that in or from approximately the first quarter of the 2019 calendar year, it was the manufacturer of Codral Plus within the meaning of section 7 of the ACL;

(c) denies that in the period on and from 1 January 2011 up until approximately the first quarter of the 2019 calendar year, being before the product was distributed, it was the manufacturer of Codral Plus within the meaning of section 7 of the ACL; and

(d) otherwise does not know and therefore cannot admit paragraph 76 of the Claim.

77. In respect of paragraph 77 of the Claim, the Respondent:

(a) says that Codral Plus is comprised of two components;

(b) says that the first component was:

(i) from approximately the first quarter of the 2019 calendar year to approximately the first quarter of the 2020 calendar year, called Codral Relief Cold & Flu + Decongestant; and

(ii) from approximately the first quarter of the 2020 calendar year onwards, called Codral Cold & Flu;

(c) says that the second component was called Codral Sore Throat Lozenges Antibacterial + Anaesthetic Lime and Lemon Flavour until approximately the first quarter of the 2020 calendar year when its name changed to Codral Duo Relief Sore Throat Lozenges; and

(d) otherwise denies paragraph 77 of the Claim.

78. In respect of paragraph 78 of the Claim, the Respondent:

(a) says that, from around the first quarter of the 2020 calendar year onwards, Codral Plus included Codral Cold & Flu instead of Codral Relief Cold & Flu + Decongestant;

(b) says Codral Cold & Flu has contained the following active ingredients:

(i) 500mg paracetamol;

(ii) 5mg phenylephrine hydrochloride;

(c) says that from around the first quarter of the 2020 calendar year, Codral Sore Throat Lozenges Antibacterial + Anaesthetic Lime and Lemon Flavour has been called Codral Duo Relief Sore Throat Lozenges; and

(d) otherwise admits paragraph 78 of the Claim.

79. The Respondent admits paragraph 79 of the Claim.

Codral Plus Mucus Cough + Cold & Flu

80. In respect of paragraph 80 of the Claim, the Respondent:

(a) says 23 November 2022 is the ARTG Start Date of Codral Plus Mucus Cough + Cold & Flu;

(b) says that it was the distributor of Codral Plus Mucus Cough + Cold & Flu from when it first distributed that product to a wholesaler or retailer in or from approximately the first quarter of the 2023 calendar year;

(c) says that it caused or permitted its trading name to be applied to the covering labels and boxes by which Codral Plus Mucus Cough + Cold & Flu is supplied from when it first distributed the product to a wholesaler or retailer from approximately the first quarter of the 2023 calendar year;

(d) says it marketed Codral Plus Mucus Cough + Cold & Flu through its marketing channels from when it first distributed the product to a wholesaler or retailer in or from approximately the first quarter of the 2023 calendar year;

(e) says that sometime prior to July 2024, the Respondent stopped distributing Codral Plus Mucus Cough + Cold & Flu and in approximately July 2024 it was removed from sale by retailers (with a small number of residual sales continuing after this time);

(f) denies that it produced Codral Plus Mucus Cough + Cold & Flu;

(g) denies that it imported Codral Plus Mucus Cough + Cold & Flu; and

(h) otherwise denies paragraph 80 of the Claim.

81. In respect of paragraph 81 of the Claim, the Respondent:

(a) refers to and repeats paragraph 80 above;

(b) admits that in or from approximately the first quarter of the 2023 calendar year, it was the manufacturer of Codral Plus Mucus Cough + Cold & Flu within the meaning of section 7 of the ACL;

(c) denies that in the period on and from 1 January 2011 up until approximately the first quarter of the 2023 calendar year, being before the product was distributed, it was the manufacturer of Codral Plus Mucus Cough + Cold & Flu within the meaning of section 7 of the ACL; and

(d) otherwise does not know and therefore cannot admit paragraph 81 of the Claim.

82. In respect of paragraph 82 of the Claim, the Respondent:

(a) says that the Cold & Flu blister pack has, at all material times, contained the following active ingredients:

(i) 500mg paracetamol; and

(ii) 5mg phenylephrine hydrochloride;

(b) otherwise admits paragraph 82 of the Claim.

83. In respect of paragraph 83 of the Claim, the Respondent:

(a) repeats paragraph 82 above; and

(b) otherwise denies paragraph 83 of the Claim.

Codral Relief Cold & Flu + Decongestant

84. In respect of paragraph 84 of the Claim, the Respondent:

(a) says 28 March 2011 is the ARTG Start Date of Codral Relief Cold & Flu + Decongestant;

(b) says that it was the distributor of Codral Relief Cold & Flu + Decongestant from when it first distributed that product to a wholesaler or retailer in or from approximately the first quarter of the 2012 calendar year;

(c) says that it caused or permitted its trading name to be applied to the covering labels and boxes by which Codral Relief Cold & Flu + Decongestant is supplied from when it first distributed the product to a wholesaler or retailer from approximately the first quarter of the 2012 calendar year;

(d) says it marketed Codral Relief Cold & Flu + Decongestant through its marketing channels from when it first distributed the product to a wholesaler or retailer in or from approximately the first quarter of the 2012 calendar year;

(e) says that sometime prior to July 2021, the Respondent stopped distributing Codral Relief Cold & Flu + Decongestant and in approximately July 2021 it was removed from sale by retailers (with a small number of residual sales continuing after this time);

(f) denies that it produced Codral Relief Cold & Flu + Decongestant;

(g) denies that it imported Codral Relief Cold & Flu + Decongestant; and

(h) otherwise denies paragraph 84 of the Claim.

85. In respect of paragraph 85 of the Claim, the Respondent:

(a) refers to and repeats paragraph 84 above;

(b) admits that in or from approximately the first quarter of the 2012 calendar year, it was the manufacturer of Codral Relief Cold & Flu + Decongestant within the meaning of section 7 of the ACL;

(c) denies that in the period on and from 1 January 2011 up until approximately the first quarter of the 2012 calendar year, being before the product was distributed, it was the manufacturer of Codral Relief Cold & Flu + Decongestant within the meaning of section 7 of the ACL; and

(d) otherwise does not know and therefore cannot admit paragraph 85 of the Claim.

86. The Respondent admits paragraph 86 of the Claim.

87. The Respondent admits paragraph 87 of the Claim.

Sinutab PE Sinus, Allergy & Pain Relief

88. In respect of paragraph 88 of the Claim, the Respondent:

(a) says that Sinutab PE Sinus, Allergy & Pain Relief is the previous name of Sudafed PE Night;

(b) refers to and repeats paragraph 96 below; and

(c) otherwise denies paragraph 88 of the Claim.

89. In respect of paragraph 89 of the Claim, the Respondent:

(a) refers to and repeats paragraphs 88 above and 97 below; and

(b) otherwise does not know and cannot admit paragraph 89 of the Claim.

90. In respect of paragraph 90 of the Claim, the Respondent refers to and repeats paragraphs 88 above and 98 below and otherwise does not know and cannot admit the allegations in the paragraph.

91. In respect of paragraph 91 of the Claim, the Respondent refers to and repeats paragraphs 88 above and 99 below and otherwise does not know and cannot admit the allegations in the paragraph.

Sudafed PE Nasal Decongestant

92. In respect of paragraph 92 of the Claim, the Respondent:

(a) says 19 January 2005 is the ARTG Start Date of Sudafed PE Nasal Decongestant;

(b) says that it was the distributor of Sudafed PE Nasal Decongestant from when it first distributed that product to a wholesaler or retailer in or from approximately the third quarter of the 2007 calendar year;

(c) says that it caused or permitted its trading name to be applied to the covering labels and boxes by which Sudafed PE Nasal Decongestant is supplied from when it first distributed the product to a wholesaler or retailer from approximately the third quarter of the 2007 calendar year;

(d) says it marketed Sudafed PE Nasal Decongestant through its marketing channels from when it first distributed the product to a wholesaler or retailer in or from approximately the third quarter of the 2007 calendar year;

(e) denies that it produced Sudafed PE Nasal Decongestant;

(f) denies that it imported Sudafed PE Nasal Decongestant; and

(g) otherwise denies paragraph 92 of the Claim.

93. In respect of paragraph 93 of the Claim, the Respondent:

(a) refers to and repeats paragraph 92 above;

(b) admits that on and after 1 January 2011, it was the manufacturer of Sudafed PE Nasal Decongestant within the meaning of section 7 of the ACL; and

(c) otherwise does not know and therefore cannot admit paragraph 93 of the Claim.

94. The Respondent admits paragraph 94 of the Claim.

95. The Respondent admits paragraph 95 of the Claim.

Sudafed PE Night

96. In response to paragraph 96 of the Claim, the Respondent:

(a) says that prior to around March 2014 the product was known as Sinutab PE Sinus, Allergy & Pain Relief;

(b) says 25 October 2005 is the ARTG Start Date of Sudafed PE Night (then called Sinutab PE Sinus, Allergy & Pain Relief);

(c) says that it was the distributor of Sudafed PE Night from when it first distributed that product (then called Sinutab PE Sinus, Allergy & Pain Relief) to a wholesaler or retailer in or from approximately the fourth quarter of the 2008 calendar year;

(d) says that it caused or permitted its trading name to be applied to the covering labels and boxes by which Sudafed PE Night is supplied from when it first distributed the product (then called Sinutab PE Sinus, Allergy & Pain Relief) to a wholesaler or retailer from approximately the fourth quarter of the 2008 calendar year;

(e) says it marketed Sudafed PE Night through its marketing channels from when it first distributed the product (then called Sinutab PE Sinus, Allergy & Pain Relief) to a wholesaler or retailer in or from approximately the fourth quarter of the 2008 calendar year;

(f) says that the product was available for sale in the following periods:

(i) between the fourth quarter of the 2008 calendar year and the first quarter of the 2012 calendar year as Sinutab PE Sinus, Allergy & Pain Relief; and

(ii) between the first quarter of the 2015 calendar year until approximately September 2018 as Sinutab PE Night;

(g) says that sometime prior to September 2018, the Respondent stopped distributing Sudafed PE Night (previously called Sinutab PE Sinus, Allergy & Pain Relief) and in approximately September 2018 it was removed from sale by retailers;

(h) denies that it produced Sudafed PE Night;

(i) denies that it imported Sudafed PE Night; and

(j) otherwise denies paragraph 96 of the Claim.

97. In respect of paragraph 97 of the Claim, the Respondent:

(a) refers to and repeats paragraph 96 above;

(b) admits that on and after 1 January 2011, in the periods when the Respondent distributed the product set out in paragraph 96(f) above, it was the manufacturer of Sudafed PE Night (at times called Sinutab PE Sinus, Allergy & Pain Relief) within the meaning of section 7 of the ACL;

(c) denies that in the periods on and from 1 January 2011 when the product was not distributed, that it was the manufacturer of Sudafed PE Night (at times called Sinutab PE Sinus, Allergy & Pain Relief) within the meaning of section 7 of the ACL; and

(d) otherwise does not know and therefore cannot admit paragraph 97 of the Claim.

98. The Respondent admits paragraph 98 of the Claim.

99. The Respondent admits paragraph 99 of the Claim.

Sudafed PE Sinus + Allergy & Pain Relief

100. In respect of paragraph 100 of the Claim, the Respondent:

(a) says 21 June 2005 is the ARTG Start Date of Sudafed PE Sinus + Allergy & Pain Relief;

(b) says that it was the distributor of Sudafed PE Sinus + Allergy & Pain Relief from when it first distributed that product to a wholesaler or retailer in or from approximately the third quarter of the 2007 calendar year;

(c) says that it caused or permitted its trading name to be applied to the covering labels and boxes by which Sudafed PE Sinus + Allergy & Pain Relief is supplied

from when it first distributed the product to a wholesaler or retailer from approximately the third quarter of the 2007 calendar year;

(d) says it marketed Sudafed PE Sinus + Allergy & Pain Relief through its marketing channels from when it first distributed the product to a wholesaler or retailer in or from approximately the third quarter of the 2007 calendar year;

(e) denies that it produced Sudafed PE Sinus + Allergy & Pain Relief;

(f) denies that it imported Sudafed PE Sinus + Allergy & Pain Relief; and

(g) otherwise denies paragraph 100 of the Claim.

101. In respect of paragraph 101 of the Claim, the Respondent:

(a) refers to and repeats paragraph 100 above;

(b) admits that on and after 1 January 2011, it was the manufacturer of Sudafed PE Sinus + Allergy & Pain Relief within the meaning of section 7 of the ACL; and

(c) otherwise does not know and therefore cannot admit paragraph 101 of the Claim.

102. The Respondent admits paragraph 102 of the Claim.

103. The Respondent admits paragraph 103 of the Claim.

Sudafed PE Sinus + Anti Inflammatory Pain Relief

104. In respect of paragraph 104 of the Claim, the Respondent:

(a) says 27 August 2009 is the ARTG Start Date of Sudafed PE Sinus & Anti Inflammatory Pain Relief (which has been used interchangeably with Sudafed PE Sinus + Anti Inflammatory Pain Relief);

(b) says that it was the distributor of Sudafed PE Sinus + Anti Inflammatory Pain Relief from when it first distributed that product to a wholesaler or retailer in or from approximately the second quarter of the 2011 calendar year;

(c) says that it caused or permitted its trading name to be applied to the covering labels and boxes by which Sudafed PE Sinus + Anti Inflammatory Pain Relief is supplied from when it first distributed the product to a wholesaler or retailer from approximately the second quarter of the 2011 calendar year;

(d) says it marketed Sudafed PE Sinus + Anti Inflammatory Pain Relief through its marketing channels from when it first distributed the product to a wholesaler or retailer in or from approximately the second quarter of the 2011 calendar year;

(e) denies that it produced Sudafed PE Sinus + Anti Inflammatory Pain Relief;

(f) denies that it imported Sudafed PE Sinus + Anti Inflammatory Pain Relief; and

(g) otherwise denies paragraph 104 of the Claim.

105. In respect of paragraph 105 of the Claim, the Respondent:

(a) refers to and repeats paragraph 104 above;

(b) admits that in or from approximately the second quarter of the 2011 calendar year, it was the manufacturer of Sudafed PE Sinus + Anti Inflammatory Pain Relief within the meaning of section 7 of the ACL;

(c) denies that in the period on and from 1 January 2011 up until approximately the second quarter of the 2011 calendar year, being before the product was distributed, it was the manufacturer of Sudafed PE Sinus + Anti Inflammatory Pain Relief within the meaning of section 7 of the ACL; and

(d) otherwise does not know and therefore cannot admit paragraph 105 of the Claim.

106. The Respondent admits paragraph 106 of the Claim.

107. The Respondent admits paragraph 107 of the Claim.

Sudafed PE Sinus + Pain Relief

108. In respect of paragraph 108 of the Claim, the Respondent:

(a) says 21 June 2005 is the ARTG Start Date of Sudafed PE Sinus - Pain Relief (which has been used interchangeably with Sudafed PE Sinus + Pain Relief);

(b) says that it was the distributor of Sudafed PE Sinus + Pain Relief from when it first distributed that product to a wholesaler or retailer in or from approximately the third quarter of the 2007 calendar year;

(c) says that it caused or permitted its trading name to be applied to the covering labels and boxes by which Sudafed PE Sinus + Pain Relief is supplied from when it first distributed the product to a wholesaler or retailer from approximately the third quarter of the 2007 calendar year;

(d) says it marketed Sudafed PE Sinus + Pain Relief through its marketing channels from when it first distributed the product to a wholesaler or retailer in or from approximately the third quarter of the 2007 calendar year;

(e) denies that it produced Sudafed PE Sinus + Pain Relief;

(f) denies that it imported Sudafed PE Sinus + Pain Relief; and

(g) otherwise denies paragraph 108 of the Claim.

109. In respect of paragraph 109 of the Claim, the Respondent:

(a) refers to and repeats paragraph 108 above;

(b) admits that on and after 1 January 2011, it was the manufacturer of Sudafed PE Sinus + Pain Relief within the meaning of section 7 of the ACL; and

(c) otherwise does not know and therefore cannot admit paragraph 109 of the Claim.

110. The Respondent admits paragraph 110 of the Claim.

111. The Respondent admits paragraph 111 of the Claim.

Sudafed PE Sinus + Pain Relief Day & Night

112. In respect of paragraph 112 of the Claim, the Respondent:

(a) says that prior to around 30 April 2018 the product was known as Sudafed PE Sinus Day & Night Relief;

(b) says 3 August 2005 is the ARTG Start Date of Sudafed PE Sinus + Pain Relief Day & Night (then called Sudafed PE Sinus Day & Night Relief);

(c) says that it was the distributor of Sudafed PE Sinus + Pain Relief Day & Night from when it first distributed that product (then called Sudafed PE Sinus Day & Night Relief) to a wholesaler or retailer in or from approximately the third quarter of the 2007 calendar year;

(d) says that it caused or permitted its trading name to be applied to the covering labels and boxes by which Sudafed PE Sinus + Pain Relief Day & Night is supplied from when it first distributed the product (then called Sudafed PE Sinus Day & Night Relief) to a wholesaler or retailer from approximately the third quarter of the 2007 calendar year;

(e) says it marketed Sudafed PE Sinus + Pain Relief Day & Night through its marketing channels from when it first distributed the product (then called Sudafed PE Sinus Day & Night Relief) to a wholesaler or retailer in or from approximately the third quarter of the 2007 calendar year;

(f) denies that it produced Sudafed PE Sinus + Pain Relief Day & Night (previously called Sudafed PE Sinus Day & Night Relief);

(g) denies that it imported Sudafed PE Sinus + Pain Relief Day & Night (previously called Sudafed PE Sinus Day & Night Relief); and

(h) otherwise denies paragraph 112 of the Claim.

113. In respect of paragraph 113 of the Claim, the Respondent:

(a) refers to and repeats paragraph 112 above;

(b) admits that on and after 1 January 2011, it was the manufacturer of Sudafed PE Sinus + Pain Relief Day & Night (previously called Sudafed PE Sinus Day & Night Relief) within the meaning of section 7 of the ACL; and

(c) otherwise does not know and therefore cannot admit paragraph 113 of the Claim.

114. The Respondent admits paragraph 114 of the Claim.

115. The Respondent admits paragraph 115 of the Claim.

B.2 Common characteristics of the J&J Pacific Oral PE Products

116. In respect of paragraph 116 of the Claim, the Respondent:

(a) says that the J&J Pacific Oral PE Products had a range of active ingredients and were directed at the temporary relief of symptoms as identified on the packaging for each product;

(b) says that, at all material times, a medicine that is approved for supply by the Therapeutic Goods Administration (**TGA**), including the J&J Pacific Oral PE Products, was and is scheduled according to the concentration of active ingredients in the formulation of the medicine (among other things);

(c) says that a medicine is a "Schedule 2 Pharmacy Medicine" in the circumstances prescribed in the Therape*utic Goods (Poisons Standard – June 2025) Instrument 2025* (Cth), s 58, sch 2 (and predecessor instruments) (the **Standard**) (including where any of the active ingredients contained in the medicine exceed the prescribed statutory threshold) and can only be sold in a pharmacy or by a holder of a pharmacy licence (**Pharmacy Medicine**);

Particulars

(i) *Therapeutic Goods (Poisons Standard – June 2025) Instrument 2025* (Cth), s 58, sch 2.

(ii) The Standard is updated annually and has at all materials times contained scheduling requirements in Schedule 2.

(d) says that phenylephrine, except when it:

(i) is included in Schedule 4 of the Standard; or

(ii) is in oral preparations containing 50 mg or less of phenylephrine per recommended daily dose in packs containing 250 mg or less of phenylephrine; or

(iii) is in topical eye or nasal preparations containing 1% or less of phenylephrine,

is a "Schedule 2 Pharmacy Medicine" under the Standard;

Particulars

(i) Refers to and repeats the particulars to paragraph 116(c).

(e) says that a medicine containing active ingredients that do not exceed the statutory thresholds set out in the Standard and are not otherwise subject to the Standard, are not scheduled by the TGA and are able to be supplied in general sale by retailers that are not a pharmacy (General Sale Medicine);

(f) says that claims and indications included on the packaging for each of the J&J Pacific Oral PE Products were required to be, and were, approved by the TGA;

(g) says that it was able to vary the claims and indications on the packaging of each of the J&J Pacific Oral PE Products provided that any variations were consistent with what was included on the ARTG for the product; and

(h) otherwise denies paragraph 116.

117. In respect of paragraph 117 of the Claim, the Respondent:

(a) repeats paragraph 116 above; and

(b) otherwise admits the paragraph.

118. In respect of paragraph 118 of the Claim, the Respondent:

(a) repeats paragraph 116 above; and

(b) otherwise admits the paragraph.

B.3 J&J Pacific's Packaging, Distribution, and Marketing

119. In respect of paragraph 119 of the Claim, the Respondent:

(a) repeats paragraphs 7, 11, 15, 19, 21, 23, 27, 31, 35, 39, 43, 47, 51, 55, 59, 63, 67, 71, 75, 80, 84, 88, 92, 96, 100, 104, 108, 112, and 116 above and paragraph 120 below;

(b) says that the packaging of each of the J&J Pacific Oral PE Products is different and has changed from time to time;

(c) says that at all material times the packaging of each of the J&J Pacific Oral PE Products was required by the TGA to, and did, include

(i) a statement of the purpose for which it is intended the product be used;

(ii) an identification of the active ingredients in the product;

(iii) directions for use, including recommended and maximum dosages; and

(iv) relevant warning statements;

Particulars

(i) Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines, cl 8.

(ii) Therapeutic Goods Order No. 69 - General requirements for labels for medicines, cl 7(2).

(d) says that the packaging of at least some of the J&J Pacific Oral PE Products has, from time to time, contained warning statements to the effect that:

(i) the consumer should ask their doctor before use if they had any medical condition or were taking any other medicine; and

Particulars

(i) Such statements appeared on the packaging of the J&J Pacific Oral PE Products at the times identified in Schedules 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26 and 27.

(ii) if symptoms persisted or worsened, or new symptoms appeared, the consumer should stop use and see their doctor;

Particulars

(i) Such statements appeared on certain versions of the packaging of the J&J Pacific Oral PE Products at the times identified in Schedules 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26 and 27.

(ii) In respect of paragraph 119(d)(ii) above, whether the statement was required to be included on certain versions of the packaging of the J&J Pacific Oral PE Products as a "warning statement" was prescribed by the relevant Poisons Standard applicable to the relevant J&J Pacific Oral PE Product and/or the Therapeutic Goods Regulations 1990 at the time of supply.

(e) says that the packaging of those of the J&J Pacific Oral PE Products which were classified as a "Schedule 2 Pharmacy Medicine" was required to, and did, display the signal words "PHARMACY MEDICINE";

Particulars

(i) Therapeutic Goods (Poisons Standard – June 2025) Instrument 2025, s 16.

(f) says that those products that were classified as a "Schedule 2 Pharmacy Medicine" were only available for sale or supply by particular persons, including pharmacists, who were able to provide advice in relation to the products; and

(g) otherwise denies paragraph 119 of the Claim.

120. In respect of paragraph 120 of the Claim, the Respondent:

(a) repeats paragraphs 116 and 119 above;

(b) says that some of the images of the J&J Pacific Oral PE Products included in the particulars provided by the Applicant in each of Schedules 1 to 27 are Pharmacy Medicines, General Sale Medicines, or for the purposes of advertisement;

Particulars

(i) In respect of packaging used in advertisements, in some circumstances it is possible to use a simplified version of the packaging that does not directly replicate the actual packaging: Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021 (Cth), Part 4, s 14.

(c) otherwise admits that the J&J Pacific Oral PE Products contained statements substantially the same as those pleaded in paragraph 120 at the specific times identified in the particulars provided in each of Schedules 1 to 27;

(d) says that any statements on the relevant packages must be read in the context of the packaging as a whole and in the context of the claims and indications contained on the packaging approved by the TGA; and

(e) otherwise denies paragraph 120 of the Claim.

121. In respect of paragraph 121 of the Claim, the Respondent:

(a) repeats paragraphs 116, 119, and 120 above;

(b) otherwise denies paragraph 121 of the Claim.

122. In respect of paragraph 122 of the Claim, the Respondent:

(a) repeats paragraphs 120 and 121 above; and

(b) otherwise denies paragraph 122 of the Claim.

123. In respect of paragraph 123 of the Claim, the Respondent:

(a) repeats paragraphs 116, 119, and 120 above; and

(b) otherwise denies paragraph 123 of the Claim.

124. In respect of paragraph 124 of the Claim, the Respondent:

(a) repeats paragraph 123 above; and

(b) otherwise denies paragraph 124 of the Claim.

125. In respect of paragraph 125 of the Claim, the Respondent:

(a) repeats paragraphs 116, 119, and 120 above; and

(b) otherwise denies paragraph 125 of the Claim.

126. In respect of paragraph 126 of the Claim, the Respondent:

(a) repeats paragraph 125 above; and

(b) otherwise denies paragraph 126 of the Claim.

127. In respect of paragraph 127 of the Claim, the Respondent:

(a) admits the definition as adopted;

(b) repeats paragraphs 121, 123 and 125 above; and

(c) otherwise denies paragraph 127 of the Claim.

B.4 Consumer Guarantees

128. In respect of paragraph 128 of the Claim, the Respondent:

(a) repeats paragraphs 7, 11, 15, 19, 23, 27, 31, 35, 39, 43, 47, 51, 55, 59, 63, 67, 71, 75, 80, 84, 88, 92, 96, 100, 104, 108, 112, and 116 above;

(b) does not know and therefore cannot admit that each supply of J&J Pacific Oral PE Products was to a consumer; and

(c) otherwise denies paragraph 128 of the Claim.

Nasal Decongestant Acceptable Quality Guarantee

129. In respect of paragraph 129 of the Claim, the Respondent:

(a) repeats paragraphs 116, 119, 120, 121, 123 and 125 above;

(b) says further that the relevant circumstances relating to the supply of the J&J Pacific Oral PE Products included that:

(i) the J&J Pacific Oral PE Products were not prescription medicines;

(ii) the J&J Pacific Oral PE Products were sold as over the counter medicines in pharmacy, or as general sale through non-pharmacy channels including grocery; and

(iii) the state of scientific knowledge at all material times was such as to indicate that each of the J&J Pacific Oral PE Products was effective in the temporary relief of the symptoms identified on the packaging for each product;

(c) otherwise denies paragraph 129 of the Claim.

Nasal Decongestant Description Guarantee

130. In respect of paragraph 130 of the Claim, the Respondent:

(a) repeats paragraphs 116, 119, 120, 121, 123 and 125 above;

(b) says that the J&J Pacific Oral PE Products were not goods supplied by description; and

(c) otherwise denies paragraph 130 of the Claim.

Nasal Decongestant Express Warranty Guarantee

131. In respect of paragraph 131 of the Claim, the Respondent:

(a) repeats paragraphs 116, 119, 120, 121, 123 and 125 above; and

(b) otherwise denies paragraph 131 of the Claim.

132. In respect of paragraph 132 of the Claim, the Respondent:

(a) repeats paragraph 131 above;

(b) otherwise denies paragraph 132 of the Claim.

133. In respect of paragraph 133 of the Claim, the Respondent:

(a) repeats paragraphs 131 and 132 above;

(b) otherwise denies paragraph 133 of the Claim.

C. APPLICANT AND GROUP MEMBERS PURCHASE J&J PACIFIC ORAL PE PRODUCTS

134. The Respondent does not know and therefore cannot admit paragraph 134 of the Claim.

135. The Respondent does not know and therefore cannot admit paragraph 135 of the Claim.

D. ALLEGED INEFFICACY OF PHENYLEPHRINE (AND THE J&J PACIFIC ORAL PE PRODUCTS)

136. In response to paragraph 136 of the Claim, the Respondent:

(a) says that the state of scientific knowledge at all material times was such as to indicate that each of the J&J Pacific Oral PE Products was effective in the temporary relief of the symptoms identified on the packaging for each product;

(b) says that, at all material times during which each of the J&J Pacific Oral PE Products were registered on the ARTG and distributed to pharmacies (in the case of Pharmacy Medicines) or through non-pharmacy channels including grocery (in the case of General Sale Medicines), some versions of the J&J Pacific Oral PE Products were classified as Schedule 2 Pharmacy Medicines and were Pharmacy Medicines, while others were unscheduled and were General Sale Medicines; and

Particulars

(i) A Pharmacy Medicine is defined under the Therapeutic Goods (Poisons Standard—June 2025) Instrument 2025 (Cth) and means "substances, the safe use of which may require advice from a pharmacist and which should be available from a pharmacy or, where a pharmacy service is not available, from a licensed person."

(c) otherwise denies paragraph 136 of the Claim.

137. In response to paragraph 137 of the Claim, the Respondent:

(a) repeats paragraph 136 above; and

(b) otherwise denies paragraph 137 of the Claim.

138. In respect of paragraph 138 of the Claim, the Respondent:

(a) refers to paragraphs 136 and 137 above; and

(b) otherwise denies paragraph 138 of the Claim.

139. In respect of paragraph 139 of the Claim, the Respondent:

(a) refers to paragraphs 136 and 137 above;

(b) otherwise denies paragraph 139 of the Claim.

E. ALLEGED ACL CONTRAVENTIONS

E.1 J&J Pacific's Alleged Consumer Guarantee Failures

140. In respect of paragraph 140 of the Claim, the Respondent:

(a) repeats paragraphs 129 and 136 to 139 above;

(b) says that the state of scientific knowledge at all material times was such as to indicate that each of the J&J Pacific Oral PE Products was effective in the temporary relief of the symptoms identified on the packaging for each product; and

(c) otherwise denies paragraph 140 of the Claim.

141. In respect of paragraph 141 of the Claim, the Respondent:

(a) repeats paragraphs 130, 136 to 139 and 140 above; and

(b) otherwise denies paragraph 141 of the Claim.

142. In respect of paragraph 142 of the Claim, the Respondent:

(a) repeats paragraphs 131, 136 to 139 and 140 above; and

(b) otherwise denies paragraph 142 of the Claim.

F. ALLEGED LOSS AND DAMAGE AND DIMINUTION IN VALUE

F.1 J&J Pacific's Alleged Consumer Guarantee Failures Diminution in Value and Loss and Damage

143. In respect of paragraph 143 of the Claim, the Respondent:

(a) repeats paragraphs 140 to 142 above; and

(b) otherwise denies paragraph 143 of the Claim.

144. In respect of paragraph 144 of the Claim, the Respondent:

(a) repeats paragraphs 140 to 142 above; and

(b) otherwise denies paragraph 144 of the Claim.

145. In respect of paragraph 145 of the Claim, the Respondent:

(a) repeats paragraphs 140 to 142 above; and

(b) otherwise denies paragraph 145 of the Claim.

146. In respect of paragraph 146 of the Claim, the Respondent:

(a) repeats paragraphs 140 to 142 above; and

(b) otherwise denies paragraph 146 of the Claim.

147. In respect of paragraph 147 of the Claim, the Respondent:

(a) repeats paragraphs 140 to 142 above; and

(b) otherwise denies paragraph 147 of the Claim.

148. In respect of paragraph 148 of the Claim, the Respondent:

(a) repeats paragraphs 140 to 142 above;

(b) says that any assessment of whether damages are recoverable under s 272(1)(b) of the ACL (the entitlement to which is denied) will necessarily depend on the circumstances of the person claiming such damages; and

(c) otherwise denies paragraph 148 of the Claim.

G. RELIEF

149. In respect of paragraph 149 of the Claim, the Respondent denies that the Applicant, on his own behalf and on behalf of Group Members, is entitled to the relief sought in the Originating Application.

H. LIMITATION PERIODS

150. In further answer to the applicant and group members' claims in respect of J&J Pacific's Consumer Guarantee Failures (as defined in the Claim), the Respondent says that those claims are time barred under the ACL, to the extent that the relevant J&J Pacific Oral PE Product was purchased, and the applicant or the group members were or ought reasonably to have become aware that the guarantee had not been complied with before 20 December 2021 (which is denied).

Particulars

(i) ACL s 273.

Date: 15 May 2026



Signed by Jason Lawrence Betts

Lawyer for the Respondent

This defence to the second further amended pleading was prepared by Imtiaz Ahmed SC, Jonathan Burnett and Emily Hall of counsel and Herbert Smith Freehills Kramer.

Certificate of lawyer

I Jason Lawrence Betts certify to the Court that, in relation to the defence filed on behalf of the Respondent, the factual and legal material available to me at present provides a proper basis for:

(a) each allegation in the pleading; and

(b) each denial in the pleading; and

(c) each non admission in the pleading.

Date: 15 May 2026

Signed by Jason Lawrence Betts

Lawyer for the Respondent

NOTICE OF FILING

Details of Filing

Document Lodged:	Defence - Form 33 - Rule 16.32
Court of Filing	FEDERAL COURT OF AUSTRALIA (FCA)
Date of Lodgment:	15/05/2026 3:57:12 PM AEST
Date Accepted for Filing:	15/05/2026 3:57:16 PM AEST
File Number:	VID1395/2024
File Title:	BADEN GREEN v JOHNSON AND JOHNSON PACIFIC PTY LTD (ACN 001 121 446)
Registry:	VICTORIA REGISTRY - FEDERAL COURT OF AUSTRALIA



Registrar

Important Information

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

The date of the filing of the document is determined pursuant to the Court's Rules.