

HIGHLY CONFIDENTIAL



**IN THE SUPREME COURT OF VICTORIA AT MELBOURNE
COMMERCIAL COURT**

No. S ECI 2020 03351

Filed on: 17/05/2024 01:08 PM

B E T W E E N

BENJUMIN HILLMAN

Plaintiff

- and -

MAYNE PHARMA GROUP LTD (ACN 115 832 963)

Defendant

DEFENCE TO AMENDED STATEMENT OF CLAIM

(Filed in accordance with order 4(b) of the orders made by Justice Nichols on 22 March 2024 and order 10 of the orders made by Justice Nichols on 6 February 2023)

Date of document: 17 May 2024 ~~17 December 2021~~

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In this defence, unless otherwise indicated, defined terms in the plaintiff's amended statement of claim filed on 26 April 2024 ~~8 October 2021~~, have the same meaning.

Headings in the statement of claim are reproduced, with modification, in this defence for ease of reference only and, to the extent of reproduction, such reproduction is not to be taken as an acceptance of the accuracy of their contents.

In answer to the amended statement of claim dated 26 April 2024 ~~8 October 2021~~, the defendant (**Mayne Pharma**) says as follows:

A. INTRODUCTION

A.1 The Plaintiff and the Group Members

1. As to paragraph 1, it:

- (a) does not plead to sub-paragraphs 1(a) and 1(c), as those sub-paragraphs make no allegations against it; and
- (b) denies sub-paragraph 1(b).

2. As to paragraph 2, it:

- (a) does not know, and therefore cannot admit, sub-paragraph 2(a); and
- (b) admits sub-paragraph 2(b), and says further that the plaintiff made the following additional transactions of Mayne Shares during and after the Relevant Period:
 - (i) acquisition of 3,297 shares with a settlement date of 4 December 2015;
 - (ii) disposal of 3,297 shares with a settlement date of 8 January 2016;
 - (iii) acquisition of 872 shares with a settlement date of 29 March 2017;
 - (iv) acquisition of 1,150 shares with a settlement date of 20 June 2017;
 - (v) acquisition of 2,100 shares with a settlement date of 26 July 2017;
 - (vi) disposal of 1,300 shares with a settlement date of 26 February 2018;
 - (vii) acquisition of 1,700 shares with a settlement date of 20 April 2018;
 - (viii) disposal of 2,000 shares with a settlement date of 27 August 2018;
 - (ix) disposal of 3,621 shares with a settlement date of 14 November 2018;
and
 - (x) disposal of 1,200 shares with a settlement date of 6 December 2018.

3. It does not know, and therefore cannot admit, paragraph 3.

A.2 The Defendant

4. It admits paragraph 4 and says further that, at trial, it will refer to the full terms and effect of the statutory provisions referred to in that paragraph.

B. MAYNE PHARMA'S BUSINESS

B.1 Mayne Pharma's Business in the United States of America

5. As to paragraph 5, it:

- (a) as to sub-paragraph 5(a):

- (i) admits that at all material times it carried on business in Australia as a specialised pharmaceutical company focussed on applying its delivery expertise to commercialise branded generic pharmaceuticals;
 - (ii) further admits that at all material times one or more of its wholly owned subsidiaries, Metrics, Inc, Libertas Pharma, Inc and Mayne Pharma Inc (which will hereafter in this Defence be referred to as **Mayne USA**), carried on business in the USA as a specialised pharmaceutical company focussed on applying its delivery expertise to commercialise branded generic pharmaceuticals; and
 - (iii) otherwise denies that sub-paragraph;
- (b) as to sub-paragraph 5(b):
- (i) admits that at all material times Mayne Pharma and its overseas subsidiaries provided contract development and manufacturing services to more than 100 clients worldwide; and
 - (ii) otherwise denies that sub-paragraph;
- (c) as to sub-paragraph 5(c), ~~it admits that sub-paragraph. says that:~~
- (i) ~~as at 24 November 2014 and in the period following that date and until 2 November 2015, its wholly owned subsidiaries Metrics, Inc and Libertas Pharma, Inc, marketed and sold generic and branded pharmaceuticals in the USA;~~
 - (ii) ~~on 31 October 2015, Metrics, Inc and Libertas Pharma, Inc merged and Metrics, Inc was the surviving entity;~~
 - (iii) ~~on 2 November 2015, Metrics, Inc, changed its name to Mayne Pharma Inc;~~
 - (iv) ~~from 2 November 2015, its wholly owned subsidiary, Mayne USA, marketed and sold generic and branded pharmaceuticals in the USA;~~
 - (v) ~~there was no entity called Mayne Pharma (USA), Inc at any material times; and~~
 - (vi) ~~it otherwise denies that sub paragraph.~~

6. It admits paragraph 6.
7. As to paragraph 7, it:
 - (a) ~~[not used] says that the reference to “most important market” is embarrassing;~~
 - (b) ~~under cover of that objection,~~ admits that during the Relevant Period the USA represented between 78-88% of its group revenue by geography; and
 - (c) otherwise denies that paragraph.

B.2 The regulatory environment in the United States applicable to Mayne Pharma

8. As to paragraph 8, it ~~refers to and repeats sub-paragraph 5(c) above and further says that:~~
 - (a) ~~[not used] as to sub-paragraph 8(a):~~
 - (i) ~~Libertas Pharma, Inc was incorporated in Georgia;~~
 - (ii) ~~Metrics, Inc was incorporated in North Carolina;~~
 - (iii) ~~Mayne USA is incorporated in North Carolina; and~~
 - (iv) ~~it otherwise denies that sub-paragraph;~~
 - (b) as to sub-paragraphs 8(b) and 8(c), it:
 - (i) admits that each of Libertas Pharma, Inc, Metrics, Inc, and Mayne USA was at all material times:
 - (A) subject to federal United States antitrust laws, namely section 1 of the Sherman Antitrust Act of 1890, codified at 15 U.S.C. § 1 (**Sherman Act**); and
 - (B) at the times it was selling products, subject to the antitrust law of those States of the United States in which it sold those products, which were to similar effect as the Sherman Act (**State Antitrust Acts**); and
 - (ii) otherwise denies those sub-paragraphs.
9. As to paragraph 9:
 - (a) it admits sub-paragraph 9(a);
 - (b) as to sub-paragraph 9(b), it:

- (i) denies that violation of section 1 of the Sherman Act rendered a person liable to an action brought on the suit of Attorney-Generals of States on behalf of individuals within their States for disgorgement of unlawful profits; and
- (ii) otherwise admits that sub-paragraph;
- (c) ~~save that it says that the reference to the codified Act is 15 U.S.C. § 12-27 (not 15 U.S.C. § 11-27)~~, it admits sub-paragraph 9(c); and
- (d) as to sub-paragraph 9(d), it:
 - (i) refers to and repeats sub-paragraph 9(b)(i) above;
 - (ii) says further that the nature of the relief available in such actions varied from State to State (not always including all of the types of relief referred to in sub-paragraph 9(d)); and
 - (iii) otherwise denies that sub-paragraph;
- (e) as to sub-paragraph 9(e), it:
 - (i) says that the nature of the relief available in such actions varied from State to State; and
 - (ii) otherwise does not admit that sub-paragraph.

B.3 The Doxy DR market in the United States

10. As to paragraph 10:

- (a) it does not know, and therefore cannot admit, that Heritage was at all material times a USA based company;
- (b) as to sub-paragraph 10(a), it:
 - (i) admits that Heritage sold generic pharmaceuticals in the USA; and
 - (ii) otherwise denies that sub-paragraph;
- (c) as to sub-paragraph 10(b), it:
 - (i) ~~[not used] refers to and repeats sub-paragraph 5(c) above;~~
 - (ii) admits that Heritage was a competitor of Mayne USA (and, when and where relevant, its predecessor entities Libertas Pharma, Inc and

Metrics, Inc) in relation to those products which both companies marketed and sold in the same markets and in the same time periods; and

(iii) otherwise denies that sub-paragraph.

11. As to paragraph 11:

(a) it does not know, and therefore cannot admit, that Mylan was at all material times a USA based company;

(b) as to sub-paragraph 11(a), it:

(i) admits that Mylan sold generic pharmaceuticals in the USA; and

(ii) otherwise denies that sub-paragraph.

(c) as to sub-paragraph 11(b), it:

(i) admits that Mylan was a competitor of Mayne USA (and, when and where relevant, its predecessor entities Libertas Pharma, Inc and Metrics, Inc) in relation to those products which both companies marketed and sold in the same markets and in the same time periods; and

(ii) otherwise denies that sub-paragraph.

12. It ~~admits~~ denies paragraph 12, ~~and in further answer to that paragraph:~~

(a) ~~refers to and repeats sub paragraph 5(c) above; and~~

(b) ~~says that in 2012, it (i.e. Mayne Pharma, not Mayne USA) acquired Metrics, Inc and its division, Midlothian Laboratories.~~

13. It ~~admits~~ denies paragraph 13, ~~and in further answer to that paragraph:~~

(a) ~~refers to and repeats sub paragraph 5(c) above; and~~

(b) ~~says that for a period of time after the Midlothian Acquisition until around August 2014, Metrics, Inc also operated under the name 'Midlothian'.~~

14. It does not know, and therefore cannot admit, paragraph 14.

15. It does not know, and therefore cannot admit, paragraph 15.

16. As to paragraph 16, it:

- (a) ~~[not used] refers to and repeats sub-paragraph 5(e) above;~~
- (b) as to sub-paragraph 16(a), says that Metrics, Inc:
 - (i) began marketing and selling Doxy DR in the 150 mg dosage strength in the USA in or around April 2014; and
 - (ii) ~~[not used] began selling Doxy DR in the 75 mg and 100 mg dosage strengths in the USA in or around August 2013,~~
and otherwise denies that sub-paragraph;
- (c) ~~[not used] as to sub-paragraph 16(b):~~
 - (i) ~~says that this paragraph is liable to be struck out as it does not disclose a cause of action and/or may prejudice, embarrass or delay the fair trial of the proceeding;~~

Particulars

~~*This is the only paragraph in the statement of claim that refers to Doryx®, and the allegations in this paragraph are irrelevant and go nowhere.*~~

- (ii) ~~under cover of that objection, it;~~
 - (A) ~~— says that the marketing and selling of Doryx®, being the branded version of Doxy DR, was re-launched by Libertas Pharma, Inc in the USA in or around May 2015; and~~
 - (B) ~~— otherwise denies sub-paragraph 16(b).~~

17. As to paragraph 17, it:

- (a) admits that from April 2014, Heritage, Mylan and Metrics, Inc, and then, from November 2015, Heritage, Mylan and Mayne USA were competitors in the wholesale and retail generic pharmaceutical market for Doxy DR in the 150 mg dosage strength in the USA;
- (b) refers to and repeats ~~sub-paragraph 5(e)~~ and paragraphs 10-16 above; and
- (c) otherwise denies that paragraph.

B.4 The market disclosure regime governing Mayne Pharma

18. As to paragraph 18, it:

- (a) admits sub-paragraph 18(a); and
- (b) admits sub-paragraph 18(b); ~~and~~
- (c) [not used] ~~denies sub-paragraph 18(c).~~

19. It admits paragraph 19, and says further that, at trial, it will refer to the full terms and effect of the ASX Listing Rules and the statutory provisions referred to in that paragraph.

B.5 Mayne Pharma's alleged exposure to reputational risk and criminal and civil penalties

20. As to paragraph 20:

- (a) as to sub-paragraph 20(a), it:
 - (i) says the references in sub-paragraph 20(a) to “risk arising from negative perception”, “adverse reputational risk outcomes flowing from the failure” and “~~other types of risks~~ across its operations (including compliance risk)” are embarrassing; and
 - (ii) under cover of that objection, denies that sub-paragraph;
- (b) as to sub-paragraph 20(b), it:
 - (i) refers to and repeats paragraphs 8 and 9 above;
 - (ii) admits that at all material times it was subject to the risk of loss of reputation if its US subsidiaries contravened the Sherman Act (or State Antitrust Acts); and
 - (iii) otherwise denies that sub-paragraph.

21. As to paragraph 21, it:

- (a) refers to and repeats ~~sub-paragraph 5(c) and~~ paragraphs 8 and 9 above;
- (b) admits that its US subsidiaries would potentially be liable to criminal and civil penalties if they contravened the Sherman Act (or and State Antitrust Acts to which they were subject);

- (c) admits that some (but not all) of the potential liabilities alleged at sub-paragraphs 21(a)-(d) were available under State Antitrust Acts in respect of any contravention of those Acts; and
- (d) otherwise denies that paragraph.

B.6 Directors and officers of Mayne Pharma

22. As to paragraph 22:

- (a) as to sub-paragraph 22(a), it:
 - (i) ~~[not used] refers to and repeats sub-paragraph 5(e) above;~~
 - (ii) admits that in the period from the start of the Relevant Period until November 2015, Mr Schneider was Executive Vice President of Generic Products at Metrics, Inc and Libertas Pharma, Inc and, from November 2015 through to the end of the Relevant Period, was Executive Vice President of Generic Products at Mayne USA; and
 - (iii) otherwise denies that sub-paragraph;
- (b) as to sub-paragraph 22(b), it:
 - (i) admits that Mr Schneider was a member of Mayne Pharma's Global Leadership Group during the 2015 financial year; and
 - (ii) otherwise denies that sub-paragraph;
- (c) as to sub-paragraph 22(c), it:
 - (i) ~~[not used] refers to and repeats sub-paragraph 5(e) above;~~
 - (ii) admits that during the Relevant Period Mr Schneider reported to Mr Cross; and
 - (iii) otherwise denies that sub-paragraph;
- (d) it denies sub-paragraph 22(d).

23. As to paragraph 23, it:

- (a) as to sub-paragraph 23(a):
 - (i) ~~[not used] refers to and repeats sub-paragraph 5(e) above;~~

- (ii) admits that in the period from the start of the Relevant Period until November 2015, Mr Cross was President of Metrics, Inc and Libertas Pharma, Inc and, from November 2015 through to the end of the Relevant Period, was President of Mayne USA; and
 - (iii) otherwise denies that sub-paragraph;
 - (b) admits sub-paragraph 23(b); and
 - (c) denies sub-paragraph 23(c).
24. As to paragraph 24:
- (a) as to sub-paragraph 24(a), it:
 - (i) ~~[not used] refers to and repeats sub-paragraph 5(c) above;~~
 - (ii) admits that in the period from the start of the Relevant Period until November 2015, Ms Peluso-Schmid was Director of National Accounts at Metrics, Inc and Libertas Pharma, Inc and, from November 2015 through to the end of the Relevant Period, was Director of National Accounts at Mayne USA; and
 - (iii) otherwise denies that sub-paragraph; and
 - (b) as to sub-paragraph 24(b), it:
 - (i) admits that during the Relevant Period Ms Peluso-Schmid reported to Mr Schneider; and
 - (ii) otherwise denies that sub-paragraph.
25. It admits paragraph 25 and says further that, at trial, it will refer to the full terms and effect of s 9 of the Corporations Act and ASX Listing Rule 19.12.
26. It admits paragraph 26 and says further that, at trial, it will refer to the full terms and effect of s 9 of the Corporations Act and ASX Listing Rule 19.12.
27. It admits paragraph 27 and says further that, at trial, it will refer to the full terms and effect of s 9 of the Corporations Act and ASX Listing Rule 19.12.
28. As to paragraph 28:

- (a) as to sub-paragraph 28(a), it admits that Mr Hodges was a non-executive director of Mayne Pharma during the Relevant Period but otherwise denies that sub-paragraph; and
 - (b) as to sub-paragraph 28(b), it admits that sub-paragraph and says further that, at trial, it will refer to the full terms and effect of s 9 of the Corporations Act and ASX Listing Rule 19.12.
29. As to paragraph 29, it:
- (a) admits sub-paragraph 29(a);
 - (b) as to sub-paragraph 29(b):
 - (i) admits that Mr Mathieson was a member of Mayne Pharma's Audit & Risk Committee from 24 November 2014 to 26 October 2016; and
 - (ii) otherwise denies that sub-paragraph; and
 - (c) admits sub-paragraph 29(c) and says further that, at trial, it will refer to the full terms and effect of s 9 of the Corporations Act and ASX Listing Rule 19.12.
30. It admits paragraph 30 and says further that, at trial, it will refer to the full terms and effect of s 9 of the Corporations Act and ASX Listing Rule 19.12.
31. It admits paragraph 31 and says further that, at trial, it will refer to the full terms and effect of s 9 of the Corporations Act and ASX Listing Rule 19.12.
32. It admits paragraph 32 and says further that, at trial, it will refer to the full terms and effect of s 9 of the Corporations Act and ASX Listing Rule 19.12.
33. It admits paragraph 33 and says further that, at trial, it will refer to the full terms and effect of s 9 of the Corporations Act and ASX Listing Rule 19.12.
34. As to paragraph 34, it:
- (a) says that at all material times ASX Listing Rule 19.12 provided that an entity becomes aware of information if, and as soon as, an officer of the entity has, or ought reasonably to have, come into possession of the information in the course of the performance of their duties as an officer of that entity;
 - (b) admits that at all material times it was bound by ASX Listing Rule 19.12;

- (c) says that at trial it will rely on the full terms and effect of the ASX Listing Rules in force during the Relevant Period;
- (d) says further that it was not aware (for the purposes of ASX Listing Rule 19.12) of every opinion held by one or more of its officers;
- (e) ~~[not used] says further that it was not constructively aware (for the purposes of ASX Listing Rule 19.12) of any opinions its officers or a majority of its board did not hold, and that its officers were not required to form any opinions they did not hold;~~
- (f) refers to and repeats paragraphs 25-32 above; and
- (g) otherwise denies paragraph 34.

35. As to paragraph 35, it:

- (a) refers to and repeats paragraphs 22, 23, 25, 33 and 34(a)-34(e)(d) above; and
- (b) otherwise denies that paragraph.

C. ALLEGED CONTINUOUS DISCLOSURE OBLIGATIONS

C.1 The information Mayne Pharma allegedly had

36. As to paragraph 36:

- (a) ~~[not used] it refers to and repeats sub-paragraph 5(c) above;~~
- (b) as to sub-paragraph 36(a), it:
 - (i) admits that Ms Peluso-Schmid had some discussions with Ms Anne Sather of Heritage in 2014 in which the possibility of allocating customers was discussed; and
 - (ii) otherwise denies that sub-paragraph;
- (c) as to sub-paragraph 36(b), it:
 - (i) admits that on or around 29 September 2015, Ms Sather sent Ms Peluso-Schmid a text message asking if Mayne USA was having doxy supply problems at Walgreens. Ms Peluso-Schmid replied no. Ms Sather said “they say they have it split with tow [sic] vendors and one or both is having supply issues.” Ms Peluso-Schmid replied that “we are not having supply issues ... we gave them pricing for the

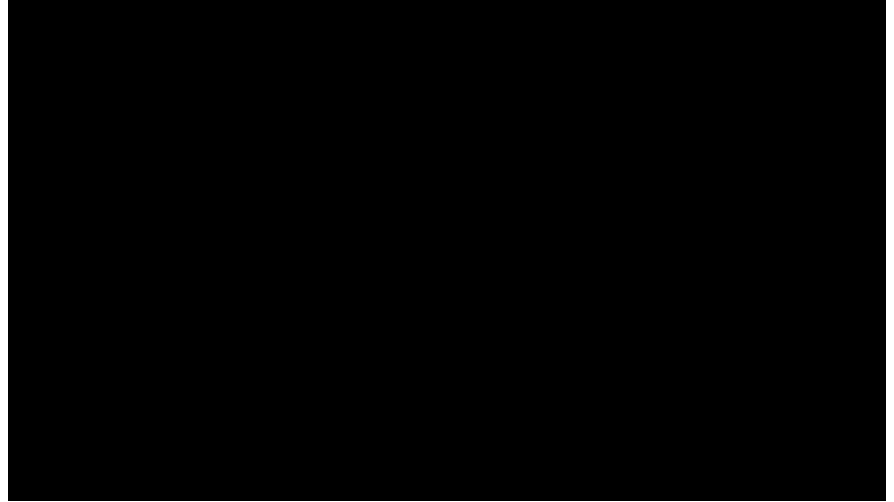
100s and 75s last week”. Ms Sather responded that it “looks like they are price checking”; and

(ii) otherwise denies that sub-paragraph;

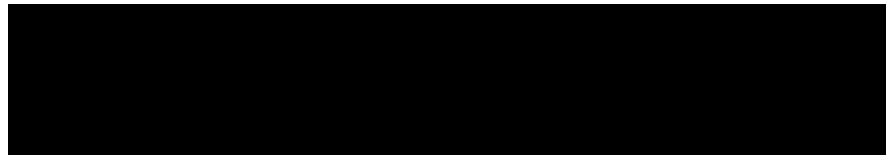
(d) as to sub-paragraph 36(c), it:

(i) admits that:

(A)



(B)



(C) on or around 4 December 2014, Ms Sather and Ms Peluso-Schmid exchanged text messages in which, among other things, Ms Sather stated: “... Were you able to rescind McKesson?”;

(D) on or around 29 September 2015, Ms Sather and Ms Peluso-Schimid exchanged text messages in which, among other things, Ms Sather stated: “... I don’t think we will bid it” and “Confirming we are not bidding”; and

(ii) otherwise denies that sub-paragraph; and

(e) it will rely on the full terms and effect of the documents particularised in paragraph 36, to the extent admitted into evidence.

36A As to paragraph 36A, it:

(a) refers to and repeats paragraph 36 above;

(b) otherwise denies paragraph 36A.

36B It denies paragraph 36B.

37. It denies paragraph 37.

37A It denies paragraph 37A.

38. It denies paragraph 38.

39. It denies paragraph 39.

40. It denies paragraph 40, and in further answer to that paragraph refers to and repeats paragraphs 36-39 above.

41. As to paragraph 41, it:

(a) [not used] refers to and repeats sub-paragraph 5(e) above;

(b) says ~~further~~ that the DOJ Subpoena was directed to “Mayne Pharmaceuticals, Inc.”;

(c) says further that Mayne USA received the DOJ Subpoena on 17 March 2016 (US Eastern Time) when a search warrant was executed at its premises in Raleigh, North Carolina;

(d) denies that the DOJ Subpoena required Mayne Pharma to produce documents;

(e) admits that the DOJ Subpoena required Mayne USA to produce documents in the terms specified in the DOJ Subpoena;

(f) as to the scope and requirements of the subpoena, says that it will at trial refer to the full terms and effect of the DOJ Subpoena; and

(g) otherwise denies paragraph 41.

42. As to paragraph 42, it:

(a) [not used] refers to and repeats sub-paragraph 5(e) above;

(b) says ~~further~~ that the AG Subpoena was directed to “Mayne Pharma (USA), Inc.”;

(c) says further that the AG Subpoena was dated 17 June 2016;

(d) admits ~~says further~~ that Mayne USA received the AG Subpoena on 20 June 2016 (US Eastern Time);

- (e) as to the scope and requirements of the subpoena and interrogatories, says that it will at trial refer to the full terms and effect of the AG Subpoena; and
 - (f) otherwise denies paragraph 42.
43. As to-paragraph 43:
- (a) as to sub-paragraph 43(a), it:
 - (i) says that Mr Richards and Mr Cansdale were informed on 18 March 2016 (Melbourne time) that the DOJ Subpoena had been received by Mayne USA;
 - (ii) says further that members of the Board of Mayne Pharma other than Mr Richards were informed on 18 March 2016 (Melbourne time) that the DOJ Subpoena had been received by Mayne USA;
 - (iii) admits that it became aware (within the meaning of ASX Listing Rule 19.12) of the DOJ Subpoena on 18 March 2016 (Melbourne time); and
 - (iv) otherwise denies that sub-paragraph;
 - (b) as to sub-paragraph 43(b), it:
 - (i) says that Mr Richards, Mr Cansdale and Mr Scholes were informed on 21 June 2016 (Melbourne time) that the AG Subpoena had been received by Mayne USA;
 - (ii) says further that Mr Corbett was informed on 22 June 2016 (Melbourne time) that the AG Subpoena had been received by Mayne USA;
 - (iii) says further that members of the Board of Mayne Pharma other than Mr Richards, Mr Scholes and Mr Corbett were informed by 27 June 2016 (Melbourne time) that the AG Subpoena had been received by Mayne USA;
 - (iv) admits that it became aware (within the meaning of ASX Listing Rule 19.12) of the AG Subpoena on 21 June 2016 (Melbourne time); and
 - (v) otherwise denies that sub-paragraph.
44. It denies paragraph 44 and in further answer to that paragraph refers to and repeats paragraphs 36-43 above.

45. It denies paragraph 45 and in further answer to that paragraph refers to and repeats paragraph 44 above.

46. It denies paragraph 46 and in further answer to that paragraph refers to and repeats paragraph 45 above.

C.2 Alleged Continuous Disclosure Contraventions

47. As to paragraph 47, it:

- (a) refers to and repeats paragraph 46 above;
- (b) denies that the alleged Heritage Anti-competitive Information (or any of it) was information that was in existence at any time during the Relevant Period or on and from any of the dates stated in sub-paragraph 47(a);
- (c) as to the alleged Investigation Information:
 - (i) admits that the fact that the DOJ Subpoena had been received by Mayne USA was information that came into existence on the date that subpoena was received by Mayne USA (17 March 2016 (US Eastern Time));
 - (ii) admits that the fact that the AG Subpoena had been received by Mayne USA was information that came into existence on the date that subpoena was received by Mayne USA (20 June 2016 (US Eastern Time)); and
 - (iii) otherwise denies that the alleged Investigation Information was information that was in existence at any time during the Relevant Period or on and from any of the dates stated in sub-paragraph 47(b); and
- (d) says that the receipt by Mayne USA of the DOJ Subpoena and the AG Subpoena and the fact that each of the DOJ and the Office of the Attorney-General in the State of Connecticut was investigating Mayne USA in relation to the marketing, pricing and sale of doxycycline hyclate delayed-release tablets (generic) and potassium chloride supplements (collectively, the **Subpoena and Investigations Information**) was generally available within the meaning of s 674(2)(c)(i) of the Corporations Act on and from 28 June 2016.

Particulars

The Subpoena and Investigations Information was publicly disclosed in the June 2016 Presentation (as defined in paragraph 54 of the statement of claim) published and lodged by Mayne Pharma with the ASX on 28 June 2016.

- (e) says further that the fact that responding to the investigations by the DOJ and the Attorney-General of the State of Connecticut (the **Investigations**) may be costly and time consuming for Mayne Pharma, and that it was possible that Mayne Pharma may be subject to additional investigations concerning the same subject matter by other regulatory bodies, be subject to class actions, have adverse judgments made against it, incur civil or criminal sanctions or enter into settlements that may be material and/or require operational changes, and that no assurances could be given as to the timing or outcome of the Investigations (collectively, the **Investigations Risk Information**) was information that was generally available within the meaning of s 674(2)(c)(i) of the Corporations Act on and from 28 June 2016; and

Particulars

The Investigations Risk Information was publicly disclosed in the June 2016 Presentation published and lodged by Mayne Pharma with the ASX on 28 June 2016.

- (f) otherwise denies the allegations in paragraph 47.
48. It denies paragraph 48 and in further answer to that paragraph refers to and repeats paragraph 47 above.
49. As to paragraph 49, it:
- (a) refers to and repeats paragraph 48 above;
 - (b) admits that it did not inform the ASX of the alleged Heritage Anti-competitive Information (the existence of which information is denied) on 24 November 2016 or during the Relevant Period;
 - (c) says that it informed the ASX of the Subpoena and Investigations Information and the Investigations Risk Information on 28 June 2016; and

Particulars

The Subpoena and Investigations Information and the Investigations Risk Information were provided to the ASX on 28 June 2016 in the June 2016 Presentation lodged by Mayne Pharma with the ASX on that day.

- (d) says further that it again provided the substance of the Subpoena and Investigations Information to the ASX on 26 August 2016 and 7 October 2016; and

Particulars

The substance of the Subpoena and Investigations Information was again provided by Mayne Pharma to the ASX on 26 August 2016 in Mayne Pharma's Financial Statements for FY16 (at page 60) lodged with the ASX on 26 August 2016, and on 7 October 2016 in Mayne Pharma's Annual Report for FY16 (at page 75) lodged with the ASX on 7 October 2016.

- (e) otherwise denies the allegations in paragraph 49.

50. It denies paragraph 50.

D. ALLEGED MISLEADING OR DECEPTIVE CONDUCT

D.1 Alleged Code of Conduct Compliance Representations

51. It admits paragraph 51.

52. As to paragraph 52, it:

- (a) denies that the Code of Conduct contained a statement that Mayne Pharma "will" do, or not do, each of the things in sub-paragraphs 52(a) to 52(m);
- (b) says that the Code of Conduct stated words to the effect that it is not a complete rulebook and acts as a guide;
- (c) otherwise admits that the Code of Conduct included wording similar, and in some respects the same as, the wording in sub-paragraphs 52(a) to 52(m) (but not the chapeau to those sub-paragraphs); and
- (d) says further that it will at trial refer to the full terms and effect of the Code of Conduct.

53. It denies paragraph 53 and in further answer to that paragraph refers to and repeats paragraphs 51 and 52 above.

D.2 Alleged June 2016 Compliance Representations

54. It admits paragraph 54.

55. It admits paragraph 55 and says further that it will at trial refer to the full terms and effect of the June 2016 Presentation.

56. It denies paragraph 56 and in further answer to that paragraph:

- (a) refers to and repeats paragraph 55 above;
- (b) says that the June 2016 Presentation included the following statements in the section titled “US Department of Justice Investigation Risk”:

“Responding to these investigations may be costly and time consuming for some members of our management team. It is possible that Mayne Pharma may be subject to additional investigations concerning the same subject matter by other regulatory bodies, be subject to class actions, have adverse judgments made against it, incur civil or criminal sanctions or enter into settlements that may be material and/or require operational changes. No assurance can be given as to the timing or outcome of these investigations”; and

- (c) says further that it will at trial rely on the full terms and effect of the June 2016 Presentation.

57. As to paragraph 57, it:

- (a) refers to and repeats paragraph 56 above;
- (b) says that the June 2016 Presentation stated that “[b]ased on currently available information, Mayne Pharma does not believe these investigations will have a material impact on future earnings”, which was a statement of opinion;
- (c) says that the June 2016 Presentation stated that responding to the Investigations may be costly and time consuming for Mayne Pharma, and that it was possible that Mayne Pharma may be subject to additional investigations concerning the same subject matter by other regulatory bodies, be subject to class actions, have adverse judgments made against it, incur civil or criminal sanctions or enter into

settlements that may be material and/or require operational changes, and that no assurances could be given as to the timing or outcome of the Investigations; and

(d) otherwise denies paragraph 57.

D.3 Alleged June 2016 Capital Raising Representations

58. It admits paragraph 58.

59. As to paragraph 59, it:

(a) as to sub-paragraph 59(a):

(i) admits that by the June 2016 Announcement and June 2016 Presentation, it announced to the Affected Market that it was to conduct an approximately \$888m equity raising;

(ii) admits ~~says~~ that the equity raising was to fund the acquisition of 37 approved and 5 FDA filed products from Teva Pharmaceuticals and Allergan plc (not Allergen plc); and

(iii) otherwise denies that sub-paragraph;

(b) admits sub-paragraph 59(b); and

(c) says further that it will rely at trial on the full terms and effect of the June 2016 Announcement and the June 2016 Presentation.

60. As to paragraph 60, it:

(a) says that the Entitlement Offer Cleansing Notice stated that “*there is no excluded information of the type referred to in sections 708AA(8) and 708AA(9) of the Corporations Act as notionally modified by the ASIC instrument*”;

(b) otherwise admits that paragraph; and

(c) says further that it will at trial rely on the full terms and effect of the Entitlement Offer Cleansing Notice.

D.4 Alleged July 2016 Capital Raising Representations

61. It admits paragraph 61 and says further that it will rely at trial on the full terms and effect of the Institutional Placement Cleansing Notice.

62. It admits paragraph 62 and says further that it will rely at trial on the full terms and effect of the Institutional Placement Cleansing Notice.

D.5 Alleged November 2016 Compliance Representations

63. As to paragraph 63, it:

- (a) ~~[not used] refers to and repeats sub-paragraph 5(c) above;~~
- (b) admits that:
 - (i) on 4 November 2016 (Melbourne time) (3 November 2016 in the United States), Bloomberg ran a televised news segment that referred to “Mayne” (**Bloomberg Report**); and
 - (ii) the article published with the Bloomberg Report (referred to in the particulars to paragraph 63 of the statement of claim) referred to “Mayne Pharma Group Ltd”;
- (c) as to sub-paragraph 63(a)(i):
 - (i) says that the banners at the bottom of the Bloomberg Report included text that “US Charges in Generic-Drug Probe Said to be Filed by Year-End” and “Criminal investigation into suspected price collusion in generic-drug industry”; and
 - (ii) otherwise denies that sub-paragraph;
- (d) ~~as to sub-paragraph 63(a)(ii): says further that:~~
 - (i) ~~says that~~ the presenter in the Bloomberg Report stated that the journalist had found that all the companies have said they are cooperating “*except for one of them, Mayne had said it did not expect the inquiry to have a material impact on its earnings...*”;
 - (ii) ~~says further that~~ the statement or implication that “Mayne” was not cooperating was incorrect and was inconsistent with the public statement made by Mayne Pharma in the June 2016 Presentation that “[t]he Company is cooperating with the DOJ and the State of Connecticut”;
 - (iii) ~~says further that~~ the article published with the Bloomberg Report stated that “*All of the companies have said they are cooperating except Covis*”; and
 - (iv) ~~otherwise denies that sub-paragraph;~~

- (e) as to sub-paragraph 63(b):
 - (i) says that the presenter, after referring to Mayne USA, stated “*we know that sometimes the Justice Department goes and subpoenas a large number of companies when they’re trying to find out information about others, and since so many of these companies make drugs that are exactly the same as each other, it’s not really surprising that the Justice Department has thrown open a wide net here*”; and
 - (ii) otherwise denies that sub-paragraph;
- (f) says further that it will at trial rely on the full terms and effect of the Bloomberg Report and the article published with the Bloomberg Report.

64. It admits paragraph 64.

65. It admits paragraph 65 and says further that:

- (a) in the November 2016 Announcement, it stated to the Affected Market that “*no assurance can be given as to the timing or outcome of the investigation*”; and
- (b) it will rely at trial on the full terms and effect of the November 2016 Announcement.

66. As to paragraph 66, it:

- (a) refers to and repeats paragraphs 47(d), 47(e), 56, 57 and 65 above;
- (b) says further that it will at trial rely on the full terms and effect of the June 2016 Presentation, the June 2016 Announcement and the November 2016 Announcement; and
- (c) otherwise denies that paragraph.

D.6 Alleged continuing nature of the representations

67. As to paragraph 67, it:

- (a) refers to and repeats paragraphs 51-66 above;
- (b) admits that it did not at any time prior to 16 December 2016 make any statement that corrected, qualified or contradicted any statement it had made in the Code of Conduct, the June 2016 Presentation, the June 2016 Announcement, the

Entitlement Offer Cleansing Notice, the Institutional Placement Cleansing Notice or the November 2016 Announcement;

- (c) says further that it was not under any obligation during the Relevant Period to correct, qualify or contradict any such statement; and
- (d) otherwise denies that paragraph.

68. As to paragraph 68, it:

- (a) says the allegation that the alleged representations were “continuing representations throughout the Relevant Period” is embarrassing in circumstances where the plaintiff has not identified how it became known to Mayne Pharma that the alleged representations were false (including particulars of who had that knowledge/formed the opinion, when that person(s) acquired the knowledge/formed the opinion, and how those matters are attributable to Mayne Pharma); and
- (b) under cover of that objection, denies paragraph 68 and in further answer to that paragraph refers to and repeats paragraphs 53, 56, 57, 60, 62 and 66 above.

D.7 Mayne Pharma’s alleged liability for misleading or deceptive conduct

D.7.1 Alleged 24 November 2014 Misleading or Deceptive Conduct Contraventions

69. It denies paragraph 69 and in further answer to that paragraph refers to and repeats paragraphs 40-46, 51-53 and 67-68 above.

70. It denies As to paragraph 70 and in further answer to that paragraph refers to and repeats paragraph 69 above. it:

- (a) ~~says that the reference to “*Likely Prosecution Information*” is embarrassing as that term is not defined in the statement of claim; and~~
- (b) ~~under cover of that objection, denies paragraph 70 and in further answer to that paragraph refers to and repeats paragraph 69 above.~~

71. As to paragraph 71, it:

- (a) refers to and repeats paragraphs 69-70 above;
- (b) admits that the statements made in the Code of Conduct section of its website were made:

- (i) in trade or commerce;
- (ii) in relation to a financial product (as that term is defined in Chapter 7 of the Corporations Act and in Part 2, Division 2 of the ASIC Act);
and
- (c) otherwise denies that paragraph.

72. It denies paragraph 72.

73. It denies paragraph 73.

D.7.2 Alleged 28 June 2016 Misleading or Deceptive Conduct Contraventions

74. It denies paragraph 74 and in further answer to that paragraph refers to and repeats paragraphs 40-46, 54-57 and 67-68 above.

75. It denies paragraph 75 and in further answer to that paragraph refers to and repeats paragraph 74 above.

76. As to paragraph 76, it:

- (a) refers to and repeats paragraphs 51-57, 71(b) and 74-75 above;
- (b) admits that the statements made in the June 2016 Presentation were made:
 - (i) in trade or commerce;
 - (ii) in relation to a financial product (as that term is defined in Chapter 7 of the Corporations Act and in Part 2, Division 2 of the ASIC Act);
and
- (c) otherwise denies that paragraph.

77. It denies paragraph 77.

78. It denies paragraph 78.

D.7.3 28 June 2016 – Alleged Defective Entitlement Offer Cleansing Notice

79. It denies paragraph 79 and in further answer to that paragraph refers to and repeats paragraphs 36, 36A, 36B, 40-46 and 60 above.

80. It denies paragraph 80 and in further answer to that paragraph refers to and repeats paragraph 79 above.

81. As to paragraph 81, it:
- (a) refers to and repeats paragraph 80 above;
 - (b) says that because the Entitlement Offer Cleansing Notice was not defective within the meaning of s 708AA(11) of the Corporations Act (or otherwise), it was under no obligation to give the ASX a notice under s 708AA(10)(c) of the Corporations Act;
 - (c) admits that it did not at any time within 12 months after the securities were issued under the Entitlement Offer give the ASX a notice under s 708AA(10)(c) of the Corporations Act;
 - (d) says further that it will at trial rely on the full terms and effect of s 708AA of the Corporations Act; and
 - (e) otherwise denies paragraph 81.
82. As to paragraph 82, it:
- (a) admits that the statement made in the Entitlement Offer Cleansing Notice set out in sub-paragraph 60(a) above was made:
 - (i) in trade or commerce;
 - (ii) in relation to a financial product (as that term is defined in Chapter 7 of the Corporations Act and in Part 2, Division 2 of the ASIC Act);and
 - (b) otherwise denies that paragraph.
83. It denies paragraph 83.
- D.7.4 7 July 2016 – Alleged Defective Institutional Placement Cleansing Notice***
84. It denies paragraph 84 and in further answer to that paragraph refers to and repeats paragraphs 36, 36A, 36B, 40-46 and 61-62 above.
85. It denies paragraph 85 and in further answer to that paragraph refers to and repeats paragraph 84 above.
86. As to paragraph 86, it:
- (a) refers to and repeats paragraph 85 above;

- (b) says that because the Institutional Placement Cleansing Notice was not defective within the meaning of s 708A(10) of the Corporations Act (or otherwise), it was under no obligation to give the ASX a notice under s 708A(9)(c) of the Corporations Act;
- (c) admits that it did not at any time within 12 months after the securities were issued under the Institutional Placement give the ASX a notice under s 708A(9)(c);
- (d) says further that it will at trial rely on the full terms and effect of s 708A of the Corporations Act; and
- (e) otherwise denies paragraph 86.

87. As to paragraph 87, it:

- (a) admits that the statements made in the Institutional Placement Cleansing Notice were made:
 - (i) in trade or commerce;
 - (ii) in relation to a financial product (as that term is defined in Chapter 7 of the Corporations Act and in Part 2, Division 2 of the ASIC Act);
and
- (b) otherwise denies that paragraph.

88. It denies paragraph 88.

D.7.5 Alleged 4 November 2016 Misleading or Deceptive Conduct Contravention

89. It denies paragraph 89 and in further answer to that paragraph refers to and repeats paragraphs 36, 36A, 36B, 40-46, 51-57 and 63-68 above.

90. It denies paragraph 90 and in further answer to that paragraph refers to and repeats paragraph 89 above.

91. As to paragraph 91, it:

- (a) refers to and repeats paragraphs 51-57, 63-66, 71(b), 76(b), and 89-90 above;
- (b) admits that the statements made in the November 2016 Announcement were made:
 - (i) in trade or commerce;

(ii) in relation to a financial product (as that term is defined in Chapter 7 of the Corporations Act and in Part 2, Division 2 of the ASIC Act); and

(c) otherwise denies that paragraph.

92. It denies paragraph 92.

93. It denies paragraph 93.

E. THE CORRECTIVE DISCLOSURES AND THEIR IMPACT

E.1 June 2016 Disclosures

94. As to paragraph 94, it:

(a) says that the reference to “*other information*” is embarrassing in the absence of that other information being identified; and

(b) under cover of that objection, denies paragraph 94.

E.2 November 2016 Disclosures

95. As to paragraph 95, it:

(a) admits that the price of Mayne Shares ~~Securities~~ fell on 4 November 2016; and

(b) otherwise denies that paragraph.

E.3 December 2016 Disclosures

96. As to paragraph 96, it:

(a) ~~[not used] refers to and repeats sub-paragraph 5(e) above;~~

(b) says further that the Original Complaint dated 14 December 2016 incorrectly named “Mayne Pharma (USA), Inc.”, which has since been amended to “Mayne Pharma Inc” in the Amended Complaint dated 15 June 2018; and

(c) ~~[not used] says further that the action number of the Original Complaint was 16-ev-2056 (not 17-3768); and~~

(d) otherwise admits that paragraph.

97. As to paragraph 97, it:

(a) refers to and repeats paragraph 96 above;

- (b) says that the AG Announcement incorrectly referred to “Mayne Pharma (USA), Inc”; and
 - (c) otherwise admits that paragraph.
98. As to paragraph 98, it:
- (a) refers to and repeats paragraph 96 above; and
 - (b) otherwise admits that paragraph.
99. It admits paragraph 99.
100. As to paragraph 100, it:
- (a) says that in the December 2016 Announcement, it stated to the Affected Market that “*as previously stated, no assurance can be given as to the timing or outcome of the investigation or legal proceedings*”;
 - (b) says further that it will rely at trial on the full terms and effect of the December 2016 Announcement; and
 - (c) otherwise admits that paragraph.
101. As to paragraph 101, it:
- (a) admits that price of Mayne ~~Shares~~ Securities fell on 16 and 19 December 2016; and
 - (b) otherwise denies that paragraph.

F. ALLEGATION THAT CONTRAVENING CONDUCT CAUSED LOSS

F.1 Market-based causation (on-market acquisitions)

102. As to paragraph 102, it:
- (a) admits sub-paragraph 102(a);
 - (b) admits sub-paragraph 102(b);
 - (c) does not know, and therefore cannot admit, sub-paragraph 102(c);
 - (d) denies sub-paragraph 102(d); and
 - (e) denies sub-paragraph 102(e).
103. [not used] ~~It denies paragraph 103.~~

104. It denies paragraph 104.

F.2 Market-based causation (capital raising acquisitions)

105. It denies paragraph 105.

106. It admits paragraph 106.

107. It admits paragraph 107.

108. It admits paragraph 108.

109. It denies paragraph 109.

110. As to paragraph 110, it refers to and repeats paragraph 105 above.

F.3 Reliance

111. It denies paragraph 111.

F.4 Alleged loss or damage suffered by the Plaintiff and Group Members

112. It denies paragraph 112.

112A. In further answer to paragraphs 102-112, it:

- (a) denies that the doctrine of market-based causation is part of Australian law;
- (b) alternatively, says that if the doctrine of market-based causation is part of Australian law (which is denied), then:
 - (i) the plaintiff and the group members are not entitled to invoke or rely on that doctrine and/or that doctrine can have no application, unless they plead and prove that, had Mayne Pharma not engaged in the alleged contravening conduct – but rather informed the ASX of the alleged material information at the time(s) the plaintiff alleges Mayne Pharma was required to do so, and not made the alleged representations the plaintiff alleges were misleading or deceptive, with the consequence (as alleged by the plaintiff) that the “inflation” in the price of Mayne Shares alleged at paragraph 104 of the statement of claim would not have been in the Mayne Share price at the time they acquired their Mayne Shares – they nevertheless would have proceeded to acquire those Mayne Shares on that counterfactual; and

- (ii) any group member who engaged in short selling of Mayne Shares Securities at any material time cannot invoke or rely on the doctrine of market-based causation in order to establish that any of the alleged contraventions (all of which are denied) caused that group member any loss or damage (which loss and damage is also denied).

112B. In further answer to the whole of the statement of claim, insofar as the plaintiff and group members make claims for compensation pursuant to s 1317HA(1) of the Corporations Act for damage resulting from one or more of Mayne Pharma's alleged contraventions of s 674(2) of the Corporations Act (all of which alleged contraventions are denied), and it appears to the Court that Mayne Pharma has, or may have, contravened s 674(2) of the Corporations Act (which is denied), it:

- (a) says that it has acted honestly;
- (b) says further that having regard to all the circumstances of the case, it ought fairly be excused for any contravention of s 674(2) of the Corporations Act;
- (c) in the premises, the Court should relieve it wholly or partly from the liability to which it would otherwise be subject, or which might otherwise be imposed on it, because of any contravention of s 674(2) of the Corporations Act.

Particulars

Mayne Pharma relies on the Corporations Act, s 1317S.

112C. In further answer to the whole of the statement of claim, insofar as the plaintiff and group members make claims for compensation pursuant to:

- (a) s 1041I(1) of the Corporations Act in relation to economic loss caused by conduct of Mayne Pharma that was allegedly done in contravention of s 1041H of the Corporations Act (which alleged contravention is denied); and/or
- (b) s 12GF(1) of the ASIC Act in relation to economic loss caused by conduct of Mayne Pharma that was allegedly done in contravention of s 12DA of the ASIC Act (which alleged contravention is denied); and/or
- (c) s 236(1) of the Australian Consumer Law in relation to economic loss caused by conduct of Mayne Pharma that was allegedly done in contravention of s 18 of the Australian Consumer Law (which alleged contravention is denied),

it says that:

- (d) if the plaintiff or any group member suffered the loss claimed or any loss at all (which is denied), it was as a result wholly or partly of the plaintiff's or that group member's failure to take reasonable care, by failing to have adequate regard to the full terms of any or all of Mayne Pharma's announcements (including disclaimers and warnings), insofar as:
 - (i) the plaintiff or that group member alleges that they directly relied on any or all of the announcements made by Mayne Pharma in their decision to acquire shares in Mayne Pharma;
 - (ii) further or alternatively, the plaintiff or that group member made the decision to purchase shares in Mayne Pharma without reading those announcements;
- (e) it did not intend to cause the loss claimed by the plaintiff or any group member, or any loss at all; and
- (f) in the premises, if the plaintiff or any group member suffered the loss claimed or any loss at all (which is denied), the damages which the plaintiff or that group member may recover in relation to any losses are to be reduced to the extent to which the Court thinks just and equitable having regard to the plaintiff's or that group member's share in the responsibility for the loss.

Particulars

Mayne Pharma relies on the Corporations Act, s 1041I(1B), the ASIC Act, s 12GF(1B) and the Competition and Consumer Act 2010 (Cth), s 137B.

G. COMMON QUESTIONS OF FACT OR LAW

113. It does not plead to paragraphs 113-117, as those paragraphs contain no allegations against it.

Dated 17 May 2024 ~~17 December 2021~~

J KIRKWOOD
M THOMAS

M GARNER

Herbert Smith Freehills

Herbert Smith Freehills
Solicitors for the defendant