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Details of Filing

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Points of Defence

VID 243 of 2020

Federal Court of Australia
District Registry: Victoria
Division: General

KELVIN MCNICKLE
Applicant

and

HUNTSMAN CHEMICAL COMPANY AUSTRALIA PTY LTD & ORS
Respondents

In answer to the Amended Points of Claim, the Second Respondent and Third Respondent state as follows:

Part A. The Respondents

A.1 The First Respondent

1. In answer to paragraph 1 of the Amended Points of Claim, the Second Respondent and Third Respondent:

   (a) admit that the First Respondent had the name Monsanto Australia Limited between 29 July 1976 and 17 April 1988;

   (b) admit that the First Respondent was a wholly owned subsidiary of Monsanto Company US (Old) between 1974 and 1987; and

   (c) say further that the First Respondent:

      (i) was called Huntsman Chemical Company Australia Limited from 6 July 1993 to 15 April 1996; and

      (ii) has been called Huntsman Chemical Company Australia Pty Ltd since 16 April 1996;

   (d) otherwise do not plead to paragraph 1 as the Applicant makes no allegations against the Second Respondent or Third Respondent.

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2. In answer to paragraph 2 of the Amended Points of Claim, the Second Respondent and Third Respondent:

   (a) say that the manufacture of Roundup Products (as defined in the Amended Points of Claim) involves conversion of intermediate products (**Glyphosate Intermediate**) to glyphosate acid (also known as Glyphosate technical) (**Glyphosate**) which in turn is further converted to glyphosate salts for use in formulation of the Roundup Products;

   (b) admit that, between 1 April 1988 and November 1993, the First Respondent produced Glyphosate for the Second Respondent pursuant to an operating agreement between Legis No 20 Pty Ltd and the First Respondent dated 31 March 1988; and

   (c) otherwise deny the paragraph.

3. The Second Respondent and Third Respondent do not plead to paragraph 3 of the Amended Points of Claim as it raises a matter of law and makes no allegations against the Second Respondent and Third Respondent.

A.2 The Second Respondent

4. In answer to paragraph 4 of the Amended Points of Claim:

   (a) in relation to sub-paragraph (a), the Second Respondent and Third Respondent admit that:

      (i) the Second Respondent was known as Monsanto Australia Limited from 19 April 1988 to 23 August 2018; and

      (ii) the Second Respondent is now known as Monsanto Australia Pty Ltd.

   (b) in relation to sub-paragraph (b), the Second Respondent and Third Respondent:

      (i) say the Second Respondent imported or caused to be imported into Australia Roundup Herbicide from various international Monsanto affiliates or related entities as follows:

         A. between October 1999 and 2018, for distribution by Scotts Australia Pty Ltd;

         B. between 1 March 2013 and 2019, for distribution by Sinochem International Crop Care (Overseas) Pte. Ltd; and

      (ii) say further that the Second Respondent and Third Respondent otherwise do not know whether the Second Respondent imported or

caused to be imported into Australia for distribution Roundup Herbicide from April 1988 and therefore cannot admit this allegation.

(c) in relation to sub-paragraph (c), the Second Respondent and Third Respondent:

(i) say, as currently known, the Second Respondent imported or caused to be imported into Australia Roundup Biactive from various international Monsanto affiliates or related entities at various times between 1 March 2013 and 2019, for distribution by Sinochem International Crop Care (Overseas) Pte. Ltd; and

(ii) say further that the Second Respondent and Third Respondent otherwise do not know whether the Second Respondent imported or caused to be imported into Australia for distribution Roundup Biactive from 1996 and therefore cannot admit this allegation.

(d) in relation to sub-paragraph (d), the Second Respondent and Third Respondent:

(i) say at various times from April 1988 until around 2013 the Second Respondent imported or caused to be imported into Australia one or other of Glyphosate Intermediate and/or Glyphosate;

(ii) refer to and repeat paragraph (8) below; and

(iii) say further that the Second Respondent and Third Respondent otherwise do not know and are unable to admit the allegations in sub-paragraph (d).

(e) in relation to sub-paragraph (e), the Second Respondent and Third Respondent:

(i) admit that, at various times between 1992 and 2002, the Second Respondent manufactured Roundup Herbicide;

(ii) admit that, at various times between 1996 and 2002, the Second Respondent manufactured Roundup Biactive;

(iii) refer to and repeat paragraph 8(a) below;

(iv) say further that:

A. from 2002 until around 2013, Nufarm Australia Limited manufactured Roundup Herbicide and Roundup Biactive;

B. from around 2011 to around 2013, Intec Industries Pty Ltd manufactured Roundup Herbicide and Roundup Biactive; and

(v) say further that the Second Respondent and Third Respondent otherwise do not know and are currently unable to admit the allegations in sub-paragraph (e).

(f) in relation to sub-paragraph (f), the Second Respondent and Third Respondent:

(i) say at various times from 1988 to 2002, the Second Respondent distributed Roundup Herbicide via a network of resellers;

(ii) say at various times from 1996 to 2002, the Second Respondent distributed Roundup Biactive via a network of resellers;

(iii) say the Second Respondent, or affiliates or related entities of the Second Respondent, appointed distributors of Roundup Herbicide and Roundup Biactive, being:

A. from 1999 to 2020, Evergreen Garden Care Australia Pty Ltd (formerly known as Scotts Australia Pty Ltd) or its affiliates/related entities (in relation to Roundup Herbicide, from time to time);

B. from 2002 to 2013, Nufarm Australia Limited (in relation to both Roundup Herbicide and Roundup Biactive); and

C. from 2013 to 2019, Sinochem International Crop Care (Overseas) Pte. Ltd (in relation to both Roundup Herbicide and Roundup Biactive);

through which Roundup Herbicide and Roundup Biactive were distributed via a network of re-sellers at various times; and

(iv) say further that the Second Respondent and Third Respondent otherwise do not know and are therefore unable to admit the allegations in sub-paragraph (f).

(g) in relation to sub-paragraph (g), the Second Respondent and Third Respondent:

(i) repeat and rely on sub-paragraph 4(f)(i)-(iii) above; and

(ii) otherwise deny the allegations.

(h) in relation to sub-paragraph (h) the Second Respondent and Third Respondent:

(i) admit that, at various times from 1988 to 3 May 2002, the Second Respondent promoted and marketed in Australia Roundup Herbicide and engaged in activities related to marketing;

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The promotion and marketing activities included preparation of marketing programs and marketing strategies; conducting promotions; preparation of media schedules.

(ii) say further that insofar as the Second Respondent, or affiliates or related entities of the Second Respondent, provided Roundup Herbicide to Evergreen Garden Care Australia Pty Ltd (formerly known as Scotts Australia Pty Ltd) or its affiliates/related entities, to Nufarm Australia Limited and to Sinochem International Crop Care (Overseas) Pte. Ltd, such entities marketed and promoted in Australia Roundup Herbicide; and

(iii) say further that the Second Respondent and Third Respondent otherwise do not know, and therefore cannot admit, the allegations in sub-paragraph (h).

(i) in relation to sub-paragraph (i) the Second Respondent and Third Respondent:

(i) admit that, at various times from 1996 to 3 May 2002, the Second Respondent promoted and marketed in Australia Roundup Biactive and engaged in activities related to marketing;

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The promotion and marketing activities included preparation of marketing programs and marketing strategies; conducting promotions; preparation of media schedules.

(ii) say further that insofar as the Second Respondent, or affiliates or related entities of the Second Respondent, provided Roundup Biactive to Nufarm Australia Limited and Sinochem International Crop Care (Overseas) Pte. Ltd, such entities marketed and promoted in Australia Roundup Biactive; and

(iii) say further that the Second Respondent and Third Respondent otherwise do not know, and therefore cannot admit, the allegations in sub-paragraph (h).

(j) in relation to sub-paragraph (j), the Second Respondent and Third Respondent:

(i) say that the Second Respondent’s name was used in some information sheets, FAQ sheets, letters, flyers and labels related to Roundup

Herbicide between 1988 to 2002 and Roundup Biactive between 1996 and 2002;

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The Second Respondent published information sheets and FAQ sheets, and distributed marketing letters and flyers and labels referring to its name (Monsanto Australia Limited) at various times.

(ii) say further that insofar as the Second Respondent, or affiliates or related entities of the Second Respondent, provided Roundup Herbicide or Roundup Biactive to Evergreen Garden Care Australia Pty Ltd (formerly known as Scotts Australia Pty Ltd) or its affiliates/related entities, Nufarm Australia Limited or Sinochem International Crop Care (Overseas) Pte. Ltd, such entities may have used the Second Respondent's name in some information sheets, FAQ sheets, letters, flyers and labels related to Roundup Herbicide and Roundup Biactive; and

(iii) say further that the Second Respondent and Third Respondent otherwise do not know whether the Second Respondent caused or permitted its name (Monsanto Australia Limited up to 24 August 2018 and thereafter Monsanto Australia Pty Ltd) to be used in other marketing materials related to Roundup Herbicide or Roundup Biactive and therefore currently cannot admit further the allegations in sub-paragraph (j).

(k) in relation to sub-paragraph (k), the Second Respondent and Third Respondent admit that the Second Respondent used 'Monsanto' and 'Roundup' trademarks from 1988 to 2015, owned in accordance with sub-paragraph 6(c)(iv) of the Amended Points of Claim and sub-paragraph 6(e)(ii)D below.

(l) in relation to sub-paragraph (l), the Second Respondent and Third Respondent admit that, until 7 June 2018, the Second Respondent was an indirect wholly owned subsidiary of Monsanto Company US (Old) and Monsanto Company US (New) and, thereafter, of Bayer Aktiengesellschaft (AG).

5. In answer to paragraph 5 of the Amended Points of Claim:

(a) in relation to sub-paragraph (a), the Second Respondent and Third Respondent:

(i) refer to and repeat paragraph 4(e)(i)-(ii) above; and

(ii) otherwise say further that the allegation raises a matter of law and the Second Respondent and Third Respondent do not know and cannot

admit that for the purposes of the *Trade Practices Act 1974* (Cth) (**TPA**) the Second Respondent was a manufacturer of Roundup Herbicide and Roundup Biactive.

(b) in relation to sub-paragraph (b), the Second Respondent and Third Respondent:

(i) refer to and repeat paragraph 4(e)(i)-(ii) above; and

(ii) otherwise say further that the allegation raises a matter of law and the Second Respondent and Third Respondent do not know and cannot admit that for the purposes of the Australian Consumer Law (**ACL**) being Schedule 2 to the *Competition and Consumer Act 2010* (Cth) (**CCA**), the Second Respondent was a manufacturer of Roundup Herbicide and Roundup Biactive.

A.3 The Third Respondent

6. In answer to paragraph 6 of the Amended Points of Claim, the Second Respondent and Third Respondent:

(a) in relation to sub-paragraph (a)(i), say that, from 2000, the Second Respondent and Third Respondent:

(i) admit that, at various times from 2000, the Third Respondent manufactured one or other of Glyphosate Intermediate and/or Glyphosate;

(ii) admit that Glyphosate Intermediate and/or Glyphosate are used in the manufacture of Roundup Herbicide and Roundup Biactive;

(iii) deny that the Third Respondent manufactured the formulated Roundup Herbicide or Roundup Biactive; and

(iv) otherwise deny the allegations.

(b) in relation to sub-paragraph (a)(ii), say that, from 2000, the Second Respondent and Third Respondent:

(i) say that at various times in 2011 and 2012 the Third Respondent supplied to the Second Respondent for importation into and/or distribution in Australia one or other of glyphosate salts, Glyphosate Intermediate, and/or Glyphosate;

(ii) say further that from 1 July 2016 to 31 August 2018, any glyphosate salts, Glyphosate Intermediate and/or Glyphosate that the Third Respondent may have supplied to the Second Respondent for

importation into and/or distribution in Australia was not for use in the manufacture of Roundup Herbicide and Roundup Biactive;

(iii) say that they do not otherwise know and therefore cannot admit whether from 2000, the Third Respondent supplied to the Second Respondent for importation into Australia one or other of Glyphosate Intermediate and/or Glyphosate for use in the manufacture of Roundup Herbicide and/or Roundup Biactive; and

(iv) deny that the Third Respondent supplied to the Second Respondent for importation into Australia Roundup Herbicide and/or Roundup Biactive.

(c) in relation to sub-paragraph (a)(iii) and (iv), the Second Respondent and Third Respondent:

(i) admit that the words 'Roundup' and 'Monsanto' and a US Monsanto vine design logo were used on product labels; and

(ii) say that the Second and Third Respondent do not otherwise currently know and therefore cannot admit whether the Third Respondent permitted the words 'Roundup' and 'Monsanto' and any Monsanto logo to be used in marketing and other materials in Australia until around 2002.

(d) in relation to sub-paragraph (b), the Second Respondent and Third Respondent repeat and rely on 6(a)-(c) above.

(e) in relation to sub-paragraph (c), the Second and Third Respondent:

(i) say that:

A. in or around early 2000, Monsanto Company US (Old) merged with Pharmacia & UpJohn Inc., a publicly-owned pharmaceuticals company, with Monsanto Company US (Old) being the surviving corporation;

B. during the merger referred to above, Monsanto Company US (New) was created and was incorporated under the laws of the State of Delaware within the United States of America on 9 February 2000 as a wholly owned subsidiary of Monsanto Company US (Old);

C. upon completion of the merger referred to above, Monsanto Company US (Old) changed its name from Monsanto Company to Pharmacia Corporation.

D. Monsanto Company US (New) entered into an agreement with Pharmacia Corporation that was effective 1 September 2000 (**Separation Agreement**);

E. the Separation Agreement related to the transfer to the operations, assets and liabilities of the agricultural business from Pharmacia Corporation to Monsanto Company US (New);

F. pursuant to the Separation Agreement, Monsanto Company US (New) was required to indemnify Pharmacia Corporation for liabilities primarily related to the agricultural business;

G. the Separation Agreement was amended on 1 July 2002 (**Amended Separation Agreement**); and

H. the Amended Separation Agreement clarified rights and obligations relating to indemnification.

(ii) say further that:

A. in relation to sub-paragraph (i), the Second Respondent and Third Respondent:

(1) admit that Monsanto Company US (Old) did manufacture one or other of Glyphosate Intermediate, Glyphosate or glyphosate salts from July 1976 to 2000; and

(2) otherwise deny sub-paragraph (i).

B. in relation to sub-paragraph (ii), the Second Respondent and Third Respondent deny that, from approximately 1976 until 2000, Monsanto Company US (Old) supplied Roundup Herbicide or Roundup Biactive to Monsanto Australia (Old) and Monsanto Australia (New) for the importation, sale and distribution in Australia;

C. in relation to sub-paragraph (iii), the Second Respondent and Third Respondent:

(1) say that, at various times from about 1988 to 2000, Monsanto Company US (Old) supplied to Monsanto Australia (Old) and/or Monsanto Australia (New) one or other of Glyphosate Intermediate and/or Glyphosate; and

(2) say that the Second Respondent and Third Respondent otherwise do not current know and are therefore unable to admit the allegations in sub-paragraph (iii).

D. in relation to sub-paragraph (iv), the Second Respondent and Third Respondent admit that:

(1) prior to the merger referred to in paragraph 6(e)(i)A above, the "Monsanto" Australian trademark number 77856 (**Monsanto Trademark**) and the "Roundup" Australian trademark number 227919 (**Roundup Trademark**) were registered to Monsanto Company US (Old);

(2) following the merger referred to in paragraph 6(e)(i)A above, and by reason of the name change referred to in paragraph 6(e)(i)C above, the Monsanto Trademark and the Roundup Trademark were held by Pharmacia Corporation; and

(3) on 4 February 2002, a full assignment from Pharmacia Corporation to Monsanto Technology LLC in respect of the Monsanto Trademark and the Roundup Trademark was registered with IP Australia.

E. in relation to sub-paragraphs (v), (vi) and (vii), the Second Respondent and Third Respondent say that, in respect of Roundup Herbicide from 1976 until 2000 and Roundup Biactive from 1996 to 2000:

(1) they admit that the words 'Roundup' and 'Monsanto' were used on product labels; and

(2) the Second Respondent and Third Respondent otherwise do not know, and therefore cannot admit, whether Monsanto Company US (Old) permitted the words 'Roundup', 'Monsanto' and any Monsanto logo to be used in marketing and other materials in Australia.

F. in relation to sub-paragraph (viii), the Second Respondent and Third Respondent deny the allegations.

7. In answer to paragraph 7 of the Amended Points of Claim, the Second Respondent and Third Respondent:

(a) say that Bayer AG acquired Monsanto Company US (New) in a transaction that closed on 1 June 2018 (subject to the fulfilment of certain conditions, which were fulfilled as of August 2018);

(b) say further that, following the acquisition, Monsanto Company US (New) was, and continues to be, an indirect wholly-owned subsidiary of Bayer AG, with a separate corporate existence in the State of Delaware, its state of incorporation; and

(c) otherwise deny the allegations in paragraph 7.

Part B. Monsanto Roundup Products

B.1 Roundup Herbicide

8. In answer to paragraph 8 of the Amended Points of Claim, the Second Respondent and Third Respondent:

(a) in relation to sub-paragraph (a):

(i) admit that Roundup Herbicide is formulated using Glyphosate Intermediate;

(ii) for the period 1987 to 2018, admit that the glyphosate was present as glyphosate isopropylamine salt; and

(iii) otherwise deny the sub-paragraph.

(b) admit sub-paragraph (b);

(c) in relation to sub-paragraph (c), admit that Roundup Herbicide is a herbicide product which presently includes ‘Roundup’ in the product name registered with the APVMA but otherwise deny the sub-paragraph; and

(d) admit sub-paragraph (d).

9. The Second Respondent and Third Respondent admit paragraph 9 of the Amended Points of Claim.

10. In answer to paragraph 10 of the Amended Points of Claim, the Second Respondent and Third Respondent:

(a) for the period 1987 to 2018, admit that the active or main active ingredient in Roundup Herbicide was glyphosate; and

(b) for the period 1987 to 2018, admit that the glyphosate was present as glyphosate isopropylamine salt.

11. In answer to paragraph 11 of the Amended Points of Claim, the Second Respondent and Third Respondent:

    (a) for the period 1997 to 2018, admit that Roundup Herbicide, when it was sold in Australia, contained surfactants;

    (b) for the period 1987 to 1996, do not currently know and therefore cannot admit that Roundup Herbicide, when it was sold in Australia, contained surfactants;

    (c) say that there is the potential for impurities to be present (although this is not always the case) in the technical active or other non-active components of Roundup Herbicide as a by-product of the anterior manufacturing of those separate constituent components which themselves are subject to regulation; and

    (d) otherwise deny the sub-paragraph.

B.2 Roundup Biactive

12. In answer to paragraph 12 of the Amended Points of Claim, the Second Respondent and Third Respondent:

    (a) in relation to sub-paragraph (a):

        (i) admit that Roundup Biactive contains glyphosate which is and was present as glyphosate isopropylamine salt; and

        (ii) otherwise deny the sub-paragraph.

    (b) admit sub-paragraph (b);

    (c) in relation to sub-paragraph (c), admit that Roundup Biactive is a herbicide product which presently includes 'Roundup' in the product name registered with the APVMA but otherwise deny sub-paragraph (c); and

    (d) admit sub-paragraph (d).

13. The Second Respondent and Third Respondent admit paragraph 13 of the Amended Points of Claim.

14. In answer to paragraph 14 of the Amended Points of Claim, the Second Respondent and Third Respondent:

    (a) say that they understand the reference to 'Roundup Herbicide' to mean 'Roundup Biactive'; and

    (b) on that basis, admit the allegation.

15. In answer to paragraph 15 of the Amended Points of Claim, the Second Respondent and Third Respondent:

    (a) for the period 1996 to 2018, admit that Roundup Biactive, when it was sold in Australia, contained surfactants; and

    (b) say that there is the potential for impurities to be present (although this is not always the case) in the technical active or other non-active components of Roundup Biactive as a by-product of the anterior manufacturing of those separate constituent components which themselves are subject to regulation; and

    (c) otherwise deny the allegation.

Part C. Properties of Roundup

16. The Second Respondent and Third Respondent deny the allegations in paragraph 16 of the Amended Points of Claim.

17. In answer to paragraph 17 of the Amended Points of Claim, the Second Respondent and Third Respondent say that:

    (a) the Roundup Products were not, at all material times, carcinogenic either at all, or because of the matters referred to in paragraph 23 of the Second Further Amended Statement of Claim;

    (b) generally, surfactants:

        (i) are surface acting agents which are designed to lower the surface tension of the medium in which they are dissolved;

        (ii) may assist in removal of lipids from the epidermal surface;

        (iii) may increase the hydration state of the skin (under closed exposure conditions);

        (iv) may decrease evaporation of water from droplets;

        (v) may increase sub-epidermal blood flow;

        (vi) may aid in intra-epidermal and sub-epidermal intercellular water accumulation; and

        even if there is an interaction between glyphosate and human skin (which is denied), such interaction is likely to be very limited and of negligible effect on humans;

(c) further and alternatively, even if Roundup Products are carcinogenic (which is denied), when used as intended they do not increase an individual's risk of developing, nor cause, NHL, having regard to:

(i) the matters referred to in sub-paragraphs 17(c)(iv) and 17(d) to 17(i) below;

(ii) the fact that the causes of NHL are many and varied; and

(iii) the many objective factors and matters personal to the Applicant which impact upon whether NHL will develop;

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A. the Second and Third Respondents rely upon matters including the matters referred to in the particulars to sub-paragraphs 17(d) to 17(i) below;

B. the types of objective factors include:

(1) methods of application of the Roundup Products;

(2) the location where the glyphosate was sourced and quality of the product;

(3) interactions between adjuvants and organic material within the environment;

(4) water quality and quantity; and

(5) metabolism and rates of excretion of glyphosate from the human body;

C. the types of matters personal to the Applicant include:

(1) age;

(2) personal medical history;

(3) allergy de-sensitisation injections;

(4) history of cancer;

(5) family medical history (including history of cancer);

(6) body weight;

(7) diet;

(8) alcohol consumption;

(9) smoking;

(10) weakened immune system (including from medications, human immunodeficiency virus (HIV), genetically inherited syndromes);

(11) autoimmune diseases including rheumatoid arthritis, systemic lupus, erythematosus, Sjogren disease or celiac disease;

(12) infections including infections that directly transform lymphocytes, including Epstein-Barr virus (EBV), human herpesvirus 8 or human T-cell lymphotropic virus; infections that weaken the immune system, HIV, infections that cause chronic immune stimulation such as Helicobacter pylori, Chlamydophilia psittaci, hepatitis C or Campylobacter jejuni;

(13) exposure to certain medications including chemotherapy and rheumatoid arthritis medications;

(14) radiation exposure;

(15) gender;

(16) race/ethnicity;

(17) exposure to chemicals including benzene;

(18) exposure to outdoor pollution;

(19) exposure to engine exhaust and diesel;

(20) exposure to combustion of biomass fuels;

(21) exposure to other herbicides, insecticides, fungicides and pesticides;

(22) solar and ultraviolet radiation; and

(23) occupational circumstances including shift work.

(iv) the numerous reasons why the Applicant may have developed NHL other than by reason of use of, or exposure to, Roundup Products or the Monsanto Roundup Products include:

A. genetic predisposition;

B. gene changes and DNA mutations caused by factors unrelated to Roundup Products including:

(1) abnormal cell division;

(2) biological or internal factors such as age, gender, inherited genetic defects;

(3) environmental exposure including through radiation and smoke;

(4) occupational risk factors;

(5) life-style factors including obesity, lack of exercise, diet;

(6) personal and family medical history including viruses, hormones, chronic inflammation; and

(7) matters referred to in the particulars to paragraph 17(c)(iii) above including;

(i) interaction of gene mutations;

(ii) random chance;

(iii) the aetiology of NHL; and

(iv) the number of sub-types of NHL.

(d) further, and alternatively, even if Roundup Products are carcinogenic (which is denied):

(i) Roundup Herbicide was marketed for lawn and garden, agricultural, commercial and/or industrial uses respectively in Australia while Roundup Biactive was marketed for agricultural, commercial and/or industrial uses respectively in Australia;

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The Roundup Products were marketed via preparation of marketing programs and marketing strategies; conducting promotions; preparation of media schedules.

(ii) the respective class of persons to whom the Roundup Products were directed would have expected that the Roundup Products, being products intended to be used for lawn and garden, agricultural, commercial and/or industrial uses, would be used only for such purposes and would not be used for any other purpose;

(iii) the Roundup Products were registered for use in Australia according to the following general registration process and could be safely used according to prescribed label directions:

A. the Commonwealth and State and Territory governments have established legislative schemes, and the Commonwealth Government has established a regulatory approval process for the registration and sale of agricultural and veterinary chemical products, being the National Registration Scheme for Agricultural and Veterinary Chemicals (National Registration Scheme) that is now administered by the APVMA, an independent statutory authority:

(1) the National Registration Scheme is embodied in the *Agricultural and Veterinary Chemicals Code Act 1994* (Cth) (**Agvet Code Act**), in delegated legislation and standards made under the Agvet Code Act and in other legislation and delegated legislation including the *Agricultural and Veterinary Chemicals Code Regulations 1995* (Cth) (**Agvet Code Regulations**), the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994* (Cth), the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Cth), the *Agricultural and Veterinary Chemicals Regulations 1999* (Cth), the *Agricultural and Veterinary Chemical Products (Collection of Levy) Regulations 1995* (Cth) and the *Agricultural and Veterinary Chemicals (Administration) Regulations 1995* (Cth);

(2) prior to the National Registration Scheme, each of the various states and territories regulated agricultural chemical products;

(3) under the Commonwealth legislative scheme:

i. agricultural chemical products are, and have been since 1995, included on the Register; and

ii. approved active constituents are included on the Record;

B. the Roundup Products:

(1) were at various times included on the Register as a herbicide containing glyphosate; and

(2) had active constituents which were recorded in the Record;

(iv) at the point in time when the Roundup Products were supplied in Australia, they were supplied with available information, including labels and warnings which complied with the applicable laws, which included information with respect to relevant poisons scheduling, first aid, safety

directions detailing personal protective equipment required to be used when handling and/or using products containing glyphosate;

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Information, including warnings, is included in the label directions and in product summaries included on the APVMA website and material safety data sheets published in various locations including on Monsanto Company US (New)'s website, on the website https://www.crop.bayer.com.au, and on the website www.roundup.com.au.

(v) it was reasonable for the Second Respondent to expect that:

A. prior to use of any of the Roundup Products, the Applicant would review all information, including warnings, and appreciate for himself a variety of pertinent matters including that:

(1) subject to legislation, the Roundup Products had signal words if required by the Poisons Standard;

(2) the Products should not be swallowed, or inhaled, and steps should be taken to protect against being absorbed through the skin, eyes or mouth; and

(3) there was a need when using and/or being exposed to Roundup Products, to follow all safety directions including requirements to use personal protective equipment and to ensure that the application equipment is not faulty and used correctly;

B. prior to use of any of the Roundup Products in an employment context, the Applicant would be informed by his respective employer(s), about the content of all information, including warnings, and appreciate for themselves a variety of pertinent matters including that:

(1) subject to legislation, Roundup Products supplied had signal words if required by the Poisons Standard;

(2) the Roundup Products should not be swallowed, or inhaled, and steps should be taken to protect against being absorbed through the skin, eyes or mouth; and

(3) there was a need when using and/or being exposed to Roundup Products, to follow all safety directions including requirements to use personal protective equipment and to ensure that the application equipment is not faulty and used correctly; and

C. the Roundup Products would be used and applied only to plants for lawn and garden, agricultural, commercial and/or industrial uses;

(e) say further that, having regard to all relevant circumstances, including:

(i) the matters set out in s 75AC (2) of the TPA;

(ii) prevailing scientific knowledge identifying the absence of any reasoned basis to conclude that glyphosate is carcinogenic;

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The scientific knowledge will be the subject of expert evidence at trial.

(iii) the fact that regulatory approval has been given for use of the Roundup Products and glyphosate in Australia and elsewhere throughout the world;

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Regulatory approvals given for use of the Roundup Products within Australia and elsewhere throughout the world will be the subject of evidence at trial. The Second Respondent relies upon regulatory approvals given for use of the Roundup Products in Australia; registrations and approvals given by the United States Environmental Protection Agency (US EPA); and regulatory evaluations of the carcinogenicity of glyphosate, including those published by:

A. the APVMA;

B. the US EPA;

C. the European Food Safety Authority;

D. the European Chemicals Agency;

E. the Health Canada Pest Management Regulatory Agency; and

F. the Environmental Protection Authority of New Zealand.

(iv) the fact that the APVMA, in its 'Final regulatory position: Consideration of the evidence for a formal reconsideration of glyphosate (March 2017)' (**APVMA 2017 Regulatory Position**), concluded that 'the scientific weight-of-evidence indicates that: exposure to glyphosate does not pose a carcinogenic or genotoxic risk to humans' and on that basis declined to formally re-consider glyphosate's registration in Australia;

(v) the fact that, on 22 June 2020 the US District Court (Eastern District of California) in *National Association of Wheat Growers et al v Becerra, Attorney General of California* found that the statement that glyphosate is 'known to the state of California to cause cancer' is 'misleading' and 'the great weight of evidence indicates that glyphosate is not known to cause cancer';

PARTICULARS

The Second Respondent relies upon pages 4 to 7 and 18 to 21 of the decision in *National Association of Wheat Growers et al v Becerra, Attorney General of California* (ED Cal, No. 2:17-cv-2401 WBS EFB, 22 June 2020).

(vi) the fact that:

A. as part of the APVMA evaluation process of an agricultural chemical product, the APVMA receives input where required regarding human and environmental safety from several government agencies including the Australian Government Department of Health, the Australian Government Department of Agriculture, Water and Environment and Food Standards Australia New Zealand;

B. when an agricultural chemical product is approved for registration by the APVMA, the APVMA must also approve each active constituent for the product (before or at the same time as the agricultural chemical product) and the label text of containers for the product (at the same time as the agricultural chemical product) in accordance with s 14 of the Agricultural and Veterinary Chemicals Code (**Agvet Code**), as set out in the Schedule to the Agvet Code Act;

C. the approval of the label is subject to the conditions of approval or registration as set out in s 23 of the Agvet Code and the conditions prescribed by the Agvet Code Regulations including the labelling standards and requirements set out in regulation 18E of the Agvet Code Regulations;

D. pursuant to sub-regulations 18F(1)(a) and (b) of the Agvet Code Regulations, a label must not contain misleading or deceptive information about either the information required by sub-regulation 18D(1) to be stated on the label; or the use, safety, environmental impact or efficacy of the chemical product to which the label relates;

E. further, pursuant to sub-regulation 18F(2), if the label is, or is required to be, attached to a container, information must not accompany or be placed on the container, including in the form of another label, if the information expressly or impliedly negates or varies information required by sub-regulation 18D(1) to be stated on the label, or qualifies or minimises the substance or effect of the information required by sub-regulation 18D(1) to be stated on the label;

F. further, pursuant to sub-regulation 18G(1) of the Agvet Code Regulations, the holder of the approval of the label in relation to the label must not make any claim, or cause or permit any claim to be made about a registered chemical product or a chemical product which contains a registered chemical product that is inconsistent with an instruction on the label for a container for the chemical product;

G. the APVMA 2017 Regulatory Position concluded that the weight of the scientific evidence indicated that exposure to glyphosate does not pose a carcinogenic or genotoxic risk to humans; and

H. in the premises, if labels for the Roundup Products included information that glyphosate was carcinogenic this would be inaccurate or otherwise misleading and would not meet prescribed Australian labelling requirements pursuant to regulations 18F and/or 18G of the Agvet Code Regulations;

(vii) the fact that the risk of any substance causing NHL is dependent upon a wide range of factors including:

A. the chemical composition of the substance said to cause the NHL;

B. the dose;

C. the duration of exposure (including whether it is short or long-term exposure);

D. the route of exposure including environmental, intentional consumption or administration;

E. the concentration of the exposed substance having regard to absorption and distribution within the body;

F. the rate of excretion; and

G. individual susceptibility including the matters referred to in the particulars to sub-paragraph 17(c)(iii) and the matters referred to in paragraph 17(c)(iv) above;

(viii) the availability of other herbicides and similar products to the Roundup Products in the marketplace; and

(ix) the use of and/or exposure to glyphosate and glyphosate-based formulations within the Roundup Products, when used in their intended application, did not, and do not, increase an individual's risk of developing NHL;

(f) say further, by reason of the matters referred to in sub-paragraphs 17(d) and (e) of the Defence to the Second Amended Further Statement of Claim, pursuant to s 75AC(1) of the TPA the safety of the Roundup Products was such as persons using such products in the manner intended were generally entitled to expect;

(g) say further, in the premises referred to in sub-paragraphs 17(d) and (e) above, the Roundup Products did not have a defect within the meaning of s 75AC of the TPA or a safety defect within the meaning of s 9 of the ACL;

(h) say further, pursuant to s 142(a) of the ACL, the safety defect which is alleged to have caused the loss or damage – the increased risk of developing NHL – did not exist at the time that the Roundup Products were supplied by the actual manufacturer; and

(i) say further and alternatively, that even if the increased risk of NHL (which is denied) was a defect or alternatively a safety defect (which is denied), and compensable as such, then:

(i) pursuant to s 75AK(1)(c) of the TPA; and

(ii) alternatively, s 142(c) of the ACL,

the state of scientific knowledge at the time when the particular Roundup Products were supplied by their actual manufacturer is not such as to enable that defect, alternatively safety defect, to be discovered. Accordingly, s 75AK(1)(c) provides a complete defence to the claim under s 74AD of the TPA and s 142 of the ACL affords a complete defence to the claim under s 138 of the ACL.

PARTICULARS

The scientific knowledge will be the subject of expert evidence at trial. The Second Respondent also relies upon all particulars provided elsewhere in sub-paragraphs 17(d)-(i).

Part D. The Applicant and his alleged injuries

18. The Second Respondent and Third Respondent do not know and cannot admit the allegations in paragraph 18 of the Amended Points of Claim.

19. The Second Respondent and Third Respondent do not know and cannot admit the allegations in paragraph 19 of the Amended Points of Claim.

20. The Second Respondent and Third Respondent do not know and cannot admit the allegations in paragraph 20 of the Amended Points of Claim.

21. The Second Respondent and Third Respondent do not know and cannot admit the allegations in paragraph 21 of the Amended Points of Claim.

22. In answer to paragraph 22 of the Amended Points of Claim, the Second Respondent and Third Respondent:

(a) deny the allegations contained therein;

(b) refer to and repeat paragraphs 16 and 17 above; and

(c) say further that after the expiry of the last relevant commercial patent relating to glyphosate in Australia held by Monsanto Technology LLC in approximately 2000, to the extent that the Applicant used glyphosate sourced from other suppliers, and consequently suffered loss and damage, such loss and damage did not arise by reason of the Roundup Products having a safety defect.

Part E. Loss and Damage

23. In answer to paragraph 23 of the Amended Points of Claim, the Second Respondent and Third Respondent:

(a) deny the allegations contained therein;

(b) say that Mr McNickle did not suffer loss and damage, nor will he continue to suffer loss and damage by reason of the matters pleaded in paragraphs 35, 48, 60 and 61(a) and (b) of the 2FASOC and they repeat and rely on sub-paragraph 17(d) to 17(i) above;

(c) say further that, pursuant to s 74D(3) of the TPA, the Roundup Products were of merchantable quality because they were as fit for the purpose or purposes for which goods of that kind are commonly bought as it was reasonable to expect having regard to:

(i) the description applied to the Roundup Products by the Second Respondent;

(ii) the price received by the Second Respondent for the goods; and

(iii) all the other relevant circumstances including:

A. the state of scientific knowledge;

PARTICULARS

The scientific knowledge will be the subject of expert evidence at trial. It also relies upon the particulars provided under sub-paragraphs 17(d) to 17(i) above.

B. the manner in which the Roundup Products have been marketed;

C. instructions for, or warnings with respect to, the Roundup Products;

D. the ordinary or usual risk of harm in other herbicides and similar products to the Roundup Products in the marketplace; and

E. the sophistication of the customers purchasing the Roundup Products;

(d) say further that if the Roundup Products were not of merchantable quality (which is denied), this occurred after the Roundup Products left the control of the Second and Third Respondents and occurred by reason of:

(i) the manner of use of, or exposure to, the Roundup Products by the Applicant, or an act or default of the Applicant or a servant or agent of him; and/or

(ii) a cause independent of human control, and accordingly, by reason of s 74D(2) of the TPA, the Second and Third Respondents are not liable to

compensate the Applicant for any loss and damage pursuant to s 74D(1) of the TPA;

(e) say further that the Roundup Products were:

(i) fit for all purposes for which goods of that kind are commonly supplied;

(ii) acceptable in appearance;

(iii) free from defect; and

(iv) safe and durable,

as a reasonable consumer fully acquainted with the state and condition of the goods (including any hidden defects of the goods) would have regarded as acceptable having regard to the matters in s 54(3) of the ACL;

(f) say further that, in the premises, pursuant to s 54(2) of the ACL, the Roundup Products were of acceptable quality having regard to a variety of matters including:

(i) the matters set out in s 54(3) of the ACL which include:

A. the nature of the goods;

B. the price of the goods (if relevant);

C. any statements made about the goods on any packaging or label on the goods;

D. any representation made about the goods by the supplier or manufacturer of the goods; and

E. any other relevant circumstances relating to the supply of the goods including the state of scientific knowledge; and

PARTICULARS

The scientific knowledge will be the subject of expert evidence at trial. The Second and Third Respondents also rely upon the particulars provided under sub-paragraphs 17(d) to 17(i) above.

(ii) the matters set out in paragraph 23(c) above;

(g) say further and alternatively, if the Roundup Products were not of acceptable quality (which is denied), they did not become of unacceptable quality because of anything inherent in the Roundup Products and accordingly, pursuant to s 54(6) of the ACL, the Roundup Products did not fail to be of acceptable quality;

(h) say that if the Roundup Products are found to present the risk pleaded in paragraph 26 of the Second Further Amended Statement of Claim (which is denied), the state of scientific knowledge was not such as to enable the Second and Third Respondents to discover that risk and accordingly the Second and Third Respondents did not breach any duty of care owed at common law;

PARTICULARS

The scientific knowledge will be the subject of expert evidence at trial. The Second Respondent also relies upon the particulars provided under sub-paragraphs 17(d) to 17(i) above.

(i) say further that to the extent that the Applicant's alleged cause of action in negligence accrued in NSW:

(i) insofar as:

A. pursuant to s 51 of the *Limitation of Actions Act 1969* (NSW) the Applicant's claim is brought after the expiration of a limitation period of 30 years running from the date from which the limitation period for the cause of action runs;

B. alternatively, pursuant to s 50C of *Limitation of Actions Act 1969* (NSW), more than 12 years has elapsed from the date of the act or omission which allegedly resulted in the injury (the 'long-stop limitation period'),

the Applicant's cause of action cannot be maintained unless the Court extends the long-stop limitation period pursuant to ss 62A and 62B of the *Limitation of Actions Act 1969* (NSW); and

(ii) further and alternatively, if these proceedings were commenced more than 3 years after the date of discoverability (as defined in s 50C of *Limitation of Actions Act 1969* (NSW)), these proceedings cannot be maintained unless the Court extends time in accordance with s 60G of the *Limitation of Actions Act 1969* (NSW);

(j) say further that, to the extent that the alleged cause of action accrued in Queensland, if more than 3 years has elapsed since the date on which the cause of action arose these proceedings cannot be maintained, pursuant to s 11 of the *Limitation of Actions Act 1974* (Qld);

(k) say further that, to the extent that the alleged cause of action accrued in the Northern Territory, if more than 3 years has elapsed since the date on which the cause of action arose these proceedings cannot be maintained pursuant to s

12(1)(b) of the Limitation Act 1981 (NT), unless the Court extends time pursuant to s 44(1) of the Limitation Act 1981 (NT);

(l) say further and alternatively, that the common law does not relevantly operate to impose obligations that are more onerous or extensive than those imposed on the Second Respondent and Third Respondent by ss 74D, 75AC and 75AD of the TPA and ss 9, 54, 138, 271 and 272 of the ACL;

(m) say further, that the Applicant's common law cause of action and claims for damages and compensation must be determined in accordance with the *Civil Liability Act 2002* (NSW), alternatively the *Civil Liability Act 2003* (Qld), further and alternatively the Personal Injuries *(Liability and Damages) Act 2003* (NT), (or such other applicable Acts as may apply depending on where the Applicant's causes of action accrued) as well as Part VIB of the TPA and Part VIB of the CCA; and

(n) say further and alternatively, that if the Second Respondent or Third Respondent were negligent (which is denied) and to the extent that the Applicant is entitled to an award of damages, such award of damages is required to be reduced by such sum as is just and equitable having regard to the Applicant's contribution to the loss and damage suffered.

The Second Respondent and Third Respondent refer to and repeat as pleaded herein the details of their defence set out in the Second Respondent's Defence to the Second Further Amended Statement of Claim dated 27 October 2020 and the Third Respondent's Defence to the Second Further Amended Statement of Claim dated 27 October 2020.

Date: 5 May 2021

Herbert Smith Freehills
Solicitors for the Second Respondent and
Third Respondent

This Points of Defence was prepared by Steven Finch SC, Robert Craig QC and Anna Robertson, counsel for the Second Respondent and Third Respondent.

Certificate of lawyer

I Peter Butler certify to the Court that, in relation to these Points of Defence filed on behalf of the Second Respondent and Third 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: 5 May 2021

Herbert Smith Freehills
Solicitors for the Second Respondent and
Third Respondent