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Details of Filing

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Form 34
Rule 16.33

Reply to Second Respondent's Defence to the ~~Third~~ Fourth Further Amended Statement of Claim

VID 243 of 2020

Federal Court of Australia
District Registry: Victoria
Division: General

KELVIN McNICKLE

Applicant

HUNTSMAN CHEMICAL COMPANY AUSTRALIA PTY LTD (ACN 004 146 338) and others named in the Schedule

First Respondent and others according to the Schedule

Capitalised terms have the meaning denoted in the ~~Third~~ Fourth Further Amended Statement of Claim filed ~~10 February~~ 4 July 2022 (**~~3FASOC~~ 4FASOC**).

In this Reply, the term '**Monsanto**' (individually and collectively) is used to refer to one or more entities within the Monsanto group of companies.

In reply to the Second Respondent's Defence to the ~~3FASOC~~ 4FASOC filed ~~11 April~~ 2 August 2022 (the **Defence**), the Applicant (**Mr McNickle**) says:

1. Save as to the admissions contained in the Defence and where otherwise pleaded in this Reply, Mr McNickle joins issue with each and every allegation in the Defence.

2. As paragraph 40(e)(ii) in the Defence, Mr McNickle:

    a. denies the allegations contained in the paragraph;

    b. refers to and repeats the matters alleged at paragraphs 26 to 27, further, paragraphs 26 to 29, further paragraphs 30 and 57 of the ~~3FASOC~~ 4FASOC; and

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c. says further the matters alleged in paragraphs 3 to 60 below.

A. SCIENTIFIC AND OTHER MATERIAL AFFECTED BY IMPROPER PRACTICES AND/OR GHOST AUTHORED BY MONSANTO EMPLOYEES

3. In 2000, a paper by Williams et al titled "Safety Evaluation and Risk Assessment of the Herbicide Roundup and its Active Ingredient, Glyphosate, for Humans" was published in the journal *Regulatory Toxicology and Pharmacology* (**Williams 2000 Paper**).

4. The Williams 2000 Paper:

a. concluded that glyphosate is noncarcinogenic;

b. concluded that, under present and expected conditions of use, Roundup herbicide does not pose a health risk to humans;

c. was initiated supported, and in part written by employees of Monsanto;

Particulars

Mr McNickle refers to, inter alia:

a. Email from Heydens dated 30 April 1999 states in part: "*virtually everything in the genotox section is there at the suggestion of Larry Kier*" [McNickleProdVolNine00009632].

b. Email from Heydens to Ian Munro copied to Farmer dated 30 July 1999 states in part: "*I have sprouted several new gray hairs during the writing of this thing, but as best I can tell, at least they have stayed attached to my head*." [McNickleProdVolNine00009645].

c. Email from Heydens to Farmer dated 21 June 1999 states in part: "*And Dougie thinks I would actually leave the final editing to him unsupervised*" [McNickleProdVolThree00005918].

d. Email from Heydens to Farmer and Wratten dated 15 September 1999 states in part: "*I'll strangle Kroes or Williams if they ask for any re-writes!!*" [McNickleProdVolNine00009652].

e. Internal Monsanto email dated 25 May 2000 refers to the publication of the Williams 2000 paper and states in part: "*Thanks to Donna Farmer, Bill Heydens, Kathy Carr, Marian Bleeke, Bill Graham, Mike McKee and Steve Wratten for their hard work over three years of data collection, writing, review and relationship building with the papers' authors*" [McNickleProdVolNine00009349].

f. Email from Heydens dated 19 February 2015 states in part: *"we would be keeping the cost down by us doing*

the writing and they would just edit & sign their names so to speak. Recall that is how we handled Williams Kroes & Munro, 2000" [McNickleProdVolNine00008055].

d. did not name the Monsanto employees as authors of the paper; and

e. did not disclose that the paper was initiated or supported by Monsanto.

5. In 2012, a paper by Williams et al titled "Developmental and Reproductive Outcomes in Humans and Animals after Glyphosate Exposure: A Critical Analysis" was published in the *Journal of Toxicology and Environmental Health* (**Williams 2012 Paper**).

6. The Williams 2012 Paper:

a. concluded that the available scientific literature provides no apparent evidence to indicate that exposure to glyphosate is associated with the potential to produce adverse developmental and reproductive effects in humans;

b. concluded that the available data demonstrates that exposure to environmentally relevant glyphosate concentrations is not anticipated to produce adverse developmental and reproductive effects in humans;

c. was in part written and edited by Donna Farmer (toxicologist at Monsanto Company US (New)) (**Farmer**) and David Saltmiras (toxicologist at Monsanto Company US (New)) (**Saltmiras**);

Particulars

Mr McNickle refers to, inter alia:

a. Email from Farmer to John De Sesso (**De Sesso**) dated 18 November 2010 states in part: "*I added in a section on genotox from the Gasnier study…Am working on a section for gasiner in the mechanistic section. Also we cut and pasted in summaries of the POEA surfactant studies*" [McNickleProdVolNine00010027]. The document attached to the email contains various amendments and comments, including the deletion of Farmers' name as an author of the paper and reference to Monsanto Company on the title page of the paper [McNickleProdVolNine00010028].

b. A draft manuscript dated 12 January 2010 contains a number of edits and comments by Farmer and Saltmiras [McNickleProdVolNine00008895].

c. Email from Amy Williams (**Williams**) to Farmer and De Sesso dated 19 November 2010 states in part "*Donna, you have added significant text to the document*" with

regard to multiple study references [McNickleProdVolNine00008883].

d. Email from Williams to Farmer and copied to DeSesso and Saltmiras dated 23 November 2020 states in part: "*David… you added this section, please respond*" [McNickleProdVolNine00008883].

d. did not name Farmer or Saltmiras as authors of the paper; and

e. did not disclose that Farmer or Saltmiras had edited or amended the paper.

7. In 2012, a paper by Séralini et al titled "Long term toxicity of a Roundup herbicide and a Round-up tolerant genetically modified maize" was published in the journal of *Food and Chemical Toxicity* (**Séralini 2012 Paper**).

8. The Séralini 2012 Paper concluded:

a. signs of liver and kidney toxicity were seen at 90 days from the consumption of Roundup-tolerant NK603 genetically modified (**GM**) maize which escalated into severe disease over an extended period;

b. negative health effects were observed in all treatment groups;

c. ill effects were not proportional to the dose of either the NK603 GM maize +/- Roundup application or Roundup alone (from 0.1 ppb [parts per billion] of the full pesticide containing glyphosate and adjuvants) suggesting that the observed disease may result from endocrine disruptive effects;

d. by the beginning of the 24th month, 50 to 80% of female animals had developed tumors;

e. metastases were observed in two cases, including one in the group receiving the highest dose of Roundup treatment; and

f. the results of the study may be explained by "*the non-linear endocrine-disrupting effect of Roundup but also the overexpression of the transgene in the GMO and its metabolic consequences*".

9. In or around September 2012, an article by Henry Miller titled "Scientists Smell a Rat in Fraudulent Study" was published in *Forbes* (**2012 Forbes Article**).

10. The 2012 Forbes Article:

a. was critical of Séralini et al's experimental design, findings and peer review process;

b. was written with the assistance or contribution of Monsanto employees including Sachs and Goldstein;

Particulars

a. Email from Sachs to Henry Miller and copied to Goldstein dated 22 September 2012 states in part: "*Where possible I think it is helpful to provide an explanation of how Seralini's methods either contribute to or directly lead to misleading outcomes. This supports your premise that Seralini is abusing the scientific method to support his ideological opposition to GM crops and glyphosate. In some cases the consequences of the faulty study design may not be clear or understandable to some readers"*. The document attached to the email contains various comments, observations, deletions and insertions by Sachs [McNickleProdVolSeven00009641].

b. Email from Goldstein to Miller and copied to Sachs dated 22 September 2012 contains various comments in respect of the draft article [McNickleProdVolNine00008032].

c. did not name the Monsanto employees (including Sachs and Goldstein) as authors of, and/or contributors to, the article; and

d. did not disclose that Monsanto employees (including Sachs and Goldstein) had provided the assistance and/or contribution referred to in sub paragraph 10b. above.

11. In around September 2012, Monsanto:

a. recognised in internal correspondence that it was in Monsanto's interests for the Séralini 2012 Paper to be retracted;

b. recognised in internal correspondence that Monsanto should not be associated with calls for retraction of the Séralini 2012 Paper;

Particulars

Internal Monsanto email from Sachs copied to Saltmiras and others dated 21 September 2012 referred to a plan for experts to submit a letter to the editor states in part "*the best outcome all*

around is for the paper to be retracted, however as Monsanto we need to keep our distance from the actual initiative. David said that Sir Colin Berry, Andrew Cockburn and Andrew Bartholomaeus are likely willing to engage, and that others can be approached. I worry about Monsanto's relationship to these experts and the optics of our involvement in the initiative to draft and submit a letter calling for retraction. My recommendation is for one expert (Sir Colin Berry?) to take the lead and to produce the letter and for Monsanto to keep our distance. We need to be able to deny involvement with such an effort" [McNickleProdVolTwentytwo00221900].

c. represented or proposed to represent in communications to shareholders that the 2012 Forbes Article was independent of Monsanto.

Particulars

Internal Monsanto email from Goldstein to Eric Sachs, Saltmiras and others with subject line "Shareholder Comments for Seralini" states in part: "*I missed the new Miller piece in Forbes…added to this version…*" [McNickleProdVolTwentytwo00367879]. The document attached to the email chain contains a link to the 2012 Forbes Article under the heading "*External and Related Responses*" [McNickleProdVolTwentyTwo00367882].

12. In 2014, the journal *Food and Chemical Toxicity* retracted the Séralini 2012 Paper.

13. In 2012, a paper by Mink et al titled "Epidemiologic studies of glyphosate and cancer: a review", was published in the journal *Regulatory Toxicology and Pharmacology* (**Mink 2012 Paper**).

14. The Mink 2012 Paper:

a. concluded that there was no consistent pattern of positive associations indicating a causal relationship between total cancer (in adults or children) or any site-specific cancer and exposure to glyphosate;

b. was written and edited in part by Farmer and Daniel Goldstein (then Lead, Medical Sciences and Outreach at Monsanto Company US (New)) (**Goldstein**);

Particulars

Mr McNickle refers to, inter alia:

a. Draft versions of the paper contain various comments, observations, deletions and insertions by Goldstein [McNickleProdVolThree00006420] and Farmer

[McNickleProdVolNine00008395; McNickleProdVolNine00008396].

b. In 2008, Farmer added the following text, in part, to the draft manuscript: "*Glyphosate is widely considered by regulatory authorities and scientific bodies to have no carcinogenic potential (US EPA 1993; EU 2002; WHO/FAO 2004). In fact, the US EPA has classified glyphosate as Group E carcinogen, meaning that there is "evidence of non-carcinogenicity for humans" (US EPA, 1993)"* [McNickleProdVolNine00008396].

c. did not name Farmer or Goldstein as authors of the paper; and

d. did not disclose that Farmer or Goldstein had edited or amended the paper.

15. Between 2007 and 2012, Monsanto Company US (New) employees made statements about the Mink 2012 paper being:

a. "*critical*" to the evaluation of glyphosate for re-registration by the European Commission; and

b. designed to "*support efforts*" against anti-glyphosate campaigners in Germany. "*among other purposes*".

Particulars

Mr McNickle refers to, inter alia:

a. Email from Farmer to Pamela Mink (**Mink**) and Jack Mandel dated 11 December 2007 refers to the European Commission evaluation of glyphosate for re-registration due to take place in 2010 and states in part: "*it is critical that we have 3rd party expert support for regulatory and non-regulatory issues*" [McNickleProdVolTwentytwo00187221].

b. Email from Farmer to Mink dated 1 February 2008 states in part: "*this project is significantly behind. Due to this delay I have missed timelines, budget forecasts and my management is not pleased"* and "*I cannot emphasize to you enough how important it is that this project be successfully completed*" [McNickleProdVolTwentytwo00187221].

c. Email from Goldstein copied to Yong Gao, Sachs and Heydens dated 1 March 2012 refers to measures to address an anti-glyphosate campaign in Germany and states in part: "*[w]e are certainly aware of and prepared to support this effort. The new publication series on Glyphosate (Williams 2012/repro, Mink 2012/non-cancer epi, Mandel – pending – cancer outcomes etc.) is*

designed to support this effort among other purposes" [McNickleProdVolNine00006174].

16. In 2013, a paper by Kier and Kirkland titled "Review of genotoxicity studies of glyphosate and glyphosate-based formulations" was published in the journal *Critical Reviews in Toxicology* (**Kier and Kirkland 2013 Paper**).

17. The Kier and Kirkland 2013 Paper:

    a. concluded that glyphosate and glyphosate-based formulations (**GBFs**) do not appear to present significant genotoxic risk under normal conditions of human or environmental exposures;

    b. was in part written by Saltmiras; and

    c. did not name Saltmiras as an author of the paper.

18. In March 2015, the International Agency for Research on Cancer (**IARC**) classified glyphosate as "*probably carcinogenic to humans*" (Group 2A) (**IARC decision**).

Particulars

IARC Monographs on the Evaluation of Carcinogenic Risk to Humans Volume 112 (**IARC Monograph**).

19. In 2015, an op ed article was published in *Forbes* titled "Viewpoint: March Madness from the United Nations" (**2015 Forbes Article**).

20. The 2015 Forbes Article:

    a. stated that the IARC had used a selected set of data in its review to determine whether glyphosate is capable of causing cancer;

    b. stated that there was an absence of linkage between glyphosate and cancer risk;

    c. was organised, directed, coordinated, edited and in part written by Monsanto employees, including Sachs and John Vicini (**Vicini**);

Particulars

Mr McNickle refers to, inter alia:

a. Email from Sachs to Vicini, Hood, Farmer, Saltmiras and others dated 24 February 2015 states in part "*Henry agreed to author an article on Forbes.com. John will work*

with a team internally to provide a draft and Henry will edit/add to make it his own" [McNickleProdVolTwentytwo00023188].

b. Email from Sachs to Miller dated 12 March 2015 asked Miller if he would be interested in writing on "*on the topic of the IARC panel, its process and controversial decision? I have background and can provide information if needed. The outcome is embargoed but will be communicated as early as next week*." and Miller replied he would if he "*could start from a high-quality draft*" [McNickleProdVolNine00007950].

c. Email from Sachs to Miller dated 17 March 2015 attached a copy of a draft article [McNickleProdVolTwentytwo00161167; McNickleProdVolTwentytwo00161170].

d. Draft version of the article dated 17 March 2015 contains various comments and edits from Vicini [McNickleProdVolTwentytwo00287683].

e. Email from Sachs to Miller dated 20 March 2015, the day IARC announced its classification of glyphosate as a probable carcinogen, directed Miller to post the article [McNickleProdVolSeven00006528].

d. did not disclose or adequately disclose Monsanto's organisation, direction, coordination, editing and/or authorship; and

e. was removed by *Forbes* during the course of litigation in the United States of America (**US**) concerning Roundup.

21. In 2015, Monsanto Company US (New) made internal statements to the effect that Monsanto employees should put forward the 2015 Forbes Article as being independent of Monsanto Company US (New) to third parties including:

a. external stakeholders; and

b. regulators.

Particulars

a. Internal Monsanto email from Kimberley Link copied to Goldstein, Sachs, Farmer, Heydens, Saltmiras and others dated 23 March 2015 has the subject line "*New third party statements on glyphosate or IARC*" and refers to the 2015 Forbes Article [McNickleProdVolTwentytwo00023053].

b. Internal Monsanto email from Aimee Hood to Goldstein, Sachs and others dated 24 March 2015 states in part: "*here are some new external resources from today for you to use as needed with external stakeholders*" and under the

heading "*Third Party Responses*" refers to the 2015 Forbes Article [McNickleProdVolTwentytwo00023048].

c. Internal Monsanto email to Nina McCormick, Adams, Heydens and others dated 6 July 2015 has the subject line "*IARC Glyphosate Monograph – Regulator Outreach Materials*" and states that included in the email are "*materials that can be utilized for proactive Regulator conversations in advance of the July 15 publication*" of the IARC Monograph. Under the heading "*Top Positive External Resources*" there is reference to the 2015 Forbes Article [McNickleProdVolTwentytwo00073250].

22. On 7 December 2015, an expert panel presented a "Review of the Carcinogenic Potential of Glyphosate" to a poster session at a meeting of the Society for Risk Assessment (the **Expert Panel Presentation**).

Particulars

Expert Panel Review of the Carcinogenic Potential of the Herbicide Glyphosate presentation by Gary Williams, Tom Sorahan, Marilyn Aardema, John Acquavella, Sir Colin Berry, David Brusick, Michele Burns, Joao Lauro Viana de Camargo, David Garabrant, Helmut Greim, Larry Kier, David Kirkland, Gary Marsh, Keith Solomon, Douglas Weed, and Ashley Roberts [McNickleProdVolTwentytwo00611290; McNickleProdVolTwentytwo00148573].

23. The Expert Panel Presentation:

a. stated that the IARC's review of the carcinogenic potential of glyphosate suffered from significant weaknesses including selectivity of data, failure to use all relevant biologic information and failure to use weight of evidence evaluations;

b. stated that there was no evidence of, or potential mechanism for, glyphosate as a human carcinogen;

c. was organised, directed, coordinated, edited and in part written by Monsanto employees, including Heydens; and

Particulars

Mr McNickle refers to, inter alia:

a. Email from Heydens to Kier copied to Farmer dated 11 November 2015 attached a draft layout for the poster and states in part: "*attached is our 'vision' for the poster*" and "*I put together a draft for the Animal Bioassay Section*" [McNickleProdVolTwentytwo00290253].

b. Email from Heydens to Kier and copied to Roberts and Farmer dated 16 November 2015 attached a further draft poster layout and made recommendations as to how the content and layout of the poster would need to be changed [McNickleProdVolTwentyTwo00301243].

d. did not disclose Heydens' organisation, direction, coordination, editing and/or authorship.

24. In 2016, the following reviews were published in the journal *Critical Reviews in Toxicology*:

a. Brusick et al titled "Genotoxicity Expert Panel review: weight of evidence evaluation of the genotoxicity of glyphosate, glyphosate-based formulations, and aminomethylphosphonic acid" (**Brusick 2016 Paper**);

b. Williams et al titled "A review of the carcinogenic potential of glyphosate by four independent expert panels and comparison to the IARC assessment" was published in the journal in 2016 (**Williams (a) 2016 Paper**);

c. Williams et al titled "Glyphosate rodent carcinogenicity bioassay expert panel review" (**Williams (b) 2016 Paper**);

d. Solomon titled "Glyphosate in the general population and in applicators: a critical review of studies on exposures" (**Solomon 2016 Paper**); and

e. Acquavella et al titled "Glyphosate epidemiology expert panel review: a weight of evidence systematic review of the relationship between glyphosate exposure and non-Hodgkin's lymphoma or multiple myeloma" (**Acquavella 2016 Paper**),

(collectively, **the 2016 CRT Expert Panel Review Papers**).

25. The Brusick 2016 Paper:

a. concluded that glyphosate, GBFs and aminomethylphosphonic acid (**AMPA**) are not consistent with characteristics of genotoxic carcinogens;

b. concluded that there was little or no reliable evidence that GBFs, at levels experienced across a broad range of end-user exposures poses any human genotoxic hazard or risk;

c. concluded that the IARC assessment of classifications regarding strong evidence of genotoxicity and oxidative stress capabilities of glyphosate, GBFs and AMPA is not supported by the available data;

d. concluded that a critical review of the complete dataset by the Expert Panel supported a conclusion that glyphosate (including GBFs and AMPA) does not pose a genotoxic hazard and therefore should not be considered support for the classification of glyphosate as a genotoxic carcinogen;

e. concluded that evidence relating to an oxidative stress mechanism of carcinogenicity was largely unconvincing and that the data profiles were not consistent with the characteristics of genotoxic carcinogens;

f. contained a statement that "*neither any Monsanto company employees nor any attorneys reviewed any of the Expert Panel's manuscripts prior to submission to the journal*";

g. was initiated and sponsored by Monsanto Company US (New);

Particulars

Email from Heydens to Ashley Roberts copied to Farmer dated 1 July 2015 states in part that Monsanto Company US (New) were "*adding David Brusick*" to potential panel participants [McNickleProdVolNine00009595].

h. was in part written, revised, edited and/or amended by Kier, a consultant of Monsanto Company US (New);

Particulars

Consulting agreement dated 17 August 2015 between Kier and Monsanto Company US (New) [McNickleProdVolNine00009836].

i. did not disclose at the time of publication that Kier was a consultant of Monsanto Company US (New);

j. was the subject of a corrigendum issued by the CRT on 26 September 2018.

Particulars

Corrigendum issued by CRT dated 26 September 2018 states in part: *"When this article was originally published on 28th September 2016, the contributions, contractual status and potential competing interests of all authors and non-author*

contributors were not fully disclosed. Specifically, the Acknowledgements and Declaration of Interest were not complete." [McNickleProdVolThree00014831]

26. The Williams (a) 2016 Paper:

a. concluded that there was no support for IARC's conclusion that glyphosate is probably carcinogenic to humans;

b. concluded that reviews of the genotoxicity of glyphosate, AMPA and GBFs that were available prior to the development of the IARC Monograph all support a conclusion that glyphosate (and related materials) is inherently not genotoxic;

c. concluded that evidence indicative of an oxidative stress mechanism of carcinogenicity is largely unconvincing;

d. concluded that glyphosate is unlikely to pose a carcinogenic risk to humans;

e. contained a statement that "*neither any Monsanto company employees nor any attorneys reviewed any of the Expert Panel's manuscripts prior to submission to the journal*";

f. was in part written, revised, edited or amended by Monsanto employees, including Heydens;

g. did not name the Monsanto employees (including Heydens) as authors of the paper; ~~and~~

h. did not disclose that Monsanto employees (including Heydens) had edited or amended the paper; and

i. was the subject of a corrigendum issued by the CRT on 30 November 2018.

Particulars

Corrigendum issued by CRT dated 30 November 2018 states in part: "*When this article was originally published on 28th September 2016, the contributions, contractual status and potential competing interests of all authors and non-author contributors were not fully disclosed to Critical Reviews in Toxicology. Specifically, the Acknowledgements and Declaration of Interest were not complete*." [McNickleProdVolTwelve00002272].

27. The Williams (b) 2016 Paper:

a. concluded that glyphosate is not a carcinogen in laboratory animals given the overall weight of evidence and the application of criteria for causality;

b. contained a statement that "*neither any Monsanto company employees nor any attorneys reviewed any of the expert panel's manuscripts prior to submission to the journal*";

c. was written with the assistance or contribution of Farmer providing "*background* [information] *for the animal section*" and assistance or contribution of Heydens;

d. did not name the Monsanto employees (including Farmer and Heydens) as authors of, or contributors to, the paper;

e. did not disclose that Monsanto employees (including Farmer) had provided the assistance or contribution referred to in sub-paragraph 27c above~~.~~; and

f. was the subject of a corrigendum issued by the CRT on 30 November 2018.

Particulars

Corrigendum issued by CRT dated 30 November 2018 states in part: "*When this article was originally published on 28th September 2016, the contributions, contractual status and potential competing interests of all authors and non-author contributors were not fully disclosed to Critical Reviews in Toxicology. Specifically, the Acknowledgements and Declaration of Interest were not complete*." [McNickleProdVolTwelve00002272]

28. The Solomon 2016 Paper:

a. concluded that based on current reference doses and acceptable daily intake, there is no hazard and no intolerable risk from exposure to glyphosate via its normal use in agriculture and management of weeds in landscape;

b. contained a statement that "*neither any Monsanto company employees nor any attorneys reviewed any of the Expert Panel's manuscripts prior to submission to the journal*";

c. was in part written, revised, edited or amended by Monsanto employees, including Marian Bleeke (**Bleeke**);

d. did not name the Monsanto employees (including Bleeke) as authors of the paper; ~~and~~

e. did not disclose that Monsanto employees (including Bleeke) had edited or amended the paper~~.~~; and

f. was the subject of a corrigendum issued by the CRT on 26 September 2018.

Particulars

Corrigendum issued by CRT dated 26 September 2018 states in part: "*When this article was originally published on 28th September 2016, the contributions, contractual status and potential competing interests of all authors and non-author contributors were not fully disclosed to Critical Reviews in Toxicology. Specifically, the Acknowledgements and Declaration of Interest were not complete*" [McNickleProdVolThree00014829].

29. The Acquavella 2016 Paper:

a. concluded that a review of the glyphosate epidemiologic literature and the application of commonly applied causal criteria do not indicate a relationship with glyphosate exposure and NHL;

b. was in part written, revised, edited or amended by Monsanto employees, including Heydens;

c. did not name the Monsanto employees (including Heydens) as authors of the paper;~~ and~~

d. did not disclose that Monsanto employees (including Heydens) had edited or amended the paper~~.~~; and

e. was the subject of a corrigendum issued by the CRT on 26 September 2018.

Particulars

Corrigendum issued by CRT dated 26 September 2018 states in part: "*When this article was originally published on 28th September 2016, the contributions, contractual status and potential competing interests of all authors and non-author contributors were not fully disclosed to Critical Reviews in Toxicology. Specifically, the Acknowledgements and Declaration of Interest were not complete"* [McNickleProdVolThree00014827].

30. By reason of the matters referred to in paragraphs 3 to 29 above, Monsanto initiated, sponsored, wrote, amended, provided assistance to, contributed to and/or edited scientific research, scientific studies, reviews of scientific studies, papers and articles, and sent or engaged in correspondence and communications with scientific journals, publishers and government agencies and representatives:

    a. which disputed, or did not support:

        i. that Roundup Products and/or glyphosate and/or GBFs are carcinogenic or potentially carcinogenic; and/or

        ii. that use of and/or exposure to Roundup Products, glyphosate and/or GBFs increased an individual's risk of developing NHL;

    b. without disclosure or adequate disclosure of the initiation, sponsorship, editing, amending or authorship of Monsanto.

31. Further, in the circumstances alleged in paragraphs 4, 6, 9, 11, 14, 16, 19, 22, 24 to 29 above, it was improper for Monsanto to fail to disclose, or adequately to disclose, that it had (as the case may be) initiated, sponsored, authored, written, provided assistance to, contributed to, amended and/or edited scientific research, scientific studies, reviews of scientific studies, papers and articles, and sent correspondence to or engaged in communications with scientific journals, publishers and government agencies and representatives.

B. MONSANTO'S CONDUCT IN UNDERMINING AND INVALIDATING SCIENTIFIC RESEARCH

B.1. The Scientific Outreach Plan

32. Further, from at least 1999, Monsanto Company Old (US) and Monsanto Company (New) adopted and implemented a 'Scientific Outreach Plan' (or howsoever otherwise described or referred to within Monsanto Company Old (US) and Monsanto Company New (US) at different times) which included the following elements:

    a. "*Monsanto people who are responsible for dissemination and coordination of scientific information within and outside of Monsanto. They will also play a role in establishing & 'managing' relationships with outside experts*";

b. "*Outside scientific experts who are influential at driving science, regulators, public opinion etc. We would have the*[se] *people directly or indirectly/behind-the-scenes work on our behalf*";

c. "*Presentations/publications in the scientific literature. Get our data out there so it can be referenced and used to counter-balance the negative stuff. In some cases, we may want to publish specific work in certain world areas to help out in that region. We may use our experts as authors*"; and

d. "*Projects/studies to generate critical, lacking data*".

Particulars

a. Email from Heydens dated 26 May 1999 [McNicklеProdVolThree00012111]; email from Farmer dated 23 June 1999 [McNicklеProdVolTwo00001499]; email from Farmer to Thomas J Hoogheem dated 4 February 2000 [MONGLY00878564]; email from Lisa Drake dated 11 May 2000 [McNicklеProdVolThree00006164].

b. The Williams 2000 Paper was described in an internal Monsanto email dated 11 May 2000 [McNicklеProdVolThree00006164] as one of the first examples of "a scientific outreach model". That same email stated that "[o]*ur plan is now to utilize* [the Williams 2000 Paper] *both in the defense of Roundup and Roundup Ready crops worldwide*…"

c. An internal Monsanto 'manuscript clearance form' for the manuscript which would become the Kier and Kirkland 2013 Paper states that the manuscript "*will be a valuable resource for future product defense against claims that glyphosate is mutagenic or genotoxic*." The manuscript followed on from the Williams 2000 Paper (the clearance form states: "[t]*his manuscript reviews glyphosate genotoxicity publications since the* [Williams 2000 Paper]") [McNicklеProdVolThree00014087].

d. A presentation authored by Sachs dated 6 March 2006 states in part: "*3rd parties, including regulatory authorities, scientists and industry groups, are usually the best sources for addressing alarmist claims*" as "*Monsanto's engagement can be like pouring fuel on the fire – it's just what biotech critics and the media want*" [McNicklеProdVolNine00011240].

e. Email from Farmer dated 14 October 2008 regarding an epidemiological study on glyphosate published by Eriksson et al stated: "*We have been aware of this paper for awhile and knew it would only be a matter of time before the activists pick it up. I have some epi experts reviewing it. As soon as I have that review we will pull together a backgrounder to use*

in response. Here is their bottom line… how do we combat this?" [McNickleProdVolNine00008873].

f. A "Monsanto Response Plan to IARC decision" from February 2015 states in part: "*others will perform the bulk of communicating about glyphosate and the IARC decision*" and "*wherever possible Monsanto should refer to third party voices and resources*" and that "*Monsanto – as a leading manufacturer of glyphosate and as a company with reputation challenges – will have very limited credibility when speaking on the topic of glyphosate safety*" [McNickleProdVolNine00011325].

B.2. Conduct in relation to the Séralini 2012 Paper

33. In or around 2012, Monsanto planned and adopted a strategy for responding to the Séralini 2012 Paper, which contained the following elements:

a. coordinated and organised correspondence criticising, discrediting or not supporting the Séralini 2012 Paper to be sent to the editor of the journal *Food and Chemical Toxicity*;

b. provided the assistance and contribution to the authorship of the 2012 Forbes Article in the circumstances alleged in paragraphs 9 and 10 above; and

c. orchestrated, arranged for or encouraged formal letters criticising, discrediting or not supporting the Séralini 2012 Paper to be sent to the editor of the journal *Food and Chemical Toxicity*, including by Helen Cunny of the National Institute of Environmental Health Sciences (US).

Particulars

Email from Saltmiras to Sachs, Heydens and Goldstein (amongst others) dated 26 September 2012 [MONGLY02063095] states in part: "*Wally Hayes (FCT Editor in Chief) called me this morning in response to my voice mail yesterday. He expressed concern that to date he has only received links to blogs, web postings, media releases, etc. and no formal letters to the Editor. He genuinely wants to provide scientific leadership at FCT based on reliable information; scientific responses from credible sources submitted as letters to the Editor are critical. Therefore, he urgently needs rational, objective and authoritative formal letters to the Editor. He said either electronic submission to FCT or direct email to him are acceptable - I suggest both. I believe he would like such letters TODAY!*

Specifically, he mentioned an email from Helen Cunny (NIEHS, North Carolina) to Brian Delaney. Wally said that an official letter to the Editor from her (and other government agency experts)

would prove valuable. Bruce - will you please call Brian Delaney and ask him to follow up with an urgent request for Helen to email a formal letter to the Editor, Wally Hayes? " (underlining in original).

B.3. Conduct in relation to IARC

B.3.1. Pre-IARC decision conduct

34. In 2015, a paper by Kier titled "Review of genotoxicity biomonitoring studies of glyphosate-based formulations" was published in the journal *Critical Reviews in Toxicology* (**Kier 2015 Paper**).

35. The Kier 2015 Paper:

    a. concluded that the results of biomonitoring studies do not contradict an earlier conclusion derived from experimental genotoxicity studies that typical glyphosate-based formulations do not appear to present significant genotoxic risk under normal conditions of human or environmental exposures;

    b. was initiated by Monsanto in preparation for a glyphosate carcinogenicity evaluation by IARC;

    c. was sponsored as a "*project*" by Monsanto; and

    d. was provided by Monsanto Company US (New) to IARC in about February 2015 for consideration by IARC at its meeting in March 2015.

36. Further, the Kier 2015 Paper:

    a. was promoted by the journal *Critical Reviews in Toxicology*, including by a 'summary' document sent to the editor of *Critical Reviews in Toxicology*; and

    b. the summary referred to in subparagraph (a) above was written in part by Saltmiras and intended to be used for promotion of the paper.

37. In March 2015, a paper by Greim et al titled "Evaluation of carcinogenic potential of the herbicide glyphosate, drawing on tumor incidence data from fourteen chronic/carcinogenicity rodent studies" was published in the journal *Critical Reviews in Toxicology* (**Greim 2015 Paper**).

38. The Greim 2015 Paper:

a. concluded that the weight of evidence supported the conclusion that glyphosate does not present concern with respect to carcinogenic potential in humans;

b. was initiated by Monsanto in preparation for a glyphosate carcinogenicity evaluation by IARC;

c. was "*the third such manuscript on relevant glyphosate (first epidemiology, then genotoxicity) which brings balance to both the published subject matter and the pool of eligible expert authors for possible election to an IARC glyphosate carcinogenicity review committee*";

d. casted doubt on the quality and integrity of the Séralini 2012 Paper; and

Particulars

Monsanto Manuscript Clearance Form date marked "05/01/2013" [MONGLY01531298].

e. was provided by Monsanto Company US (New) to IARC in about February 2015 for consideration by IARC at its meeting in March 2015.

B.3.2. Post-IARC decision conduct

39. In or around 2015, Monsanto planned and adopted a strategy for responding to the IARC decision which contained the following elements:

a. the preparation of a plausibility paper involving experts "*only for the areas of contention, epidemiology and* [mechanism of action]" with sections concerning exposure, toxicology and genotoxicity to be "*ghost-written*" by Monsanto employees;

Particulars

a. Email from Heydens to Farmer, Saltmiras, Michael Koch (**Koch**) and Kimberly Hodge-Bell (**Hodge-Bell**) dated 19 February 2015 [KMN.001.001.0547].

b. Heydens proposed that the plausibility paper should be published in the journal of *Critical Reviews in Toxicology* [McNickleProdVolTwentytwo00317024]. Mr McNickle refers to and repeats paragraphs 24 to 31 above.

b. the preparation of a manuscript regarding the animal data cited by IARC to be "*initiated by* [Monsanto] *as ghost writers*";

Particulars

Email from Heydens to Farmer, Saltmiras, Koch and Hodge-Bell dated 11 May 2015 states in part: "*It was noted that this is only* [sic] *other idea that could be done prior to IARC Monograph publication. Manuscript to be initiated by MON as ghost writers. It was noted that this would be more powerful if authored by non-Monsanto scientists (e.g., Kirkland, Kier, Williams, Greim and maybe Keith Solomon). Decide within 1-2 weeks if we recommend going forward with this*" [McNickleProdVolThree00006618].

c. persuading the EPA to "[defend] *the science behind a determination that glyphosate is not carcinogenic*";

Particulars

Undated internal Monsanto Company US (New) memorandum [McNickleProdVolSeven00002006] attached to email from Daniel Jenkins dated 25 February 2016 and commented upon by Heydens.

d. obtaining a "*clarification*" from the World Health Organisation and/or the United Nations Food and Agricultural Organisation:

i. that IARC reviews published studies in order to identify potential hazards and does not estimate the level of risk to the population associated with exposure to the hazard; and

ii. that glyphosate was unlikely to pose a carcinogenic risk to human at realistic exposure levels;

Particulars

Internal Monsanto US (New) email dated 5 June 2015 [McNickleProdVolThree00013570] sent by Michael Dykes (**Dykes**) and copied to Ty Vaughn (**Vaughn**), Daniel Jenkins (**Jenkins**), Farmer and others.

e. briefing officials, including those at the US Department of Health and Human Service (**HHS**), the EPA, the US Trade Representative, the US Department of Agriculture and members of Congress to obtain support to secure the WHO clarification referred to in sub-paragraph 39 d. above;

Particulars

Internal Monsanto US (New) email dated 5 June 2015 [McNickleProdVolThree00013570] sent by Dykes and copied to Vaughn, Jenkins, Farmer and others.

f. briefing senior staff of Senators for the US State of Missouri "*with the goal of those senators sending a letter to Ambassador Jimmy Kolker, the Assistant Secretary of Global Health at HHS, that underscores the urgent need for a WHO clarification with a direct ask that HHS do so*";

Particulars

Internal Monsanto US (New) email dated 19 June 2015 [McNickleProdVolThree00013625] sent by Dykes to Jenkins and others.

g. organising, arranging or securing submissions of 'Questions for the Record' to the HHS Secretary testifying before the House of Representatives House Ways and Means Committee which will "*underscore the domestic and international confusion that has been generated and squarely asks the Secretary to seek a much needed clarification from the WHO*";

Particulars

Internal Monsanto US (New) email dated 19 June 2015 [McNickleProdVolThree00013625] sent by Dykes to Jenkins and others.

h. organised, directed, coordinated, edited and/or wrote the 2015 Forbes Article in the circumstances described in paragraphs 19 and 21 above; and

i. initiated, sponsored, wrote, amended and/or edited and arranged for publication, the 2016 CRT Expert Panel Review Papers in the circumstances described in paragraphs 24 to 31 above.

40. By reason of the matters alleged in paragraphs 32 to 39 above, Monsanto undermined or invalidated scientific research, scientific reviews, reviews of scientific studies, papers and/or articles, including by IARC, containing conclusions that:

a. Roundup Products and/or glyphosate and/or GBFs are carcinogenic or potentially carcinogenic; and/or

b. use of and/or exposure to Roundup Products, glyphosate and/or GBFs increased an individual's risk of developing NHL.

C. MONSANTO'S CONDUCT IN FAILING TO UNDERTAKE TESTING OR UNDERTAKE ADEQUATE TESTING AND FAILING TO PROVIDE INFORMATION TO REGULATORY AUTHORITIES

41. In or around 1999, Professor James Parry was engaged by Monsanto to undertake a review of studies and/or papers concerning the potential genotoxicity of glyphosate and Roundup Products.

42. In or around 1999, Monsanto obtained a report, or series of reports, authored by Professor Parry (**the Parry Reports**).

Particulars

Report titled "*Evaluation of Potential genotoxicity of glyphosate and Round up Mixtures*" and letter from Professor Parry dated 11 February 1999 [McNickleProdVolNine00007835] (**First Parry Report**); Report of Professor Parry titled "*An analysis of potential genotoxicity of glyphosate and its various formulations*" dated 18 August 1999 [McNickleProdVolTwentytwo00077385] (**Second Parry Report**); Third Report of Professor Parry titled "*Evaluation of the potential genotoxicity of glyphosate, glyphosate mixtures and component surfactants*" received by Monsanto on 28 October 1999 [McNickleProdVolNine00007851] (**Third Parry Report**).

43. The First Parry Report concluded that the overall data provided by the four publications reviewed provided evidence to support a model that glyphosate is capable of producing genotoxicity both *in vivo* and *in vitro* by a mechanism based upon the production of oxidative damage.

44. The Second Parry Report concluded, amongst other matters:

a. that the studies provided for the purpose of the preparation of the report provided some evidence that glyphosate may be capable of inducing oxidative damage under both *in vitro* and *in vivo* conditions;

b. that the studies provided for the purpose of the preparation of the report provided some evidence that Roundup mixture produces DNA lesions *in vivo*, probably due to the production of oxidative damage;

c. there is published *in vitro* evidence that glyphosate is clastogenic and capable of inducing sister chromatid exchange in both human and bovine lymphocytes;

d. observations by Lioi et al (1998a, 1998b) and Bolgnesi et al (1997) indicate that glyphosate may be capable of inducing a pro-oxidant state leading to the formation of the oxidative damage lesion 8-OHdG;

e. observations of Bolognesi et al (1997) indicate that Roundup mixture is capable of inducing oxidative damage *in vivo*;

f. studies of Bolognesi et al (1997) suggest that glyphosate mixtures may be capable of inducing oxidative damage *in vivo*;

g. studies of Bolognesi et al (1997) indicates that clastogenic activity may be reproduced *in vivo* in somatic cells; and

h. glyphosate is a potential clastogenic *in vitro*.

45. The Third Parry Report concluded, amongst other matters, that published information on glyphosate and its formulations provide some evidence for genotoxic activity.

46. Further, the Parry Reports contained recommendations of further testing, evaluation and provision of data, including with respect to testing of glyphosate and GBFs:

a. the provision of comprehensive *in vitro* cytogenetic data on glyphosate-based formulations;

b. evaluation of the clastogenic activity of glyphosate in the presence or absence of a variety of antioxidant activities, including incorporation of glyphosate formulations to clarify the validity of reports of differences in activity;

c. that the study referred to in sub-paragraphs 46 a. and b. above should be undertaken using the *in vitro* micronucleus assay in human lymphocytes;

d. evaluation of the induction of oxidative damage *in vivo* and determination of the influence of the antioxidant status of the animals;

e. consideration of the use of the COMET assay (single-cell gel electrophoresis) as a marker of tissue-specific damage in any *in vivo* studies;

f. evaluation of the stability of the formulations and its influence on genotoxic activity;

g. provision of comprehensive *in vitro* data on surfactants; and

h. if the genotoxic activity of glyphosate and its formulations is confirmed, it would be advisable to determine whether there are exposed individuals and groups within the human population. If such individuals can be identified then the extent of exposure should be determined and their lymphocytes analysed for the presence of chromosome aberrations.

47. Monsanto did not undertake, or did not adequately undertake, the testing or evaluation or provision of data that was recommended by Professor Parry as set out in paragraph 46 above.

48. Further, in 2002, Monsanto engaged TNO Nutrition Food and Research (**TNO**) to undertake a dermal penetration study in rats (**TNO Study**).

49. In or around 14 June 2002, Monsanto Europe SA-NV obtained a draft copy of the TNO Study (**Draft TNO Report**).

Particulars

Facsimile from Johan van Burgsteden to Dr Fabrice Broeckaert of Monsanto Europe SA-NV dated 14 June 2002 [MONGLY00888353].

50. The TNO Report concluded, amongst other matters:

a. 48 hours after application of concentrated MON 35012, 10.3% +/- 4.2% of the dose glyphosate had penetrated through rat skin membranes;

b. when MON 35012 was applied as field dilution, the relative penetration was 2.6% +/- 1.4% after 48 hours;

c. for MON 0139 70% solution (70% glyphosate, 30% water) was 1.3% +/- 1.9% for concentrate and 1.4% +/- 2.2% for the field dilution; and

d. an 8-hours exposure resulted in a penetration of *ca.* 10% (MON 35012), *ca*. 2.6% (MON 35012 field dilution), *ca*, 1.3% (MON 0139 70% concentrate) and *ca.* 1.4% (MON 0139 70% field dilution) over a period of 48 hours in viable skin membranes.

51. On a date unknown to Mr McNickle, TNO proposed, and Monsanto agreed to repeat, the *in vitro* dermal penetration study with rat skin proposed by TNO.

Particulars

Email from Dr Broeckaert to Farmer and Heydens (amongst others) dated 4 April 2002 [MONGLY03737014].

52. In or around 2002, Monsanto terminated the TNO Study without the repetition of the *in vitro* dermal penetration study with rat skin proposed by TNO.

Particulars

a. An internal Monsanto email from Richard Garnett copied to Wratten, Farmer, Heydens and others dated 5 April 2002 [MONGLY03737014] stated in part that TNO Study was "*dropped*" because a "*further study*" "*was not likely to help*" meet the project objective of meeting regulatory requirements for operator exposure. That same email also states that "*from the regulatory angle, there is no point in pursuing the studies further*."

b. An internal Monsanto email 4 April 2002 [MONGLY03737014] states that a repetition of the TNO Study was proposed by TNO and agreed to by Monsanto, but subsequently the study was stopped because "*the penetration of glyphosate would have been [probably] greater than the 3% already imposed by the German authorities*" (parentheses in original).

53. On 10 April 2003, TNO provided to Monsanto a further draft report dated 9 April 2003 (**Further Draft TNO Report)**.

Particulars

a. Email of Drs J. A. van Burgsteden to Broeckart and attached draft report titled "*In vitro percutaneous absorption study with [14C]glyphosate in viable rat skin membranes*" dated 9 April 2003 [McNickleProdVolNine00009452; McNickleProdVolNine00009453].

b. Email from Broeckart to Farmer copied to Heydens dated 30 April 2003 attaching a copy of the Further Draft TNO Report [McNickleProdVolNine00009452].

54. On a date unknown to Mr McNickle, TNO provided to Monsanto a final report dated 29 July 2003 (**Final TNO Report**).

Particulars

Report of Drs J. A. van Burgsteden titled "*In vitro percutaneous absorption study with [^{14}C]glyphosate using viable rat skin membranes*" dated 29 July 2003 [McNickleProdVolEleven00002963].

55. The Final TNO Report concluded, amongst other matters:

a. 48 hours after application of concentrated MON 35012, 10.3% +/- 4.2% of the dose glyphosate had penetrated through rat skin membranes;

b. when MON 35012 was applied as field dilution, the relative penetration was 2.6% +/- 1.4% after 48 hours;

c. for MON 0139 70% solution (70% glyphosate, 30% water) was 1.3% +/- 1.9% for concentrate and 1.4% +/- 2.2% for the field dilution; and

d. an 8-hours exposure resulted in a penetration of *ca.* 10% (MON 35012), *ca*. 2.6% (MON 35012 field dilution), *ca*, 0.5% (MON 0139 70% concentrate) and *ca.* 1.4% (MON 0139 70% field dilution) over a period of 48 hours in viable skin membranes.

56. Further, Monsanto failed to, or did not undertake:

a. a repetition of the two-year carcinogenicity study on mice conducted in 1983;

Particulars

In 1983, Monsanto undertook a two-year carcinogenicity study on mice for submission to regulators. Following submission to the EPA, the EPA's Toxicology Branch classified glyphosate as a substance that is possibly carcinogenic to humans. Following this classification, a Dr Marvin Kuschner, a noted pathologist, was retained to review the results from the study "*in an effort to persuade the [EPA] that the observed tumours … are not related to glyphosate*". Monsanto then presented a further report concerning the study to the EPA in 1985, and as a result the EPA downgraded the classification of glyphosate as "*not classifiable as to human carcinogenicity*" but recommended that the 1983 mice study be repeated. The 1983 mice study was not repeated.

b. 12-month or longer chronic toxicity studies on glyphosate after 1991;

c. long term animal carcinogenicity studies on any formulated pesticide product;

d. epidemiological studies to study the association between glyphosate containing formulations and NHL;

e. further studies, epidemiologic research and agricultural chemical exposure assessments which were proposed, put forward or recommended (including) in or around 1999 by Dr John Acquavella (then Senior Fellow and epidemiologist, Monsanto Company US (Old));

Particulars

Memorandum entitled “Rough First Draft NHL Proposal for ECPA” sent by Dr Acquavella to Farmer on or about 3 November 1999 [McNickleProdVolThree00019916].

f. Mr McNickle further refers to and repeats particulars (i) – (v) subjoined to paragraph 58(a) of the ~~3PFASOC~~ 4FASOC which relate to the deficiencies in the toxicity studies undertaken on behalf of Monsanto Company US (Old) by IBT in or around 1970 to 1974. The studies did not identify glyphosate as having carcinogenic properties;

g. testing or research or adequate testing or research on the interaction between glyphosate and/or the Roundup Products and the gut microbiome; and

Particulars

Mr McNickle refers to, inter alia:

a. Paragraphs [138] – [143], [152] – [155] and [162] of the Smith Report.

b. Email from Christophe Gustine copied to Farmer, Saltmiras and others dated 14 October 2010 stated in part, in respect of potential testing of rabbit gut flora testing: “*We need to be very careful that we don’t create new issues when generating this kind of data!”* [McNickleProdVolNine00009945].

c. Email from Goldstein copied to Sachs and others dated 15 April 2015 responded to a query regarding the gut microbiome and whether or not glyphosate plays a role. The email states in part: “*It may – and probably will – turn out that some important things happen in the microbiome. We don’t know yet how to measure them, what they are, how to make them happen, and what adverse effects they have. Until the science developments, spinning unsubstantiated theories and acting on them is highly unlikely to help anything and quite likely to cause unanticipated problems*.” [McNickleProdVolNine00010628].

h. adequate testing on the pharmacokinetics of glyphosate and/or the Roundup Products.

Particulars

Mr McNickle refers to, inter alia:

a. Paragraphs [477] – [480] of the Sawyer Report.

b. Internal Monsanto email chain between Christophe Gustin and Richard Garnett copied to Saltmaris, Farmer,

Graham and others dated 1 July 2008 in which Garnett asked the "*old taboo question. Is the Wester study still an adequate pharmaco-kinetic study on which to base the key value of an average of 95% of the systemically available glyphosate which could be recovered in the urine?*... *I realise that there are risks in doing new studies but also our management must recognise the risks of submitting non-standard studies for such a critical end point.*" Gustin replies: "*You know this has been and still is one of my biggest concerns*" [McNickleProdVolNine00008171].

c. Internal Monsanto presentation dated 15 July 2008 in the possession of Farmer queries whether the Wester study is "*adequate*" for "*regulatory purposes*" [McNickleProdVolNine00008397].

d. Internal Monsanto email from Garnett to Saltmiras, Farmer and others dated 10 November 2008 stated in part: "*To me all this discussion continues to show that we still need solid data for ADME arising from dermal exposure"* and *"dermal exposure is the greatest risk of exposure for operators. Therefore, we need to be secure on the ADME of such exposure"* [McNickleProdVolNine00008180].

e. Internal Monsanto email from Garnett to Gustin and Saltmaris dated 23 September 2009 stated in part: "*The ADME has always been the weak link in our argument and the Spanish response highlights that we have not got rid of the problem.*" [McNickleProdVolNine00011909]

57. By reason of the matters alleged in paragraphs 41 to 56 above, Monsanto did not undertake testing or evaluation, sufficient testing or evaluation and/or further testing or evaluation in relation to the question of whether:

a. Roundup Products and/or glyphosate and/or GBFs are carcinogenic or potentially carcinogenic; and/or

b. use of and/or exposure to Roundup Products, glyphosate and/or GBFs increased an individual's risk of developing NHL.

58. Further, neither:

a. the Parry Reports; or

b. the Draft TNO Report, Further Draft TNO Report and/or Final TNO Report;

i. were provided to regulatory authorities; or

ii. were made publicly available by Monsanto until their disclosure during the course of litigation in the US concerning Roundup.

Particulars

The Parry Reports, the Draft TNO Report, Further Draft TNO Report and Final TNO Report were "relevant information" as defined in section 161(2) of the *Agricultural and Veterinary Chemicals Code Act 1994* (Cth) (the **Code**) and therefore should have been provided to the APVMA by Monsanto Australia (New) in accordance with ss 161(1) and (2A) of the Code.

59. By reason of the matters alleged in paragraph 58 above, Monsanto withheld information, data, studies and/or reports, including from regulatory authorities, which supported the conclusion that Roundup Products and/or glyphosate and/or GBFs are carcinogenic or potentially carcinogenic.

60. By reason of the matters alleged in paragraphs 3 to 59 above, published scientific literature, research and data concerning the carcinogenic properties or potential carcinogenic properties of:

a. Roundup Products;

b. glyphosate; and/or

c. GBFs,

was and is incomplete and/or distorted.

61. As to paragraph 40(e)(iii) of the Defence, Mr McNickle:

a. admits that regulatory approval has been given for use of the Monsanto Roundup Products and/or glyphosate in Australia and elsewhere throughout the world; and

b. says further that by reason of the matters alleged at paragraphs 3 to 60 above, regulatory approvals in Australia and elsewhere throughout the world are and have been based upon, at least in part, incomplete and/or distorted published scientific literature, research and data; and

c. otherwise denies that paragraph.

62. As to paragraphs 40(e)(iv)and (vi)(G) of the Defence, Mr McNickle:

a. admits that, in 2017, the APVMA concluded that the weight of scientific evidence indicated that exposure to glyphosate does not pose a carcinogenic or genotoxic risk to humans and declined to formally re-consider the approval and registration of glyphosate in Australia;

b. says further that by reason of the matters alleged at paragraphs 3 to 60 above, that decision was based upon, at least in part, incomplete and/or distorted published scientific literature, research and data; and

c. otherwise denies that paragraph.

63. As to paragraphs 40(h), 53(c)(iii)(A), 53(f)(i)(E) and 66(c) of the Defence, Mr McNickle:

a. denies the allegations contained in the paragraphs; and

b. refers to and repeats the matters alleged in paragraphs 3 to 60 above.

64. As to paragraph 24(b)(ii), Mr McNickle:

a. admits that regulatory approval was given for the Roundup Herbicide and Roundup Biactive labels in Australia;

b. says further that by reason of the matters alleged at paragraphs 3 to 60 above, regulatory approvals in Australia and elsewhere throughout the world are and have been based upon, at least in part, incomplete and/or distorted published scientific literature, research and data; and

c. otherwise denies that paragraph.

65. As to paragraph 58(c)(iv) of the Defence, Mr McNickle:

a. denies that paragraph; and

b. says further that the AHS study publications suffered from methodological, statistical and analytic errors such that the AHS study publications do not provide valid or reliable indications of the relationship between exposure to glyphosate and/or glyphosate-based formulations and the risk of NHL.

Particulars

Paragraphs [3] – [5], [40] – [187] of the Gordon Report.

66. As to paragraph 58(c)(v) of the Defence, Mr McNickle:

    a. admits that the AHS study publications purported to conclude that exposure to glyphosate-based formulations does not result in an increased risk of NHL;

    b. refers to and repeats sub-paragraph 65.b above and the particulars subjoined therefore; and

    c. otherwise denies that paragraph.

D. LIMITATIONS PERIODS

67. In response to paragraph 43(c) of the Defence, Mr McNickle says that insofar as any supply by Monsanto Australia (New) of glyphosate, glyphosate intermediate or the Roundup Products occurred on or after 13 July 2004:

    a. s.75AO of the TPA has no application to the claims made by Mr McNickle and the Safety Defect Group Members against Monsanto Australia (New) pursuant to s.75AD and/or s.75AE of the TPA; and

    b. the applicable limitation period provisions in respect of the claims made by Mr McNickle and the Safety Defect Group Members against Monsanto Australia (New) pursuant to s.75AD and/or s.75AE of the TPA are those contained in Part VIB of the TPA, including s.87F.

68. In response to paragraph 43(c) to (f) of the Defence, Mr McNickle will, and the Safety Defect Group Members may, make an application, at the trial of this proceeding, pursuant to s.87H of the TPA, for an extension of the long-stop period of 12 years in respect of his cause of action under s.75AD of the TPA against Monsanto Australia (New), insofar as that cause of action arises from any supply or supplies by Monsanto Australia (New) of glyphosate, glyphosate intermediate or the Roundup Products on or after 13 July 2004.

69. In response to paragraph 55(c) of the Defence, Mr McNickle says that insofar as any supply by Monsanto Australia (New) of the Roundup Products occurred on or after 13 July 2004:

    a. s.74J of the TPA has no application to the claims made by Mr McNickle and the Consumer Guarantee Group Members against Monsanto Australia (New) pursuant to s.74D of the TPA; and

b. the applicable limitation period provisions in respect of the claims made by Mr McNickle and the Consumer Guarantee Group Members against Monsanto Australia (New) pursuant to s.74D of the TPA are those contained in Part VIB of the TPA, including s.87F.

70. In response to paragraph 55(c) to (e) of the Defence, Mr McNickle will, and the Consumer Guarantee Group Members may, make an application, at the trial of this proceeding, pursuant to s.87H of the TPA, for an extension of the long-stop period of 12 years in respect of his and or their cause/s of action under s. 74D of the TPA against Monsanto Australia (New), insofar as those causes of action arise from any supply or supplies by Monsanto Australia (New) of the Roundup Products on or after 13 July 2004.

71. In response to paragraph 72(d) of the Defence, Mr McNickle will make applications, at the trial of this proceeding:

a. pursuant to s.62A of the *Limitation of Actions Act 1969 (NSW)* (**the LAA NSW**), for an extension of the 12 year long-stop limitation period imposed by s.50C of the LAA NSW in respect of his cause of action in negligence against Monsanto Australia (New) insofar as it arises from acts or omissions of Monsanto Australia (New) on or after 6 December 2002 which allegedly resulted in the occurrence of his injury and insofar as it is governed by the law of New South Wales;

b. pursuant to s.60G of the LAA NSW for an extension of:-

i. the limitation period imposed by s.14 of the LAA NSW in respect of his cause of action in negligence against Monsanto Australia (New), to the extent, if any, that it accrued before 1 September 1990;

ii. the limitation period imposed by s.18A of the LAA NSW in respect of his cause of action in negligence against Monsanto Australia (New), to the extent, if any, that it accrued on or after 1 September 1990 and before 6 December 2002;

iii. the limitation period imposed by s.50C of the LAA NSW in respect of his cause of action in negligence against Monsanto Australia (New), insofar as his injury resulted from acts of omissions of Monsanto Australia (New) on or after 6 December 2002;

insofar as his cause of action in negligence against Monsanto Australia (New) is governed by the law of New South Wales.

72. In response to paragraph 72(e) of the Defence, Mr McNickle will make an application, at the trial of this proceeding, pursuant to s.31 of the *Limitation of Actions Act 1974 (Qld)* (**the LAA Qld**), for an extension of the limitation period imposed by s.11 of the LAA Qld in respect of his cause of action in negligence against Monsanto Australia (New), insofar as it is governed by the law of Queensland.

73. In response to paragraph 72(f) of the Defence, Mr McNickle will make an application, at the trial of this proceeding, pursuant to s.31 of the *Limitation Act 1981 (NT)* (**the LA NT**), for an extension of the limitation period imposed by s.12(1)(b) of the LA NT in respect of his cause of action in negligence against Monsanto Australia (New), insofar as it is governed by the law of the Northern Territory.

74. In response to paragraph 109 of the Defence, Mr McNickle says that application may be made by Group Members for extensions to limitations periods as are or may be applicable pursuant to the legislation particularised.

Date: ~~5 May 2022~~ 7 October 2022

Signed by Lee Taylor
Lawyer for Mr McNickle

This pleading was prepared by Jack Rush QC, Andrew Clements QC, Melanie Szydzik, Rebecca Howe and Rose Singleton, counsel for Mr McNickle.

Certificate of lawyer

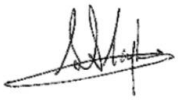
I, Lee Taylor, certify to the Court that, in relation to the reply filed on behalf of Mr McNickle, the factual and legal material available to me at present provides a proper basis for:

(a) each allegation in the pleading; and

(b) each denial in the pleading; and

(c) each non admission in the pleading.

Date: ~~5 May 2022~~ 7 October 2022



Signed by Lee Taylor
Lawyer for Mr McNickle

Schedule

VID 243 of 2020

Federal Court of Australia
District Registry: Victoria
Division: General

Respondents

Second Respondent: Monsanto Australia Pty Ltd (ACN 006 725 560)

Third Respondent: Monsanto Company

Fourth Respondent: Pharmacia LLC