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Details of Filing

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Important Information

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Form 34
Rule 16.33

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

VID 243 of 2020

Federal Court of Australia
District Registry: Victoria
Division: General

KELVIN M^{C}NICKLE

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 Second Further Amended Statement of Claim filed 19 October 2020 (**2FASOC**).

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 2FASOC filed 28 October 2020 (the **Defence**), the Applicant says:

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

2. As to paragraph 35(d)(ii), the Applicant:

    a. denies the allegations contained in the paragraph;

    b. refers to and repeats the matters alleged at paragraphs 23 to 24, further, paragraphs 23 to 25, further paragraphs 26 and 53 of the 2FASOC; and

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c. says further the matters alleged in paragraphs 3 to 55 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;

   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**);

   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 September 2012, written correspondence was sent to the editor of the journal *Food and Chemical Toxicity* by Professor Bruce Chassy following the publication by that journal of a paper by Séralini et al titled "Long term toxicity of a Roundup herbicide and a Round-up tolerant genetically modified maize" (**Séralini 2012 Paper**).

Particulars

Emails between Professor Chassy to A. Wallace Hayes dated 26 September 2012 [MONGLY00900629].

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 was observed in two cases, including one in the group receiving the highest does 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. The correspondence referred to in paragraph 7 above:

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

b. called for the retraction of the publication of the Séralini 2012 Paper;

c. was coordinated and organised in part by Monsanto, including Eric Sachs (scientist at Monsanto Company US (New) (**Sachs**)); and

d. did not disclose Monsanto's coordination or organisation of the correspondence.

10. 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**).

11. 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;

Particulars

Email from Sachs to Henry Miller (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].

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

d. did not disclose that Monsanto employees (including Sachs) had provided the assistance or contribution referred to in sub paragraph 11b. above.

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**);

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. 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**).

16. 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.

17. 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**).

18. A letter dated 9 October 2015 was sent to Ms Esther Barajas-Ochoa, of the Office of Environmental Health Hazard Assessment (**OEHHA**) from Dr Samuel M. Cohen of the University of Nebraska Medical Center (**OEHHA Letter**).

19. The OEHHA Letter:

a. was critical of the IARC decision;

b. criticised IARC's consideration of the Séralini 2012 Paper;

c. was written in part by employees of Monsanto;

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

e. did not disclose that Dr Cohen was writing at Monsanto's initiation or instigation.

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

21. 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;

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

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

22. 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**).

23. 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 in part written, revised, edited or amended by Monsanto employees, including William Heydens (toxicologist at Monsanto Company US (New) (**Heydens**));

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

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

24. 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.

25. 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*";

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

e. did not disclose that Monsanto employees (including Farmer) had provided the assistance or contribution referred to in sub-paragraph 25 b. above.

26. 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 Heydens;

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

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

27. 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.

28. By reason of the matters referred to in paragraphs 3 to 27 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.

29. Further, in the circumstances alleged in paragraphs 4, 6, 9, 11, 14, 16, 19, 21, 23 to 28 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

30. Further, on a date presently unknown to the Applicant, Monsanto adopted a 'Scientific Outreach Plan' 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 [McNickleProdVolThree00012111]; email from Farmer dated 23 June 1999 [McNickleProdVolTwo00001499]; email from Farmer to Thomas J Hoogheem [MONGLY00878564]; email from Lisa Drake dated 11 May 2000 [McNickleProdVolThree00006164]

b. The Williams 2000 Paper was described in an internal Monsanto email dated 11 May 2000 [McNickleProdVolThree00006164] 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]") [McNickleProdVolThree00014087].

d. Further particulars may be provided following discovery.

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

31. 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* by Professor Chassy in the circumstances alleged in paragraphs 7 and 9 above;

b. provided the assistance and contribution to the authorship of the 2012 Forbes Article in the circumstances alleged in paragraphs 10 and 11 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

32. 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**).

33. 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.

34. 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 34 a. above was written in part by Saltmiras and intended to be used for promotion of the paper.

35. 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**).

36. 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].

Further particulars may be provided following discovery.

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

37. 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

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

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].

Further particulars may be provided following discovery.

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].

Further particulars may be provided following discovery.

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 37 d. above;

Particulars

Internal Monsanto US (New) email dated 5 June 2015 [McNickleProdVolThree00013570].

Further particulars may be provided following discovery.

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].

Further particulars may be provided following discovery.

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].

Further particulars may be provided following discovery.

h. organised, directed, coordinated, edited and/or wrote the 2015 Forbes Article in the circumstances described in paragraphs 20 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 22 to 29 above.

38. By reason of the matters alleged in paragraphs 30 to 37 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

39. 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.

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

Particulars

Report and letter from Professor Parry dated 11 February 1999 [MONGLY01312093] (**First Parry Report**); undated reports [MONGLY01314233] (**Second and Third Parry Reports**).

Further particulars may be provided following discovery.

41. 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.

42. 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*.

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

44. 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-paragraph 44 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.

45. Monsanto did not undertake the testing or evaluation or provision of data that was recommended by Professor Parry as set out in paragraph 44 above.

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

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

Particulars

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

48. 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.

49. On a date unknown to the Applicant, 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].

50. 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 5 April 2002 [MONGLY03737014] states that the 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).

c. Further particulars may be provided following discovery.

51. 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)); and/or

Particulars

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

Further particulars may be provided following discovery.

f. the Applicant further refers to and repeats particulars (ii)(a) and (b) subjoined to paragraph 53 of the 2FASOC 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.

52. By reason of the matters alleged in paragraphs 39 to 51 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.

53. Further, neither:

a. the Parry Reports; or

b. the 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

Further particulars may be provided following discovery.

54. By reason of the matters alleged in paragraph 53 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.

55. By reason of the matters alleged in paragraphs 3 to 54 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.

56. As to paragraph 35(d)(iii), the Applicant:

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 55 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.

57. As to paragraphs 35(d)(iv) and (vi)(G), the Applicant:

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 55 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.

58. As to paragraphs 35(h), 48(c)(iii)(A), 48(f)(i)(E) and 61(c), the Applicant:

a. denies the allegations contained in the paragraphs; and

b. refers to and repeats the matters alleged in paragraphs 3 to 55 above.

Date: 25 November 2020

Signed by Andrew Watson
Lawyer for the Applicant

This pleading was prepared by Jack Rush QC, Melanie Szydzik and Rebecca Howe, counsel for the Applicant.

Certificate of lawyer

I, Andrew Watson, certify to the Court that, in relation to the reply filed on behalf of the Applicant, 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: 25 November 2020

Signed by Andrew Watson
Lawyer for the Applicant

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