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Court of Filing	FEDERAL COURT OF AUSTRALIA (FCA)
Date of Lodgment:	2/02/2023 9:27:46 AM AEDT
Date Accepted for Filing:	2/02/2023 9:27:51 AM AEDT
File Number:	VID243/2020
File Title:	KELVIN MCNICKLE v HUNTSMAN CHEMICAL COMPANY AUSTRALIA PTY LTD & ORS
Registry:	VICTORIA REGISTRY - FEDERAL COURT OF AUSTRALIA

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Rejoinder of the Third Respondent to the Applicant's Reply to the Third 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 LTD & ORS and others named in the Schedule

Respondents

By way of Rejoinder to the Applicant's Reply to the Third Respondent's Defence to the ~~Third~~ Fourth Further Amended Statement of Claim filed on ~~5 May 2022~~ 7 October 2022 (**the Applicant's Reply to the Third Respondent's Defence**), the Third Respondent pleads as follows:

1. It does not plead to the allegations in paragraph 1 as the Applicant makes no allegations against it.

2. In answer to paragraph 2, it:

   (a) refers to and repeats paragraphs 26 – 30, 40 and 57 of its defence to the Applicant's ~~Third~~ Fourth Further Amended Statement of Claim;

   (b) otherwise denies the allegations;

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

3. It admits the allegation in paragraph 3.

Filed on behalf of Monsanto Company, Third Respondent
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4. In answer to paragraph 4, it

(a) admits that the paper by Gary M Williams, Robert Kroes and Ian C Munro titled *'Safety Evaluation and Risk Assessment of the Herbicide Roundup and its Active Ingredient, Glyphosate, for Humans'* (**Williams 2000 Paper**) did not name Monsanto employees as authors;

(b) otherwise denies the allegations in paragraph 4;

(c) says further that:

(i) subject to production by the Applicant of the Williams 2000 Paper, and reference at trial to its full terms and effect, the Williams 2000 Paper stated, among other things, that:

(A) *'Reviews on the safety of glyphosate and Roundup herbicide that have been conducted by several regulatory agencies and scientific institutions worldwide have concluded that there is no indication of any human health concern';*

(B) '[Glyphosate and AMPA] *are eliminated essentially unmetabolized. Dermal penetration studies with Roundup showed very low absorption';*

(C) *'No significant toxicity occurred in acute, sub-chronic and chronic studies';*

(D) *'There was no convincing evidence for direct DNA damage in vitro or in vivo, and it was concluded that Roundup and its components do not pose a risk for the production of heritable/somatic mutations in humans';*

(E) *'Multiple lifetime feeding studies have failed to demonstrate any tumorigenic potential for glyphosate. Accordingly, it was concluded that glyphosate is noncarcinogenic';*

(F) '*The balance of the credible data from in vitro and in vivo test results confirms the safety of glyphosate and Roundup as nongenotoxic and conforms to the fact that glyphosate is noncarcinogenic*';

(G) *'It was concluded that, under present and expected conditions of use, Roundup herbicide does not pose a health risk to humans';*

(ii) the Williams 2000 Paper did not name Monsanto employees as authors, and it was only required to do so in circumstances where ~~would have been inappropriate for it to do so because~~ the contribution made ~~by Monsanto employees~~ was ~~not a~~ significant ~~contribution~~ to the conception, design, or interpretation of the reported study;

(iii) the assistance of Monsanto employees who participated in the preparation of the Williams 2000 Paper was expressly acknowledged by the authors;

Particulars

The acknowledgement is in writing, contained on page 160 of the Williams 2000 Paper, and is in the following terms:

'The authors acknowledge the assistance of individuals who participated in the preparation of this document. First, we are grateful to those who gathered and made available the large amount of information used to write the manuscript for this document. Second, we thank the toxicologists and other scientists at Monsanto who made significant contributions to the development of exposure assessments and through many other discussions. The authors were given complete access to toxicological information contained in the great number of laboratory studies and archival material at Monsanto in St. Louis, Missouri, and elsewhere. Key personnel at Monsanto who provided scientific support were William F. Heydens, Donna R. Farmer, Marian S. Bleeke, Stephen J. Wratten, and Katherine H. Carr.'

(iv) it denies that any involvement of Monsanto had an impact on the validity of the underlying scientific data or conclusions reached in the Williams 2000 Paper by Gary M Williams, Robert Kroes and Ian C Munro; and

(v) in the premises identified in paragraphs 4(c)(ii) to 4(c)(iv) above the contribution made by Monsanto employees did not amount to authorship.

5. It admits the allegations in paragraph 5 and says further that the paper by Amy Williams, Rebecca Watson and John DeSesso titled *'Developmental and Reproductive Outcomes in Humans and Animals after Glyphosate Exposure: A Critical Analysis'* published in the Journal of Toxicology and Environmental Health (**Williams 2012 Paper**) was also published online on 27 December 2011.

6. In answer to paragraph 6, it:

(a) admits that the Williams 2012 Paper did not name Donna Farmer or David Saltmiras as authors;

(b) otherwise denies the allegations in paragraph 6;

(c) says further that:

(i) subject to production by the Applicant of the Williams 2012 Paper, and reference at trial to its full terms and effect, the Williams 2012 Paper stated, among other things, that:

(A) '*An extensive, in-depth analysis of the available 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) '*In conclusion, a thorough evaluation of the available data demonstrates that exposure to environmentally relevant glyphosate concentrations is not anticipated to produce adverse developmental and reproductive effects in humans*.'

(ii) Donna Farmer and David Saltmiras assisted the authors of the Williams 2012 Paper with:

(A) articles, studies, data; and

(B) suggestions in the form of amendments and additions to the draft of the Williams 2012 Paper; which did not make a significant scientific contribution to the paper.

(iii) the Williams 2012 Paper does not name Donna Farmer and David Saltmiras as authors of the paper and it would have been inappropriate for it to do so because:

(A) according to the Author Guidelines published by Taylor & Francis, the company that published the Williams 2012 Paper in the Journal of Toxicology and Environmental Health, at the time of the Williams 2012 Paper, authors were advised, *inter alia,* that: (1) *'Co-authors' are defined as any person who has made a significant scientific contribution to the work reported, and who shares responsibility and accountability for the results.'* (2) *'all named co-authors:… must have made a significant contribution to the work reported, in terms of research conception or design, and/or acquisition of data, and/or the analysis and interpretation of those data' (3) 'all named co-authors:… are responsible for drafting, writing, and revising the article, or checking and confirming the article prior to submission' (4) 'all named co-authors:… approve the final version of the article prior to submission';*

(B) the contribution made by Donna Farmer and David Saltmiras was not significant in the context of the Williams 2012 Paper;

(C) the authors of the Williams 2012 Paper retained complete authority to accept or reject suggested amendments to the Williams 2012 Paper;

(D) to the extent that amendments and additions were accepted by the authors and adopted in the Williams 2012 Paper, the authors of the Williams 2012 Paper independently verified and approved the suggested amendments and additions provided by Donna Farmer and David Saltmiras;

(E) the Williams 2012 Paper manuscript was considered by five independent reviewers prior to publication; and

(F) the Williams 2012 Paper disclosed that Monsanto Company had provided:

(1) funding for the Williams 2012 Paper;

(2) unpublished glyphosate and surfactant toxicity study reports to the authors of the Williams 2012 Paper; and

(3) other data for the purpose of the Williams 2012 Paper.

Particulars

The disclosure is contained in:

(1) the footer on the page marked 39 (page one of the Williams 2012 Paper itself) of the Williams 2012 Paper and is in the form '*The authors acknowledge the Monsanto Company for funding and for providing its unpublished glyphosate and surfactant toxicity study reports';*

(2) a statement on pages marked 41 to 42 of the Williams 2012 Paper that '*Experimental investigations conducted by the Monsanto Company in support of regulatory requirements were made available to the authors';* and

(3) a statement on the page marked 42 that '*animal studies (both published reports as well as unpublished studies owned by Monsanto) addressing appropriate toxicity endpoints were reviewed'*.

(iv) it denies that any involvement of Monsanto had an impact on the validity of the underlying scientific data or conclusions reached in the Williams 2012 Paper by Amy Williams, Rebecca Watson and John DeSesso; and

(v) in the premises identified in paragraphs 6(c)(ii) to 6(c)(iv) above the contribution made by Monsanto employees did not amount to authorship.

7. It admits the allegations in paragraph 7.

8. In answer to paragraph 8, it:

(a) denies the allegations in paragraph 8;

(b) says further that:

(i) subject to production by the Applicant of the Séralini 2012 Paper, and reference at trial to its full terms and effect, the Séralini 2012 Paper as originally published stated, among other things, that:

(A) '*Metastases were observed in only 2 cases; one in a group fed with 11% GM maize, and another in the highest dose of R treatment group*'; and

(B) '*These results can be explained by the non-linear endocrine-disrupting effects of Roundup, but also by the overexpression of the transgene in the GMO and its metabolic consequences.*';

(ii) the Séralini 2012 Paper was retracted from the journal Food and Chemical Toxicology in November 2013, following criticism from the scientific community and an investigation by the journal itself, because, among other things, it contained a number of deficiencies;

Particulars

(1) A number of letters to the editor of the journal Food and Chemical Toxicology were critical of the Séralini 2012 Paper, including letters from individuals at:

i. Monsanto Company [McNickleProdVolFive00143046];

ii. the University of Melbourne [McNickleProdVolFive00183234];

iii. the Brazilian Biosafety Association [McNickleProdVolFive00129721];

iv. the Agricultural Genetics Institute, Vietnam [McNickleProdVolFive00131959];

v. the Flanders Institute for Biotechnology, Belgium [McNickleProdVolFive00142322];

vi. the Russian Academy of Sciences [McNickleProdVolFive00167182];

vii. Vancouver Island University, and 24 others [McNickleProdVolFive00186505];

viii. the University of Adelaide [McNickleProdVolFive00153925] and [McNickleProdVolFive00182364];

ix. the University of London [McNickleProdVolFive00119900];

x. The University of Edinburgh [McNickleProdVolFive00183225];

xi. The European Society of Toxicologic Pathology [McNickleProdVolFive00175375],

and a letter from:

xii. Dr Louis Ollivier [McNickleProdVolFive00279081] in his personal capacity.

(2) A reply to the letters to the editor of the journal Food and Chemical Toxicology, drafted by Dr Wallace Hayes, which stated, among other things, that *'A careful and time-consuming analysis found that the data* [in the Séralini 2012 Paper] *were inconclusive, and therefore the conclusions described in the article were unreliable. Accordingly, the article was retracted'* [McNickleProdVolFive00143783].

(3) Letter from Professor A. Wallace Hayes, editor-in-chief of the journal Food and Chemical Toxicology, to Professor Séralini concerning the retraction of the Séralini 2012 Paper following an investigation [McNickleProdVolFive00110958].

(iii) the deficiencies in the Séralini 2012 Paper included that:

(A) '*The claimed toxicity of Roundup is implausible and doesn't align with extensive data from well designed and conducted long-term studies that used the active ingredient of Roundup; glyphosate, in multiple species (i.e. mice, rats, rabbits and dogs) at higher doses where no effects were observed'*;

Particulars

Food Standards Australia response to the Séralini 2012 Paper <https://www.foodstandards.gov.au/consumer/gmfood/Séralini/pages/default.aspx> (accessed 18 December 2020).

(B) there were flaws in the experimental design, including that the study did not comply with internationally recognised standards for long-term carcinogenicity studies, including as to the minimum number of animals to be used;

Particulars

i. Monsanto's comments on the Séralini 2012 Paper [McNickleProdVolFive00110960], page 2.

ii. Monsanto's detailed technical comments on the Séralini 2012 Paper [McNickleProdVolFive00110994], pages 1 and 2.

iii. Food Standards Australia response to the Séralini 2012 Paper <https://www.foodstandards.gov.au/consumer/gmfood/Séralini/pages/default.aspx> (accessed 18 December 2020).

iv. European Food Safety Authority review of the Séralini 2012 Paper [McNickleProdVolFive00110927], pages 5 and 9.

(C) there was an inappropriate application of statistical methods to analyse the toxicology data, and the number of animals used was too small and insufficient for statistically assessing the claimed differences between the test groups and the control group;

Particulars

i. Monsanto's comments on the Séralini 2012 Paper [McNickleProdVolFive00110960], pages 3 and 4.

ii. Monsanto's detailed technical comments on the Séralini 2012 Paper [McNickleProdVolFive00110994], pages 2, 3 and 11.

iii. European Food Safety Authority review of the Séralini 2012 Paper [McNickleProdVolFive00110927], pages 6 and 9.

iv. Health Canada and the Canadian Food Inspection Agency's review of the Séralini 2012 Paper <https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/canadian-food-inspection-agency-statement-Séralini-2012-publication-2-year-rodent-feeding-study-glyphosate-formulations-maize-nk603.html> (accessed 18 December 2020).

(D) the main conclusions of the authors were not supported by the presented data, which was incomplete or missing;

Particulars

i. Monsanto's comments on the Séralini 2012 Paper [McNickleProdVolFive00110960], pages 3 and 5.

ii. Monsanto's detailed technical comments on the Séralini 2012 Paper [McNickleProdVolFive00110994], page 10.

(E) *'The methodology used was inadequately described, the full data set was not presented, and the data that was reported was not presented in a transparent manner.';*

Particulars

Health Canada and the Canadian Food Inspection Agency's review of the Séralini 2012 Paper <https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/canadian-food-inspection-agency-statement-Séralini-2012-publication-2-year-rodent-feeding-study-glyphosate-formulations-maize-nk603.html> (accessed 18 December 2020).

(F) the authors misinterpreted the study's findings, and failed to acknowledge that tumour rates fell within historical norms for the relevant strain of laboratory rat;

Particulars

i. Monsanto's comments on the Séralini 2012 Paper [McNickleProdVolFive00110960], page 3.

ii. Monsanto's detailed technical comments on the Séralini 2012 Paper [McNickleProdVolFive00110994], pages 3 to 5.

iii. Food Standards Australia response to the Séralini 2012 Paper <https://www.foodstandards.gov.au/consumer/gmfood/Séralini/pages/default.aspx> (accessed 18 December 2020).

(G) '*The study was underpowered, it was poorly presented and poorly analysed*';

Particulars

Deposition of the US Plaintiffs' expert witness, Christopher Portier, dated 17 April 2018 [McNickleProdVolEight00075602] at 591:8-21.

(H) it '*wasn't conducted very well…it wasn't adequate… It's just not a good study.*';

Particulars

Deposition of the US Plaintiffs' expert witness, Charles Jameson, dated 27 September 2018 [McNickleProdVolEight00030637] at 269:21-270:6.

(I) *'The study was widely rejected by the scientific community as poorly planned and executed. There is no evidence that the study was scientifically significant in any way.'*;

Particulars

Pilliod v Monsanto, Order on Motions in Limine No. 18, Mar. 19, 2019, per Judge Smith.

(c) in 2014, the results of the Séralini 2012 Paper were republished in the open-access journal Environmental Sciences Europe (**Republished Séralini Paper**);

Particulars

Republished Séralini Paper [McNickleProdVolFive00176433].

(d) the Republished Séralini Paper stated, among other things, that:

(i) *'Our data show that the signs of liver and kidney toxicity seen at 90 days from the consumption of NK603 GM maize [3, 7] do indeed escalate into severe disease over an extended period'*;

(ii) *'Furthermore, similar negative health effects were observed in all treatment groups (NK603 GM maize with or without R application and R alone)'*;

(iii) *'What is also evident from our data is that ill effects were not proportional to the dose of either the NK603 GM maize ± R or R alone. This suggests that the observed disease may result from endocrine disruptive effects, which are known to be non-monotonic.'*; and

(iv) *'By the beginning of the 24th month, 50-80% of female animals had developed tumors in all treated groups'*.

(e) the Republished Séralini Paper was given no weight by the International Agency for Research on Cancer (**IARC**), who stated that '[the study] *was inadequate for evaluation because the number of animals per group was small, the histopathological description of tumours was poor, and incidences of tumours for individual animals were not provided'*;

Particulars

IARC Monograph on Glyphosate [McNickleProdVolEight00008820], page 35.

9. It admits the allegation in paragraph 9.

10. In answer to paragraph 10, it:

(a) admits that the article by Henry Miller titled *'Scientists Smell a Rat in Fraudulent Study'* published in Forbes in 2012 (**2012 Forbes Article**) did not name Monsanto Employees as authors of, or contributors to, but says that it would have been inappropriate for it to do so, as the contribution of Monsanto employees was limited and was in the nature of general suggestions and identification of inaccuracies in the draft article;

(b) otherwise denies the allegations in paragraph 10;

(c) says further that subject to production by the Applicant of the 2012 Forbes Article, and reference at trial to its full terms and effect:

(i) the scientific community had raised criticisms of the Séralini 2012 Paper;

(ii) the 2012 Forbes Article stated, among other things, that:

(A) '*There is so much wrong with the experimental design that the conclusion is inescapable that the investigators intended to get a spurious, preordained result*';

(B) '*mortality rates and tumor incidence in all experimental groups fall within historical norms for this strain of laboratory rats*';

(C) '*the statistical methods employed were unconventional and appeared to be selected specifically in order to give a certain result*';

(D) '*absence of statistical analysis for mortality or tumor incidence*';

(E) '*inappropriate, unnecessary suffering of the rats, which should have been euthanized long before the tumors became so huge – an especially egregious ethics violation*';

(F) '*the reported results conflict with innumerable experiments conducted by laboratories around the world on both genetically engineered corn and glyphosate, and also with vast real-world experience*'; and

(G) '*the publication of this article represents an abject, egregious failure of peer-review and editorial competence at Food and Chemical Toxicology, the journal in which it appeared'*; and

(iii) it denies that any involvement of Monsanto in the preparation of the 2012 Forbes Article had an impact on the validity of the conclusions reached in the 2012 Forbes Article by Henry Miller;

11. In answer to paragraph 11:

(a) denies the allegations in paragraph 11;

(b) it refers to and repeats paragraphs 8(b)(iii) and 10 above;

(c) it says further that the deficiencies in Séralini 2012 warranted the retraction of the paper.

12. It admits the allegations in paragraph 12.

13. In answer to paragraph 13, it:

(a) admits the allegations in paragraph 13; and

(b) says further that the 2012 paper by Pamela Mink, Jack Mandel, Bonnielin Sceurman and Jessica Lundin titled *'Epidemiologic studies of glyphosate and cancer: a review'* (**Mink 2012 Paper**) was also published online on 7 June 2012.

14. In answer to paragraph 14, it:

(a) admits that the Mink 2012 Paper did not name Donna Farmer or Daniel Goldstein as authors of the paper, and it says that it would have been inappropriate for it to do so:

(i) the suggested amendments to the Mink 2012 Paper were primarily confined to the introduction to the Mink 2012 Paper and did not alter any of the authors' evaluations or conclusions;

(ii) the authors of the Mink 2012 Paper retained complete authority to accept or reject suggested amendments to the Mink 2012 Paper;

(iii) to the extent that amendments and additions provided by Donna Farmer and/or Daniel Goldstein were adopted in the Mink 2012 Paper, the authors of the Mink 2012 Paper approved those suggestions;

(iv) the Mink 2012 Paper acknowledged:

(A) the contribution of Monsanto Company to the Mink 2012 Paper;

(B) the funding arrangements for the Mink 2012 Paper;

Particulars

The Mink 2012 Paper contains (a) a conflict of interest statement in the form *'The authors have disclosed the funding source for this research. JSM has served has (sic) a paid consultant to Monsanto Company. Final decisions regarding the content of the manuscript were made solely by the four authors' and (b) an acknowledgement in the form 'This research was supported by the Monsanto Company, St. Louis, Missouri''*.

(b) otherwise denies the allegations contained in paragraph 14;

(c) says further that:

(i) subject to production by the Applicant of the Mink 2012 Paper and reference at trial to its full terms and effect:

(A) the abstract to the Mink 2012 Paper contains the statement that *'Our review found 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) the Mink 2012 Paper contains the statements:

(1) *'Our review of the currently available epidemiologic literature on glyphosate and cancer found no evidence of a consistent pattern of positive associations that would be indicative of a causal relationship between any site—specific cancer and exposure to glyphosate.'*; and

(2) *'None of the AHS cohort study analyses reported statistically significant positive findings for glyphosate exposure and total cancer or any site—specific cancer in adults or children.'*;

(ii) Donna Farmer and Daniel Goldstein assisted the authors of the Mink 2012 Paper by providing them with relevant publicly available articles and suggested amendments and additions to a draft of the Mink 2012 Paper;

(iii) the authors at all times retained the ability to accept or reject any suggested amendments or additions to the draft of the Mink 2012 Paper;

(iv) the involvement of Monsanto was appropriately acknowledged and it denies that any involvement of Monsanto had an impact on the validity of the underlying scientific data or conclusions reached in the Mink 2012 Paper by Pamela Mink, Jack Mandel, Bonnielin Sceurman and Jessica Lundin; and

(v) in the premises identified in paragraphs 14(a), 14(c)(ii) to (iv) above the contribution made by Monsanto employees did not amount to authorship.

15. In answer to paragraph 15:

(a) it refers to and repeats paragraph 14 above;

(b) it says further that employees of the Third Respondent made a variety of communications about Mink 2012;

(i) none of which reflected an intention to inappropriately influence the European Commission; and

(ii) which reflected a desire to enhance an accurate understanding of the science concerning the safety of glyphosate in the public domain;

(c) it denies the allegations in paragraph 15.

16. It admits the allegations in paragraph 16.

17. In answer to paragraph 17, it:

(a) admits that a paper by Kier and Kirkland titled *'Review of genotoxicity studies of glyphosate and glyphosate-based formulations'* described in paragraph 16 of the Applicant's Reply (**Kier and Kirkland 2013 Paper**) did not name David Saltmiras as an author;

(b) otherwise denies the allegations in paragraph 17 and says further that subject to production by the Applicant of the paper described in paragraph 16 of the Applicant's Reply (the Kier and Kirkland 2013 Paper), and reference at trial to its full terms and effect:

(i) the Kier and Kirkland 2013 Paper stated, among other things, that:

(A) '*An overwhelming preponderance of negative results in well-conducted bacterial reversion and in vivo mammalian micronucleus and chromosomal aberration assays indicates that glyphosate and typical GBFs* [glyphosate-based formulations] *are not genotoxic in these core assays*';

(B) '*Negative results for in vitro gene mutation and a majority of negative results for chromosomal effect assays in mammalian cells add to the weight of evidence that glyphosate is not typically genotoxic for these endpoints in mammalian systems*';

(C) '*Glyphosate and typical GBFs do not appear to present significant genotoxic risk under normal conditions of human or environmental exposures*';

(ii) the Kier and Kirkland 2013 Paper was the result of an amalgamation of two different projects, specifically:

(A) a review manuscript of the glyphosate genotoxicity literature and the Monsanto genotoxicity data set, authorised on or around 22 February 2011 (**Initial Project**); and

(B) a review manuscript involving all glyphosate genotoxicity studies owned by the European Glyphosate Task Force (**GTF**) member companies on both the active ingredient and formulated products, authorised in or around July 2012 (**Subsequent Project**),

which merged into one project in or around July 2012 (**Combined Project**);

Particulars

Email from David Saltmiras to William Graham, among others, dated 13 July 2012 [MONGLY02145917].

(iii) David Saltmiras was involved in assisting, to a limited extent, and facilitating Larry D. Kier with his draft manuscript for the Initial Project;

Particulars

The assistance and facilitation provided by David Saltmiras with respect to the Initial Project was limited to:

(1) facilitating Larry D Kier's access to studies from Monsanto; and

(2) reviewing drafts of the manuscript and making suggested amendments which did not contribute substantially to the technical content of those drafts.

(iv) David Saltmiras was precluded from authoring the Subsequent Project because it required the review of the raw data of proprietary glyphosate genotoxicity studies held by other glyphosate registrant companies in the taskforce which were competitors of Monsanto Company;

Particulars

Email from David Saltmiras to William Graham, among others, dated 13 July 2012 [MONGLY02145917].

(v) by reason of the matters pleaded at subparagraph 17(b)(iii) to 17(b)(iv) above, David Saltmiras was removed as a potential author of the Combined Project and David J. Kirkland, an expert in genotoxicity, co-authored the Combined Project alongside Larry D. Kier;

(vi) further and alternatively, it would have been inappropriate for David Saltmiras to be named as an author because:

(A) the authorship requirements as set forth by Taylor & Francis (the company that published the Kier and Kirkland 2013 Paper in the journal Critical Reviews in Toxicology) at the relevant time provided that an author:

(1) *'must have made a significant contribution to the work reported, in terms of research conception or design, and/or acquisition of data, and/or the analysis and interpretation of those data'*;

(2) is responsible for drafting, writing, and revising the article, or checking and confirming the article prior to submission;

(3) approves the final version of the article prior to submission;

(4) is aware and approves that the final version of the article has been submitted;

(5) accepts responsibility and accountability for all content; and

(6) accepts that if the article is found to be unsafe, in error, or in some way fraudulent, or in breach of warranties made, that responsibility is shared by all named co-authors;

(B) David Saltmiras' contribution to the Combined Project was not significant enough to amount to authorship, nor, for the reasons set out at subparagraph 17(b)(iv) above could it be significant having regard to the fact that David Saltmiras was precluded from authoring the Subsequent Project;

(C) the contribution and service of David Saltmiras in respect of the Kier and Kirkland 2013 Paper was expressly acknowledged;

Particulars

(1) The acknowledgements section within the Kier and Kirkland 2013 Paper stated the following:

i. '*The authors would like the thank the following individuals for their contributions to this work by providing regulatory studies and their thoughtful review of the manuscript: David Saltmiras (Monsanto Company)…*'; and

ii. '*We would also like to acknowledge David Saltmiras for his invaluable service in providing coordination with individual companies and the Glyphosate Task Force'*; and

(vii) it denies that any involvement of Monsanto had an impact on the validity of the underlying scientific data or conclusions reached in the Kier and Kirkland 2013 Paper by Larry D. Kier and David J. Kirkland.

18. It admits the allegation in paragraph 18 and says further that:

(a) the IARC working group that examined glyphosate met for one week, between 3 March 2015 and 10 March 2015, in Lyon, France;

(b) in addition to examining glyphosate, the IARC working group also examined four other substances in the same week as glyphosate;

(c) the IARC working group that examined glyphosate did not examine all scientific studies, assays or data concerning glyphosate or glyphosate-based formulations, but rather:

(i) for epidemiological studies, cancer bioassays and mechanistic data, the IARC working group only considered reports that had been published or accepted for publication in the openly available scientific literature;

(ii) the IARC working group did not examine, or request to examine, the study reports of any of the toxicology studies referred to in its Monograph concerning glyphosate;

(iii) to the extent that the IARC working group derived information about toxicology studies performed concerning glyphosate, glyphosate-based formulations and surfactants, it derived that information solely from secondary sources, such as summaries of studies that appeared in documents prepared by national regulators or international organisations concerning glyphosate;

(iv) the IARC working group gave limited consideration to documents prepared by national regulators or international organisations concerning glyphosate;

(d) the IARC working group, in its Monograph concerning glyphosate, examined only a small proportion of the toxicology studies that are summarised in the documents prepared by regulators and international organisations concerning glyphosate;

(e) in its assessment of glyphosate, the IARC working group:

(i) did not perform, or attempt to perform, a human health risk assessment of glyphosate;

(ii) did not evaluate, nor did it attempt or purport to evaluate, the risk to humans of developing cancer from exposure to or use of glyphosate;

(iii) when considering studies that purported to show a carcinogenic effect of glyphosate, did not consider the distinction between an apparent effect that arises by virtue of any intrinsic carcinogenic potential of glyphosate and an effect that arises as a secondary effect of particular test conditions, such as excessive dosage levels or unusual administration mechanisms;

(f) after the publication by IARC of its Monograph concerning glyphosate, numerous regulators and international organisations and bodies specifically examined the IARC Monograph and concluded that exposure to glyphosate does not pose a carcinogenic risk to humans.

Particulars

Australian Pesticides and Veterinary Medicines Authority:

- Regulatory position: consideration of the evidence for a formal reconsideration of glyphosate, September 2016.

- Review of IARC Monograph 112 (Glyphosate): Tier 1, 2016.

- Review of IARC Monograph 112 (Glyphosate): Tier 2, 2016.

- Final regulatory position: consideration of the evidence for a formal reconsideration of glyphosate, March 2017.

Canadian Pest Management Regulatory Authority, Proposed Re-evaluation Decision, April 2015.

European Chemicals Agency, Committee for Risk Assessment's Opinion proposing harmonised classification and labelling at EU level of glyphosate, March 2017.

European Food Safety Authority, Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate, October 2015.

German Federal Institute for Occupational Safety and Health (BAuA), CLH Report for Glyphosate: Proposal for Harmonised Classification and Labelling, May 2016

German Federal Institute for Risk Assessment (BfR)

- Renewal Assessment Report – Glyphosate Addendum 1 to Renewal Assessment Report – Assessment of IARC Monographs Volume 112, 31 August 2015.

New Zealand Environmental Protection Agency, Review of the Evidence Relating to Glyphosate and Carcinogenicity, August 2016

United States Environmental Protection Agency (**EPA**):

- Glyphosate: Report of the Cancer Assessment Review Committee, October 2015.

- Glyphosate Issue Paper: Evaluation of Carcinogenic Potential, September 2016.

- Transmission of Meeting Minutes and Final Report of the December 13-16, 2016 FIFRA SAP Meeting Held to Consider and Review Scientific Issues Associated with EPA's Evaluation of the Carcinogenic Potential of Glyphosate, March 2017.

- Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential, December 2017.

- Glyphosate: Response to Comments on the Human Health Draft Risk Assessment, April 2018.

- Glyphosate: Response to Comments on the Proposed Interim Decision Regarding the Human Health Risk Assessment, January 2019.

- Glyphosate: Proposed Interim Registration Review Decision Case Number 0178, April 2019.

19. It admits the allegations in paragraph 19.

20. It denies the allegations in paragraph 20 and says further that:

(a) in February 2015, an employee of Monsanto made enquiries with Henry Miller, then a professor at Stanford University, regarding the preparation of a column piece on IARC's review of glyphosate and confirmed that they had *'background'* and could *'provide information'* to Mr Miller, if required;

(b) on 20 March 2015 the *'op ed'* article titled 'Viewpoint: March Madness from the United Nations' was published online in Forbes (**2015 Forbes Article**);

(c) subject to production by the Applicant of the 2015 Forbes Article and reference at trial to its full terms and effect, the 2015 Forbes Article, referred to in paragraph 20 of the Applicant's Reply stated, among other things, that '*The same applies to the IARC's analysis of glyphosate. The data (and a selected set of data, at that) were reviewed to determine whether glyphosate is capable of causing cancer*' and *'So, could any of these new documents have led IARC to their less favourable conclusion? No – because these reviews further affirmed the safety of glyphosate and the absence of linkage between glyphosate and cancer risk*'; and

(d) the 2015 Forbes Article was subsequently removed from the Forbes website but was not formally retracted.

21. In answer to paragraph 21:

(a) it denies the allegations in paragraph 21;

(b) it refers to and repeats paragraph 20 above.

22. In answer to paragraph 22:

(a) it denies the allegations in paragraph 22;

(b) it says further that the Expert Panel Review of the Carcinogenic Potential of the Herbicide Glyphosate was a poster displayed at a meeting of the Society for Risk Assessment;

(c) the poster was displayed at a booth in a conference hall at which meeting attendees could stop and discuss the poster;

(d) the Expert Panel Review was otherwise not the subject of a formal presentation at the meeting which occurred on 7 December 2015.

23. In answer to paragraph 23:

(a) it denies the allegations in paragraph 23;

(b) it says further that:

(i) the Expert Panel Review indicated that an expert panel was assembled to review the primary evidence in the areas evaluated by IARC in relation to glyphosate;

(ii) the Expert Panel Review stated that the Animal Bioassay and Genotoxicity expert panels concluded that IARC's equivalent working groups' reviews suffered from significant weaknesses;

(iii) the expert panels for each of the areas of animal bioassays, genotoxicity, exposure and epidemiology agreed the text of the section in the Expert Panel Review corresponding to their expert panel;

(iv) each expert panel agreed the text for their section of the Expert Panel Review in the course of, and as a result of, the review by each expert panel of the relevant studies and data concerning glyphosate;

(c) it otherwise refers to and repeats paragraphs 24 to 29 below.

24. It admits the allegations in paragraph 24.

25. In answer to paragraph 25, it:

(a) admits that the paper by David Brusick, Marilyn Aardema, Larry D. Kier, David J. Kirkland and Gary Williams titled *'Genotoxicity Expert Panel review: weight of evidence evaluation of the genotoxicity of glyphosate, glyphosate-based formulations, and aminomethylphosphonic acid'*, described in paragraph 25 of the Applicant's Reply (**Brusick 2016 Paper**) does not name Monsanto employees as authors of the paper and says that it would have been inappropriate for it to do so because according to the authorship requirements as set forth by Taylor & Francis (the company that published this article in the journal Critical Reviews in Toxicology) authorship should be limited to those who have made *'a significant contribution'* to the *'research conception or design, acquisition of data, analysis and interpretation or in all these areas.'*

Particulars

The authorship requirements as set forth by Taylor & Francis required that:

(1) the relevant person has made a significant contribution to the work reported, whether that's in the research conception or design, acquisition of data, analysis and interpretation, or;

(2) in all of the areas referred to in (1) above, the relevant person:

i. has drafted, written or revised the article;

ii. has reviewed and agreed on the final version of the article before submission;

iii. has agreed on the journal to which the article will be submitted;

iv. is aware that they are taking responsibility and accountability for the content of the article;

v. is aware that the corresponding author will be acting on their behalf in any communications about the article, through submission, peer review, production and after publication; and

vi. shares responsibility with all named co-authors if the article is found to be unsafe, in error or in some way fraudulent or in breach of the publishing agreement in place.

(b) denies the allegations in paragraph 25;

(c) says further that:

(i) on 1 July 2015, the Third Respondent and Intertek Health Sciences Inc. (**Intertek**) entered into a Consulting Agreement whereby Intertek were required to organise and conduct a panel of independent third party experts who would undertake a thorough review in the four areas considered by IARC (the **Intertek Consulting Agreement**);

(ii) the Intertek Consulting Agreement contained the following objectives:

(A) *'Intertek will organise, host and facilitate an Expert Panel meeting(s)';*

(B) *'prior to the meeting(s) and after review of all Information Intertek will request feedback from each of the Panellists regarding conclusions on the safety of glyphosate';*

(C) *'Monsanto will prepare and supply, as needed, documentation and references to support the evaluation of glyphosate.'*

(iii) subject to production by the Applicant of Brusick 2016 Paper, and reference at trial to its full terms and effect, the Brusick 2016 Paper stated, among other things, that:

(A) *'The Expert Panel concluded that glyphosate, GBFs, and AMPA genotoxicity response profiles are not consistent with characteristics of genotoxic carcinogens (Table 4)';*

(B) *'The Expert Panel 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';*

(C) *'A critical review of the complete dataset by the Expert Panel supports 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';*

(D) *'The evidence for oxidative stress/damage as a mechanism or predictor of carcinogenesis is unconvincing';*

(E) *'…A number of published and regulatory approval reviews of the carcinogenic and genotoxic potential of glyphosate, AMPA and GBFs were available prior to the development of the IARC Monograph (Health and Welfare Canada 1991; US EPA 1993; WHO 1994; Williams et al 2000; European Commission 2002; Kier & Kirkland 2013; US EPA 2013). The consensus among these reviews was that proper use of glyphosate and GBFs does not pose a genotoxic or carcinogenic hazard/risk with hazard indicating potential for adverse effects and risk*

indicating potential for adverse effects under actual conditions and amounts of exposure. As a result, glyphosate-based herbicides have been approved for use in over 160 countries. The recent IARC conclusion was therefore inconsistent with these other reviews. Consequently, the Monsanto Company commissioned Intertek Scientific & Regulatory Consultancy to assemble a panel of experts to conduct a thorough review in the four areas considered by IARC including mechanistic data (focused on genotoxicity and oxidative stress). This review section reports the views of the Expert Panel of genetic toxicologists on the genotoxicity of glyphosate, GBFs and AMPA and discusses how they relate to the IARC opinions. The views and conclusions represent those of the Expert Panel of genetic toxicologists as independent scientific consultants and neither employees of the Monsanto Company nor attorneys reviewed this manuscript prior to submission';

(iv) Monsanto personnel provided the necessary background and historical data on glyphosate to the authors and provided non-substantive contributions in the nature of final formatting suggestions on the article;

(v) in the premises, the contribution made by the Monsanto employees did not amount to authorship;

Particulars

It refers to and repeats the particulars to paragraph 25(a) above.

(vi) it denies that any involvement of Monsanto had an impact on the validity of the underlying scientific data or conclusions reached in the Brusick 2016 Paper by David Brusick, Marilyn Aardema, Larry D. Kier, David J. Kirkland and Gary Williams; and

(vii) further and alternatively, on 26 September 2018, the journal Critical Reviews in Toxicology published a corrigendum in relation to the Brusick 2016 Paper which clarified and amended the Acknowledgements and the Declaration of Interest section as it originally appeared in the

article, such that there was disclosure of various consultancy arrangements between the Third Respondent and certain authors and confirmation that employees of the Third Respondent had assisted with the final formatting of the article.

26. In answer to paragraph 26, it:

(a) admits that the paper by Gary M Williams, Marilyn Aardema, John Acquavella, Sir Colin Berry, David Brusick, Michele M. Burns, Joao Lauro Viana de Camargo, David Garabrant, Helmut A. Greim, Larry D. Kier, David J. Kirkland, Gary Marsh, Keith R. Solomon, Tom Sorahan, Ashley Roberts and Douglas L. Weed titled *'A review of the carcinogenic potential of glyphosate by four independent expert panels and comparison to the IARC assessment'* published in the journal Critical Reviews in Toxicology, described in paragraph 26 of the Applicant's Reply (**Williams (a) 2016 Paper**), does not name Monsanto employees as authors of the paper;

(b) otherwise denies paragraph 26;

(c) says further that:

(i) subject to production of the Williams (a) 2016 Paper, and reference at trial to its full terms and effect, the Williams (a) 2016 Paper stated, among other things, that:

(A) *'Given these differences, even without the data IARC did not include, there is no support for IARC's conclusion that 'glyphosate is probably carcinogenic to humans.';*

(B) *'Overall, extensive reviews of the genotoxicity of glyphosate, AMPA and GBFs that were available prior to the development of the IARC Glyphosate Monograph all support a conclusion that glyphosate (and related materials) is inherently not genotoxic. Further, evidence indicative of an oxidative stress mechanism of carcinogenicity is largely unconvincing.';*

(C) *'In summary, the totality of the evidence, especially in light of the extensive testing that glyphosate has received, as judged by the Expert Panels, does not support the conclusions that*

glyphosate is a 'probable human carcinogen' and, consistent with the previous regulatory assessments, the Expert Panels conclude that glyphosate is unlikely to pose a carcinogenic risk to humans';

(ii) it refers to and repeats paragraph 25(c) with respect to the Intertek Consulting Agreement;

(iii) employees of Monsanto facilitated the preparation of the article by providing the necessary historical data on glyphosate to the authors and providing comments on drafts of the article;

(iv) it would have been inappropriate for the Williams (a) 2016 Paper to name Monsanto employees as authors of the paper because according to the authorship requirements as set forth by Taylor & Francis (the company that published this article in Critical Reviews in Toxicology) authorship should be limited to those who have made '*a significant contribution*' to the '*research conception or design, acquisition of data, analysis and interpretation or in all these areas*.'

Particulars

The authorship requirements as set forth by Taylor & Francis (the company that published this article in the journal Critical Reviews in Toxicology) required that:

(1) the relevant person has made a significant contribution to the work reported, whether that's in the research conception or design, acquisition of data, analysis and interpretation, or;

(2) in all of the areas referred to in (1) above, the relevant person:

i. has drafted, written or revised the article;

ii. has reviewed and agreed on the final version of the article before submission;

iii. has agreed on the journal to which the article will be submitted;

iv. is aware that they are taking responsibility and accountability for the content of the article;

v. is aware that the corresponding author will be acting on their behalf in any communications about the article, through submission, peer review, production and after publication; and

vi. shares responsibility with all named co-authors if the article is found to be unsafe, in error or in some way fraudulent or in breach of the publishing agreement in place;

(v) it denies that any involvement of Monsanto had an impact on the validity of the underlying scientific data or conclusions reached in the Williams (a) 2016 Paper by Gary M Williams, Marilyn Aardema, John Acquavella, Sir Colin Berry, David Brusick, Michele M. Burns, Joao Lauro Viana de Camargo, David Garabrant, Helmut A. Greim, Larry D. Kier, David J. Kirkland, Gary Marsh, Keith R. Solomon, Tom Sorahan, Ashley Roberts and Douglas L. Weed;

(vi) further and alternatively, on 30 November 2018, the journal Critical Reviews in Toxicology published a corrigendum in relation to the Williams (a) 2016 Paper which clarified and amended the Acknowledgements and the Declaration of Interest section as it originally appeared in the article, such that there was disclosure of various consultancy arrangements and confirmation that employees of the Third Respondent had provided a regulatory history overview for use by the authors in the preparation of the paper and had provided comments on drafts of the article but they had not participated in the deliberations of the expert panel and did not contribute to the conclusions drawn by the expert panel; and

(vii) in the premises, the contribution made by the Monsanto employees did not amount to authorship.

27. In response to paragraph 27, it:

(a) admits that the paper by Gary M Williams, Colin Berry, Michele Burns, Joao Lauro Viana de Camargo and Helmut Greim titled *'Glyphosate rodent carcinogenicity bioassay expert panel review'* published in the journal Critical Reviews in Toxicology, described in paragraph 27 of the Applicant's Reply (**Williams (b) 2016 Paper**), does not name Monsanto employees as authors of the paper;

(b) otherwise denies paragraph 27;

(c) says further that:

(i) subject to production of the Williams (b) 2016 Paper, and reference at trial to its full terms and effect, the Williams (b) 2016 Paper stated, among other things, that *'Application of criteria for causality considerations to the above mentioned tumor types and given the overall WoE* [weight of evidence], *the expert panel concluded that glyphosate is not a carcinogen in laboratory animals*.';

(ii) it refers to and repeats paragraph 25(c) above with respect to the Intertek Consulting Agreement;

(iii) it admits that an employee of the Third Respondent provided background information and documents for a section of the Williams (b) 2016 Paper;

(iv) employees of Monsanto facilitated the preparation of the Williams (b) 2016 Paper by providing the necessary historical data on glyphosate to the authors and providing comments on drafts of the article;

(v) it would have been inappropriate for the Williams (b) 2016 Paper to name Monsanto employees as authors of the paper because according to the authorship requirements as set forth by Taylor & Francis (the company that published this article in the journal Critical Reviews in Toxicology) authorship should be limited to those who have made '*a significant contribution*' to the *'research conception or design, acquisition of data, analysis and interpretation or in all these areas.'*

Particulars

The authorship requirements as set forth by Taylor & Francis (the company that published this article in the journal Critical Reviews in Toxicology) required that:

(1) the relevant person has made a significant contribution to the work reported, whether that's in the research conception or design, acquisition of data, analysis and interpretation, or;

(2) in all of the areas referred to in (1) above, the relevant person:

i. has drafted, written or revised the article;

ii. has reviewed and agreed on the final version of the article before submission;

iii. has agreed on the journal to which the article will be submitted;

iv. is aware that they are taking responsibility and accountability for the content of the article;

v. is aware that the corresponding author will be acting on their behalf in any communications about the article, through submission, peer review, production and after publication; and

vi. shares responsibility with all named co-authors if the article is found to be unsafe, in error or in some way fraudulent or in breach of the publishing agreement in place.

(vi) it denies that any involvement of Monsanto had an impact on the validity of the underlying scientific data or conclusions reached in the Williams (b) 2016 Paper by Gary M Williams, Colin Berry, Michele Burns, Joao Lauro Viana de Camargo and Helmut Greim; and

(vii) further and alternatively, on 30 November 2018, the journal Critical Reviews in Toxicology published a corrigendum in relation to the Williams (b) 2016 Paper which clarified and amended the

Acknowledgements and the Declaration of Interest section as it originally appeared in the paper such that the involvement of Monsanto was acknowledged.

(viii) in the premises, the contribution made by the Monsanto employees did not amount to authorship.

28. In answer to paragraph 28, it:

(a) admits that the paper by Keith R. Solomon titled *'Glyphosate in the general population and in applicators: a critical review of studies on exposures'* published in the journal Critical Reviews in Toxicology, described in paragraph 28 of the Applicant's Reply (**Solomon 2016 Paper**) does not name Monsanto employees as authors of the paper;

(b) otherwise denies paragraph 28;

(c) says further that:

(i) subject to production of the Solomon 2016 Paper, and reference at trial to its full terms and effect, the Solomon 2016 Paper stated, among other things, that: '*Based on the current RfDs* [current reference doses] *and ADIs* [acceptable daily intakes], *there is no hazard and no intolerable risk from exposure to glyphosate via its normal use in agriculture and management of weeds in landscapes';*

(ii) it refers to and repeats paragraph 25(c) with respect to the Intertek Consulting Agreement;

(iii) employees of Monsanto provided access to reports from exposure studies for glyphosate in applicators and clarification on some of the methods used in those studies;

(iv) it would have been inappropriate for the Solomon 2016 Paper to name Monsanto employees as authors of the paper because according to the authorship requirements as set forth by Taylor & Francis (the company that published this article in the journal Critical Reviews in Toxicology) authorship should be limited to those who have made *'a significant contribution'* to the *'research conception or design, acquisition of data, analysis and interpretation or in all these areas.'*

Particulars

The authorship requirements as set forth by Taylor & Francis (the company that published this article in Critical Reviews in Toxicology) required that:

(1) the relevant person has made a significant contribution to the work reported, whether that's in the research conception or design, acquisition of data, analysis and interpretation, or;

(2) in all of the areas referred to in (1) above, the relevant person:

i. has drafted, written or revised the article;

ii. has reviewed and agreed on the final version of the article before submission;

iii. has agreed on the journal to which the article will be submitted;

iv. is aware that they are taking responsibility and accountability for the content of the article;

v. is aware that the corresponding author will be acting on their behalf in any communications about the article, through submission, peer review, production and after publication; and

vi. shares responsibility with all named co-authors if the article is found to be unsafe, in error or in some way fraudulent or in breach of the publishing agreement in place.

(v) it denies that any involvement of Monsanto had an impact on the validity of the underlying scientific data or conclusions reached in the Solomon 2016 Paper by Keith R. Solomon;

(vi) further and alternatively, on 26 September 2018, Critical Reviews in Toxicology published a corrigendum in relation to the Solomon 2016. The corrigendum clarified and amended the Acknowledgements and the Declaration of Interest section as it originally appeared in the paper such

that there was full disclosure of various consultancy arrangements and confirmation that *'KRS* [Keith R Solomon] *was not provided with comments from William Heydens of Monsanto Inc, either directly or via Intertek';* and

(vii) in the premises, the contribution made by the Monsanto employees did not amount to authorship.

29. In answer to paragraph 29, it:

(a) admits that the paper by John Acquavella, David Garabrant, Gary Marsh, Tom Sorahan and Douglas L. Weed 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'* published in the journal Critical Reviews in Toxicology, described in paragraph 29 of the Applicant's Reply (**Acquavella 2016 Paper**) does not name Monsanto employees as authors of the paper;

(b) otherwise denies paragraph 29;

(c) says further that:

(i) subject to production of the Acquavella 2016 Paper and reference at trial to its full terms and effect, the Acquavella 2016 Paper stated, among other things, that: '*Our review of the glyphosate epidemiological literature and the application of commonly applied causal criteria do not indicate a relationship with glyphosate exposure and NHL';*

(ii) it refers to and repeats paragraphs 25(c) with respect to the Intertek Consulting Agreement;

(iii) Monsanto personnel provided the necessary background and historical data on glyphosate and suggested non-substantive edits on a draft of the article;

(iv) it would have been inappropriate for the Acquavella 2016 Paper to name Monsanto employees as authors of the paper because according to the authorship requirements as set forth by Taylor & Francis (the company that published this article in the journal Critical Reviews in Toxicology) authorship should be limited to those who have made '*a significant*

contribution' to the '*research conception or design, acquisition of data, analysis and interpretation or in all these areas*.'

Particulars

The authorship requirements as set forth by Taylor & Francis (the company that published this article in the journal Critical Reviews in Toxicology) required that:

(1) the relevant person has made a significant contribution to the work reported, whether that's in the research conception or design, acquisition of data, analysis and interpretation, or;

(2) in all of the areas referred to in (1) above, the relevant person:

i. has drafted, written or revised the article;

ii. has reviewed and agreed on the final version of the article before submission;

iii. has agreed on the journal to which the article will be submitted;

iv. is aware that they are taking responsibility and accountability for the content of the article;

v. is aware that the corresponding author will be acting on their behalf in any communications about the article, through submission, peer review, production and after publication; and

vi. shares responsibility with all named co-authors if the article is found to be unsafe, in error or in some way fraudulent or in breach of the publishing agreement in place.

(v) it denies that any involvement of Monsanto had an impact on the validity of the underlying scientific data or conclusions reached in the Acquavella 2016 Paper by John Acquavella, David Garabrant, Gary Marsh, Tom Sorahan and Douglas L. Weed;

(vi) further and alternatively, on 26 September 2018, the journal Critical Reviews in Toxicology published a corrigendum in relation to the Acquavella 2016 Paper referred to in paragraph 29 of the Applicant's Reply which clarified and amended the Acknowledgements and the Declaration of Interest section as it originally appeared in the paper, such that there was full disclosure of various consultancy arrangements and confirmation that *'William Heydens of Monsanto reviewed the initial draft of our manuscript and commented that the section on analytic selection bias was unclear to him and that we might define the term 'grey literature.' He also pointed out some typographical errors. Based on his feedback, the authors decided to clarify the section on analytic selection bias, define grey literature in a footnote, and correct the typos. All additions, deletions, and changes to the draft manuscript were made only by the authors, with unanimous agreement.';* and

(vii) in the premises, the contribution made by the Monsanto employees did not amount to authorship.

30. In answer to paragraph 30, it:

(a) denies the allegations in paragraph 30;

(b) refers to and repeats paragraphs 3 to 29 above; and

(c) says further that:

(i) the prevailing scientific knowledge has not identified any reasoned basis to conclude that glyphosate is carcinogenic.

Particulars

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

(ii) certain documents pertaining to the allegations contained in the Reply in respect of alleged ghost-writing and alleged manipulation of the state of scientific knowledge, known colloquially as the *'Monsanto Papers'*, have also come into the public domain commencing from 2017;

Particulars

(1) The unsealing of the first tranche of the Monsanto Papers was ordered in *MDL No. 2741* pursuant to *'Pre-trial order No. 15: Third-party discovery and pending motions to seal'* of Judge Chhabria dated 13 March 2017, following an application for the *'de-designation'* of confidentiality of the documents by plaintiffs in the United States.

(2) Since that time plaintiffs have sought the de-designation of further tranches of 'Monsanto Papers'.

(3) The *'Monsanto Papers'* were and are published on the internet, including on the website of the law firm Baum, Hedlund, Aristei & Goldman <https://www.baumhedlundlaw.com/toxic-tort-law/Monsanto-roundup-lawsuit/Monsanto-secret-documents/> (accessed 24 December 2020).

(4) Some or all of the Monsanto Papers are published on the website U.S Right to Know (USRTK) <https://usrtk.org/monsanto-papers/> (accessed 24 December 2020).

(iii) the EPA, the California Office of Environmental Health Hazard Assessment and the European Parliament, have been aware of some or all of the allegations contained in the Reply in respect of alleged ghost-writing and alleged manipulation of the state of scientific knowledge since at least 1 August 2017;

Particulars

Letters from R Brent Wisner Esq, Michael L. Baum Esq., and Pedram Esfandiary, Esq. (Baum, Hedlund Aristei Goldman, Consumer Attorneys) dated 1 August 2017 to (a) Bart Staes, Heidi Hautala, Benedek Javor, and Michel Rivasi, members of the European Parliament, (b) Arther A. Elkins, then Inspector General (EPA) and (c)

'whom it may concern' at the Office of Environmental Hazard Assessment (OEHHA).

(iv) since the *'Monsanto Papers'* have come into the public domain commencing from 2017, the EPA, Health Canada and the European Food Safety Authority have affirmed their existing assessments in respect of the carcinogenicity of glyphosate.

Particulars

(1) Environmental Protection Agency, Glyphosate: Interim Registration Review Decision, dated 22 January 2020.

(2) Statement from Health Canada on Glyphosate dated 11 January 2019 re-affirming Re-evaluation Decision RVD2017-01, Glyphosate dated 28 April 2017 available at: <https://www.canada.ca/en/health-canada/news/2019/01/statement-from-health-canada-on-glyphosate.html> (accessed 18 December 2020).

(3) Statement from the European Food Safety Authority (**EFSA)** dated 23 May 2017 titled *'EFSA statement addressing stakeholder concerns related to the EU assessment of glyphosate and the 'Monsanto papers'* available at: <https://www.efsa.europa.eu/sites/default/files/170523-efsa-statement-glyphosate.pdf> (accessed 18 December 2020)

(v) on 23 May 2017 the European Food Safety Authority issued a statement entitled *'EFSA statement addressing stakeholder concerns related to the EU assessment of glyphosate and the 'Monsanto papers''* which stated in part that *'the recent publication of internal emails by Monsanto in relation to glyphosate (the so-called 'Monsanto papers') has given rise to concerns from some stakeholders and reports in some media that industry improperly influenced the EU assessment of glyphosate, both with regards to the scientific studies used in the assessment and with regards to those who participated in the process. The nature of the information contained within the 'Monsanto papers' was serious enough*

for EFSA to investigate their significance in relation to the EU assessment of glyphosate. Following this investigation, EFSA can confirm: that there are no grounds to suggest that industry improperly influenced the EU assessment of glyphosate; and that the role of industry and of other actors in the process was carried out according to standard procedures.'

Particulars

Statement from the European Food Safety Authority **(EFSA)** dated 23 May 2017 titled *'EFSA statement addressing stakeholder concerns related to the EU assessment of glyphosate and the 'Monsanto papers'* available at: <https://www.efsa.europa.eu/sites/default/files/170523-efsa-statement-glyphosate.pdf> (accessed 18 December 2020).

(vi) on 8 June 2017 the EFSA issued a statement titled *'EFSA Statement regarding the EU assessment of glyphosate and the so-called 'Monsanto papers''* regarding the EFSA's review process in light of the Monsanto Papers. This statement stated that:

(A) *'There is no information contained within the 'Monsanto papers' or that EFSA is otherwise aware of that indicates that industry attempted to falsify or manipulate the findings and raw data of the regulatory guideline studies used in the glyphosate assessment';*

(B) *'The nature of the information contained within the 'Monsanto papers' and the reported allegations regarding ghostwriting were serious enough for EFSA to investigate the significance of the two identified scientific review articles in relation to the EU assessment of glyphosate* [being the Kier and Kirkland 2013 Paper and the Williams 2000 Paper]. *Following this investigation, EFSA can confirm that even if the allegations regarding ghostwriting proved to be true, there would be no impact on the overall assessment as presented in the EFSA Conclusion on glyphosate';*

(C) *'Notwithstanding the fact that these two review papers might have been ghostwritten by Monsanto, their provenance was evident from the Declarations of Interest and Acknowledgements in the papers themselves… This means that Member State and EFSA experts were under no illusion about the links between the study authors and the companies that funded or facilitated their work when the experts carried out the risk assessment.'*; and

Particulars

Statement from the European Food Safety Authority **(EFSA)** dated 8 June 2017 titled *'EFSA Statement regarding the EU assessment of glyphosate and the so-called 'Monsanto papers''* available at <https://www.efsa.europa.eu/sites/default/files/topic/20170608_glyphosate_statement.pdf> (accessed 18 December 2020).

(vii) on 11 January 2019 Health Canada issued a statement in which it, inter alia, specifically addressed its consideration of the Monsanto Papers and stated:

(A) *'After a thorough scientific review, we have concluded that the concerns raised by the objectors could not be scientifically supported when considering the entire body of relevant data. The objections raised did not create doubt or concern regarding the scientific basis for the 2017 re-evaluation decision for glyphosate. Therefore, the Department's final decision will stand.'*

(B) *'Our scientists left no stone unturned in conducting this review. They had access to all relevant data and information from federal and provincial governments, international regulatory agencies, published scientific reports and multiple pesticide manufacturers. This includes the reviews referred to in the Monsanto Papers… To help ensure an unbiased assessment of the information, Health Canada selected a*

group of 20 of its own scientists who were not involved in the 2017 re-evaluation to evaluate the notices of objection'.

Particulars

Statement from Health Canada on Glyphosate dated 11 January 2019 re-affirming Re-evaluation Decision RVD2017-01, Glyphosate dated 28 April 2017 available at: <https://www.canada.ca/en/health-canada/news/2019/01/statement-from-health-canada-on-glyphosate.html> (accessed 18 December 2020).

31. It denies the allegations in paragraph 31 and refers to and repeats paragraphs 3 to 30 above.

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

B.1 The Scientific Outreach Plan

32. In answer to paragraph 32, it:

(a) denies the allegations in paragraph 32;

(b) says further that in or around May 1999, Monsanto developed a plan, sometimes known as the *'Scientific Outreach Plan'*, designed to refute challenges and present accurate information about glyphosate containing herbicide; and

(c) says further that at 26 May 1999, the elements of the Scientific Outreach Plan included those described in subparagraphs 32(a) to 32(d) of the Applicant's Reply.

Particulars

Email from Bill Heydens to William Graham dated 26 May 1999 [McNickleProdVolThree00012111].

B.2 Conduct in relation to the Séralini 2012 Paper

33. In response to paragraph 33, it:

(a) admits that Monsanto planned and adopted a strategy for responding to the Séralini 2012 Paper;

(b) otherwise denies the allegations in paragraph 33; and

(c) says further that:

(i) it refers to and repeats paragraphs 7 to 12 above; and

(ii) no letter to the editor from Helen Cunny in response to the Séralini 2012 Paper was ever published with the journal Food and Chemical Toxicology.

Particulars

All letters to the Editor and the response is contained at Food and Chemical Toxicology 53 (1), March 2013, pages 440 to 483.

B.3 Conduct in relation to IARC

B.3.1. Pre-IARC decision conduct

34. It admits the allegations in paragraph 34.

35. In answer to paragraph 35, it:

(a) admits the allegation in subparagraph 35(d);

(b) otherwise denies the allegations in paragraph 35;

(c) says further that:

(i) subject to production by the Applicant of the paper by Larry D. Kier '*Review of genotoxicity biomonitoring studies of glyphosate-based formulations'* published in the journal Critical Reviews in Toxicology (**Kier 2015 Paper**) and reference at trial to its full terms and effect:

(A) the abstract to the Kier 2015 Paper contains a statement that *'The results of the biomonitoring studies do not contradict an earlier conclusion derived from experimental genotoxicity studies that typical GBF's do not appear to present significant genotoxic risk under normal conditions of human or environmental exposures';*

(B) the Kier 2015 Paper was initiated by Monsanto Company prior to the evaluation of glyphosate carcinogenicity by IARC;

(C) the Declaration of Interest in the Kier 2015 Paper disclosed that the author was a paid consultant for the Kier 2015 Paper; and

Particulars

The Kier 2015 Paper contains a declaration of interest which states '*Larry Kier is a paid consultant of the Monsanto Company for the preparation of this review. Larry Kier is also a past employee of Monsanto Company. Monsanto Company was the original producer and marketer of glyphosate formulations. The author has not participated in any legal or regulatory proceedings in the past 5 years concerning the class of compounds that is the subject of this review that has drawn on material presented in the review paper. The author had sole responsibility for the writing and content of the paper and the interpretations and opinions expressed in the paper are those of the author and may not necessarily be those of Monsanto Company.*'

(ii) it denies that any involvement of Monsanto had an impact on the validity of the underlying scientific data or conclusions reached in the Kier 2015 Paper by Larry D. Kier.

36. In answer to paragraph 36, it:

(a) does not know and therefore cannot admit whether the Kier 2015 Paper was promoted by the journal Critical Reviews in Toxicology or, if it was, how it was promoted;

(b) otherwise denies the allegations in paragraph 36 and says further that:

(i) a summary of the Kier 2015 Paper was drafted by David Saltmiras (**Draft Kier Summary**) and the Draft Kier Summary was provided to Charles Whalley, then the Managing Editor of Medicine & Health Journals at Taylor & Francis Group by Roger McClellan, editor of the journal Critical Reviews in Toxicology on 19 February 2015 for use in promoting the Kier 2015 Paper;

Particulars

Email from Roger McClellan to Charles Whalley dated 19 February 2015 [MONGLY01087281].

(ii) subsequent to the Draft Kier Summary, Kier drafted and provided an alternate summary of the Kier 2015 Paper to Charles Whalley on 20 February 2015; and

Particulars

Email from Larry Kier to Charles Whalley dated 20 February 2015 [MONGLY01087285].

(iii) on 27 February 2015 Donna Farmer drafted a third iteration of the summary of the Kier 2015 Paper which was subsequently agreed with Larry Kier.

Particulars

Correspondence between Donna Farmer and Larry Kier dated 27 February 2015 [MONGLY01252800].

37. In answer to paragraph 37, it:

(a) admits the allegations contained in paragraph 37; and

(b) says further that the paper by Helmut Greim, David Saltmiras, Volker Mostert and Christian Strupp titled *'Evaluation of carcinogenic potential of the herbicide glyphosate, drawing on tumor incidence data from fourteen chronic / carcinogenicity rodent studies'* published in the journal Critical Reviews in Toxicology (**Greim 2015 Paper**) was also published online on 26 February 2015.

38. In answer to paragraph 38, it:

(a) admits the allegations in subparagraphs 38 (c), (d) and (e);

(b) otherwise denies paragraph 38; and

(c) says further that:

(i) the Greim 2015 Paper was initiated by Monsanto Company prior to the evaluation of glyphosate carcinogenicity by IARC;

(ii) the Greim 2015 Paper's conclusion is contained in the statement that *'The lack of a plausible mechanism, along with published epidemiology studies, which fail to demonstrate clear, statistically significant, unbiased and non-confounded associations between glyphosate and cancer of any single etiology, and a compelling weight of evidence, support the conclusion that glyphosate does not present concern with respect to carcinogenic potential in humans'*;

(iii) David Saltmiras was one of the named authors on the Greim 2015 Paper and the paper disclosed his affiliation with Monsanto Company;

(iv) the Greim 2015 paper stated that correspondence in relation to the paper was to be directed to David Saltmiras at his Monsanto Company address;

(v) the Greim 2015 Paper acknowledged the contribution of Monsanto Company employees to the paper; and

Particulars

The Greim 2015 Paper contains (a) a footnote to the Saltmiras authorship which states *'Monsanto Company, 800 North Lindbergh Blvd., 63167 St. Louis, MO, USA'* (b) addresses for correspondence which are Monsanto Company physical and email addresses (c) a Declaration of Interest which included the words '*David Saltmiras and Christian Strupp are employed by member companies of the GTF, Monsanto and ADAMA Agriculture B.V. (formerly Feinchemie Schwebda GmbH) respectively. David Saltmiras is also Chair of the Toxicology Technical Working Group of the GTF…. Monsanto Company was the original producer and marketer of glyphosate formulations'* and (d) an acknowledgement in the form '*Special thanks go to Elizabeth Webb, Monsanto Toxicologist, for her detailed attention to document and data table formatting and as the reference library curator. Quality control and review of data transcription were valued services provided by Carrie Leigh Logan and Aparna Desai Nemali, Monsanto Quality Assurance Specialists*.'

(vi) it denies that any involvement of Monsanto had an impact on the validity of the underlying scientific data or conclusions reached in the Greim 2015 Paper by Helmut Greim, David Saltmiras, Volker Mostert and Christian Strupp

B.3.1. Post-IARC decision conduct

39. In answer to paragraph 39:

(a) it admits that Monsanto planned and adopted a strategy for responding to the IARC decision;

(b) in response to subparagraph 39(a), it denies the allegations and says further that:

(i) the development of a plausibility paper was:

(A) an early idea developed by Monsanto in preparation for the release of the IARC decision in March 2015; and

(B) a precursor to what ultimately became the 2016 CRT Expert Panel Review Papers referred to in paragraph 24 of the Applicant's Reply;

(c) in response to paragraph 39(b), it denies the allegation;

(d) in response to paragraph 39(c), it denies the allegations and says that Monsanto Company liaised with the EPA in relation to the IARC decision and, as is usual practice, sought to support, and provide scientific information to, the EPA;

(e) in response to paragraph 39(d), it says that in the wake of the IARC classification to provide proper context for governments and regulators around the world, so they could defend the science-based decisions reached by their respective regulatory authorities, Monsanto sought clarification from the World Health Organisation as to the basis upon which IARC reviewed published studies and specifically clarification as to whether IARC undertook a hazard assessment rather than a risk-based or weight of evidence assessment;

(f) in response to paragraph 39(e), it says that as set out in paragraph 39(d), in seeking clarification in relation to the basis upon which IARC reviewed published studies and specifically whether it undertook a hazard assessment as opposed to a risk-based or weight of evidence approach, and in ensuring that the

different hazard based approach adopted by IARC was properly understood, employees of Monsanto briefed certain staff of the EPA, the US Trade Representative, the US Department of Agriculture, the relevant state department, Health and Human Services and some members of Congress who were interested in maintaining scientific integrity, consumer confidence, international trade and safe products for farmers to use;

(g) in response to paragraph 39(f), it admits that it briefed the senior staff of senators for the US State of Missouri requesting their assistance with obtaining the clarification referred to in paragraph 39(e) above;

(h) in response to paragraph 39(g), it says that it was aware that a Senate Representative, Lynn Jenkins, intended to submit a statement to the Secretary of the US Department of Health and Human Services requesting that the Secretary seek the clarification from WHO that is referred to in paragraph 39(e) above;

(i) in response to paragraph 39(h), it denies the allegation and refers to and repeats paragraphs 19 to 22 above; and

(j) in response to paragraph 39(i), it denies the allegation and refers to and repeats paragraphs 24 to 31 above.

40. It denies the allegations in paragraph 40 and refers to and repeats paragraphs 30 to 39 above.

MONSANTO'S CONDUCT IN FAILING TO UNDERTAKE TESTING OR UNDERTAKE ADEQUATE TESTING

41. It admits paragraph 41.

42. In answer to paragraph 42 it:

(a) admits that it received:

(i) a report from Professor Parry dated 11 February 1999 which is MONGLY01312093 at MONGLY01312094 to MONGLY01312104 (**First Parry Report**);

(ii) a further report from Professor Parry dated 18 August 1999 which is MONGLY01314233 at MONGLY01314270 to MONGLY01314283 (**Second Parry Report**); and

(iii) a further report from Professor Parry dated in or around October 1999, which is in two parts, being (a) a report titled *'Evaluation of the potential genotoxicity of Glyphosate, Glyphosate mixtures and component surfactants'* which is MONGLY01314233 to MONGLY01314263 and (b) a report titled *'Key issues concerning the potential genotoxicity of glyphosate, glyphosate formulations and surfactants; recommendations for future work'* which is MONGLY01314233 at MONGLY01314264 to MONGLY01314267 (**Third Parry Report**);

(b) says that it refers to the First Parry Report, the Second Parry Report and the Third Parry Report together as defined above as the **Parry Reports**;

(c) it refers to and repeats paragraph 58(d) of the Third Respondent's Defence to the Applicant's ~~Third~~ Fourth Further Amended Statement of Claim;

(d) otherwise denies the allegations in paragraph 42.

43. In answer to paragraph 43, it:

(a) refers to and repeats paragraph 42(a) above;

(b) denies paragraph 43 and says further that:

(i) subject to production by the Applicant of the First Parry Report and reference at trial to its full terms and effect, the First Parry Report [MONGLY01312093 at MONGLY01312094 to MONGLY01312104] stated, among other things that '*The overall data provided by the four publications provide 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. If confirmed, such a mechanism of genetic damage would be expected to be produced at high concentration of the herbicide and would be relevant only when the anti-oxidant protective mechanisms of the cell are overwhelmed. Thus I would conclude that if the mechanism of action can be proved to be based upon oxidative damage then hazard and risk assessment could be based upon a non-linear model with a threshold of activity at low doses'*;

(ii) all of the studies considered by the First Parry Report contained deficiencies in their methodology; and

(c) otherwise relies on each of the Parry Reports for their full terms and effects.

44. In answer to paragraph 44, it:

(a) refers to and repeats paragraph 42 above;

(b) says further that:

(i) the first part of the Third Parry Report as defined in paragraph 42(a)(iii) above and titled *'Evaluation of the potential genotoxicity of Glyphosate, Glyphosate mixtures and component surfactants'* [MONGLY01314233 to MONGLY01314263] contained the following statements:

(A) *'These studies provide some evidence that glyphosate may be capable of inducing oxidative damage under both in vitro and in vivo conditions';*

(B) *'These studies provide some evidence that Roundup mixture produces DNA lesions in vivo, probably due to the production of oxidative damage';*

(C) *'2) There is published in vitro evidence that glyphosate is clastogenic and capable of inducing sister chromatid exchange in both human and bovine lymphocytes…';*

(D) *'11) Glyphosate induced G6PD activity in both bovine and human lymphocytes… and the production of 8-OHdG in mouse liver… Both observations indicate that glyphosate may be capable of inducing a pro-oxidant state leading to the formation of the oxidative damage lesion 8-Ohdg';*

(E) *'12) A roundup mixture containing glyphosate was shown to produce 8-OhdG in both liver and kidneys of mice… These observations indicate the Roundup mixture is capable of producing oxidative damage in vivo';*

(F) *'The studies of Bolognesi et al (1997) suggests that glyphosate mixtures may be capable of inducing oxidative damage in vivo'; and*

(G) *'On the basis of the study of Lioi et al (1998a and 1998b) I conclude that glyphosate is a potential clastogenic in vitro. The study of Bolognesi et al. (1997) indicates that this clastogenic activity* ***may*** *be reproduced in vivo in somatic cells* [emphasis in original]. *However the dominant lethal assay (of limited sensitivity) indicates that this genotoxic activity is not reproduced in germ cells. The work of Bolognesi et al (1997) and Lioli et al (1998a and 1998b) suggests that the genotoxicity may be derived from the generation of oxidative damage in the presence of glyphosate';* and

(c) relies each of the Parry Reports for their full term and effect;

(d) otherwise denies the allegations in paragraph 44.

45. In answer to paragraph 45, it:

(a) refers to and repeats paragraph 42 above;

(b) says the Second Parry Report as defined above [MONGLY01314233 at MONGLY01314270 to MONGLY01314283], contains the following statements:

(i) *'The published information on glyphosate and its formulations provide some evidence for genotoxic activity';*

(ii) *'The overall results of the studies are combined together in Table 2. This table illustrates that in none of the studies evaluated was there evidence that glyphosate had genotoxic potential. However there are a number of deficiencies in the studies provided… ';* and

(iii) *'There was no evidence in any of the studies evaluated that the various surfactants used in glyphosate formulations were potential genotoxins';*

(c) relies on each of the Parry Reports for their full terms and effects;

(d) otherwise denies the allegations in paragraph 45.

46. In answer to paragraph 46, it:

(a) refers to and repeats paragraph 42 above; and

(b) admits that the Parry Reports as defined above contained recommendations of further testing, evaluation and provision of data, including with respect to testing of glyphosate and glyphosate-based formulations and relies on each of the Parry Reports for their full terms and effects

(c) otherwise denies the allegations in paragraph 46.

47. In answer to paragraph 47, it:

(a) denies paragraph 47;

(b) says further that it was unnecessary to perform all the tests, evaluation or provision of data recommended by Professor Parry because:

(i) at the time the recommendations were made it had already performed numerous studies recommended by Professor Parry;

(ii) after the recommendations were made by Professor Parry, Professor Parry subsequently indicated to Monsanto Company that some of the recommended testing was no longer necessary;

Particulars

Email from Richard Garnett to Donna Farmer, William Heydens, Mark Martens and William Graham dated 16 February 2001 [MONGLY02626553].

(iii) in any event, it undertook such testing as recommended by Professor Parry that it considered necessary and appropriate and in the form that it considered most effective to elicit the information sought by Professor Parry;

(iv) provided such further data to Professor Parry as it considered necessary and appropriate in order for him to address all of the actions he recommended; and

Particulars

A list of the testing and studies responsive to the recommendations contained in paragraph 46 (both those commenced before and after the recommendations made by Professor Parry) is **McNickleProVolThree00005432**.

(v) Professor Parry ultimately agreed with Monsanto Company that glyphosate is not genotoxic and that the finding of oxidative stress in certain studies was an *'artefactual effect'* and did not demonstrate the mutagenicity of glyphosate, and no longer requested any studies on the final formulation.

Particulars

Meeting with Professor Parry on 15 February 2001 as recorded in an email from Richard Garnett to Donna Farmer, William Heydens and Mark Martens of 16 February 2001 [**MONGLY02626553**]

(c) it refers to and repeats paragraph 58(d) of the Third Respondent's Defence to the Applicant's ~~Third~~ Fourth Further Amended Statement of Claim

(d) it says further that no criteria is pleaded in paragraph 47 of the Reply by which the adequacy of testing referred to therein may be evaluated;

(e) otherwise relies on each of the Parry Reports for their full terms and effects.

48. It denies the allegation in paragraph 48 and says further that in 2002 Monsanto contracted with the Netherlands Organization for Applied Scientific Research (**TNO**) to conduct an experiment on *in vitro* percutaneous absorption of Roundup formulations MON 35012 and MON 0139 through viable rat skin membranes (**TNO Experiment**).

49. In answer to paragraph 49, it:

(a) says an unaudited draft report named *'In vitro percutaneous absorption study with [14C]glyphosate using viable rat skin membranes'* (**TNO Draft Report**) was sent to a representative of Monsanto Europe SA-NV; and

(b) otherwise denies the allegation in paragraph 49.

50. In answer to paragraph 50, it:

(a) assumes that the reference to the "TNO Report" ought to be a reference to what is defined in paragraph 49 as the "Draft TNO Report";

(b) says that:

(i) at trial it will refer to the full terms and effect of the TNO Draft Report;

(ii) the Roundup formulation MON 0139 70% was composed of the isopropylamine salt of glyphosate (ca. 62% w/w) and water (ca. 38%); and

(c) otherwise admits the allegations in paragraph 50.

51. It denies the allegations in paragraph 51 and says further that:

(a) on 29 March 2002 Monsanto Europe SA-NV received the preliminary results of the TNO Experiment which showed between 5% and 10% dermal penetration of glyphosate in MON 35012 concentrate, and around 2% dermal penetration for the MON 35012 spray dilution;

(b) on 29 March 2002, a representative of Monsanto Europe SA-NV sent an email to other Monsanto employees indicating that:

(i) the preliminary results of the TNO Experiment suffered from very bad reproducibility which TNO could not explain; and

(ii) TNO proposed to repeat the TNO Experiment in parallel with the human skin study;

Particulars

Email from a representative of Monsanto Europe SA-NV to other Monsanto employees dated 29 March 2002 [MONGLY03738295] which says in part: *'Preliminary results with rat skin are not acceptable (see fax); due to very bad reproducibility that TNO <u>cannot</u> explain, they proposed to repeat the study in parallel with the human skin study…'*

(c) on 4 April 2002, a representative of Monsanto Europe SA-NV sent an email to other Monsanto employees indicating that the TNO Experiment had been stopped.

Particulars

Email from a representative of Monsanto Europe SA-NV to other Monsanto employees dated 4 April 2002 [MONGLY03737014].

52. In answer to paragraph 52:

(a) it denies the allegations in paragraph 52;

(b) it refers to and repeats paragraphs 50 and 51 above;

(c) it otherwise says that:

(i) on 2 July 2002, notwithstanding that the TNO Experiment had been stopped, a representative of Monsanto Europe SA-NV circulated the TNO Draft Report to Monsanto employees;

(ii) on 14 July 2002, following receipt of the TNO Draft Report, Donna Farmer sent a reply email to the representative of Monsanto Europe SA-NV indicating that:

(A) it was her understanding that its integrity had been compromised and Monsanto agreed to terminate the study; and

(B) she wanted to see no more than a one-page summary of the TNO Experiment indicating the above and that it had been terminated;

Particulars

Email from Donna Farmer to a representative of Monsanto Europe SA-NV dated 14 July 2002 [MONGLY00888421].

(iii) a formal report was unnecessary because:

(A) the TNO Experiment was experimental in nature;

(B) the TNO Experiment had failed;

(C) the TNO Experiment was deficient in a number of ways, including that:

(1) it suffered from poor reproducibility;

(2) the dermal penetration results for the concentrated formulation were anomalous when compared with the diluted formulation;

(3) the recoveries were poor; and

(4) there was high variation within the glyphosate test groups.

53. It admits the allegations in paragraph 53.

54. It admits the allegations in paragraph 54.

55. In answer to paragraph 55:

(a) it denies the allegations in paragraph 55;

(b) it says further that page 19 of the Final TNO Report recorded the following data:

(i) 48 hours after application of concentrated MON 35012, 10.34+/-4.19% of the dose glyphosate had penetrated through rat skin membranes;

(ii) when MON 35012 was applied as field dilution, the relative penetration of glyphosate was 2.62 +/- 1.42% after 48 hours;

(iii) for MON 0139 70% these values were 0.52+/- 0.45% for the concentrate and 1.42+/-2.20% for the field dilution;

(iv) at the end of the 8-hour exposure period, 111.7% (MON 35012 concentrate), 44.8% (MON 35012 field dilution), 120.8% (MON 0139 70% concentrate) and 78.3% (MON 0139 70% field dilution) of the applied dose glyphosate could still be removed from the application site with cotton swabs;

(c) the conclusion of the study's authors was that because of the high variation in dermal penetration within the test groups and the poor recoveries, the data presented in the report are not acceptable for regulatory use and risk assessment;

(d) in the premises of paragraphs 55(b) and (c) above, the data in the Final TNO Report was not a valid or reliable measure of the dermal penetration of glyphosate or glyphosate-based formulations.

56. In answer to paragraph 56, it:

(a) denies the allegations in paragraph 56;

(b) says further that:

(i) it did not, nor was it required to, undertake a repetition of the two-year carcinogenicity study on mice conducted in 1983, referred to in subparagraph 56(a) of the Applicant's Reply, and says further that on 10 November 1988, following a meeting between representatives of the United States Environmental Protection Agency (**EPA**) and Monsanto, the EPA decided to reconsider their interpretations of the mouse study, and requested that Monsanto provide additional historical data, which was provided;

Particulars

Letter from Monsanto to the EPA dated 12 December 1988 [MONGLY01287148].

(ii) on 6 July 1989, after reviewing the additional historical data on the mouse study, the EPA wrote to Monsanto saying, among other things, that *'*[a] *repeat of the mouse oncogenicity* [study] *will not be required at this time'* and that *'after the results of the new 2-year rat chronic toxicity and oncogenicity study are reviewed, the Agency will reconsider if a repeat mouse oncogenicity study is needed'*;

Particulars

Letter from Monsanto to the EPA dated 6 July 1989, page 2 [McNickleProdVolThree00016442].

(iii) on 26 September 1990, Monsanto completed and submitted to the EPA a two-year rat study;

Particulars

Study dated 26 September 1990 titled *'Chronic Study of Glyphosate Administered in Feed to Albino Rats'* [McNickleProdVolFive00097185].

(iv) in or around June 1991, the EPA's Toxicology Branch recommended the carcinogenic potential of glyphosate be addressed by the EPA's Peer Review Committee, based on a high incidence of pancreatic islet cell tumours in each of the treated male groups the two-year rat study;

Particulars

Facsimile from Dr Sheila Schuette to Dr William Heydens attaching EPA review of the two-year rat study [MONGLY01287106].

(v) on 30 October 1991, after reviewing the two-year rat study and other material submitted to the EPA, the EPA's Peer Review Committee concluded that *'glyphosate should be classified in the lowest cancer classification as a Group E chemical (evidence of non-carcinogenicity for humans)'*;

Particulars

EPA's memorandum regarding the second peer review of glyphosate [MONGLY02448773].

(c) it did not, nor was it required to, undertake a 12-month or longer chronic toxicity study on glyphosate after 1991, as referred to in subparagraph 56(b) of the Applicant's Reply;

(d) it did not, nor was it required to, undertake long term animal carcinogenicity studies on any formulated pesticide product, as referred to in subparagraph 56(c) of the Applicant's Reply, and says further that:

(i) the EPA does not require long-term animal carcinogenicity studies to be conducted on formulated glyphosate-containing products;

(ii) component parts of Monsanto Roundup Products, in particular glyphosate and surfactants, have been analysed by the EPA and have been found not to be carcinogenic;

Particulars

(1) <u>EPA Second Peer Review of Glyphosate (October 30, 1991) [MAL.001.036.0503].</u>

(2) EPA Reregistration Eligibility Decision (RED) Glyphosate (February 16, 1994) [McNickleProdVolTwentyone00008169].

~~(1)~~(3) 2017 EPA OPP Report [McNickleProdVolThree00017888] at 143-144.

~~(2)~~(4) EPA's memorandum regarding Alkyl Amine Polyalkoxylates (surfactants) (April 3, 2009) [McNickleProdVolThree00002181].

~~(3)~~(5) Alkyl Amine Polyalkoxylates; Exemption from the Requirement of a Tolerance, 74 Fed. Reg. 28616 (June 17, 2009) [McNickleProdVolEight00004576] at 28619~~.~~

(iii) long term animal carcinogenicity studies of glyphosate-based formulations would be of no, or very limited, utility in contributing to the state of scientific knowledge concerning the carcinogenic potential of glyphosate or glyphosate-based formulations because:

(1) the most appropriate animals to be used in long term carcinogenicity studies are rodents and such studies typically last for 18 months (in the case of mice) or 24 months (in the case of rats);

(2) administering a glyphosate-based formulation reflecting the limit dose level to rodents over the period of a long-term study would result in severe damage to the gastro-intestinal tract of the rodents, by reason of the surfactant, such that the rodents would in all likelihood die as a consequence before the end of the study such that the study could not be completed;

(3) administering a glyphosate-based formulation reflecting the limit dose level to rodents would require the administration of an excessive volume of test material to the rodents such that their stomachs would likely rupture, causing them to die

before the end of the study such that the study could not be completed;

(e) epidemiological studies have been conducted to study the association between glyphosate containing formulations and NHL, and have found no association between glyphosate use and NHL overall or any NHL subtypes; and

Particulars

Gabriella Andreotti et al., 'Glyphosate Use and Cancer Incidence in the Agricultural Health Study,' JNCI J. Nat'l Cancer Inst. 110(5) (2018) 509-16 (**Andreotti et al. 2018**) [McNickleProdVolTwo00008268].

(f) since 1999, various further studies, epidemiologic research and/or agricultural chemical exposure assessments have been conducted, including:

(i) Andreotti et al. 2018, in respect of which:

(A) enrolments into the study had commenced from around 1993 to 1997 (involving the completion of a questionnaire as to use of glyphosate based herbicides and other pesticides); and

(B) follow-up phone interviews with participants were being conducted from around 1999 to 2005;

(ii) the Farm Family Exposure Study authored by John Acquavella and others, which was published in 2004.

Particulars

Acquavella, J. et al., '*Glyphosate biomonitoring for farmers and their families: results from the Farm Family Exposure Study,'* 2004, Env. Health Perspect 112, pp. 321-326 [McNickleProdVolFive00073109].

(g) some toxicology studies conducted by IBT in or around 1970 to 1974 in respect of glyphosate were determined to be invalid by the EPA, but:

(i) it denies anything done by Monsanto caused the invalidity; and

(ii) it says further that;

(A) the toxicology studies which had been determined to be invalid by the EPA, and which the EPA had requested Monsanto to repeat, were repeated;

(B) the results of each repeated toxicology studies were consistent with the results of the studies conducted by IBT in or around 1970 to 1974 to the effect that no carcinogenic effects of glyphosate were found; and

(C) Monsanto does not currently rely on any IBT generated data to support glyphosate registration anywhere in the world.

(h) as to subparagraphs 56(g) and (h):

(i) the EPA does not require, and has not required, Monsanto to conduct the further research described in subparagraphs 56 (g) and (h)

(ii) those subparagraphs fail to specify what exactly such research would examine;

(iii) there is no reason to conclude that, had such further testing been conducted, it would reveal data indicating that exposure to glyphosate or glyphosate-based formulations can cause the development of, or increase the risk to an individual of developing, NHL.

57. It denies the allegations in paragraph 57 and says further that:

(a) at the time of filing this Rejoinder, it is unaware of any regulator that considers Monsanto has undertaken insufficient testing or evaluation in relation to the questions of whether:

(i) Roundup Products and/or glyphosate and/or GBFs are carcinogenic or potentially carcinogenic; or

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

(b) it otherwise refers to and repeats paragraph 60 below.

58. It admits the allegations in paragraph 58, and says further that it was under no obligation to provide either the TNO Report or the Parry Reports (which was a summary review of

previously submitted and/or publicly available studies and data) to regulatory authorities or to make them publicly available.

59. It denies the allegations in paragraph 59 and repeats paragraphs 41 to 58 above. It says further to the extent that it held information which was not shared with regulatory authorities, such information was:

(a) in respect of the Parry Reports:

(i) an analysis of studies which were available to regulators; and

(ii) misleading in that the Parry Reports do not reflect his ultimate opinion, which was that glyphosate is not genotoxic;

(b) in respect of the TNO Experiment, experimental, inconclusive and suffered from the deficiencies in paragraphs 52(c)(iii) and 55 above.

60. In answer to paragraph 60:

(a) it denies the allegations in paragraph 60;

(b) it repeats paragraphs 3 to 59 above;

(c) it says further that:

(i) the matters alleged in paragraphs 3 to 59 of the Applicant's Reply to the Third Respondent's Defence do not involve any allegations about toxicology testing with glyphosate, surfactants, glyphosate-based formulations or metabolites of glyphosate that was conducted by or on behalf of the First, Second and/or Third Respondents. This is aside from the allegations made in paragraph 56(f) to 56(h) of the Applicant's Reply to the Third Respondent's Defence in relation to toxicity studies undertaken on behalf of the Third Respondent by IBT in or around 1970 to 1974, as well as testing concerning the gut microbiome and the pharmacokinetics of glyphosate and/or Roundup Products;

(ii) the Third Respondent has conducted, or engaged contract research laboratories to conduct on its behalf, hundreds of toxicology studies with glyphosate, surfactants, glyphosate-based formulations or metabolites of glyphosate, in respect of which:

(A) the vast majority of study reports were submitted to relevant regulators and international organisations, either in the form of copies of study reports or summaries of study reports; and

(B) no allegations of misconduct are made in the Applicant's Reply, aside from the allegations made in paragraph 56(f) to 56(h);

Particulars

Appendix B and Appendix C of the Reregistration Eligibility Decision – Glyphosate (United States Environmental Protection Agency, September 1993).

Annex B-5 of the EU Monograph on Glyphosate, (2001)

Report of the Joint Food and Agriculture Organization of the United Nations / World Health Organization Meeting on Pesticide Residues 2004 (**2004 JMPR**) and Toxicological Evaluations of the 2004 JMPR.

Application for Approval Renewal by the Glyphosate Task Force, dated 24 March 2011 and updated 9 May 2011, submitted to the EU Rapporteur Member State Germany.

Annex I Renewal Dossier, submitted to the Rapporteur Member State on 25 May 2012 by the European Union Glyphosate Task Force, of which the Third Respondent was a member.

Proposed Re-evaluation Decision of the Pest Management Regulatory Agency, Canada, 13 April 2015.

Report of the Joint Food and Agriculture Organization of the United Nations / World Health Organization Meeting on Pesticide Residues 2016 (**2016 JMPR**) and Toxicological Evaluations of the 2016 JMPR.

Report of the Food Safety Commission of Japan Regarding Glyphosate, July 2016.

Re-evaluation Decision of the Pest Management Regulatory Agency, Canada, 28 April 2017.

Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential, of the EPA's Office of Pesticide Programs, 12 December 2017.

Glyphosate Proposed Interim Registration Review Decision of the EPA, 23 April 2019.

Application for Approval Renewal for an Active Substance: Glyphosate, by the Glyphosate Renewal Group, dated 12 December 2019 and revised on 22 January 2020, 24 April 2020, and 1 July 2020, submitted to the EU Rapporteur Member States France, Hungary, Sweden and The Netherlands.

Annex I Renewal Dossier, submitted to the Rapporteur Member States for the European Union on 8 June 2020 by the Glyphosate Renewal Group, of which the Third Respondent was a member.

numerous companies other than the Third Respondent have conducted, or engaged contract research laboratories to conduct on their behalf, their own toxicology studies with glyphosate, surfactants, glyphosate-based formulations and/or metabolites of glyphosate, in respect of which the vast majority of study reports were provided (either individually or as part of a joint taskforce) to one or more regulators and/or international organisations, either in the form of copies of study reports or summaries of study reports.

Particulars

Those companies include: Adama, Agrichem, Agro Trade, Albaugh, Alkaloida, Arysta Life Sciences, Barclay Chemicals, Cheminova, Ciba-Geigy, Dow AgroSciences, DuPont, Excel Industries, Feinchemie Schwebda, Helm, Herbex Produtos Quimicos, Industrias Prodotti, Luxan, Nufarm, Sanachem, Sankyo/Mitsui Chemical, Sinon, Sumisho Agro, Syngenta, Zeneca,

(iii) the results of the toxicology studies conducted by or on behalf of companies other than the Third Respondent with glyphosate, surfactants, glyphosate-based formulations or metabolites of glyphosate, that were provided to regulators and/or international organisations are consistent with the results of studies undertaken by or on behalf of the Third Respondent in that, taken together, they demonstrate that neither glyphosate nor glyphosate-based formulations are carcinogenic.

Particulars

Reregistration Eligibility Decision – Glyphosate (United States Environmental Protection Agency, September 1993.

EU Monograph of Glyphosate, 2001.

European Commission Review Report for Glyphosate, 21 January 2002.

2004 JMPR and Toxicological Evaluations of the 2004 JMPR.

Annex I Renewal Dossier, submitted to EFSA on 25 May 2012 by the European Union Glyphosate Task Force, of which the Third Respondent was a member.

Renewal Assessment Report of the EU Rapporteur Member States, Volume 1 – Report and Proposed Decision, and Volume 3 Section B.6 – Toxicology and Metabolism, dated 18 December 2013 (revised on 29 January 2015 and 31 March 2015).

Proposed Re-evaluation Decision of the Pest Management Regulatory Agency, Canada, 13 April 2015.

Final Addendum to the Renewal Assessment Report of the EU Rapporteur Member States, October 2015.

2016 JMPR and Toxicological Evaluations of the 2016 JMPR.

Report of the Food Safety Commission of Japan Regarding Glyphosate, July 2016.

Opinion of the Risk Assessment Committee of the European Chemicals Agency, 15 March 2017.

Re-evaluation Decision of the Pest Management Regulatory Agency, Canada, 28 April 2017.

Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential, of the EPA's Office of Pesticide Programs, 12 December 2017.

Glyphosate Proposed Interim Registration Review Decision of the EPA, 23 April 2019.

Annex I Renewal Dossier, submitted to the Rapporteur Member States for the European Union on 8 June 2020 by the Glyphosate Renewal Group, of which the Third Respondent was a member.

Summary of the procedure and outcome of the draft Renewal Assessment Report on glyphosate of the Assessment Group on Glyphosate, 15 June 2021.

(iv) in the premises:

(A) the articles, studies and matters canvassed by the allegations in paragraphs 3 to 59 of the Applicant's Reply to the Third Respondent's Defence comprise a small proportion of the total amount of research and data concerning glyphosate, glyphosate-based formulations, surfactants and metabolites of glyphosate;

(B) even if the scientific literature, research and data concerning the carcinogenic properties or potential carcinogenic properties of Roundup Products, glyphosate and/or glyphosate-based formulations as enumerated in paragraphs 3 to 59 of the Applicant's Reply to the Third Respondent's Defence is or was incomplete and/or distorted by reason of the allegations in paragraphs 3 to 59 of the Applicant's Reply to the Third Respondent's Defence (which is denied), that had no effect on the adequacy, accuracy and validity:

(1) of the results of the toxicology studies conducted by or on behalf of the Third Respondent with

glyphosate, surfactants, glyphosate-based formulations and metabolites of glyphosate, described in paragraphs 60(c)(i) and 60(c)(ii) above;

(2) of the results of the toxicology studies conducted by or on behalf of companies other than the Third Respondent with glyphosate, surfactants, glyphosate-based formulations and or metabolites of glyphosate, and which were submitted to regulators and international organisations.

61. In answer to paragraph 61, it:

(a) refers to and repeats paragraphs 40(d) of the Third Respondent's Defence to the Applicant's ~~Third~~ Fourth Further Amended Statement of Claim;

(b) otherwise does not plead to paragraph 61(a) and 61(c) as they make no allegations against it;

(c) as to subparagraph 61(b):

(i) it denies the allegations in paragraph 61(b);

(ii) it refers to and repeats paragraphs 30(c) and 60 above;

(iii) it says further that:

(A) regulatory approvals of glyphosate in Australia and elsewhere throughout the world are based primarily on the study reports and dossiers containing summaries of study reports submitted to them by companies or joint task forces seeking to register or re-register glyphosate;

(B) regulatory approvals of glyphosate in Australia and elsewhere throughout the world are, and have for many years, also been based on scientific literature, research and data produced by companies in addition to that which was produced by the Third Respondent;

(C) despite the fact that for several years the allegations which are made in paragraphs 3-61 of the Applicant's Reply to the Third

Respondent's Defence have been made in a variety of forms in thousands of court cases concerning Roundup in various parts of the world, at the time of filing this Rejoinder the Third Respondent is unaware of any regulator which considers that its approval of glyphosate is based upon incomplete and/or distorted published scientific literature, research and data.

62. In answer to paragraph 62:

(a) it says that the allegations are embarrassing and are liable to be struck out because it is unclear which party's defence is referred to;

(b) it does not plead to paragraph 62(a) as the Applicant in that paragraph makes no allegations against it;

(c) it refers to and repeats paragraphs 3-61 above;

(d) it otherwise denies the allegations in paragraph 62.

63. In answer to paragraph 63:

(a) it refers to and repeats paragraphs 40, 53, 58, and 66 of the Third Respondent's Defence to the Applicant's ~~Third~~ Fourth Further Amended Statement of Claim;

(b) it refers to and repeats paragraphs 3 to 62 above;

(c) it otherwise does not plead to paragraph 63 as the Applicant makes no allegations against it.

64. In answer to paragraph 64:

(a) it does not plead to paragraph 64(a) as in that paragraph the Applicant makes no allegations against it;

(b) it refers to and repeats paragraphs 3-61 above;

(c) it otherwise denies the allegations.

65. In answer to paragraph 65:

(a) it denies the allegations in paragraph 65;

(b) it says further that:

(i) the AHS study publications do not suffer from statistical and analytic errors which render them invalid or unreliable indications of the relationship between exposure to glyphosate and/or glyphosate-based formulations and the risk of NHL;

(ii) neither the APVMA nor the EPA has ever reported that the AHS study publications suffer from statistical and analytic errors which render the publications invalid or unreliable indications of the relationship between exposure to glyphosate and/or glyphosate-based formulations and the risk of NHL;

(iii) the EPA relies and has relied on the AHS study publications in the evaluations it has conducted in respect of the alleged carcinogenicity of glyphosate.

Particulars

EPA Memorandum: Glyphosate: Epidemiology Review of Zhang et al. (2019) and Leon et al. (2019) publications for Response to Comments on the Proposed Interim Decision, 6 January 2020 [McNickleProdVolThirtyfour00000651].

66. In answer to paragraph 66:

(a) it says that the allegations amount to a conclusion of law that can only be determined by the Court at the conclusion of the trial of this proceeding;

(b) it otherwise does not admit the allegations.

67. In answer to paragraph 67 it refers to and repeats paragraphs 43(b) to (e) of the Third Respondent's Defence.

68. In answer to paragraph 68:

(a) it says that the allegations amount to a conclusion of law that can only be determined by the Court at the conclusion of the trial of this proceeding;

(b) it otherwise does not admit the allegations.

69. In answer to paragraph 69 it refers to and repeats paragraphs 55(c) to (e) of the Third Respondent's Defence.

70. In answer to paragraph 70 it refers to and repeats paragraph 72(d) of the Third Respondent's Defence.

71. In answer to paragraph 71 it refers to and repeats paragraph 72(e) of the Third Respondent's Defence.

72. In answer to paragraph 72 it refers to and repeats paragraph 72(f) of the Third Respondent's Defence.

73. In answer to paragraph 73 it refers to and repeats paragraph 109 of the Third Respondent's Defence.

74. It says further, that as the paragraphs 3 to 62 of the Applicant's Reply to the Third Respondent's Defence are pleaded responsively to the allegations of scientific knowledge pleaded in paragraph 40(d) of the Third Respondent's Defence to the Applicant's ~~Third~~Fourth Further Amended Statement of Claim, the allegations in paragraphs 3 to 62 of the Reply (if proved) are irrelevant to:

    (a) the state of scientific knowledge prevailing at any time prior to each of the allegations made; and

    (b) the claims made by any group member exposed to glyphosate or Roundup Products in the time prior to the period traversed in paragraphs 3 to 62 of the Reply.

75. Save for any positive admissions in the Rejoinder above, the Third Respondent joins issue with each and every allegation in the Applicant's Reply to the Third Respondent's Defence.

Date: 2 February 2023

Herbert Smith Freehills

Herbert Smith Freehills
Solicitors for the Third Respondent

This pleading was prepared by Herbert Smith Freehills, solicitors for the Third Respondent and Raph Ajzensztat, counsel for the Third Respondent, and settled by Robert Craig QC.

Certificate of lawyer

I **Peter Holloway**, Australian Legal Practitioner and a Partner of Herbert Smith Freehills, the solicitors for the Third Respondent in this proceeding, certify to the Court that in relation to the Rejoinder filed on behalf of the Third Respondent, the factual and legal material available to me at present provides a proper basis for:

(a) each allegation in the pleading; and

(b) each denial in the pleading; and

(c) each non admission in the pleading.

Date: 2 February 2023

Peter Holloway
Partner
Herbert Smith Freehills
Solicitors for the Third Respondent

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