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Details of Filing

Document Lodged:	Reply - Form 34 - Rule 16.33
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File Title:	KELVIN MCNICKLE v HUNTSMAN CHEMICAL COMPANY AUSTRALIA PTY LTD & ORS
Registry:	VICTORIA REGISTRY - FEDERAL COURT OF AUSTRALIA

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Important Information

As required by the Court's Rules, this Notice has been inserted as the first page of the document which has been accepted for electronic filing. It is now taken to be part of that document for the purposes of the proceeding in the Court and contains important information for all parties to that proceeding. It must be included in the document served on each of those parties.

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Form 34
Rule 16.33

Reply to Second Respondent's Defence

VID 243 of 2020

Federal Court of Australia
District Registry: Victoria
Division: General

KELVIN MCNICKLE

Applicant

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

First Respondent and others according to the Schedule

Capitalised terms have the meaning denoted in the Amended Statement of Claim filed 16 June 2020.

In reply to the Second Respondent's Defence filed 10 July 2020 (the **Defence**), the Applicant says:

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

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

    a. denies the allegations contained in the paragraph;

    b. refers to and repeats the matters alleged at paragraphs 23 to 26 and 53 of the Amended Statement of Claim; and

    c. says further that:

        i. one or more entities within the group of Monsanto companies (individually or together, **Monsanto**) initiated, funded, wrote and/or edited scientific

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research, studies and/or papers which disputed, or did not support, that Roundup Products and/or glyphosate is carcinogenic or potentially carcinogenic:

A. without disclosure or adequate disclosure of the involvement or influence of Monsanto; and/or

B. to defend against, undermine or invalidate scientific studies, research, papers and/or reviews, including by IARC, containing conclusions that Roundup Products and/or glyphosate is carcinogenic or potentially carcinogenic;

Particulars

As to A., the Applicant refers to *inter alia*:

(i) A paper by Williams et al titled "Safety Evaluation and Risk Assessment of the Herbicide Roundup and its Active Ingredient, Glyphosate, for Humans", published in the journal *Regulatory Toxicology and Pharmacology* in 2000 (**Williams 2000 Paper**) which was initiated, funded and written (at least in part) by employees of Monsanto. These employees were not named as authors and the paper did not disclose that it was initiated by Monsanto.

(ii) A paper by Williams et al titled "Developmental and Reproductive Outcomes in Humans and Animals after Glyphosate Exposure: A Critical Analysis", published in the *Journal of Toxicology and Environmental Health* in 2012 which was funded by Monsanto and edited and redrafted by employees of Monsanto, namely Donna Farmer (toxicologist) and David Saltmiras (toxicologist) (**Saltmiras**). The paper did not disclose the involvement of these employees.

(iii) A paper by Kier and Kirkland titled "Review of genotoxicity studies of glyphosate and glyphosate-based formulations", published in the journal *Critical Reviews in Toxicology* in 2013 (**Kier and Kirkland 2013 Paper**) which was written (at least in part) by an employee of Monsanto, namely Saltmiras. The publication does not acknowledge the extent of Saltmiras' authorship or involvement.

As to B., the Applicant refers to *inter alia*:

(i) the "*Scientific Outreach Plan*" adopted by Monsanto, which included the following elements:

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

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

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

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

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

(iv) Monsanto Company US (New)'s plan to "*orchestrate outcry with the IARC decision*" (before IARC had published its conclusion) and Monsanto's goals to "*invalidate relevance of IARC*" and seek "*WHO retraction*", as recorded in internal Monsanto Company US (New) and Monsanto documents; and

(v) A series of reviews published in the journal *Critical Reviews in Toxicology*, including in the areas of exposure, epidemiology, cancer in experimental animals and mechanistic and other data, which were:

a. critical of IARC's assessment of glyphosate as a probable carcinogen to humans; and

b. organised, funded, directed, edited and (at least in part) written by Monsanto, including William Heydens (toxicologist) (**Heydens**), without Monsanto's involvement or influence being disclosed or adequately disclosed (until complaint was made to the journal following revelation of that involvement or influence during the course of litigation in the US concerning Roundup, following which disclosure remained incomplete).

Further particulars may be provided following discovery.

ii. information, data, studies and/or reports which supported the conclusion that Roundup Products and/or glyphosate is or is potentially carcinogenic was available to Monsanto but which was not made publicly available and/or were withheld from regulatory authorities;

Particulars

The Applicant refers to *inter alia*:

(i) Reports available to Monsanto prepared by Professor James Parry, a genetic toxicologist, in 1999. Professor Parry conducted a review of several studies and/or papers concerning the potential genotoxicity of glyphosate and Roundup Products for provision to Monsanto. Professor Parry concluded that there was evidence of a possible genotoxic effect for both glyphosate and Roundup Products and recommended further testing. As far as the Applicant is aware, the reports were not made publicly available nor provided to regulatory authorities.

(ii) A study concerning dermal absorption of Roundup Products by Johan van Burgsteden of the Dutch consultancy group, TNO Nutrition and Food Research, in or around June 2002. An internal Monsanto document shows that an employee of Monsanto (Heydens), stated about the study "*My primary concern is with the glyphosate in terms of the potential for this work to blow Roundup risk evaluations (getting a much higher dermal penetration than we've ever seen before*". As far as the Applicant is aware, the study was not made

publicly available nor provided to regulatory authorities.

Further particulars may be provided following discovery.

iii. Monsanto did not undertake testing or sufficient testing, including which was recommended and/or requested internally and/or externally, including by the EPA, in relation to the question of whether Roundup Products and/or glyphosate is or is potentially carcinogenic;

Particulars

The Applicant refers to *inter alia*:

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

(ii) Further testing was recommended in a report of Professor Parry, referred to in particular (i) to paragraph 2(c)(ii) above.

(iii) An internal Monsanto email shows that the study concerning dermal absorption, referred to in particular (ii) to paragraph 2(c)(ii) above, was "*dropped*" because a "*further study*" "*was not likely to help*" meet the project objective of meeting regulatory requirements for operator exposure. That same email also states that "*from the regulatory angle, there is no point in pursuing the studies further*."

Further particulars may be provided following discovery.

iv. by reason of the matters alleged above, published scientific literature, research and data concerning the carcinogencic properties or potential carcinogenic properties of glyphosate and/or Roundup Products was and is incomplete and/or distorted.

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

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

    b. says further that by reason of the matters alleged at paragraphs 2(c)(i) to (iv) above, regulatory approvals in Australia and elsewhere throughout the world are and have been based upon, at least in part, incomplete and/or distorted published scientific literature, research and data.

4. As to paragraph 35(d)(iv), the Applicant:

    a. admits that, in 2017, the APVMA declined to formally re-consider the approval and registration of glyphosate in Australia; and

    b. says further that by reason of the matters alleged at paragraphs 2(c)(i) to (iv) above, that decision was based upon, at least in part, incomplete and/or distorted published scientific literature, research and data.

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

    a. denies the allegations contained in the paragraphs; and

    b. refers to and repeats the matters alleged in paragraphs 2 and 3 above.

Date: 4 August 2020

Signed by Andrew Watson
Lawyer for the Applicant

This pleading was prepared by Melanie Szydzik, counsel for Mr McNickle.

Certificate of lawyer

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

(a) each allegation in the pleading; and

(b) each denial in the pleading; and

(c) each non admission in the pleading.

Date: 4 August 2020

Signed by Andrew Watson
Lawyer for the Applicant

Schedule

VID 243 of 2020

Federal Court of Australia
District Registry: Victoria
Division: General

Respondents

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

Third Respondent: Monsanto Company