

DECLARATION

Patents Act 1990

In the matter of

Australian patent application no 2017261483

in the name of Dow AgroSciences LLC

- and -

In the matter of

Opposition by Nufarm Australia Limited

I, David G Ouse, of 9330 Zionsville Road, Indianapolis, IN 46268, United States of America, make the following declaration under the *Patents Act 1990*:

A. INTRODUCTION

- 1 I am currently a Research Biologist at Dow AgroSciences LLC ("**Dow**") in Indianapolis, Indiana.
- 2 Unless otherwise stated, I make this declaration from my own knowledge. My opinions set out in this declaration are wholly or substantially based on my specialized knowledge and expertise in the fields of discovery and product development for herbicides and herbicide tolerance traits, except to the extent otherwise stated.

B. EXPERIENCE

- 3 I have 31 years of research experience in the fields of agronomy and herbicide science.
- 4 I received a Bachelor of Science degree (B. S.) in Agronomy, from North Dakota State University (1985) and a Master of Science (M. S.) degree in Agronomy/Weed Science, from North Dakota State University (1989).
- 5 I am a co-inventor on 9 granted U. S. patents or priority patents. I am an author or co-author on 14 presentations given to my peers at Scientific Meetings of the North Central Weed Science Society or the American Chemical Society (ACS). I have also given external presentations in China and the UK. My research has been in the areas of Formulation Chemistry and Novel Herbicides.
- 6 Amongst other awards, I have been awarded the CPRD Progress Award for Novel Design of Experiments for Assessing Herbicide Volatility (2012).
- 7 Between 1989 and 1995, I was employed by Dow AgroSciences as an Assistant Research Leader for Cereal Herbicide Discovery. I evaluated several chemical

families for grass and broadleaf weed control of cereals, including key environmental fate trials which helped the advancement of florasulam.

- 8 From 1995-1996, I was Rice Herbicide Discovery Project Leader at Dow AgroSciences. I was responsible for evaluating several chemical families for utility as rice herbicides, including field testing.
- 9 From 1997-1999, I was Cereal Herbicide Discovery Project Leader at Dow AgroSciences. I led a team responsible for evaluating several chemical families for utility as herbicides and in the cereals project, including field testing in Europe and North America. These field trials identified a pyroxsulam and safener formulation that went on to be commercialized.
- 10 From 1999-2009, I was Greenhouse Biologist for Formulations Science and Technology and the Product Integrity Program at Dow AgroSciences. I was responsible for evaluating several novel herbicide formulations, including new forms of herbicide safeners. I led greenhouse testing to establish no-observable effect level testing for herbicides.
- 11 From 2009 – 2017, I have been Crop Protection R&D Research Biologist and Global No-Observable Effect Level team Leader/ Product Integrity Biologist at Dow AgroSciences. Amongst other responsibilities, I lead a team to coordinate greenhouse and lab trials for several areas including; herbicidal formulation testing, adjuvant comparisons, herbicide:safener ratio optimization, weed resistance testing, herbicide volatility, rainfastness, and spray tank cleanout. In this role I designed and developed novel methods to evaluate herbicidal volatility and identified the reaction product of 2,4-D and choline hydroxide as a form of 2,4-D with ultra-low volatility.
- 12 From 2017 – present, I am a Scientist in the Integrated Field Sciences R&D function for Biological Characterization in the greenhouse and laboratory. In this role I coordinate greenhouse and lab trials for several areas including; herbicidal formulation testing, adjuvant comparisons, herbicide:safener ratio optimization, weed resistance testing, herbicide volatility, rainfastness, and spray tank cleanout. I also coordinate greenhouse testing for changes made to existing commercial products to insure those changes do not affect the products performance. And, I am responsible for calculating trace component limits for shared manufacturing equipment globally for Corteva internal sites and at contract facilities
- 13 A copy of my curriculum vitae is attached and marked as **Exhibit DGO-1**.
- 14 Based on my experience in herbicide formulation, it is a field where there are global understandings over certain technical aspects, due to the widespread application in agricultural industries and global trade in such commodities. My presentations in the UK and China demonstrate the global nature of the herbicide

industry. I would expect that my knowledge and understanding of herbicide formulation, based on my experiences in the United States at February 2007 would be similar to those working in Australia in this field at that time.

- 15 In my current and former roles, I would search for and consider journals and patents relating to topics such as 2,4-D, agro-chemistry, herbicide formulation and testing. I may find a range of documents in these searches. I would generally skim the identified documents and focus particularly on those relating to plant sensitivity to herbicides and the herbicidal effects of formulations. I would generally disregard documents describing growth enhancement or regulation, or other discussions that did not relate to herbicides or herbicidal effects.

C. INSTRUCTIONS

- 16 I have been informed by FPA Patent Attorneys ("**FPA**"), patent attorneys acting on behalf of Dow AgroSciences LLC, that this proceeding concerns Australian Patent Application 2017261483 (the "**Patent Application**"). I am an inventor of the Patent Application.
- 17 FPA have confirmed to me that the Patent Application is a divisional application of Australian Patent 2016202508 (the Parent) being the application the subject of the opposition that I previously provided a declaration for. FPA informed me that that opposition was wholly unsuccessful, and the claims were granted in the form in which they were initially allowed. To provide me with some context, FPA have further confirmed that the claims in this Patent Application are similar to those granted in the Parent, the difference being that the reaction product is not isolated.
- 18 I have been requested by FPA to provide this Declaration for the purpose of this proceeding. FPA provided me with a copy of the Expert Evidence Practice Note as issued by Chief Justice Allsop of the Federal Court of Australia on 25 October 2016 (the "**Practice Note**"). I have read Annexure A to the Practice Note titled "Harmonised Expert Witness Code of Conduct" (the "**Code**") which applies to any expert witness engaged or appointed to give opinion evidence in proceedings. A copy of the Code is attached and marked as **Exhibit DGO-2**.
- 19 FPA provided me with a copy of Phillip Maxwell Hay's Declaration (the "**Hay Declaration**"). A copy of the Hay Declaration is attached and marked as **Exhibit DGO-3**. I was asked to review the Hay Declaration and provide answers to questions from FPA.
- 20 FPA also provided me with a copy of the Patent Application. A copy of the B2 publication of the Patent Application is attached and marked as **Exhibit DGO-4**. I was also asked a series of questions in relation to the Patent Application. I answered these questions using my knowledge before February 2007 (the "**Relevant Date**").

D. OTHER MATTERS RELATING TO THE PATENT APPLICATION

- 21 I was asked by FPA to comment on paragraphs 67 to 90 and 220 to 244 of the Hay Declaration and in particular, the comments in those paragraphs that relate to the Patent Application.
- 22 In making this Declaration I will seek to address Hay's evidence to the extent that I consider it relevant to the main issues in dispute in this proceeding. My decision not to comment on all the statements made in the Hay Declaration either in part or in full should not be taken as an indication of my agreement with that evidence generally or the comments made therein.
- 23 As an overarching comment, as I read paragraphs 67 to 90 and 220 to 244 of the Hay Declaration, I note that Hay's comments in respect of certain issues he identifies are repeated several times under various subheadings. I set out below my comments in respect of the issues rather than repeat myself. My comments below apply to each instance of the issue that Hay refers to.
- 24 I generally agree with Hay's statements in paragraphs 67 to 70 regarding the disclosure in the Patent Application. I have not reviewed the documents D29, D7 and D5 that Hay cites in these paragraphs and provide no comment regarding his analysis of the disclosure of those references.

Alleged aim of the invention

- 25 In paragraph 72 (and later at paragraph 221), Hay states that "the aim" of the alleged invention is to provide a herbicidal carboxylic acid derivative that is at least as active as the commercially used carboxylic acid herbicide salts, but which is less volatile so that its use would not damage nearby sensitive crops. I have identified the relevant passage of the Patent Application as page 2, lines 1 to 3. But rather than state it to be an "aim" the Patent Application in fact describes it as being "desirable" to have a herbicidal carboxylic acid derivative that is at least as active as the commercially used carboxylic acid herbicide salts. I therefore consider Hay has overstated what is described in the Patent Application as being a "desirable" advantage of the invention. I don't see the Patent Application as saying that a composition with this advantage is critical or essential.
- 26 This is clarified immediately underneath at page 2 line 8 where the compounds of the invention are described as being comparable to the commercially used carboxylic acid herbicide salts. In paragraph 73, Hay acknowledges this disclosure in the Patent Application, stating that the "*Patent Application purports to achieve this aim by providing compounds formed by combining a carboxylic acid herbicide with either a (tetraalkyl)ammonium or an (arylalkyl)trialkylammonium hydroxide having a herbicide activity on an acid equivalent basis which is at least comparable to the commercial used carboxylic acid herbicide salts, but with reduced volatility*",

citing page 2, lines 5 to 9. But I still do not see the Patent Application as saying that a compound of the invention must be at least as active as the commercially used carboxylic acid herbicide salts.

27 FPA asked me what I did see the Patent Application as saying in this section. The collective message I get from page 2 lines 1 to 9 is that there is a need for a herbicide compound with lower volatility. It would be desirable to achieve at least the same level of activity as the existing commercial products but that what was found was compounds which overall, had comparable activity. And having read the Patent Application again to re-familiarise myself with its content, there is nothing in the Patent Application that alters my conclusion or is inconsistent with that conclusion. The problem set out at page 1 of the Patent Application is the volatility issue.

28 FPA asked me to clarify what I understood by 'comparable' as used in this context. I understand "comparable" to mean that the claimed carboxylic acid herbicide has, overall when averaged across all weeds tested, activity within + / - 10% compared to existing commercial products.

29 In addition, when it comes to the question of what the aim of the invention is understood to be, Mr Hay appears to overlook the fact that in both instances – whether the Patent Application is referring to the compounds as being desirably at least as active or being comparable to commercial products – the claimed carboxylic acid herbicide also has reduced volatility.

30 So, in summary I understand the aim of the invention is to form a herbicidal compound by combining a carboxylic acid with a tetra(alkyl)ammonium hydroxide. That compound has comparable activity to existing products but with the added property of lower volatility. It would be nice – or to use the words of the Patent Application, "desirable" - if the compounds were even more active than existing products. But there is no statement anywhere in the Patent Application that this desirable activity is essential – I would call such activity a "nice to have but not a must have".

Herbicidal activity

31 Hay's comments on the background discussion and what he perceives as being the promise of the invention to be at least as active or better than the existing products form the basis for his later criticisms that the claims do not achieve the stated promise of the invention. I disagree with his conclusions.

32 Specifically, at paragraph 220, Hay comments that claims 1 to 15 encompass embodiments that do not achieve the stated promise of the invention as described in the Patent Application. Specifically, Hay considers the promise of the invention is to provide a herbicidal carboxylic acid derivative that is "*at least as active*" as the

commercially used carboxylic acid herbicide salts, but which is less volatile so that its use would not damage nearby sensitive crops. As I have stated above, the Patent Application discusses that it would be desirable to have a compound with this advantage (see page 2, lines 1-3). However, I don't see the Patent Application as saying that a compound with this advantage is essential, and the claims don't mention this either. And Hay disregards the subsequent comments in the Patent Application regarding it having been found that compounds formed as described at page 2 lines 5 to 9 are "*at least comparable to the commercially used carboxylic acid herbicide salts, but with reduced volatility*".

- 33 In my opinion compounds with comparable activity to commercial products, especially those with improvement characteristics of reduced volatility, meet the promise of the invention. In fact, even if for arguments sake, a compound with slightly lower activity than commercial compounds but with the highly desirable characteristic of reduced volatility would still meet the promise of the invention. Volatility and vapour drift, as described at page 1, was the problem to be overcome. And Hay seems to disregard this point and read lines 1 and 2 of page 2 in isolation.
- 34 FPA have asked me to further expand upon why I do not agree with Hay's conclusion at paragraph 220.
- 35 What I am told about the invention at page 2 lines 11-13 is that "*The present invention concerns herbicidal compounds comprising the reaction product of an herbicidal carboxylic acid and an N-((C₁-C₁₆) alkyl or arylalkyl) tri((C₁-C₁₆) alkyl)ammonium hydroxide*". And at page 2 lines 16 -20 that "*The invention also includes a method of use of the compounds and their compositions of the present invention to kill or control undesirable vegetation*". This aligns with my understanding of the claims of the Patent Application, which relate to a herbicidal compound (and compositions having that compound) that is a reaction product produced by combining 2,4-dichlorophenoxyacetic acid and a (tetraalkyl) ammonium hydroxide (claims 1 – 11) and their use in controlling undesirable vegetation (claims 12 – 15). The claimed compound is defined as being a herbicidal compound, which informs me that it has herbicidal activity.
- 36 I was asked by FPA what I understand a compound that is a herbicide to be. I, and I believe others in the field, understand "herbicide" or herbicidal compound, to mean that the compound in ordinary use will kill or suppress an undesirable plant. This corresponds with the definition of "herbicide" provided on page 4, lines 13 to 17 of the Patent Application, which states that the term "*is used herein to mean an active ingredient that kills, controls or otherwise adversely modifies the growth of plants. An herbicidally effective or vegetation controlling amount is an amount of active ingredient which causes an adversely modifying effect and includes*

deviations from natural development, killing, regulation, desiccation, retardation, and the like." The undesirable plant may not be a weed *per se*; but for convenience I will use the term weed throughout my declaration to collectively mean any undesirable plant.

37 As part of his explanation as to why the compound and compositions of claims 1 to 11 allegedly do not achieve the stated promise, Hay refers to the results (at paragraph 221) to the efficacy testing as presented in Table II of the Patent Application. He specifically calls out that compound 1e "*was shown to have significantly less activity*" compared to the control.

38 I consider the data in Table II of the Patent Application (Page 11, reproduced below for convenience) supports that the compounds exhibit herbicidal activity and therefore satisfy the requirement in the claim of being a herbicidal compound. As described in the Patent Application at page 11 lines 11 to 13, percent visual injury assessments were made on a scale of 0 to 100% as compared to untreated control plants (where 0 is equal to no injury and 100 is equal to complete death of the plant). The data in Table II of the Patent Application shows the results of the herbicidal activity of compounds 1a, 1b, 1c, 1e, 2a, 2b, 2c compared to commercially used herbicidal salts 2,4-D DMA and triclopyr triethylamine (triclopyr TEA) in respect of two weeds, Broadleaf Dock and Kochia:

- The compounds 1a, 1b, 1c and 1e, having 68% to 79% herbicidal activity against Broadleaf Dock are comparable to 2,4-D DMA having 77% herbicidal activity
- The compounds 1a, 1b, 1c and 1e, having 83% to 89% herbicidal activity against Kochia are comparable to 2,4-D DMA having 86% herbicidal activity
- The compounds 2a, 2b and 2c having 79% to 85% herbicidal activity against Broadleaf Dock are comparable to triclopyr TEA, having 81% herbicidal activity
- The compounds 2a, 2b and 2c having 79% to 95% herbicidal activity against Kochia are comparable to triclopyr TEA, having 91% herbicidal activity.

TABLE II. Efficacy data generated in the greenhouse for 2,4-D and triclopyr on broadleaf weeds. Data are from evaluations taken 14 days after application.

| Treatment / Compound Number | Rate (g ae/ha) | Broadleaf Dock <i>Rumex obtusifolia</i> | Kochia <i>Kochia scoparia</i> |
|-------------------------------|----------------|--|----------------------------------|
| | | ----- % Control ----- | |
| 2,4-D dimethylamine (DMA) | 560 | 77 | 86 |
| 1a | 560 | 77 | 83 |
| 1b | 560 | 79 | 89 |
| 1c | 560 | 73 | 83 |
| 1e | 560 | 68 | 86 |
| Triclopyr triethylamine (TEA) | 560 | 81 | 91 |
| 2a | 560 | 85 | 79 |
| 2b | 560 | 79 | 88 |
| 2c | 560 | 79 | 95 |

- 39 When considering whether weed control data supports the claim of herbicidal properties you evaluate it on the basis of its overall activity, not on a weed by weed basis. In addition, you compare the data with what the definition of a herbicide is and the data in the above table demonstrates that the claimed compounds / composition meet the definition of a herbicide and that all compounds are fairly effective at controlling those two weeds. Additionally, I maintain they provide weed control comparable to reference standards
- 40 Hay alleges at paragraphs 221 and 226 that the activity of compound 1e, 2,4-D choline, is significantly less compared to 2,4-D DMA in respect of Broadleaf Dock (68% and 77% respectively). As stated above, I don't see this as relevant given the claims only require the compound to be herbicidal, and do not specify an amount of herbicidal activity. And the Patent Application states at page 2 that the compounds are comparable – not that they need to be better. In my opinion it is misleading for Hay to continue to contend that a single result against one weed is how the industry makes a determination of herbicidal activity and efficacy.
- 41 The complete result set in Table II shows herbicidal activity for each compound in respect of two species. Hay is noticeably silent on the fact that the activity for compound 1e, 2,4-D choline, is the same as 2,4-D DMA in respect of Kochia (both 86%).
- 42 But even if this was the correct way to make an assessment of whether a compound had comparable activity I disagree with Hay that the activity of compound 1e is “significantly less” compared to 2,4-D DMA. The herbicidal activity of compound 1e and 2,4-D DMA are within about +/- 10% of each other with respect to total herbicidal activity. I, and I believe others in the field, would consider

this variance in activity to be “comparable”. In the context of biological systems error margins of about +/- 10% are typical.

- 43 The data in Table II shows compound 1e has comparable herbicidal activity as 2,4-D. I consider this data, taken together with the data for the other compounds in respect of the two tested species compared to the commercially used compounds are all within approximately +/- 10% of total herbicidal activity. I consider this data supports that the compounds have herbicidal activity as required by the claims. I further consider that the herbicidal activity of the compounds as shown in Table II is at least comparable to commercially used herbicidal salts.
- 44 Moreover, I believe what is important is whether they function as a herbicide. Claims 1 -11 define “a herbicidal compound or composition”. So the promise is that the compounds are herbicidal. I note some herbicides may not completely control specific weeds and still be considered herbicides. On page 10 of the label for the Nufarm’s commercial 2,4-D product “Amine 625 Selective **Herbicide**” for Australia it states “*Where weeds are to be sprayed in a CROP or PASTURE use only the rates given for the particular crop or situation indicated under the Directions for Use table. In most cases this will give control, however some hard to kill weeds or those in advanced stages of growth may only be suppressed.*” A copy of this label is attached as **Exhibit DGO-5**. By these statements in Nufarm’s own 2,4-D label it can be seen that a specific level of control is not required to meet the definition of being a ‘herbicide’. Clearly, the terms control and suppression are used to describe the level of weed control a herbicide may deliver.
- 45 I maintain the results are comparable and in Hay’s own words in paragraph 224, “...*the herbicidal compounds of the prior art including the tetramethylammonium salt of 2,4-D and the triclopyr quaternary ammonium salts are no different from the quaternary ammonium salts of 2,4-D that fall within the scope of claims 1 to 7 both in respect to their (a) herbicidal effect*”...So from Hay’s perspective, they are certainly no less effective.

Prevention of injury

- 46 At paragraphs 222 and 224 Hay comments that the data in Table III of the Patent Application in respect of compounds 2b and 4a, which show 6% and 12% injury to sensitive grape crops respectively, “*do not attain the result promised in the opposed Patent Application of the prevention of injury to neighbouring crops*”.
- 47 Firstly, I do not understand why Hay is commenting on the data in Table III of the Patent Application and why the promise of the invention has suddenly become something different to what Hay alleged in paragraph 72 and 221. The current claims relate to preparing herbicidal compounds/compositions and their use in controlling undesirable vegetation. These claims say nothing about the impact on

neighbouring crops and do not assert anything about prevention of injury at all, let alone a degree of prevention of injury. These claims, as I said, relate to production of a composition. However, for completeness, I respond as follows.

48 Even if the data did relate to the current claims, I disagree with Hay's conclusion that the data shows the compounds fail to attain the result of prevention of injury by way of being less volatile, for the reasons I set out below.

49 I do not consider "preventing", in the context of the Patent Application, to be an absolute term with a meaning of 0% injury, which I understand Hay attributes to the term in paragraph 222. I consider this a narrow view, which does not reflect the understanding of those working in this field and which does not match the description of the invention provided in the Patent Application. For example, as described in the Patent Application at page 11 lines 11 to 13, visual injury is assessed on a scale, ranging from 0% being no injury and 100% being complete death of the plant. While in this section of the Patent Application visual injury is in the context of herbicidal activity, this scale is a measure of injury regardless of whether it is assessing herbicidal activity or prevention of injury. It is a measure of injury full stop. If Hay's interpretation of 'prevention of injury' was correct, there would be no need for a range which accounts for degrees of injury prevention, and the assessments would be simply 'yes or no'.

50 Moreover, while I am not involved in the regulatory approval stages for any new herbicide, I am aware that a herbicide seeking regulatory approval must comply with efficacy and crop safety criteria, and I am not aware of any Regulatory Authority that requires these criteria to be absolutes. For example, a herbicide deemed 'safe to a crop' does not necessarily mean that *no* injury occurs. Rather, the injury may be only minor or transient. Similarly, a claim in an application seeking regulatory approval to prevent injury would not require 0% injury.

51 Table III (page 13 of the Patent Application, reproduced below for convenience) shows the results of injury to a sensitive species of grapes following exposure to vapor from herbicide compounds derived according to the invention, in comparison to a period of vapor exposure to other herbicide standards:

- Compound 1b (2,4-D (tetraethyl)ammonium hydroxide) showed 0% injury compared to 2,4-D BEE and 2,4-DMA which showed 100% and 78% injury, respectively
- Compound 2b (triclopyr (tetraethyl)ammonium hydroxide) showed only 6% injury compared to triclopyr TEA which showed 57% injury
- Compound 4a (dicamba (tetramethyl)ammonium hydroxide) showed only 12% injury compared to dicamba DMA which showed 70% injury.

Table III. Injury to grapes from vapor exposure for 24 hours to various forms of 2,4-D, Triclopyr and Dicamba. Evaluations were taken 7 days after exposure to the vapors.

| Treatment / Compound Number | ----- % Injury ----- --- |
|-------------------------------|-----------------------------|
| 2,-4-D butoxyethylester (BEE) | 100 |
| 2,-4-D dimethylamine (DMA) | 78 |
| 1b | 0 |
| Triclopyr triethylamine (TEA) | 57 |
| 2b | 6 |
| Dicamba DMA | 70 |
| 4a | 12 |

- 52 You do not even have to be a person working in this field to appreciate that there has been no or only very minor vapor drift given the % of crop injury compared to the control compounds.
- 53 As I have stated above, I do not consider “prevention of injury”, in the context of the Patent Application, nor as understood by those working in the field, to mean 0% injury. Accordingly, I consider this data shows that the inventive compounds prevent injury to non-target sensitive species, within the approximate 10% error margin. I and others in the field, would recognize only 6% and 12% injury to be representative of preventing injury.
- 54 Furthermore, the inventive compounds show significantly less injury to sensitive crops compared to herbicidal standards. In the context of the Patent Application, which describes the compounds as having reduced volatility compared to commercially used carboxylic acid herbicidal salts so that its use would not damage nearby sensitive crops, the compounds prevent injury compared to herbicidal standards.

Substituted (tetraalkyl)ammonium hydroxide

- 55 At paragraphs 223, 230, 232 and 239 Hay comments that there is no data in Table III for herbicidal compounds prepared using a substituted (tetraalkyl)ammonium hydroxide, including choline hydroxide. As I have stated in the “Prevention of injury” section above, I do not consider the data in Table III relevant to the current claims. The claims are directed to preparing herbicidal compounds/compositions and their use in controlling undesirable vegetation.
- 56 I am instructed by FPA that the relevant questions that I have to answer are:
- (i) whether I see in the Patent Application a clear disclosure of the compound of claim 1, including herbicidal compounds using a substituted (tetraalkyl)ammonium hydroxide;
 - (ii) whether I am instructed how to prepare such a compound; and

(iii) whether, based on the information in the Patent Application and the information commonly known in the field, I would expect a herbicidal compound using a substituted (tetraalkyl)ammonium hydroxide to control undesirable vegetation.

57 I understand claim 1 to describe a herbicidal compound comprising the reaction product of 2,4-D and a (tetraalkyl)ammonium hydroxide. As I read the Patent Application, I see this compound described, e.g. at page 2, lines 5 to 13. And at page 2, line 21 to page 3, line 4, the substituents are described.

58 I understand that Table I provides examples of (tetraalkyl)ammonium hydroxides that can form salts with 2,4-D and other herbicidal carboxylic acids such as triclopyr, cyhalofop and dicamba. I note that compounds prepared using a substituted (tetraalkyl)ammonium hydroxide are provided in Table I, including compounds 1e and 2e (choline hydroxide).

59 A general method for preparing a reaction product formed between herbicidal carboxylic acids and unsubstituted or substituted N-alkyl/arylalkyl ammonium hydroxide is described on page 4, lines 6 – 12 of the Patent Application. Three more descriptive preparative methods are provided on page 9. I note that at least the first method described on page 9, lines 2 – 8 of the Patent Application would result in a compound according to claim 1. Specifically, the method described on page 9, lines 2 – 8 of the Patent Application states:

“the carboxylic acid herbicide and the N-((C₁-C₁₆) alkyl or arylalkyl)tri((C₁-C₁₆)alkyl)ammonium hydroxide are combined in equimolar amounts in methanol at room temperature to give a solution of the ammonium salt of the carboxylic acid. The product is then isolated by evaporative removal of the methanol (and any water present) at room temperature to 50°C.”

60 This method provides me, and I believe others in the field, with the necessary information to prepare a herbicidal compound comprising the reaction product produced by the process of combining 2,4-D and an unsubstituted or substituted (tetraalkyl)ammonium hydroxide (as defined in claim 1), thereby producing the herbicidal compound.

61 I see that the Patent Application at page 2, lines 16 – 20, and page 4, line 20 – page 5, line 2 describes a general method of applying the claimed compounds to undesirable vegetation. General application rates are provided on page 5, lines 3 – 7 and exemplary concentration ranges are provided on page 8, lines 7 – 15. In addition, the method on page 10 – 11 and the data in Table II are exemplary of applying the herbicidal compound to unwanted vegetation.

62 As discussed in the “Herbicidal activity” section above, I consider the data in Table II of the Patent Application supports that the inventive compounds (including

unsubstituted and substituted compounds) have herbicidal activity as required by the claims. Additionally, this data shows that the herbicidal activity of the inventive compounds as shown in Table II is at least as comparable to commercially used herbicidal salts (a desirable but not critical advantage of the claimed invention).

- 63 Given that the method on page 12 for assessing volatility and the data in Table III measuring injury from vapor exposure is not relevant to the claims, I consider the additional comments Hay provides in paragraphs 232, 233 and 240 irrelevant. But for completeness, I will provide my response to his comments.
- 64 At paragraphs 232, 233 and 240, Hay imports a requirement into claim 7 that when a herbicidal compound comprising the reaction product in which the (tetraalkyl)ammonium hydroxide is choline hydroxide is administered to the locus of unwanted vegetation there must be *"no injury/damage to the crop"*. Hay alleges that the Patent Application does not support this alleged requirement of claim 7.
- 65 Firstly, I note that claim 7 is directed to a process for preparing a herbicidal compound, not a method of use. There is no mention in claim 7 of administering the compound to the locus of unwanted vegetation. There is also no mention in claim 7 of *"reduced volatility of the herbicidal compound of claim 7"* (Hay paragraph 232) nor *"injury to an adjacent/neighbouring crop"* (Hay paragraph 240).
- 66 From my understanding, the only activity required by claim 7 (in fact all of the claims) is that the compound is a herbicide, which is supported by the data provided in Table II of the Patent Application.
- 67 In paragraph 232, Hay goes on to say that the method on page 12 and the data in Table III relate to an artificially high application rate and a semi-enclosed system, and does not provide any basis for the asserted activity of the compound of claim 7 at normal application rates in an open environment. I disagree. The method on page 12 and the data in Table III are exemplary of applying the herbicidal compound to unwanted vegetation. It is well understood by those working on herbicides that the testing methods utilized in the laboratory do not need to be identical to the commercial processes applied to vegetation. There are many methods available to simulate what happens in the field or paddock. Further, most would understand the technique of using exaggerated rates may be used to more easily detect differences at low level exposure in trials.
- 68 Hay further states in paragraph 232 that *"from the data in Table III, I would assume that grapes (and potentially other Vitales plants) are simply less susceptible to herbicides comprising quaternary ammonium salts than they are to herbicides comprising less substituted ammonium salts"*. I disagree. In the experiments underlying the results shown in Table III, different forms of the compounds were directly sprayed to wheat (page 12 of the Patent Application). In this example,

wheat is representative of the unwanted vegetation. After drying, the sprayed wheat plants were moved into a clean pot flat. Then a known sensitive species (representative of the crop), namely grapes were placed at the opposite end of the flat. So, the grapes were not directly sprayed on, on purpose, but then a humidome was put over the pots and air was pulled from the treated wheat plants to the grape plants with a small box fan. This method simulates a sensitive crop being grown downwind from treated unwanted vegetation.

69 At paragraph 231, I understand Hay to be saying that he considers vapor pressure data in respect of the salts in Table III, as well as other salts encompassed by the claims, is required to enable him to compare the volatility. I do not understand the basis for his comment. The claims do not say anything about vapor pressure or reduced volatility.

70 Despite my understanding that prevention of injury and the data in Table III is not relevant to the claims, I do not consider, and the additional data proves me right (see below), that substitution of the (tetraalkyl)ammonium hydroxide would substantially influence the general principle described in the Patent Application that the reaction product of a herbicidal carboxylic acid and a (tetraalkyl)ammonium hydroxide exhibits reduced volatility.

Additional data to support the data in the Patent Application

71 At paragraph 232, Hay alleges that the Patent Application does not include any support for the reduced volatility of the herbicidal compound of claim 7. In direct response to Hay raising this identical point in the Parent opposition, I conducted additional experiments which I set out again in paragraphs below. This data confirms what is said in the Patent Application - that herbicidal compounds according to the invention including the reaction product of 2,4-D and choline hydroxide (being the reaction product of claim 7) exhibit reduced volatility compared to prior art compounds.

72 With the method (including the rates and amounts) described in page 12 of the Patent Application, I tested further 2,4-D herbicides. To assess the rate of volatility would require samples to be taken over time. This method uses grapes as a bio-indicator species when exposed to herbicide vapors for 24 hours and then injury is evaluated 7 days after exposure. This method is used to make relative comparisons of one compound to another and volatility is assessed on the level of injury observed on the bio-indicator crop, grapes. The results were as follows:

| | Compound | % grape injury |
|---------------------|-----------------------------------|----------------|
| Prior art compounds | 2,4-D diethylamine (DEA) | 20 |
| | 2,4-D triethylamine (TEA) | 11 |
| | 2,4-D dimethylethanolamine (DMEA) | 33 |

| | | |
|----------------------------|--|----|
| | 2,4-D diethylethanolamine (DEEA) | 10 |
| Compounds of the invention | 1a (2,4-D (tetramethyl)ammonium hydroxide) | 0 |
| | 1b (2,4-D (tetraethyl)ammonium hydroxide) | 0 |
| | 1e (2,4-D choline hydroxide) | 0 |

- 73 Further, to simulate a worst-case scenario I evaluated the volatility of various forms of 2,4-D from an inert surface, in particular from a glass petri dish. Glass petri dishes were used as inert surface and were sprayed with solutions of various forms of the prior art compounds namely with 2,4-D free acid, 2,4-D DMA, 2,4-D DMEA and a compound of the invention, 2,4-D/choline hydroxide. The herbicides were applied at 1120 g ae/ha in 187 L/ha of water. A suspension concentrate containing 25% acid of 2,4-D by weight was used to address the water solubility of 2,4-D acid. The sprayed petri dishes were allowed to dry for 10 minutes, which was sufficient time for all of the solvent to be removed. The essentially dry petri dishes were then moved into sealed bell jars with a vent cap installed in the lid. Air sampling tubes were connected to a port on the side of the bell jar near the bottom and were under vacuum pulling 1L/min through the sampling tube. The temperature was set to 40°C and samples collected from 144 to 240 hours after spraying. Sampling tubes were processed, and the samples quantified for 2,4-D acid using LC-MS/MS analytical equipment. The data from the bell jar trial compared the recovery of herbicides from 144 to through 240 hours after application. Herbicide vapor was collected for the whole 96 hour duration. It is a relative comparison of the volatility of different forms of the herbicides.
- 74 There was about 1.5% recovery for 2,4-D acid, about 0.5% recovery for 2,4-D DMA, about 0.3% recovery for 2,4-D DMEA and about 0.1% recovery for 2,4-D/choline hydroxide. These results show a clearly reduced volatility of the inventive compound of between 3- and 15-fold compared to formulations of the prior art.
- 75 These types of comparisons, using plants as bio-indicators for assessments of herbicide volatility and comparisons of analytical data of recovery of herbicides vapors at various time periods have been made in the literature for a long time. I cite a paper published in Weed Science entitled "*Dicamba Volatility*" by Behrens and Lueschen, 1979, as an example. The authors used both soybean as a bio-indicator species and ¹⁴C radiolabelled dicamba to detect volatility of different salt forms of dicamba at 0, 12, 24, 48, 72 and 96 hours after application. A copy of this publication is attached as **Exhibit DGO-6**.
- 76 In a setup similar to the one described in page 12 of the Patent Application, I tested the volatility of a compound of the invention triclopyr/choline hydroxide, and the prior art compounds triclopyr/triethylamine and triclopyr/butoxyethylester

by visual evaluation on injury caused to grapes and tomatoes, respectively. In particular, the herbicidal compound was sprayed on ryegrass pots. The ryegrass pots were then placed in a humidome next to grapes and tomatoes and air was pulled through the humidome with a small fan to pass in direction from the rye grass to the grapes and tomatoes. The observed injury levels were as follows:

| | | %injury | | | |
|-----------------------|-----------------------------|-------------|-------|-----------|-------|
| | | on tomatoes | | on grapes | |
| | | Day 1 | Day 7 | Day 1 | Day 7 |
| Prior art compounds | Triclopyr butoxyethylester | 42 | 61 | 51 | 50 |
| | Triclopyr triethylamine | 30 | 59 | 42 | 27 |
| Compound of invention | Triclopyr/choline hydroxide | 3 | 2 | 1 | 0 |

77 This additional data supports the data presented in the Patent Application in Table III, that triclopyr/choline hydroxide provides excellent safety from off-target movement due to low volatility compared to triclopyr triethylamine and compared to triclopyr butoxyethylester.

Operating conditions

78 At paragraphs 234, 236 and 237, Hay comments that the claims do not define the operating conditions required to perform the method of claims 12 to 15.

79 I understand that as the claims do not specify the operating conditions, any operating conditions that control undesirable vegetation, as required by the claims, would meet the requirement of the claims. I consider that a skilled person familiar with dose rates of 2,4-D would be able to readily determine effective operating conditions. Further, I note that there is guidance in the Patent Application to direct a skilled person to suitable dose rates and application methods.

80 As I have stated above, general application rates of 1 to 2,000 g/Ha are provided on page 5, lines 3 – 7 and exemplary concentration ranges for concentrates and diluted compositions are provided on page 8, lines 7 – 15. In addition, the method on page 10 – 11, which utilizes application rates of 560 g ae/ha, and the data in Table II are exemplary of applying the herbicidal compound to unwanted vegetation.

81 This description and method provides me, and I believe others in the field, with the necessary information to determine the operating conditions required to control undesirable vegetation. Further, I, and I believe others in the field, would consider it routine to determine effective concentrations and rates of application to control undesirable vegetation. Indeed this is what the Patent Application says at page 5,

lines 1 – 7 “*These and other factors can be adjusted as is known in the art to promote non-selective or selective herbicidal action. Application rates of 1 to 2,000 g/Ha are generally employed in both postemergence and preemergence applications. The higher rates designated generally give non-selective control of a broad variety of undesirable vegetation. The lower rates typically give selective control and can be employed in the locus of crops.*”

Selective herbicidal properties

- 82 At paragraphs 235 and 236, Hay alleges that the Patent Application is silent as to how the method of claims 12 – 15 could be reproduced to achieve the “selective herbicidal properties” purported to be provided.
- 83 Firstly, I understand Hay to be saying that there is a “selectivity” requirement in claims 12 to 15. But there is no mention of selective herbicidal properties in claims 12 to 15. These claims only require the use of the herbicide compounds/compositions of the invention to control undesirable vegetation. I note on page 5, lines 4 – 7 of the Patent Application, that the herbicidal compounds/compositions may be applied at higher rates to give non-selective control of a broad variety of undesirable vegetation, or at lower rates to give selective control. Given that the claims do not mention “selective herbicidal properties”, I understand the method of claims 12 – 15 include both non-selective and selective control of undesirable vegetation.
- 84 For completeness I provide my comments on what I understand “selective herbicidal properties” to mean. I understand “selective herbicidal properties” to mean that the herbicide is selective to the crop and will have activity on the weed when used at lower rates of application as described on page 5, line 6 of the Patent Application. In other words the herbicide kills or suppresses the weeds but not the crop. Some crops are naturally tolerant to 2,4-D. Other crops, as described in the Patent Application at page 6 lines 3 to 10, such as soybean, cotton and corn, which are naturally susceptible to 2,4-D may be genetically modified to introduce traits to make them tolerant or resistant to 2,4-D. I would expect that the claimed 2,4-D compounds would exhibit selective herbicidal properties consistent with prior art 2,4-D compounds. I would therefore expect the claimed compounds to be selective to crops that are naturally tolerant to 2,4-D (claims 12 and 13) and to crops that have been made tolerant or resistant to 2,4-D by genetic modification (claims 14 and 15). But as I have already stated above, I do not see the issue of “selective herbicidal properties” as relevant to claims 12 to 15, as they don’t mention it.
- 85 I see that the Patent Application at page 4, line 20 – page 5, line 2 describes a general method of applying the claimed compounds to undesirable vegetation. The use of the claimed compounds to control undesirable vegetation in crops that have

been genetically modified to confer tolerance or resistance is described on page 5, line 27 – page 6, line 9. As I outlined above, general application rates are provided on page 5 lines 3-5 and exemplary concentration ranges are provided on page 8 lines 7 to 15. In addition, the method on pages 10 – 11 and the data in Table II are exemplary of applying the herbicidal compound to unwanted vegetation and informs a skilled person how to assess the herbicidal activity of the compounds utilized in the claimed method.

86 I further consider that the data in Tables II provides representative data for the herbicidal compositions utilized in the claimed method, and I would have no difficulty obtaining data for additional herbicidal compositions that fall within the scope of the claims.

Selective administration

87 At paragraph 241, Hay states that method claims 12 – 15 are directed to “selective administration” of a herbicidal compound/composition to control of undesirable vegetation and alleges that such a method is not supported by the Patent Application.

88 Firstly, I do not understand what Hay means by “selective administration”. Hay has imported a requirement that the herbicidal compound is ‘selectively’ applied to the unwanted vegetation. Given this language is not present in the claims, I do not understand what he means by selective administration. The claims require “*contacting the vegetation or the locus thereof with, or applying to the soil to prevent the emergence of vegetation*” with a herbicidal compound of the invention. As I have stated above, the Patent Application provides a description of, and data to support, the method of claims 12 – 15.

89 I consider selective administration to mean the herbicidal compound/composition is applied to one area and not another area. For example, in some circumstances, the herbicidal compound/composition may be selectively applied to the weed growing on the ground and not the crop, such as orchards or vineyards. But I don't see how that is relevant here.

90 Based on Hay's comments in paragraphs 235, 236 and 241, it appears that Hay considers that the claims require both “selective herbicidal properties” and “selective administration”. I do not understand Hay's logic. If “selective herbicidal properties” are required, such that the herbicide is selective for the crop and will control the weed, then there is no need to selectively administer the herbicide to the weed and not the crop. But as I have already stated, I do not see a requirement in the claims for either selective herbicidal properties or selective administration.

Clarity and Succinctness

91 Hay alleges that the “*open ended definition of the term alky*” in the claims is unclear given the general chemical structure used in the patent application. I believe the definitions for the R-groups provides the necessary clarity for what is claimed.

I make this declaration conscientiously believing the statements contained in this declaration to be true and correct.

sign here ► *David G. Ouse*

Signature of person making the declaration

Declared at Indianapolis, IN USA on

24 of July 2020