UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IN RE: ROUNDUP PRODUCTS LIABILITY LITIGATION	MDL No. 2741 Case No. 16-md-02741-VC
This document relates to: ALL ACTIONS	

PLAINTIFFS' CASE MANAGEMENT STATEMENT

Pursuant to the Court's February 1, 2017 order, Plaintiffs submit this joint case management statement.

PLAINTIFFS' POSITION

I. Introduction

Plaintiffs request that the Court order the Defendants to produce the custodial files of Monsanto employees Mark Martens, Lisa Hodge-Bell, Lisa Flagg, and Gary Klopf. Plaintiffs further request that the Court order the Defendants to produce employees Richard Garnett and Eric Haupfear for deposition. These are narrowly tailored and modest requests and are proportional to the magnitude of this litigation.

Under Rule 26(b)(1), Parties have a joint responsibility to determine whether discovery is proportional. The Advisory Committee Notes explain that "Restoring the proportionality calculation to Rule 26(b)(1)...does not place on the party seeking discovery the burden of addressing all proportionality considerations. Nor is the change intended to permit the opposing party to refuse discovery simply by making a boilerplate objection that it is not proportional." "[F]actors that must be considered in weighing proportionality include 'the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and

whether the burden or expense of the proposed discovery outweighs its likely benefit.' Id. Discovery need not be admissible in evidence to be discoverable. *Salazar v. McDonald's Corp.*, No. 14-CV-02096-RS (MEJ), 2016 WL 736213, at *2 (N.D. Cal. Feb. 25, 2016).

The Rule 26 factors weigh heavily in favor of granting Plaintiffs' limited requests. The importance of the issue of whether Roundup® causes cancer is immense. Since 1974, over three billion pounds of glyphosate has been sprayed in the United States alone. Benbrook, *Trends in glyphosate herbicide use in the United States and globally*, Environmental Sciences Europe, 28:3 (2016). Approximately 275 million pounds of glyphosate were sprayed in the United States in 2014. *Id.* Glyphosate is now the most widely used agricultural in the history of the world.[1] There is a high public interest in thoroughly exploring whether this pesticide causes cancer. The amount-in-controversy is also great. There are currently hundreds of cases filed against Monsanto in state and federal courts alleging that Roundup® causes NHL. Several thousand more cases are likely to be filed. The damages suffered by these Plaintiffs would likely exceed several billion dollars. Unfortunately, Monsanto is not forthcoming with sharing their information on Roundup® with the public. Therefore, most of the information on the health effects of Roundup® are solely within Defendants' hands which necessitates extensive discovery. The Defendants have extensive resources as Monsanto is currently valued at 66 billion dollars.[2] Plaintiffs will highlight the importance of each request below which demonstrates that the benefit of the discovery easily outweighs the burden.

II. Requested Custodial Files

Mark Martens:

[1] http://www.newsweek.com/glyphosate-now-most-used-agricultural-chemical-ever-422419

[2] http://www.news.bayer.com/baynews/baynews.nsf/id/ADSF8F-Bayer-and-Monsanto-to-Create-a-Global-Leader-in-Agriculture

Mark Martens is a vital witness to this litigation, he was Monsanto's Toxicology Director, Europe/Africa from 1994 to approximately 2004. Exhibit 1 (MONGLY01870235). His job duties included "gathering (i.e. literature search, Monsanto studies, and commissioning of toxicology studies in contract laboratories), selection and interpretation of health effects data within the European regulatory context.. positioning of cancer classification issues of herbicides ... and registration defence of Monsanto's pesticides in EU member states..." *Id.* In January 2002, Martens was nominated to the Monsanto Fellow's Program. It was noted that Martens strengths and contributions included:

- Broad toxicology expertise, ingenuity, persuasiveness and external recognition by scientific societies and regulators
- A "hands-on" scientist who develops the strong scientific basis for regulatory decisions and for maintaining key regulatory approvals
- Consistent delivery on key scientific issues which impact/protect Monsanto ' s bottom line..

Exhibit 2 MONGLY00905589. Among Marten's most important contributions was that he "Developed the data to gain key EU scientific support that the reported genotoxicity of Roundup herbicide was due to secondary consequences unrelated to glyphosate, thereby preventing adverse effect on Roundup business." *Id.* Certainly, Plaintiffs are entitled to get the data developed by Martens regarding the genotoxicity of Roundup® and documents relating to how that data was developed. Scientific data and contacts with scientists developed in Europe were not always shared with Monsanto U.S. employees. Exhibit 3 (MONGLY00891769) ("One of the problems with email - everyone can start running around looking for solutions. Can we keep this to a limited number of people as we have the opinions and the solutions in Europe.")

There are several other examples of why Dr. Martens' file is important. Of particular importance to this litigation is Mark Martens' work on the genotoxicity of Roundup®. In 1999, he was assigned to work with Dr. James Parry, a highly respected expert in genotoxicity. Dr.

Parry, who passed away in 2010 "was at the forefront of studies in genetic toxicology and he was the founding father of much of this discipline within the UK." Waters, et al. *James M. Parry (1940–2010)* Mutagenesis (2011) 26 (1): 1-2. Dr. Martens' work with Dr. Parry in 1999 left Monsanto in what was called a "genotox hole." Exhibit 4 (MONGLY00878595). After reviewing the published literature and Monsanto's unpublished in-house genotoxicity studies, Dr. Parry concluded that "glyphosate is a potential clastogenic *in vitro*" and that the "clastogenic activity **may** be reproduced *in vivo* in somatic cells." Exhibit 5, p. 12 (MONGLY01314233). A clastogen is as substance that causes "structural damage of genetic material." Exhibit 6 (Farmer Dep. Trans. 178:11-20). Dr. Parry concluded that the literature "suggests that the genotoxicity observed may be derived from the generation of oxidative damage in the presence of glyphosate." Exhibit 5, p. 12. Sixteen years later IARC came to the same conclusion that glyphosate is genotoxic because of its ability to induce oxidative stress. Exhibit 6 at 287:6-288:6. Dr. Parry's report has never been made public nor submitted to the EPA.

In his report, Dr. Parry recommended that Monsanto conduct multiple additional tests including the COMET assay to determine genotoxicity. *Id.* at 34. Dr. Parry noted that if an "oxidative damage mechanism is proved then it may be necessary to consider the possibility of susceptible groups within the human population" and that "if such individuals can be identified then the extent of exposure should be determined and their lymphocytes analysed for the presence of chromosome aberrations." *Id.* at 34-35. After reading the report, Monsanto employees questioned whether he had "ever worked with industry before" and "hoped that it didn't cost too much." *Id.* at 37. William Heydens from Monsanto upon reading the Parry report stated they needed to find another expert because "[w]e simply aren't going to do the studies Parry suggests." Exhibit 7 MONGLY03734971. For example, Monsanto has to date never conducted the Comet Assay on glyphosate. Exhibit 6 at 188:20-24. Plaintiffs can also find no evidence that Monsanto has ever tested the lymphocytes of agricultural works for the

presence of chromosome aberrations.

Mark Marten's custodial file is important because he was the point of contact for Dr. Parry and would have in his possession all communications and studies that were sent to Dr. Parry. *See e.g.* Exhibit 5, p. 38; *see also* Exhibit 8 (MONGLY00905534)(email from Dr. Parry exclusively to Mark Martens, which was then forwarded to other employees). Emails suggest that there was data sent to Dr. Parry after his report and that there were numerous communications between Dr. Parry and Mark Martens through 2002, but these communications do not show up in the database because Plaintiffs don't have Mark Martens'custodial file. Exhibit 3; Exhibit 6 at 151:3-194:16. Searching Dr. Parry's email address in documents received to date turns up in only a handful of emails from Dr. Parry and there is no mailed correspondence subsequent to 1999. It would seemingly be to Defendants' benefit to produce Marten's file to show that Dr. Parry changed his mind with respect to the genotoxic nature of Roundup® as claimed by Dr. Farmer at her deposition. Exhibit 6 194:10-16. Currently there is no correspondence from Dr. Parry to support Donna Farmer's claim.

Mark Martens was also the author of a paper explaining how the surfactants in Roundup® formulations increase the absorption of glyphosate in the human skin. Specifically Dr. Martens wrote:

> Surfactants are able to increase glyphosate absorption through the skin by (1) removal of lipids (sebum) from the epidermal surface due to surfactant action, (2) increase of the hydration state of the skin (under closed exposure conditions), (3) increase of skin contact (spreading of water droplets by surfactant action), (4) increase of contact time with the skin due to decrease of evaporation of water from the droplets containing surfactant (surfactant monolayer at surface of droplets slows down passage to vapour phase,) increase of sub epidermal blood flow due to irritant action of surfactant, (6) intra-epidermal and sub epidermal intercellular water accumulation due to the irritant action of the surfactant.
>
> Exhibit 9, p. 3 (MONGLY01839476).

Plaintiffs found several draft versions of this paper in Donna Farmer's custodial file. When asked whether it was true that surfactants increase the absorption of glyphosate in human skin,

Dr. Farmer responded "I have no data to support that statement." Exhibit 6, 57:4-12. When asked about the paper by Dr. Martens, Defense Counsel continually objected to the document because it was a draft paper and Dr. Farmer claimed she was unable to answer any questions about the document because she said didn't write it and because she said it was a draft. Exhibit 6, 58:17-63:3. Obviously Dr. Martens has data to support these statements and these would be in his custodial file. Plaintiffs did receive a custodial file from Christophe Gustin, another author on the document, but there was no reference to this paper in his files. Where Defendants will continue to deny that surfactants increase absorption of glyphosate in the skin, Plaintiffs need the reports of Dr. Martens and the underlying data he used to conclude that surfactants increase human exposure to glyphosate.

Lisa Flagg

Lisa Flagg is part of Monsanto's Quality Assurance Unit which monitors levels of N-ntirosoglyphosate ("NNG") in Roundup®. Exhibit 6, 200:1-15. She is also the communication point of contact for quality control issues involving Roundup®. https://www.linkedin.com/in/lisa-flagg-6576507. There are several carcinogens in Roundup® in addition to Glyphosate. NNG is a potential carcinogen in Roundup® formulations that is formed when glyphosate interacts with nitrites [redacted] in the human body. Exhibit 10, pp. 14-19 (MONGLY01377215); Exhibit 11 (MONGLY00925905). The public will not find any reference to NNG on the Roundup® label. NNG is part of a family of carcinogenic chemicals called nitroso compounds. Nitroso compounds that have been tested have consistently been shown to be carcinogenic. Loh, et al. *N-nitroso compounds and cancer incidence: the European Prospective Investigation into Cancer and Nutrition (EPIC)–Norfolk Study*, Am J Clin Nutr May 2011, vol. 93 no. 5 1053- 061

The EPA initially required that Monsanto test for the carcinogencity of NNG in the 1970s and early 1980s. The testing for NNG by Monsanto was mainly conducted by IBT laboratories

which was shut down in the 1970s due to fraud. The EPA determined that these NNG studies were not acceptable to show that NNG was not mutagenic. Exhibit 12 (MONGLY01298438). The EPA, however, did not require additional testing on NNG provided that Monsanto keep the levels of NNG below 1 ppm. *Id.* Before getting a pass from the EPA, Monsanto did conduct one long-term carcinogenicity test of NNG in mice outside of IBT laboratories. This study demonstrated a statistically significant increase in malignant lymphomas in male mice. Exhibit 13 (MONGLY04272196). Plaintiffs can't find any evidence that this study was provided to the EPA. In order to avoid the debate, Monsanto has endeavored to keep NNG levels below 1 ppm "rather than to engage in scientific debate around its biological activity." Exhibit 14 (MONGLY01185582)

[redacted] Within the last few years, there seems to be an uptick in NNG testing at Monsanto which is why the custodial file of a current Quality Assurance employee, such as Lisa Flagg is needed. In an email dated 5/19/2014, wherein Lisa Flagg was copied, it was noted that "[w]e are completing so Much work around NNG that there is a real backlog in the number of samples we can run through the analytical system." Exhibit 16 (MONGLY03771170). Lisa Flagg is currently involved with testing of how long-term storage of glyphosate increases NNG levels. Exhibit 17 (MONGLY06758730) ("I would suggest we agree in writing that `bad results' of NNG due to accelerated ageing can be caused by the heat level and is therefore not representative for "normal ageing'.") Monsanto itself acknowledges in internal emails that NNG is indeed toxic. Exhibit 18 (MONGLY03549275) (" If you talk to Kerry [Liefer, an EPA employee], I wouldn't push the

NNG issue too hard --- don't want to draw attention to the toxicity of our product...")

At Donna Farmer's deposition, Plaintiffs asked Dr. Farmer who they should talk to in order to learn more about NNG levels in Roundup®. Dr. Farmer told Plaintiffs counsel that the Quality Assurance Unit and Lisa Flagg would know about the levels of NNG in glyphosate. Exhibit 6, 200:1-15. Plaintiffs would need Monsanto's most up-to-date knowledge about how NNG forms in Roundup® and therefore the custodial file of Lisa Flagg, a current Quality Assurance Unit employee would be important in resolving the issue of whether Roundup® is carcinogenic.

Gary Klopf

According to Monsanto discovery responses, Gary Klopf is the Team Lead, Chemistry and.and/or process Technology (2000-2010; and Team Lead, Chemistry, Formulations & Delivery Technology (2010-2016). In addition to being involved with manufacturing issues such as NNG, Klopf is in charge of Surfactant Science & Formulations. *See e.g.* Exhibit 16; Exhibit 19 (MONGLY03993451). Gary Klopf actually has patents for the detection of impurities in glyphosate formulates. http://patents.justia.com/inventor/gary-klopf. Of particular interest to this litigation is how the Surfactants in Roundup® interact with glyphosate to increase the cancer risk to humans. One of the ingredients in surfactants is 1, 4 dioxane, which is carcinogenic in animals and likely to be carcinogenic humans. https://www.atsdr.cdc.gov/phs/phs.asp?id=953&tid=199 . Reference to 1, 4 Dioxane will not be found on the Roundup label. As noted in an internal email by Monsanto employees, 1, 4 Dioxane "is an impurity in the ethoxylated surfactants and not in the glyphosate manufacturing process itself" and that :

> we have to be very careful before we go slinging mud about 1,4-dioxane in Chinese glyphosate in public, because whether it is 1 ppm or 10 ppm, we most likely have it on our products too, and the general public does not understand the difference between 1 ppm and a bucket full...if there is a chemical that is considered to be a cancer-causing, it don't matter how much is in there, just that it is in there!

Exhibit 20 (MONGLY01041300). However, the surfactant manufacturers believe that 1, 4 Dioxane warrants a cancer warning. Exhibit 21 (MONGLY03829270) ("there is still 1,4-dioxane, and the Prop 65 reference on our product will remain on the SURFONIC AGM-550 MSDS.")

One of the deficiencies in the production to date are communications and safety studies conducted by the surfactant manufacturers. Gary Klopf's custodial file would help fill in those gaps. We know that Gary Klopf was involved with communications with Huntsman and Azko Nobel, the two main manufacturers of surfactants, because of an email chain that was eventually forwarded to Steve Adams. Exhibit 22 (MONGLY04175012). The subject of this 2013 email chain is particularly concerning because it involves Monsanto pressuring a surfactant manufacturer, Azko Nobel, to take off a Prop 65 cancer warning from their surfactant material safety data sheets, so that Monsanto can avoid a Prop 65 warning on Roundup®. *Id.* It was noted in this email that Gary Klopf or Andy Dyszlewski would approach Huntsman, the other surfactant manufacturer, to have them remove the Prop 65 warning. These communications with third party surfactant manufacturers are much less likely to appear in the current custodial files, because the custodians to date are not points of contact with these manufacturers. The data provided by these manufacturers to Monsanto would be important to resolving the issues in this case because it would help clarify the carcinogenic nature of the surfactants which compelled the surfactant manufacturers to put cancer warnings on their Material Safety Data Sheets.

Kimberley Hodge-Bell

Kimberly Hodge-Bell is a known participant and orchestrator in drafting waiver requests to regulatory agencies. Ex. 23 (MONGLY0211857 (email), MONGLY02111919 (attachment)). Waiver requests ask regulatory bodies to waive certain testing/study submission requirements. Although connected to regulatory bodies, this issue is more germane to Plaintiffs' instant case

concerns and begs the questions: How and why does Monsanto determine the certain adjuvants (additives) need no additional toxicity testing, such that a waiver from the agency is consistent with the adjuvant's safety?

Kimberly Hodge-Bell is known to monitor laboratory studies related to exploratory surfactants for the purpose of potential use in Roundup®. Ex. 24 (MONGLY02155592 (Study Report)). Surfactants and other additives that make the eventual formulated Roundup® product are important to Plaintiffs' cases as the allegations include and concern overall toxicity of the marketed Monsanto product.

At least five (5) Toxicology Studies relating to Roundup® ingredients were authored by Kimberly Hodge-Bell: MIRD Nos.: 48117115-48117119. It is believed that these summaries relate to toxicity findings in surfactants and are part of Monsanto's catalog of studies related to inert submissions to regulatory bodies to support Roundup® safety. Ex. 25 (MONGLY05190476 (email), MONGLY05190478 (attachment) at MONGLY05190481)

In addition to her work with surfactants and other additives, Ms. Hodge-Bell also appears to be Monsanto's point person for dermal absorption studies. In fact, she self describes her involvements as "the St. Louis point of contact" for dermal absorption studies where she considers and analyzes the protocols and studies related to same. Ex. 26 (MONGLY05359546 at 0359550 (email chain)).

Topically, Ms. Hodge-Bell is not duplicative of other Monsanto toxicologists. Unlike Donna Farmer and David Saltmiras, her work relates to studies of dermal exposure to the formulated product as well as toxicology studies of the adjuvant/surfactant in Roundup®. Monsanto has represented that Ms. Hodge-Bell has the same/similar function of other toxicologists – this is simply not so. Plaintiffs do acknowledge that presently, Ms. Hodge-Bell appears to hold a similar position as her counterparts, though historically, most documents of interest highlight topics and issues not yet fully produced to Plaintiffs. Production of the custodial file of Ms. Hodge-Bell will clear up any transparency and/or completeness issues of the already produced custodial files of Monsanto identified custodians, Donna Farmer, Davis Saltmiras, et al., [redacted]

[redacted]

III. Requested Depositions

Richard Garnett:

Richard Garnett is a vital witness to this litigation and Plaintiffs request his deposition. His custodial file contains over 80,000 documents. In addition to being a Monsanto employee, Richard Garnett is the Chairman of the Glyphosate Task Force, which is "a consortium of companies joining resources and efforts in order to renew the European glyphosate registration with a joint submission." http://www.glyphosate.eu/legal-notice. The Glyphosate Task Force funded such studies as Kier & Kirkland (2013) and Greim (2015) which are going to be recurring names in this litigation. Garnett is currently also Monsanto's Global Crop Protection Regulatory Lead. https://be.linkedin.com/in/richard-garnett-6b986a18. Plaintiffs would like to ask Richard Garnett how the Glyphosate Task Force developed the scientific database necessary to support Glyphosate registration in Europe.

Garnett has a long history of dealing with issues involving Roundup®. For example, in 2002, Garnett was assigned the task of "coordinator and filter for glyphosate issues in Europe..." Exhibit 28 (MONGLY06414231). Part of his duty would be to create a team to "kill" issues related to glyphosate that popped up in the scientific literature. *Id.* This job was created in response to the Sea Urchin study which showed that the Roundup® ingredients acted synergistically to affect cell cycle regulation. Marc, et al. *Pesticide Roundup provokes cell division dysfunction at the level of CDK1/cyclin B activation*, Chem Res Toxicol. 2002 Mar;15(3):326-31. This email was not forwarded to any U.S. employees who have been deposed. Richard Garnett was also key to managing issues with the toxicity of surfactants that haver regularly arisen in Europe, but not the United States. In 2008, Garnett was in charge of protecting "tallow amine formulations" in Europe and to counter allegations of "synergistic effects of tallow amine with glyphosate." Exhibit 29 (MONGLY06449761). Monsanto uses tallow amine as a surfactant in both Europe and the U.S., but Europe has been more vigilant in regulating this toxic chemical which is being banned later this year. Exhibit 6 at 79:13-80:19.

Plaintiffs would like to ask how Monsanto went about killing safety issues about glyphosate that were raised by European scientists and how they went about protecting tallow amine in Europe. Plaintiffs would further like to examine Richard Garnett on what scientific data caused Europe to ban Tallow Amine.

Richard Garnett was also involved with issues of the absorption of glyphosate into human skin. Plaintiffs' counsel attempted to ask David Saltmiras at deposition about the dermal absorption and excretion of Roundup, but Dr. Saltmiras did not seem to have all of the data.

> Plaintiffs Counsel: [Y]ou're aware that it's more appropriate to measure -- the excretion [of glyphosate] is significantly more in the feces than in the urine for dermal absorption of Roundup, right?
>
> Saltmiras: There is no scientific basis for saying that glyphosate absorbed through the skin is found in the feces. That's utter nonsense. I don't know where you're coming up with this.

Exhibit 30, 250:11-251:12. Plaintiffs' question, however, was not utter nonsense and Plaintiff came up with the question from an email of Richard Garnett. Richard Garnett, in a 2008 email, states that:

> The movement of glyphosate in the blood flow from dermal contact, is different to that through oral or intravenous exposure. The little data we have suggests that the excretion is significantly more through the faeces than the urine.
>
> Dermal exposure is the greatest risk of exposure for operators. Therefore, we need to be secure on the ADME of such exposure.

Exhibit 31 (MONGLY02155826). Unfortunately, despite Garnett's recommendation, Monsanto declined to do additional testing on dermal absorption because the potential of finding a new glyphosate metabolite was "too risky." *Id.*

The issue of whether glyphosate is excreted through the urine rather than feces is important because Monsanto only considers urine levels of glyphosate in an effort to underestimate glyphosate exposure and does not measure levels in feces. For that reason Dr. Farmer and Dr. Saltmiras both deny that dermally absorbed glyphosate is excreted through the

feces. Exhibit 4 at 56:5-8, Exhibit 30 at 250:11-22. Since the Monsanto U.S. employees contradict statements by Richard Garnett, it is necessary to take Richard Garnett's deposition.

Eric Haupfear:

Eric Haupfear has been the director for process technology at Monsanto for twenty years. https://www.linkedin.com/in/eric-haupfear-bba48210 . As part of his job, Haupfear is an expert on impurities in glyphosate manufacturing. Exhibit 32 (MONGLY02478386). Earlier in his career, Haupfear was involved in monitoring NNG levels of glyphosate. For example in 2000, Haupfear found that the levels of NNG exceeded the limit of 1 ppm due to a manufacturing defect. Exhibit 33 (MONGLY04683604); *see* [redacted]

Haupfear is not duplicative of Lisa Flagg, because there are no substantive documents from his file on NNG after 2014. Lisa Flagg, however, starts working on NNG in 2014 until present where there is increased testing on NNG levels. Plaintiffs would like to examine Haupfear on the reasons that NNG exceeded safe levels and on the frequency that such excessive levels occurred. Plaintiffs would like to examine Haupfear on the frequency of testing of glyphosate samples and on the likelihood that glyphosate with excessive amounts of NNG is being sold to the public.

IV. Conclusion

For the aforementioned reasons, Plaintiffs request the custodial files of Monsanto

employees Mark Martens, Lisa Hodge-Bell, Lisa Flagg, and Gary Klopf. Plaintiffs further request that the Court order the Defendants to produce employees Richard Garnett and Eric Haupfear for deposition.

MONSANTO'S POSITION

I. Introduction

Plaintiffs have requested depositions of Group C custodians Dr. Eric Haupfear, Director, Trait Delivery, Biotechnology at Monsanto, Dr. John Acquavella, formerly an epidemiologist at Monsanto, and Group D custodian Dr. Richard Garnett, Global Chemistry Regulatory Strategy Lead at Monsanto's European subsidiary. Monsanto has agreed to facilitate the deposition of Dr. Acquavella. The other two Group C and D deponents are in dispute. At the time that the telephone conference on this submission occurs, plaintiffs will have taken six depositions: three U.S.-based regulatory toxicologists for Monsanto (Dr. Donna Farmer, Dr. William Heydens, and Dr. David Saltmiras), one U.S.-based medical toxicologist (Dr. Daniel Goldstein), one U.S. regulatory affairs professional (Steve Adams), and the U.S.-based Director, Global Glyphosate Sustainability (Dr. David Heering). The parties have jointly agreed to defer two additional depositions of U.S. regulatory professionals (Daniel Jenkins – a former Monsanto employee – and Susan Martino-Catt) until the resolution of the pending briefing regarding the lack of relevance of regulatory affairs to *Daubert* pursuant to Pretrial Order No. 8 ("PTO8") (Dkt. #120). On December 23, 2016, this Court entered Pretrial Order No. 5 ("PTO5") (Dkt. #78) governing the taking of depositions from individuals in Groups C and D. PTO5 provides that, if there is a disagreement as to any Group C and D deponents, "the plaintiffs must include in the case management statement a detailed and particularized explanation for their position on each disputed individual, including citations as to any documents or deposition testimony they rely on for support." *Id.* at 2.

Plaintiffs have requested that Monsanto produce documents from seven additional document

custodians as Group E custodians. Monsanto has agreed to produce documents for three of these custodians: U.S. regulatory affairs professional Eric Sachs and former Monsanto regulatory toxicologists Richard Dirks and Timothy Long. Plaintiffs' withdrew their request for an eighth custodian, U.S. regulatory affairs professional Tracey Reynolds, in exchange for Monsanto's agreement to provide documents from Mr. Sachs. Four additional document custodians are in dispute: Lisa Flagg, Crop Protection Global Quality Lead, Dr. Mark Martens, formerly a regulatory toxicologist for Monsanto's European subsidiary, Dr. Kimberly Hodge-Bell, Monsanto's current regulatory toxicologist for glyphosate, and Gary Klopf, Chemistry, Formulations & Delivery Technology – Team Lead, Surfactant Science and Formulation. Plaintiffs have received 700,000 documents from nineteen document custodians as of the date that the telephone conference on this submission will occur.[5] PTO5 provides that if the parties are unable to reach agreement on Group E document custodians, "the plaintiffs should include a detailed and particularized explanation of why production from each disputed custodian would yield relevant, non-duplicative information." *Id.*

PTO5 clearly places the burden on plaintiffs to justify the additional burdens that these depositions and document productions will impose on Monsanto pursuant to Federal Rule of Civil Procedure 26(b)(1). As shown below, plaintiffs' justifications above are inadequate to satisfy the burden established by this Court in PTO5. Instead the disputed requests for additional discovery are needlessly cumulative and duplicative, and not proportional to the needs of this phase of the litigation.[6] Plaintiffs' requests for depositions from two Group C and D custodians

[5] This document count does not include documents produced for Dr. John Acquavella or the productions from other third parties.

[6] Plaintiffs misconstrue the proportionality analysis of Rule 26. The 10 million pages of documents produced by Monsanto to date from voluminous productions of non-custodian-based categories and nearly 20 custodians, and additional custodians Monsanto has agreed to produce here more than account for the amount in controversy and other considerations that plaintiffs ask the Court to consider. But plaintiffs' continued requests are

and for the production of documents from four of the seven Group E custodians they have identified should be denied.

A. Group C and D Deponents

Two of the depositions plaintiffs have requested from the Group C and D document custodians are in dispute: Group C custodian Eric Haupfear, a U.S.-based employee engaged in the manufacturing process, and Group D custodian Richard Garnett, a European regulatory professional. For the reasons discussed below, plaintiffs cannot meet their burden of demonstrating that deposition testimony from these two individuals would be relevant, non-cumulative, and non-duplicative of deposition testimony that plaintiffs have already obtained on general causation issues. Accordingly, Monsanto requests that the Court preclude plaintiffs from taking the depositions of these individuals during the current discovery phase on general causation.

1. Eric Haupfear

Dr. Haupfear is a Group C document custodian.[7] He is currently Director, Trait Delivery, Biotechnology at Monsanto. His current role, which he assumed in 2014, is unrelated to glyphosate-based herbicides ("GBHs"). Between 1997 and 2014, he held a variety of roles involved in the manufacturing process that creates "technical glyphosate" and the process by

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the type of "over-discovery" that the federal rule amendments seek to avoid. *See, e.g.*, *In re Bard IVC Filters Prods. Liab. Litig.*, 317 F.R.D. 562, 566 (D. Ariz. 2016) (denying requested discovery in products MDL as not proportional where "substantial discovery" was already permitted and additional requests were "marginally relevant"). Monsanto has provided substantial information regarding the burdens associated with collecting, processing, and producing its files, and those same considerations apply here. Monsanto has provided substantial information regarding the burdens associated with collecting, processing, and producing its files, and those same considerations apply here. *See Hardeman v. Monsanto Co.*, No. 3:16-cv-00525, ECF No. 63-4 (RAND, Where the Money Goes, Understanding Litigation Expenditures for Producing Electronic Discovery, http://www.rand.org/content/dam/rand/pubs/monographs/2012/RAND_MG1208.pdf); ECF No. 88-1 (declaration regarding discovery burdens associated with producing custodial files of Mr. Garnett and Mr. Gustin).

[7] Monsanto offered to put up Dr. Haupfear for deposition voluntarily if plaintiffs would withdraw their request for documents from Lisa Flagg. Plaintiffs refused that compromise.

which technical glyphosate is mixed with surfactants to create formulated Roundup® products. His most recent title in that role was Production Technology Lead. Plaintiffs wish to depose Dr. Haupfear in support of their arguments that certain impurities in technical glyphosate (formaldehyde and non-nitrosoglyphosate (NNG)) and impurities in certain surfactants (1,4 dioxaine) could be cancer-causing components of Roundup® products.

Plaintiffs' relevancy argument is based upon a false predicate - that the scientific studies on the safety of glyphosate or surfactants were conducted with "pure" glyphosate or "pure" surfactants that did not contain the trace levels of impurities (NNG, formaldehyde, 1,4 dioxaine) and that the presence of these impurities in the glyphosate based herbicides ("GBHs") used by plaintiffs thus adds some separate, unmeasured cancer risk. Plaintiffs provide no basis for this predicate. The trace impurities at issue are introduced in the ordinary course of the manufacturing process and they were thus present in the glyphosate, surfactants and GBHs analyzed in all of the scientific carcinogenicity, epidemiology, and genotoxicity studies that will be addressed by the general causation experts in the Phase I proceedings. In other words, if the presence of these impurities created any cancer risk, that risk already would be reflected in the scientific studies at issue. For example, fourteen animal cancer bioassays of glyphosate at issue in this litigation *each* studied glyphosate with measured levels of impurities ranging as high as 5.4%. *See* Helmut Greim et al., *Evaluation of carcinogenic potential of the herbicide glyphosate, drawing on tumor incidence data from fourteen chronic/ carcinogenicity rodent studies*, 45 Critical Revs. In Toxicology 185, 189-90, 192-93, 195-96, 199-202 (2015) (purity levels in studies highlighted) (Ex. 36). And, of course, all of the epidemiological studies at issue in this litigation studied exposures to formulated GBHs, which likewise would have included these same levels of impurities. The presence of these impurities thus does not provide any separate scientific basis for an expert causation opinion regarding the carcinogenicity of glyphosate and GBHs, and it has no impact on the general causation issue before the court.

Plaintiffs are already aware of this fact through the testimony of Donna Farmer and through a Monsanto scientific analysis produced in discovery and explained by Dr. Farmer that establishes this very point. Plaintiffs also have questioned a number of the regulatory toxicologists on the levels of impurities in glyphosate and how those levels compare to EPA guidances (the levels are well within EPA safety standards).

Accordingly, because the allegations have been thoroughly discussed in prior depositions and plaintiffs can identify nothing in Dr. Haupfear's documents that contradicts this prior testimony, deposing Dr. Haupfear on NNG would be unduly burdensome, irrelevant, cumulative, and duplicative of prior deposition testimony.

2. Richard Garnett

Dr. Garnett is a Group D document custodian. He is a weed scientist by training. Weed scientists have expertise in herbicide efficacy and the movement of herbicides in soil and water, but they do not have expertise on issues of toxicology regarding the safety of herbicides to humans. During his employment by Monsanto's European subsidiary, his job has been to support the registration of glyphosate and Roundup® products in European countries. His current title is Global Chemistry Regulatory Strategy Lead and he has held that position in Europe since 2013. He is also currently the Chair of the European Glyphosate Task Force, a group formed by multiple companies that manufacture GBHs to provide joint submissions related to the renewal of regulatory approval of glyphosate in Europe. Between 1998 and 2013, Dr. Garnett served as the European, Middle East, and Africa ("EMEA") Regulatory Affairs Manager for Glyphosate and then the EMEA Chemistry Regulatory Affairs Lead for Monsanto. He has not been involved directly in Monsanto's regulatory interactions with the United States Environmental Protection Agency.

In providing guidance to the parties at the November 16, 2016 Case Management Conference ("November CMC"), the Court noted that document collection from European

custodians would be allowed "to the extent a European agency's conclusion about Roundup is relevant to these proceedings … why can't we, sort of, examine what went into the agency's decision and what information the agency was receiving from Monsanto compared to the information that Monsanto had." November CMC Tr. at 103. The Court also premised its guidance regarding allowing discovery of European regulatory issues at all on its "reluctan[ce] to say that, you know, there can be no discovery on the people from Europe and the communications they – you know, the sort of, pitch that Monsanto was making to European regulatory agencies in light of the fact that it is going to be, on some level, part of the case." November CMC at 106.

As Monsanto argued recently in its briefing responding to this Court's Pretrial Order No. 8, although the regulatory agencies in Europe, the United States, and elsewhere have consistently found that GBHs are unlikely to present any cancer risk, those decisions have all been made under regulatory standards that are different from those this Court must apply under *Daubert*. *See* Monsanto Company's Brief Regarding the Relevance of IARC and EPA to General Causation, ECF No. 134, at 1-2 ("PTO8 Brief"). *Daubert* requires an evaluation of the science itself, and is not focused on regulatory or other conversations regarding it. Therefore, any deposition testimony by Dr. Garnett regarding these regulatory matters is irrelevant at this stage of the litigation.

Plaintiffs point to Dr. Garnett's involvement in European regulatory authorities' evaluation of tallow amine surfactants as grounds for his deposition. Again, Dr. Garnett's communications with European regulators are not relevant to this Court's upcoming evaluation of the scientific evidence under the different *Daubert* standard. Moreover, plaintiffs have already obtained deposition testimony from Dr. Donna Farmer regarding European efforts to ban such surfactants, the lack of scientific evidence underpinning those efforts, and whether such efforts demonstrate "vigilance" or an unscientific approach by the regulators to account for

political pressures. Dr. Garnett's testimony on this issue would be duplicative of Dr. Farmer's testimony.

Furthermore, even if testimony regarding regulatory affairs is relevant (which it is not), to the extent that Dr. Garnett would offer any testimony relevant to the regulation of GBHs in the United States, his testimony would be cumulative and duplicative of Steve Adams, the U.S.-based Chemical Regulatory Affairs Manager for Glyphosate, whom plaintiffs have already deposed in this litigation. Plaintiffs claim that Dr. Garnett worked to respond to isolated papers challenging the robust data set demonstrating the safety of GBHs. Plaintiffs have already collected documents and obtained deposition testimony on those issues. During the first five depositions, Monsanto's response to efforts to challenge the safety of GBHs in the United States has been explored in great detail. Any testimony by Dr. Garnett on similar efforts in Europe is cumulative and duplicative. In any event, the general causation issue before the Court turns on the substance of the scientific studies at issue, not on allegations regarding how Monsanto responded to those studies.

As for Dr. Garnett's purported involvement in dermal absorption studies, Monsanto has already produced voluminous dermal absorption studies through its non-custodian-based productions of its scientific and regulatory files. Such studies are not likely to be available uniquely in the files of document custodians. *See, e.g.*, 5/23/16 Decl. of Donna Farmer, 3:16-cv-00525-VC, ECF No. 62-2 ("Email and other custodian-based-records collections would not be expected to contain unique copies of studies or other scientific research relevant to the safety of glyphosate-containing herbicides to people or animals."). Plaintiffs do not explain how Dr. Garnett's testimony regarding these studies would not be duplicative of testimony they did or could have obtained from the four Monsanto toxicologists that they have already deposed.

B. Group E Document Custodians

On February 11, 2017, plaintiffs named eight additional document custodians from whom

they sought the production of documents in Group E. Monsanto has agreed to provide documents for three of these eight custodians: U.S.-based regulatory professional Eric Sachs and former U.S.-based regulatory toxicologists Richard Dirks and Timothy Long. Plaintiffs agreed to withdraw their duplicative request for documents from U.S.-based regulatory professional Tracey Reynolds in exchange for Monsanto's agreement to produce documents from Mr. Sachs.[8] Plaintiffs cannot satisfy their burden of demonstrating that the remaining four Group E custodians possess relevant, non-cumulative, and non-duplicative documents for the general causation phase of this litigation. Further, discovery also would not be proportional to the needs of this general causation phase, given the nearly 900,000 documents (estimated to total around 10 million pages) already produced by Monsanto, as well as the other information that plaintiffs and their experts have access to through public sources. Monsanto requests that the Court deny plaintiffs' excessive and unduly burdensome requests for yet more documents on irrelevant issues from the four remaining Group E custodians.

1. Lisa Flagg

Ms. Flagg is currently Crop Protection Global Quality Lead at Monsanto. She is responsible for global quality assurance for the manufacturing of GBHs. She has been in that role for only three years. Her prior positions at Monsanto did not involve glyphosate-based products. Like Mr. Haupfear, plaintiffs seem to be interested in Ms. Flagg's documents based on their theory that NNG in technical glyphosate or GBHs render those products carcinogenic.[9] Any potential carcinogenic effect of trace impurities in glyphosate or GBHs is already addressed in the epidemiology, animal toxicology, and genotoxicology studies of glyphosate and GBHs.

[8] Mr. Sachs had previously been named as a Group D custodian, but plaintiffs elected to forgo production of his documents as part of a compromise on the scope of the Group D custodians.

[9] Plaintiffs use the word "toxic" in their section, which is not the same as carcinogenic. Plaintiffs also misrepresent the contents of Ex. 16 when they portray it as a concession that NNG is toxic.

Documentation regarding NNG levels in GBHs accordingly does not provide any additional information that could impact the general causation issue before the Court.[10]

Plaintiffs have already received thousands of documents that mention formaldehyde, NNG and 1,4 dioxaine in technical glyphosate and formulated Roundup® products via the document collection of Group C custodian Dr. Eric Haupfear (more than 4000 documents on formaldehyde, more than 1500 documents on NNG and several hundred on 1,4 dioxaine). Accordingly, any relevant documents in Ms. Flagg's possession are likely cumulative and duplicative of the information contained in Mr. Haupfear's document collection.

Plaintiffs cite to documents that they contend show an "uptick" in NNG testing since 2014, when Ms. Flagg assumed her current role. They point to no documents, however, that demonstrate that NNG tolerance levels have been exceeded during that time period and no evidence that Ms. Flagg was involved in evaluating the safety of NNG in GBHs – because she was not. As noted above, the presence of NNG in GBHs is not relevant to the question before the court of whether glyphosate or GBHs can cause the blood cancer non-Hodgkin's lymphoma because any purported risk already would be reflected in the scientific studies at issue. Accordingly, evidence regarding what sort of testing is done for NNG and whether tolerances have been exceeded is not relevant to the issues currently before the Court.

2. Mark Martens

Dr. Martens is a regulatory toxicologist formerly employed by Monsanto's European subsidiary. He is presently located in Europe. Thus, production of his documents would present additional challenges due to foreign privacy law concerns, as did the prior production of documents from European custodians Richard Garnett and Christophe Gustin. As a result of

[10] Plaintiffs' citation to a 2011 paper from the American Journal of Clinical Nutrition is misleading, as NNG was not considered in that paper. Plaintiffs have pointed to no evidence that NNG, as opposed to other non-nitroso compounds, is carcinogenic.

those concerns the Court was required to enter a discovery order with special safeguards and findings (Dkt. #66). Such an order would be required here before Monsanto could produce any documents from Dr. Martens.[11]

There is no reason to go to such an effort here. Plaintiffs have obtained documents from and deposed three U.S.-based regulatory toxicologists and a U.S.-based medical toxicologist in this litigation. Monsanto has agreed to produce documents from two additional regulatory toxicologists (Dirks and Long). Plaintiffs also have received documents from two European regulatory affairs professionals (Garnett and Gustin). There is no basis for this court to conclude that Dr. Martens' documents are non-cumulative and non-duplicative of information that plaintiffs have already received in discovery from these custodians on the issue of general causation.

Dr. Martens was a regulatory toxicologist in Europe responsible for the registration of GBHs in European countries and associated regulatory testing. As noted above with respect to Dr. Garnett, if the Court agrees with Monsanto's argument in its PTO8 Brief that regulatory consideration of glyphosate science is not relevant to the Court's *Daubert* inquiry, then Monsanto's interactions with regulatory authorities are not relevant to this general causation phase of the litigation.

Plaintiffs point to interactions between Dr. Martens and a Dr. James Parry addressing various published genotoxicity studies and possible additional research suggested by Dr. Parry.

[11] The additional burdens and foreign privacy law concerns associated with producing foreign custodians provide further grounds for denying plaintiffs' request with respect to Dr. Martens. *See, e.g.*, *In re: Bard*, 2016 WL 4943393, at *5 (D. Ariz. Sep. 16, 2016) (holding defendant Bard "need not search the ESI of foreign Bard entities" because "the burden and expense" of the search "outweighs the benefit of the proposed discovery"); *see also Benicar*, 2016 WL 5817262, at *7 (refusing to direct defendants to produce documents from Daiichi Europe unless "plaintiffs satisfy the Court that requests are well-grounded, materially relevant and non-cumulative"). Monsanto has briefed discovery from European custodians more extensively at ECF No. 28 (discovery letter) and ECF No. 61 (consent motion).

Plaintiffs have in their possession documents regarding those interactions and have obtained many pages of deposition testimony from Monsanto toxicologist Donna Farmer regarding them. Plaintiffs also cite an email regarding Dr. William Heydens' position on Dr. Parry's involvement as justification for his deposition, but fail to inform the Court that they elected not to elicit any testimony from Dr. Heydens on that document. There is no basis to conclude that Dr. Martens' documents on that issue are not cumulative and not duplicative of the information and testimony that plaintiffs have already obtained. In fact, plaintiffs admit that the examples of communications between Dr. Martens and Dr. Parry they have seen were forwarded on to other Monsanto employees whose files have been produced and some of whom have been deposed. There is no basis to conclude that Dr. Martens' files contain unique information on interactions with Dr. Parry.

Plaintiffs' also point to a memorandum purportedly prepared by Dr. Martens which suggested hypothetical reasons why surfactants might increase the absorption of glyphosate through the skin. Plaintiffs do not explain the relevance of dermal absorption studies or this memorandum to their general causation arguments. Any such relevance would turn on the data from actual studies, not hypotheses. Moreover, plaintiffs have already obtained deposition testimony and documents addressing that draft study and testimony regarding its meaning from Dr. Donna Farmer and failed to ask the other three Monsanto toxicologists who have been deposed any questions about that draft study.

In addition, any documents Dr. Martens may have in his own possession are not in the custody or control of Monsanto and documents in his personal possession created after he left the company would need to be sought by independent subpoena directed to Dr. Martens himself. Monsanto requests that the Court not require the production of any documents from Dr. Martens.

3. Kimberly Hodge-Bell

Dr. Hodge-Bell is the current regulatory toxicologist for glyphosate products. She has

been in that role since January 2015, less than a year and a half. Between 2010 and 2015, she was a senior toxicologist on glyphosate supervised by Dr. David Saltmiras, who has already been deposed in this litigation. Two other regulatory toxicologists for glyphosate (Donna Farmer and William Heydens) and the medical toxicologist for glyphosate (Daniel Goldstein) also have been deposed. Documents from these four Monsanto toxicologists have already been produced in this litigation and Monsanto has agreed to produce documents from two additional regulatory toxicologists who worked at Monsanto during the period in which many of the carcinogenicity studies at issue in this litigation were conducted (Richard Dirks and Timothy Long). The information contained in Dr. Hodge-Bell's documents is cumulative and duplicative of documents previously produced to plaintiffs or that will be produced and deposition testimony already obtained.

Plaintiffs' contend that they are interested in Dr. Hodge-Bell's documents because she has been involved in dermal-absorption studies and studies on surfactant toxicity. As to the dermal-absorption studies, the studies at issue did not evaluate carcinogenicity, systemic exposure, or the metabolism of glyphosate. As noted above, Monsanto has already produced voluminous dermal absorption studies through its non-custodian-based productions of its scientific and regulatory files. At most, the files of Dr. Hodge-Bell are expected to contain duplicative copies. *See, e.g.*, 5/23/16 Decl. of Donna Farmer, 3:16-cv-00525-VC, ECF No. 62-2 ("Email and other custodian-based-records collections would not be expected to contain unique copies of studies or other scientific research relevant to the safety of glyphosate-containing herbicides to people or animals."). Accordingly, these studies do not provide a basis for the production of her documents in this litigation, which alleges that GBHs pose a risk of the blood cancer non-Hodgkin's lymphoma in humans. Plaintiffs point to five exploratory surfactant studies connected with Dr. Hodge-Bell. Multiple witnesses have already testified about the testing Monsanto conducts on any surfactant and the need for regulatory approval before that

surfactant is available for use in a formulated Roundup® product. Plaintiffs provide no basis to assume testimony on these five studies is anything other than duplicative of the larger set of genotoxicity tests they received from the production of Monsanto's scientific files and through other toxicologists' testimony.

The suggestion that the work of Dr. Hodge-Bell is somehow unique or segregated from the work of the other four toxicologists who have been deposed and who have produced documents in this matter is untrue and unfounded. Dr. Hodge-Bell was doing the normal work of toxicologists at Monsanto and was supervised by Dr. David Saltmiras and worked closely with Dr. Donna Farmer, Dr. William Heydens and Dr. Daniel Goldstein for her entire career at Monsanto. There is no basis other than speculation to conclude that Dr. Hodge-Bells files contain unique information regarding the regulatory toxicology studies.

4. Gary Klopf

Gary Klopf's current title at Monsanto is Chemistry, Formulations & Delivery Technology – Team Lead, Surfactant Science & Formulation. In that role and prior roles held since 1995, he has been responsible for evaluating the viability of using various different surfactants in formulated Roundup® products. His work has focused on whether the surfactant is compatible with technical glyphosate to create stable formulated product and evaluating whether particular surfactants have any impact on the efficacy of Roundup® formulated products. Mr. Klopf has never had any responsibility for studying the safety of surfactants or resulting formulated product. That work is the responsibility of the regulatory toxicology department and, as previously noted, three regulatory toxicologists and one medical toxicologist have already been deposed and served as document custodians in this case. The documents for two more toxicologists will also be produced as a part of Group E. Their testimony and documents included information regarding the evaluation of the safety of surfactants used in formulated Roundup®. Accordingly, any relevant documents in Mr. Klopf's files related to surfactants are

duplicative of the information already obtained from other custodians and through depositions already taken in this litigation.

The fact that some of the information that Mr. Klopf received from the manufacturers of surfactants include safety information does not mean that Mr. Klopf was involved in evaluating the safety of those surfactants or resulting formulated product. There is no basis to conclude that production of Mr. Klopf's documents would contain studies on surfactant safety from product manufacturers and every reason to believe that, if he had received such studies, he would have passed them on to the regulatory toxicologists responsible for human safety of GBHs. Those regulatory toxicologists have produced documents and been deposed. The absence of such documents in the production to date does not demonstrate that Mr. Klopf has them. It is just as likely that they don't exist because no such documents were provided to Monsanto. Mr. Klopf's work is not relevant to the claims and defenses in this litigation and, to the extent he possesses documents regarding the safety of surfactants, information contained in his documents is cumulative and duplicative of information obtained from other custodians and through deposition testimony. Accordingly, Monsanto requests that the Court not require production of Mr. Klopf's documents during this general causation discovery period.

C. Conclusion

Monsanto requests that, for the foregoing reasons, the Court deny plaintiffs' request to depose Dr. Richard Garnett and Dr. Eric Haupfear, two of the three Group C and D custodians plaintiffs have requested, and deny plaintiffs' request for documents from four of the seven Group E designees: Lisa Flagg, Dr. Mark Martens, Dr. Kimberly Hodge-Bell and Dr. Gary Klopf.

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Respectfully submitted,

/s Robin Greenwald, Michael Miller and Aimee Wagstaff
Robin Greenwald
rgreenwald@weitzlux.com
Weitz & Luxenberg
700 Broadway
New York NY 10003
Ph 212-558-5500
F 212-344-5461

Michael Miller
mmiller@millerfirmllc.com
The Miller Firm LLC
108 Railroad Ave
Orange VA 22960
Ph 540 672 4224
F 540 672 3055

Aimee Wagstaff
Aimee.wagstaff@andruswagstaff.com
Andrus Wagstaff, P.C.
7171 West Alaska Drive
Lakewood CO 80226
Ph 303-376-6360
F 303-376-6361

Attorneys for Plaintiffs

/s/ Joe G. Hollingsworth
Joe G. Hollingsworth (*pro hac vice*)
(jhollingsworth@hollingsworthllp.com)
Eric G. Lasker (*pro hac vice*)
(elasker@hollingsworthllp.com)
HOLLINGSWORTH LLP
1350 I Street, N.W.
Washington, DC 20005
Telephone: (202) 898-5800
Facsimile: (202) 682-1639
Attorneys for Defendant

Attorneys for Monsanto Company