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FILED VIA ECF
Honorable Vince Chhabria
United States District Court, Northern District of California

Re: *In re Roundup Prod. Liab. Litig.*, No. 3:16-md-02741-VC

To the Honorable Vince Chhabria,

The following discovery dispute is being submitted by the parties pursuant to paragraph 15 of the Standing Order for Civil Cases Before Judge Vince Chhabria, which requires that the Parties submit a discovery dispute letter stating the nature and status of their dispute. The parties jointly request a 2-page enlargement for this discovery dispute submission.

Monsanto's Position

Following briefing regarding the relevance of EPA and IARC to general causation, the Court found that "EPA reports and the IARC monograph are relevant to the first phase of these proceedings," but that discovery into EPA and IARC would be governed by "principles of proportionality." 2/27/2017 Case Mgmt. Tr. at 11, 25. To that end, the Court provisionally indicated that plaintiffs would be allowed to depose former EPA employee Dr. Jess Rowland. *Id.* at 22. At both parties' request, the Court also allowed the deposition of Dr. Aaron Blair, an epidemiologist who chaired the IARC Monograph 112 Working Group on glyphosate and participated in the subgroup on epidemiology.

The basis for the selection of Dr. Blair as the sole deponent on IARC discovery matters focused on the expectation that, as the chair, Dr. Blair would be able to testify to the Working Group's conclusions in the three main scientific areas covered by Monograph 112: human epidemiology, experimental animal data, and mechanistic data. However, at his March 20, 2017 deposition, Dr. Blair made clear that he only had knowledge about the deliberations and conclusions of the subgroup on epidemiology. That group's conclusion – that there is *limited* evidence of carcinogenicity in humans but that chance, bias or confounding could not be ruled out – formed only one-third of the Working Group's ultimate evaluation of glyphosate. As confirmed by Dr. Blair's testimony, IARC's 2A classification was driven by the evaluation of experimental animal and mechanistic data, evaluations Dr. Blair did not participate in and disavowed any knowledge of. Therefore, Monsanto requests leave to obtain relevant documents from and depose Dr. Charles Jameson, chair of the experimental animal subgroup, and to depose Dr. Matthew Ross, a member of the mechanism subgroup whose documents have already been produced in this litigation.

A. Dr. Blair was unable to provide any insight into the determinations reached by the experimental animal and mechanism subgroups.

At his deposition, Dr. Blair was questioned by both parties about the conclusions reached by the experimental animal and mechanism subgroups following their respective evaluations of glyphosate. Dr. Blair could not confirm or deny that during a plenary session halfway through the Working Group's week-long meeting, the animal subgroup's determination appeared to be *limited* to *inadequate*. *See* Blair Dep. Tr. at 126:3-14 (no basis to disagree with Dr. Ross' handwritten notes from the Working Group's plenary session that set forth the animal subgroup's initial evaluation as *limited* to *inadequate* evidence).[1] At the end of the week, however, the subgroup's ultimate determination was *sufficient*. *See* IARC Monograph 112, https://www.iarc.fr/en/media-centre/iarcnews/pdf/MonographVolume112.pdf. Despite his role as Working Group chair, Dr. Blair expressly disavowed any knowledge of the basis or process by which the animal group changed its evaluation, testifying that he "was not in [that] subgroup, so I have no idea what the discussion was." Blair Dep. Tr. at 126:22-127:2. With regard to the mechanism subgroup's determination that there is *strong* evidence that glyphosate is genotoxic and induces oxidative stress – the highest classification available to that group – Dr. Blair eschewed a deep understanding of the basis, testifying that those conclusions "come[] from the subgroups with a discipline that I'm not as knowledgeable about." *Id.* at 51:4-20. Dr. Blair explained that during the five-day period that the Working Group met in France to evaluate the five different pesticides covered in Monograph 112[2], only a day or two, "spread over the five days," went into the analysis and classification of glyphosate. *See id.* at 115:12-18. As an epidemiology subgroup member, Dr. Blair "was not privy to discussions" of the other subgroups. *Id.* at 127:16.

B. Further discovery is warranted because at this point Monsanto has *no* illuminating discovery as to what drove the IARC classification.

Dr. Blair's lack of knowledge about the other subgroups' processes leaves Monsanto without any discovery on the key considerations that drove IARC's 2A classification. In fact, plaintiffs admit that the animal subgroup's conclusions are the "crux of Plaintiffs case." *See infra.* As Dr. Blair conceded, if the animal subgroup's evaluation had remained *limited* or *inadequate*, the full working group would "probably not" have reached the determination that glyphosate is a probable carcinogen. *See* Blair Dep. Tr. at 127:22-128:4. In fact, if the animal subgroup's conclusion had been *limited*, the highest classification that the IARC Working Group could have come to is that glyphosate is a 2B, possible carcinogen. *Id.* at 128:6-13. And if the

[1] Pursuant to this Court's Standing Order, Monsanto has not attached Dr. Blair's deposition transcript to this letter. However, Monsanto will provide a copy to the Court upon request.

[2] In addition to glyphosate, the IARC Monograph 112 Working Group evaluated malathion, diazinon, tetrachlorvinphos and parathion.

animal subgroup's evaluation had been *inadequate*, the IARC Working Group could have concluded that glyphosate is "not classifiable as to its carcinogenicity to humans." *See* IARC, Agents Classified by the IARC Monographs, Volumes 1-117, http://monographs.iarc.fr/ENG/Classification; Blair Dep. Tr. at 128:14-19. Further, the deliberations of the mechanism subgroup are an important subject of inquiry because, as noted above, the group's evaluation provided *strong* support for the Working Group's overall conclusion.

Monsanto disagrees with plaintiffs' misleading characterizations of selected excerpts of Dr. Blair's testimony about the relevant epidemiology evidence in this case. For example, plaintiffs claim that the North American Pooled Project (NAPP) "shows a relative risk of 2.66 among people who use glyphosate for more than two days per year." *See infra*. In fact, Dr. Blair conceded that he did not know whether that data was controlled for exposures to other pesticides or not controlled, but that when the pooled data for all case-control studies in North America *is* controlled, there is no statistically significant positive association between glyphosate and NHL. *See* Blair Dep. Tr. at 295:6-14, 296:18-22. Plaintiffs also cite testimony from Dr. Blair regarding the purported "problem with lack of follow-up in the AHS study" published in 2005, *see infra*, but fail to mention Dr. Blair's testimony that the 2013 AHS study data shows no association between glyphosate and any subtype of NHL. *See id.* at 172:11-15. Dr. Blair also admitted that although he was aware of this data at the time of the IARC meeting, he neglected to inform any of his fellow IARC Working Group members or any of the other members of the subgroup on epidemiology. *Id.* at 177:13-178:7. These concessions by Dr. Blair regarding the weaknesses of the epidemiology data further underscore the extent to which the other subgroups' decisions drove the IARC classification. Monsanto will be unfairly prejudiced without an opportunity for meaningful discovery regarding these two core aspects of IARC's classification of glyphosate.

C. Monsanto seeks discovery from Dr. Charles Jameson and Dr. Matthew Ross, members of the experimental animal and mechanism subgroups.

Dr. Charles Jameson is a U.S.-based toxicologist who served as the subgroup chair for the experimental animal subgroup of Monograph 112. Plaintiffs' counsel Aimee Wagstaff is already in possession of Dr. Jameson's IARC-related documents, even though she has represented to Monsanto that she is not representing Dr. Jameson in the context of the production of those materials.[3] Plaintiffs retained Dr. Jameson as an expert for this litigation following his participation on the Working Group and, consequently, have had a significant and exclusive opportunity to discuss with him the basis for the animal subgroup's conclusions. Accordingly, Monsanto seeks an order requiring plaintiffs' counsel to turn over the IARC-related documents Dr. Jameson produced and permitting the scheduling of his deposition before the April 17, 2017 cutoff for fact discovery. Monsanto expects Dr. Jameson will be able to testify about the scientific debate and key findings that led to the animal subgroup's change in evaluation.

[3] Any purported IARC privilege attached to Dr. Jameson's documents was waived when he provided those documents to plaintiffs.

Dr. Matthew Ross is a Mississippi State University professor who participated in the mechanism subgroup of Monograph 112. Monsanto already received Dr. Ross's IARC-related documents. Monsanto now seeks permission to subpoena Dr. Ross for deposition, prior to April 17, to explore the mechanism subgroup's conclusions about glyphosate.

The proposed discovery from Drs. Jameson and Ross is not duplicative of any existing or upcoming discovery. Moreover, allowing this limited additional discovery will not impact the current schedule and will not cause any prejudice to plaintiffs. Rather, it will remedy the prejudice caused to Monsanto by the disproportionate access plaintiffs have had to date to the key considerations that affected IARC's classification of glyphosate and Dr. Blair's inability to shed any substantive light on the methodology or deliberations of the animal and mechanism subgroups. Indeed, without the conclusions of these subgroups, Dr. Blair agreed that glyphosate would not be classified as a 2A carcinogen. Given the Court's determination regarding the relevance of IARC, Monsanto is entitled to gain a greater understanding of the underlying methodology of those groups, especially in light of Dr. Blair's admission that the conclusions of those groups drove the IARC classification.

PLAINTIFFS' POSITION

Monsanto chose to take the deposition of Dr. Blair, the deposition went badly for them, and now they want another bite at the apple at the eleventh hour. Monsanto's request is untimely, duplicative and should be denied. "The opinions of the IARC and EPA about what the studies show, while important, are secondary" to this phase of the litigation. PTO 15 at 2. During this general causation phase, the experts in this case "will need to analyze the studies themselves and offer opinions about what they show." *Id*. As such, while "the parties may conduct some third-party discovery relating to the conclusions drawn by the IARC and the EPA, any such discovery will be limited so that it does not take on an outsized role relative to its importance." *Id*. Contrary to the words and intent of PTO 15, Monsanto Company is seeking relief from this Court for the purpose of learning the impetus behind IARC's classification of glyphosate as a 2A human carcinogen. As noted by this Court, the purpose and goal of this general causation phase is for each party's experts to analyze the available science as it relates to the association between exposure to Roundup®/glyphosate and Non-Hodgkin's Lymphoma. Thus, Monsanto's request for additional discovery related to IARC's "evaluative process" is irrelevant at this juncture in the litigation.

The Court made clear at the February 27, 2017 conference that discovery of IARC will be governed by proportionality and will be limited, in part, because, ordinarily discovery is not conducted on study authors particularly where the scientist "is just minding his own business trying to help the world by doing a study." 2/27/2017 Case Mgmt. Tr. 24:4-19. Monsanto chose to depose Dr. Blair as its IARC deponent, as he was the chair of the Monograph 112 Working Group for Glyphosate. With respect to Monsanto's decision to depose Dr. Blair, the Court stated that "arguably, Monsanto is getting more than its [sic] entitled to by taking the deposition of the chair of the IARC Working Group." *Id.* at 25:6-10.

Moreover, Monsanto, in its submission pursuant to PTO No. 8, stated its belief that IARC is not relevant to general causation: "IARC's hazard identification methodology thus falls far short of the standards of scientific reliability and relevance required for an expert to opine as to causation under *Daubert*." Def's Brief 7 (ECF No. 134). Regarding IARC's animal toxicology assessment, in particular, the role that Dr. Jameson filled in the IARC evaluation of glyphosate, Monsanto has argued that IARC's classification studies are insufficient because of its stringent study selection: "For example, IARC acknowledges that under its selective hazard identification system, '[a] single [animal] study in one species and sex might be considered to provide sufficient evidence of carcinogenicity' under some circumstances." *Id.* at 10. Based on these and many other statements Monsanto has made about IARC's relevance, Monsanto cannot credibly show why they would be entitled to additional IARC depositions.

Monsanto's purpose in deposing Dr. Blair was an attempt at "finding fault with the IARC's conclusion." PTO 15. The purpose was not achieved, and now Monsanto wants another try. During his deposition, Dr. Blair answered the questions posed to him in full compliance with the deposition notice and Federal Rules. The fact that Monsanto might have preferred to

elicit different answers from Dr. Blair is not grounds for further discovery of IARC working group members. Dr. Blair gave careful testimony on the IARC Monograph 112 process, including the months of preparatory work and research, how studies are selected for review, the framework of plenary sessions and subgroups that comprise the week-long meeting of experts, his decision to participate in Monograph 112, etc. The deposition also addressed in detail the IARC protocols for assessing a chemical, including glyphosate, and confirmed that the protocols were followed for Monograph 112. Blair Tr. at 278:22-279:3. Dr. Blair testified that he has worked with IARC since 1985 and is very familiar with its procedures. *Id.* at 23:5. Those procedures were followed for the Monograph 112 assessment.[4]

As to the epidemiology relating to glyphosate, Dr. Blair explained that he has worked at the National Cancer Institute as an epidemiologist since 1976, Blair Tr. at 16:2-20, and that epidemiology involves studying a particular agent to determine if it causes a human disease. *Id.* at 26:21-27:1. As part of his work, Dr. Blair has also studied the causes of NHL. 14:21-24. Dr. Blair has worked with IARC since 1985 and is very familiar with its procedure. *Id.* at 23:5. Dr. Blair confirmed that IARC uses the Bradford-Hill criteria when assessing whether an agent causes cancer, including in its assessment of glyphosate. *Id.* at 32:16-33:4. Dr. Blair even co-authored a 2015 article examining IARC's history, concluding that IARC gets "it right most of the time." *Id.* at 85:17-87:14. Dr. Blair confirmed that epidemiology is a cornerstone of IARC and that "[e]pidemiology is based on real world exposures. That's what humans get." *Id.* at 74:1-20.

Dr. Blair confirmed that the epidemiological literature showed a positive association between glyphosate and non-Hodgkin's Lymphoma. *Id.* at 50:1-15. He defined a positive association as meaning that "there were studies that showed an excess risk for people exposed." *Id.* at 50:10-11. Dr. Blair confirmed that a number of case control studies showed at least a doubling of the risk of NHL for glyphosate users, as well as a dose-duration response. *Id.* at 55:4-7, 57:5-18, 59:9-14, 60:25-61:8, 69:10-20, 63:20-25. Dr. Blair is also the author of the North American Pool Project (NAPP), which has not been published yet and was not considered by IARC but which shows a relative risk of 2.66 among people who use glyphosate for more than two days per year. *Id.* at 273:5-277:23.

Dr. Blair presided over the full working group session where he remembers (but could not state so with 100% confidence) that the vote was unanimous that glyphosate was a probable human carcinogen. *Id.* at 43:1-3. Dr. Blair was also a member of the sub-working group on epidemiology. He did not participate in the sub-working group meetings on animal and mechanistic data, but Monsanto has been well aware of this fact for over two years. In fact, Monsanto hired epidemiologist Thomas Sorahan to observe and speak on Monsanto's behalf at

[4] As chairman of the Monograph 112 working group, *id.* at 37:13-38:7, Dr. Blair was not compensated for the months of time spent reviewing glyphosate literature. *Id.* In assessing glyphosate, Dr. Blair confirmed the working group of 17 experts reviewed material on glyphosate for three months before the seven day working group meeting. *Id.* at 34:17-21. After this extensive review of glyphosate, these 17 experts concluded that glyphosate probably causes cancer in humans. *Id.* at 34:6-35:11.

the IARC working group meetings for glyphosate. *Id.* at 44:21-45:13. Dr. Sorahan reported back to Monsanto every day of the IARC meeting and summarized his experience at the meeting as follows: "I found the chair, sub-chairs and invited experts to be very friendly and prepared to respond to all comments I made. ... In my opinion the meeting followed the IARC guidelines." (ECF No. 187-4). Despite reassurance by its observer, Monsanto subsequently asked IARC to retract the conclusions on glyphosate and IARC refused. Blair Tr. at 52:5-14.

The real reason that Defendants request additional discovery is because Dr. Blair's testimony rebuked Monsanto's talking points for this litigation. Monsanto will be heavily relying on the Agricultural Health Study (AHS), an outlier study which did not show an association between glyphosate and NHL.[5] Dr. Blair, an author on this study, testified that it is not the most powerful study and there is a problem with lack of follow-up in the AHS study. Blair tr. at 69:21-70:4, 271:14-272:19, 286:1-9. With respect to case control studies, Blair determined that recall bias was not a problem and determined that confounding would be rare. *Id. at* 88:6-89:2, 283:5-24. In a nutshell, in assessing glyphosate, Dr. Blair weighed the totality of evidence from the numerous positive case-control studies and his own negative AHS cohort study and concluded that there was an association between glyphosate and NHL. *Id.* at 70:10-15, 365:7-25. After three hours and forty minutes of cross-examination, Defendants were unable to change Dr. Blair's opinion that glyphosate is a probable human carcinogen. *Id.* at 293:6-15.

Defendant's request to depose either or both Drs. Jameson and Ross should be denied pursuant to the Federal Rules and pursuant to the aforementioned statements of Your Honor. Defendant has not presented valid reasons as to why any such additional deposition testimony is relevant to the first phase of this litigation; it is a fishing expedition to hope to find a crack in IARC's methodology and/or conclusion. First, with respect to Dr. Jameson, Defendant well knows that he is a Plaintiffs' expert and thus will be subject to an expert deposition by Monsanto pursuant to PTO No. 7. Further, Monsanto Company states, "additional discovery will not impact the current schedule and will not cause any prejudice to plaintiffs." Plaintiffs' expert reports are due in this litigation in less than 30 days. To require Dr. Jameson to prepare and sit for a deposition as a fact witness within the next 15 days is highly prejudicial to plaintiffs, as well as to Dr. Jameson. In any event, Defendant's reasons for needing the deposition of Dr. Jameson are based solely on the expectation that Dr. Jameson could testify over "key findings" that led to the animal subgroup's conclusions related to the carcinogenicity of glyphosate. To counter, Plaintiffs submit that any and all key findings are properly found in the published Monograph 112 on glyphosate. Such key findings are the crux of Plaintiffs case and have been available to Defendant for many months.[6]

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[5] http://news.monsanto.com/press-release/research-and-development/monsanto-reinforces-decades-data-and-regulatory-review-clearl

[6] On or around August 19, 2016, Monsanto subpoenaed Dr. Jameson, seeking documents related to his work as a member of IARC's Monograph 112 Panel. By that time, Plaintiffs had engaged Dr. Jameson as an expert in this matter, and rather than respond directly to Monsanto, Dr. Jameson corresponded with and provided Plaintiffs' counsel with responsive documents. As Plaintiffs' counsel was preparing to forward these documents to Monsanto,

Next, with respect to Dr. Matthew Ross, Defendant offered no additional explanation or example that supports a need to depose Dr. Ross. In fact, Defendant acknowledges that it is in receipt of Dr. Ross' documents and simply "seeks permission" to subpoena Dr. Ross. This is not the standard for obtaining additional discovery, particularly of a side issue and within the context of the Court's application of proportionality in this litigation. Dr. Ross is simply another scientist who volunteered his time to take on the important task of evaluating the pesticides, including glyphosate, of Monograph 112.

For these reasons, Plaintiffs respectfully submit that the Court should deny Monsanto's request to take the depositions of Drs. Jameson and Ross.

Dr. Jameson was contacted by the Principal Legal Officer of the World Health Organization and instructed not to produce any documents. Plaintiffs' counsel informed Monsanto's counsel of this notice, which resulted in a request by Monsanto that Plaintiffs' counsel maintain the documents as produced, which has been done.

DATED: April 4, 2017

Respectfully submitted,

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