2001 M STREET NW
10th Floor
WASHINGTON, DC 20036

WILKINSON WALSH + ESKOVITZ

WASHINGTON, D.C. | LOS ANGELES

WWW.WILKINSONWALSH.COM

A LIMITED LIABILITY PARTNERSHIP

March 7, 2019

VIA ECF

Hon. Vince Chhabria
San Francisco Courthouse, Courtroom 4
450 Golden Gate Avenue
San Francisco, CA 94102

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

Dear Judge Chhabria:

Monsanto respectfully requests leave to elicit testimony from its case-specific pathology expert, Dr. Daniel Arber, that:

(1) Mr. Hardeman's 2015 pathology report was "positive for BCL6 (3q27) rearrangement in 29% of cells," Ex. A (TX 1191, Arber Expert Report at 4 ¶ 18); and

(2) BCL6 genetic abnormalities are associated with Hepatitis C, *see, e.g.* Ex. B (TX 1124, Couronné 2018 at 95); Ex. C (TX 1343, Machida 2004 at 4262-64, 4266); Ex. D (TX 1413, Nieters 2006 at 1884 (introduced by Plaintiff during redirect examination of Dr. Weisenburger)).

Monsanto's position is that Plaintiff opened the door to this testimony during the direct examination of Dr. Weisenburger. *See* Tr. at 925:17-20 (Ex. E) (Court stating that part of its ruling concerning Dr. Arber "depends on what Weisenburger says, of course. It may be what your expert testifies to – can testify to, may depend in part on what Weisenburger testifies to."). Dr. Weisenberger testified unequivocally that any gene rearrangement that may have occurred in Mr Hardeman as a result of Hepatitis C would have been eliminated over a decade before his NHL diagnosis. The testimony above Monsanto seeks to elicit is necessary to rebut that incorrect impression.

At the beginning of the March 6, 2019 portion of Dr. Weisenburger's direct examination, Plaintiff published to the jury an article by Eli Zuckerman (and others) titled "The Effect of Antiviral Therapy on t(14;18) Translocation and Immunoglobulin Gene Rearrangement in Patients with Chronic Hepatitis C Virus Infection." *See id.* at 1205:23-1206:2 (Ex. F (introducing TX 1599 to the jury)). Dr. Weisenburger then offered the following testimony, using a demonstrative drawn from Table 3 of the article:

- "So there is a treated group and a non-treated group or a control group, and some patients with chronic active hepatitis C viral infection have abnormal cells – B cells in their blood. Some of them are clonal. They have this – what we call immunoglobulin gene rearrangement." *Id.* at 1206:5-10;
- "[S]ome of them have another abnormality called the T14;18 translocation." *Id.* at 1206:14-15;
- "[I]t has been postulated that these cells are the ones that are sort of like pre-lymphoma cells; that they are on their way to becoming lymphoma cells; that they are on their way to becoming lymphoma cells, but they are not yet true lymphoma cells. So they have some genetic abnormalities, but they don't have all the abnormalities they need to become malignant, sort of premalignant cells. So they are circulating in the blood of some patients with hepatitis C viral infection." *Id.* at 1206:19-25;
- "[W]hen they looked at the treated group, there were nine patients with this immunoglobulin gene rearrangement, which they call IGH positive. So it had this gene rearrangement. So 9 of the 15 patients had this abnormality, okay. And after treatment, seven of the nine lost the abnormal cells, okay. And six of the seven were ones that had a complete virologic response. So what this says is a complete virologic response, not only does it get rid of the virus; but it gets rid of the abnormal cells that are there because of the virus because these cells need the virus to proliferate and exist. So once the virus is gone, the cells die off, okay." *Id.* at 1207:21-1208:7;
- "So what this says is that if you treat, the cells go away. If you don't treat, the cells persist, okay. And that's why these people are at increased risk for non-Hodgkin's lymphoma and these people are not, okay. And the story is the same for the cells that had this 14;18 translocation." *Id.* at 1208:23-1209:3.

Dr. Weisenburger then directly tied this study to Mr. Hardeman's case. He first stated that "the story here is that, you know, if you have a complete virologic response like Mr. Hardeman had, if he had these abnormal cells in his blood, they would have gone away, okay." *Id.* at 1208:12-14. Shortly thereafter, the following exchange took place:

> Q. So once he was cured in 2006 of hep C, what happened to any abnormal cells he may have had, based on the data here?
> A. Well—
> MR. STEKLOFF: Objection, Your Honor.
> THE COURT: Overruled.
> THE WITNESS: So they would have disappeared just, like they did in the study, okay. They would be gone because the abnormal cells depend on the presence of the virus. When the virus is not there, the cells are not stimulated. They are not infected and they die off, okay.

Id. at 1210:10-19; *see also id.* at 1211:7-13 ("Q. And so in your opinion, Dr. Weisenburger, based on your experience and your review of the literature, in Mr. Hardeman's case then once he was cured in 2006, if he had any damaged cells or abnormal cells as you called it, then what happened in 2006 to those cells? A. Those cells would have died off during the antiviral treatment."). Later on, Dr. Weisenburger testified that he reviewed Mr. Hardeman's tissue slides and pathology report,

and that his review of the pathology did not change his opinion in any way. *Id.* at 1216:13-1217:22. Notably, Dr. Weisenburger's analysis of the Zuckerman paper, and the conclusions he drew from it, did not appear in either of his reports, his prior deposition testimony, or his prior *Daubert* hearing testimony. But the upshot of his testimony was to communicate to the jury that antiviral treatment completely eliminated any gene rearrangement that may have occurred in Mr. Hardeman as a result of Hepatitis C.

It is undisputed, however, that Mr. Hardeman's 2015 pathology report reflected a genetic abnormality in the BCL6 gene. *See, e.g.*, Ex. A (TX 1191, Arber Expert Report at 4 ¶ 18); Ex. G (TX 1023 at 911-912, Hardeman Final Pathologic Diagnosis). Further, scientific papers on Dr. Arber's reliance list, as well as a paper introduced by Plaintiff during Dr. Weisenburger's redirect, draw an association between BCL6 abnormalities and Hepatitis C. *See* Exs. B-D. To be clear, Monsanto does not intend to elicit any testimony from Dr. Arber that these abnormalities—or any other aspect of Mr. Hardeman's pathology—"support the view that NHL was caused by hepatitis C." Tr. 928:14-15 (Ex. E). But Monsanto should be permitted to elicit the factual points described above to rebut the misleading impression created by Dr. Weisenburger, as well as to support Dr. Arber's conclusions that "Plaintiffs' experts inappropriately dismiss or disregard several potential contributors to Mr. Hardeman's lymphoma and provide no reliable or medically accepted basis for how they rule out these various factors," and that "Mr. Hardeman had a very long period of exposure to HCV with apparent liver damage, and therefore, based on the potential of HCV to cause mutations over his many years of exposure, Mr. Hardeman remained at risk for development of hepatocellular carcinoma and NHL even after his successful treatment of the virus." Ex. A (TX 1191, Arber Expert Report at 5 ¶¶ 23, 26).

Respectfully submitted,

/s/ Brian L. Stekloff

Brian L. Stekloff (*pro hac vice*)
(bstekloff@wilkinsonwalsh.com)
Tamarra Matthews Johnson (*pro hac vice*)
(tmatthewsjohnson@wilkinsonwalsh.com)
Rakesh Kilaru (*pro hac vice*)
(rkilaru@wilkinsonwalsh.com)
WILKINSON WALSH + ESKOVITZ LLP
2001 M St. NW, 10th Floor
Washington, DC 20036
Tel: 202-847-4030
Fax: 202-847-4005

Cc: Counsel of Record (via ECF)

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 7th day of March 2019, a copy of the foregoing was filed with the Clerk of the Court through the CM/ECF system which sent notice of the filing to all appearing parties of record.

/s/ Brian L. Stekloff