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

ARNOLD & PORTER KAYE SCHOLER
Pamela Yates (CA Bar No. 137440)
(Pamela.Yates@arnoldporter.com)
777 South Figueroa St., 44th Floor
Los Angeles, CA 90017
Tel: 213-243-4178
Fax: 213-243-4199

HOLLINGSWORTH LLP
Eric G. Lasker (*pro hac vice*)
(elasker@hollingsworthllp.com)
1350 I St. NW
Washington, DC 20005
Tel: 202-898-5843
Fax: 202-682-1639

COVINGTON & BURLING LLP
Michael X. Imbroscio (*pro hac vice*)
(mimbroscio@cov.com)
One City Center
850 10th St. NW
Washington, DC 20001
Tel: 202-662-6000

Attorneys for Defendant
MONSANTO COMPANY

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IN RE: ROUNDUP PRODUCTS LIABILITY LITIGATION	MDL No. 2741
	Case No. 3:16-md-02741-VC
Hardeman v. Monsanto Co., et al., 3:16-cv-0525-VC	**MONSANTO COMPANY'S RESPONSE TO EDWIN HARDEMAN'S SUPPLEMENTAL BRIEF PURSUANT TO PTO 81**

INTRODUCTION

Plaintiff Edwin Hardeman's ("Plaintiff") supplemental brief concerning Industrial Bio-Test Labs ("IBT") misrepresents the historical record and IBT has no relevance to any of the issues in Phase 2. Contrary to Plaintiff's suggestion, the IBT fraud was not specific to

Monsanto, and there is no evidence that Monsanto was in any way complicit in that fraud. Rather, Monsanto was a victim of a widespread fraud perpetrated by IBT on dozens of manufacturers, including pharmaceutical and other pesticide producers, as well as numerous government agencies. *See* TX 504 (also available at https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=91014ULV.txt).[1] The U.S. Environmental Protection Agency ("EPA") did not revoke approval of any pesticide, the safety of many of which (including glyphosate) were supported by other, validated studies. *Id.* at 1, 3-4. Instead, EPA required manufacturers to fill any data gaps by conducting new studies. Plaintiff's attempt to blame Monsanto for IBT's misconduct is without basis.

In the 1970s, IBT was a leading provider of toxicology testing to industry and government agencies. In 1976, the U.S. Food and Drug Administration ("FDA") discovered discrepancies in some of the toxicology tests produced by IBT. *Id.* at 8. Because of this, the EPA demanded an audit of all IBT studies which were used to support pesticide registration. The EPA audit identified widespread problems involving 38 companies, 140 chemicals and 801 studies. *Id.* at 7. Monsanto repeated all of the glyphosate studies in question according to EPA guidelines, and no IBT data are currently used in support of glyphosate registration.

ARGUMENT

The evidence that Plaintiff seeks to introduce concerning IBT is not relevant to the issues in this case and would only serve to waste time and confuse the jury. Such evidence would also be unduly prejudicial against Monsanto.

Plaintiff claims that the IBT evidence is relevant to "whether Monsanto used reasonable care to prevent harm to Mr. Hardeman" and to punitive damages. *See* Edwin Hardeman's Suppl. Br. Pursuant to PTO 81 at 3, ECF No. 2813. Specifically, Plaintiff claims that the evidence shows Monsanto's "awareness of and indifference to" IBT's fraud, which he states is directly relevant to his claim of negligence. *Id.* at 3. But Monsanto was a victim of IBT's fraud, and

[1] *See also* Mark Seaton, Ph.D., *An Update on FDA's Good Laboratory Practice (GLP) for Nonclinical Laboratory Studies Proposed Rule*, SOT: Regulatory and Safety Evaluation Specialty Section Webinar, FDA, at 12 (Sept. 29, 2017), http://www.toxicology.org/groups/ss/rsess/doc/2017SOTWebinar_with_notesRSESS_Seaton.pdf.

there is no evidence that Monsanto knew of the problems with the glyphosate studies until they were discovered by the government investigation. Monsanto is no different than the dozens of other manufacturers and government agencies that were victimized by IBT's misconduct. Plaintiff further seeks to tar Monsanto with the misconduct of one of the implicated IBT scientists, David Wright, but there is no evidence that Mr. Wright engaged in any misconduct while employed by Monsanto or that he was at any time involved in any toxicology studies involving glyphosate. Nor is there any evidence that Monsanto was ever implicated in IBT's fraud.

The IBT fraud is not relevant to the Phase 2 issue of whether Roundup® is a defective product or whether it should have included a cancer warning. The relevant studies were all replaced decades ago. Monsanto at all times complied with EPA regulations and requirements in selling its Roundup® products. And EPA repeatedly has approved Roundup® and Roundup® labeling without any cancer warning, consistent with its extensive scientific reviews and determinations that glyphosate does not pose a cancer risk in humans.

Nor is evidence concerning IBT relevant to punitive damages. Plaintiff has no evidence that demonstrate that Monsanto was involved in perpetuating IBT's fraud and cannot connect IBT's fraud in the 1970s to his own much later use of Roundup® products.

Allowing a sideshow into IBT would serve no purpose but to confuse and potentially inflame the jury with facts that have nothing to do with the issues before them in this trial. Monsanto should not be required to prove its innocence in a decades-old third-party fraud – in which Monsanto was a victim – to defend the present product liability lawsuit.

Date: March 4, 2019

/s/ Eric G. Lasker

Brian L. Stekloff (*pro hac vice*)
(bstekloff@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

Pamela Yates (CA Bar No. 137440)
(Pamela.Yates@arnoldporter.com)
ARNOLD & PORTER KAYE SCHOLER
777 South Figueroa St., 44th Floor
Los Angeles, CA 90017
Tel: 213-243-4178
Fax: 213-243-4199

Eric G. Lasker (*pro hac vice*)
(elasker@hollingsworthllp.com)
HOLLINGSWORTH LLP
1350 I St. NW
Washington, DC 20005
Tel: 202-898-5843
Fax: 202-682-1639

Michael X. Imbroscio (*pro hac vice*)
(mimbroscio@cov.com)
COVINGTON & BURLING LLP
One City Center
850 10th St. NW
Washington, DC 20001
Tel: 202-662-6000

Attorneys for Defendant
MONSANTO COMPANY