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Case Number 672,2012D

IN THE SUPREME COURT OF THE STATE OF DELAWARE

WENDOLYN TUMLINSON, JAKE TUMLINSON, JILLVEH ONTIVEROS and PARIS ONTIVEROS, by her natural mother and next friend JILLVEH ONTIVEROS,	§	REDACTED PUBLIC VERSION
	§	No. 672,2012D
Plaintiffs Below, Appellants,	§	Appeal from the Superior Court of the State of Delaware in and for New Castle County
v.	§	C.A. No. 08C-07-106 FSS
ADVANCED MICRO DEVICES, INC.,	§	
Defendant Below, Appellee.	§	

ADVANCED MICRO DEVICES, INC.'S ANSWERING SUPPLEMENTAL MEMORANDUM IN ACCORDANCE WITH THE DELAWARE SUPREME COURT'S ORDER OF OCTOBER 16, 2013

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INTRODUCTION

In almost 50 pages of written opinions, the Superior Court has carefully considered the unusually extensive record in this case and concluded that both with and without the application of Texas substantive law on causation, Dr. Frazier's testimony is inadmissible. The Superior Court did not abuse its discretion.

Although the Superior Court credited Dr. Frazier's qualifications, it also observed that *Daubert* requires much more than mere credentials. Delaware courts "steadfastly guard the gates of the courtroom and demand that the science, if it is to advance, be enriched in the laboratories, hospitals, universities or other research centers where serious scientists consider such matters."[1] Dr. Frazier's causation opinions in this case fall short of this standard.[2] Dr. Frazier did not properly employ her scientific training and experience to derive her causation opinions in this case—instead, she abandoned those scientific principles at the courthouse door. Her purported meta-analysis of disparate, inapposite articles in an attempt to provide scientific grounding is contrary to valid scientific method because it lacks the scholarly discipline and rigor that scientists use in non-litigation contexts. As such, her opinions are unreliable under *Daubert*, as the Superior Court found.

Plaintiffs' "summary" of the record cites to numerous pages of their own

[1] *See Scaife v. Astrazeneca LP*, 2009 WL 1610575, at *20 (Del. Super. Ct. June 9, 2009).
[2] Superior Court Opinion of October 15, 2013 ("10/15/13 Opinion"); *see also* Superior Court Opinion of January 6, 2012.

experts' materials, the direct examination of Dr. Frazier, and a small amount of scientific literature they claim support Dr. Frazier's opinions, but fails to show—as she failed to demonstrate—that any of these items support her novel causation theory. Ultimately, their arguments falter on the erroneous premise that because Dr. Frazier relied upon peer-reviewed literature, her conclusions are themselves the equivalent of peer-reviewed.[3] As the Superior Court aptly summarized,

> Dr. Frazier . . . has not asked her peers[4] to review what she has made of those studies, not through an article, case note, correspondence, or otherwise. Instead, Dr. Frazier contends, in effect, that because her personal opinion was formed by synthesizing peer reviewed foundational studies, that is as strong as if her opinion was peer reviewed. That notion is illogical and against the scientific method itself.[5]

Plaintiffs have offered no reason to find that the Superior Court abused its discretion in so holding. In fact, their arguments underscore the rigors of Judge Silverman's analysis and the deficiencies in Dr. Frazier's opinions.

ARGUMENT AND AUTHORITIES

A review of the record, including the articles on which Plaintiffs rely, reveals that Plaintiffs are taking exceptional liberties with the evidence. As explained, the Superior Court was well within its broad discretion in excluding Dr. Frazier's purported methodology as unreliable.

First, Plaintiffs assert myriad complaints with the remand opinion, primarily

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[3] *E.g.*, *id.* at 12.

[4] The other Plaintiffs' experts in this case are not "peers" because they have only provided opinions in the context of this litigation and they in turn rely on Dr. Frazier's opinions.

[5] 10/15/13 Opinion at 19.

its discounting of the Lin male study. *Plaintiffs Below-Appellants' Opening Supplemental Memorandum* ("Supp. Mem.") at 4-5. But Plaintiffs do not dispute that every fact and quotation that Judge Silverman took from the Lin study was accurately reflected in his Opinions—and Dr. Frazier conceded as much during cross examination or in questioning by Judge Silverman. Plaintiffs' disagreement with his analysis fails to demonstrate an abuse of discretion.

The Superior Court was correct in concluding that there is no evidence of comparable exposure levels between the Taiwanese factories studied by Lin and the U.S. fabs at issue. As the Lin researchers stated in their peer-reviewed study:

- "[T]here is ***little information on the exact chemicals*** applied in the manufacturing processes."
- "One of the important limitations of our study was the ***lack of adequate exposure measurements of ambient chemicals in the workplace, as we experienced considerable difficulty in carrying out the critical exposure assessments***."
- "There was ***no information on cumulative dose of specific solvent exposure*** in any of these studies."

A1036; A1039; A1446 (emphasis added to each). Indeed, the Lin scientists cautioned that conclusions like the ones Dr. Frazier makes here are unwarranted: "[t]he possible etiological basis needs to be corroborated in further research." A1036. Plaintiffs simply ignore the Lin researchers' statements and point instead to a non-peer-reviewed affidavit from another of their retained experts—prepared solely for this litigation—which they characterize as "confirming substantial

similarity of exposure." Supp. Mem. at 4-5 (citing A1530-37). Dr. Stewart's affidavit does no such thing. Instead of providing scientific measurements or objective quantifications of exposure, he hypothesized that because the Taiwanese fabs were subcontracting with U.S. companies, "***it seems reasonable to expect*** that the Taiwanese semiconductor companies would have to have cleanrooms/fabs that were similar enough to compete and win these contracts." A1534 (emphasis added). He then concluded that "there is ***no scientific basis*** for concluding that Taiwan semiconductor fabs are ***meaningfully different***, *i.e.*, have higher exposure levels (or lower), use different process steps or use different chemicals than the European and United States based semiconductor industry in a given timeframe." A1536 (emphasis added); *see also* A1530. His after-the-fact,[6] double-negative comment does not establish that the U.S. and Taiwanese environments are similar—nor does it refute the contrary statements the Lin researchers published. The Superior Court was well within its discretion to credit the published studies instead of the litigation-driven conjecture of Dr. Stewart.

Plaintiffs claim that Lin understated the odds ratio for heart anomalies by including only mortality figures. Supp. Mem. at 5. But they fail to mention that the Lin researchers had no way to determine: (i) the number of children in the

[6] In fact, Dr. Stewart's 2006 contact with the Lin researchers significantly post-dated the Lin 1980-1994 study period. *See* A1536; *see also* A1037. His affidavit post-dated the *Daubert* hearing. A1530.

control group with birth defects; (ii) background rates for congenital anomalies in the general Taiwanese population; or (iii) any basis for correlating mortality rates to birth defect rates for the children of semiconductor workers. A1037.[7]

Further, the Lin male study was completely inapplicable to Tumlinson and in fact, the Lin study of ***female*** workers concluded that there was ***no*** causal relationship, B128, which Dr. Frazier candidly admitted and failed to adequately explain. *Defendant Below, Appellee's Answering Brief* ("AMD Answering Br.") at part II.C.2.(c)(ii). Plaintiffs cannot rely on the Lin male study as the linchpin of their allegations regarding Ontiveros, while simultaneously failing to address the contrary conclusions reached by the Lin female study.

Second, the Superior Court was correct that the Plaintiffs' exposures were not quantified in any way that could impact the causation analysis. *See* AMD Answering Br. at part II.C.2.(c)(i). Plaintiffs' record cites do not establish exposure or dose levels of the parent Plaintiffs, much less correlate those levels to any particular scientific studies (many of which admit to lacking dose measurements). While "precise quantification is not always possible or required," Supp. Mem. at 5, reliably grounded causation opinions require at least identification of the purported causative chemical and a concrete, non-theoretical

[7] The Lin researchers did not and could not calculate an odds ratio for the relevant inquiry here, *i.e.*, the risk of bearing a child with a birth defect, because the National Birth Defects registration system in Taiwan did not begin until 1998—four years after the Lin working period studied. A1045. Dr. Frazier's assumptions cannot substitute for this unavailable data.

quantification of dose. Here, Dr. Frazier provided neither. *See, e.g.*, A1399; A1403-1404. Not knowing the chemical supposedly implicated, it is impossible to correlate a dose, or even identify the relevant literature.

Instead of citing to reported measurements, Plaintiffs can only point the Court to swaths of Dr. Frazier's written materials that speculate about how particular chemicals ***may*** have been absorbed or inhaled. And Drs. Stewart and Reynolds' calculations are not only completely contrary to each other, but also to Dr. Frazier's unsupported assumption that exposures would be consistent across all semiconductor companies, in all countries, at all fabs, all work areas within the fabs, and all types of workers at all times in history. A1400 (testifying that "the proportion of chemicals in the mixture" was the same for Mrs. Tumlinson and Mr. Ontiveros). Other scientists have refused to equate semiconductor environments: "The use of statistical models to examine personal exposure determinants in the semiconductor industry was hampered by the number of chemical mixtures in use across the industry and the variety of tasks performed by a single worker." Woskie 2000 (B148);[8] *see also* B127. It cannot be said all fabs are similar; exposure ranges vary greatly for different workers performing the same job. B153 (Table IV showing range of differing exposure levels for coater operators at three fabs).

Third, Plaintiffs misstate the Superior Court's statements regarding vapor

[8] Five exhibits that were submitted to the Superior Court in connection with AMD's motion to exclude Dr. Frazier and reply brief are submitted as a Supplemental Appendix (B142-B192).

concentrations and dermal exposure and take them out of context. The Superior Court did not hold that vapor concentrations or dermal exposure could never be considered. Instead, it listed a number of disconnects in Dr. Frazier's exposure analysis, including her assumption that the "dosages must be higher due to peak exposure episodes and dermal absorption." 10/15/13 Opinion at 18. Other than to state the obvious that peak and dermal exposures might occur, Plaintiffs fail to show that Judge Silverman abused his discretion.

Fourth, the Superior Court was correct in questioning the reliability of Dr. Frazier's opinions because they were created solely for litigation and have never been put to peer review. *See Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1317, 1320 (9th Cir. 1995) (*Daubert II*). That her co-experts signed off on her analysis—again solely in the context of this litigation—adds no further reliability. Nor did their individual publications set out this particular causation theory. And the Superior Court fully explained why it discounted the "extensive peer-reviewed literature as to reproductive toxicity of clean room exposures," Supp. Mem. at 6-7, because those materials related to different end points—spontaneous abortion and fertility—not birth defects. 10/15/13 Opinion at 24-25.

Plaintiffs misrepresent the findings of the Johns Hopkins University ("JHU") researchers who conducted the IBM studies by claiming they "did not look for" birth defects and "the data reveals that birth defects at IBM were elevated," Supp.

Mem. at 7 n.6. On the very page of the study Plaintiffs cite, the JHU authors observed "no adverse effects" on "birth weight, prematurity, ***birth defects***, or childhood neoplasms." A898 (emphasis added); *see also* A899 (same). Plaintiffs also reference a chart from their Joint Affidavit based on a re-analysis of data from the JHU study—conducted without peer review and solely for purposes of this litigation (A1360)—in connection with two conditions (Wilms tumor and Hirschsprung's disease) that Dr. Frazier has conceded these children ***did not have***. A1358-59. Plaintiffs also ignore the final reports in two semiconductor industry studies, confirming that the frequency of birth defects in pregnancies of female workers ***were within the expected rate*** of 1-4% for the unexposed population. A1436; *see also* Pastides 1988 at 547 (finding only "minor differences" in birth defect incidence between the study and control populations) (B161).

Fifth, contrary to Plaintiffs' suggestion, the Superior Court actually "accept[ed] that dose-response is a legitimate scientific and pharmacological concept." 10/15/13 Opinion at 25.[9] But Dr. Frazier never supported her opinion that, with respect to any so-called causation chemical, human birth defects were on a dose-response relationship with spontaneous abortion based on anything more than her own view. When Dr. Frazier was later questioned about the scientific

[9] As explained in AMD's prior brief to this Court, Dr. Frazier improperly extrapolated from studies involving semiconductor workers and spontaneous abortion and other fertility issues. *See* AMD Answering Br. at part II.C.2.(c)(viii).

basis for her assumption at the hearing, she could only point to the standard textbook Patty's Toxicology, A1353, which she admitted says nothing about a dose-response curve for any particular chemical, A1354.

Sixth, the Superior Court never suggested that there must be a general consensus that chemicals were toxic to have an admissible expert opinion or that only signature injuries count.[10] What it said—and rightly so—was that "as the established scientific proof for causation decreases [such as in the case of novel, non-peer-reviewed theories and non-signature injuries], an expert's methodology for forming her opinion must be increasingly detailed." 10/15/13 Opinion at 10. Dr. Frazier never provided specific detail needed to support a reliable opinion that the semiconductor chemicals used in the AMD fabs are capable of causing birth defects like the ones at issue here. In fact, despite decades of study of the semiconductor industry, ***no scientist*** has concluded that semiconductor fab exposures cause human birth defects—except for Plaintiffs' causation experts whose opinions have been formed in and expressed solely for this tort litigation. *See Eskin v. Carden*, 842 A.2d 1222, 1228 (Del. 2004) (gatekeeper judge must determine whether expert is offering a sufficiently informed and scientifically substantiated opinion that can be tested and is "verifiable on an issue to be determined at trial"). As the Superior Court aptly summarized, "[u]nder Delaware

[10] General acceptance of a theory or technique remains one of the factors that can be considered under a *Daubert* analysis. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 591-94 (1993).

precedents alone, none admits an opinion including as many untested extensions of published studies as Dr. Frazier's here." 10/15/14 Opinion at 10; *see also Minner v. Am. Mortg. & Guar. Co.*, 791 A.2d 826, 843 (Del. Super. Ct. 2000) ("The polestar must always be scientific or other validity and the evidentiary relevance and reliability of the principles that underlie a proposed submission.").

Seventh, Plaintiffs are simply wrong when they intimate that the sheer volume of materials submitted by Dr. Frazier somehow fills the gap. Throughout the four-day evidentiary hearing, both the Superior Court and AMD's counsel repeatedly probed the basis for Dr. Frazier's assumptions, which that court ultimately and properly concluded was lacking. For example, Dr. Frazier principally relied on Cordier 1997 (A1054) for her analysis of [redacted] maternal-mediated birth defects, claiming that Cordier reflected outcomes that were similar to the injuries alleged by the Tumlinson plaintiffs. A1385. Yet, Dr. Frazier ignored that Cordier, who examined occupations logically involving exposures exceeding anything in the semiconductor industry (cleaners, leather work, ceramics, and plastics manufacturing), concluded that there were no excesses of birth defects for working women. A1060 (Table VI); *see also* Maldonado (B181) ("Current evidence [including Cordier] is insufficient"). And Dr. Frazier admitted that she could not provide the dose of 2-EEA in the study subjects, A1408, so she could not possibly correlate the doses of any Cordier study

subject to any workplace exposure of Mrs. Tumlinson. Even more remarkable, Dr. Frazier ultimately admitted that only one person in the study population—of 991 cases and 1144 controls—worked with the four glycol ethers included in her 10 "causation chemicals." A1408-09; B172-73. The other participants provide no basis for extrapolation, despite her assumption to the contrary.[11]

Although Plaintiffs do cite voluminous pages of the record, their inability—like that of their expert—to provide the Court with specific record cites and a comprehensible roadmap effectively proves the Superior Court's point.

Eighth, Plaintiffs ignore the Superior Court's own opinion in asserting that it considered diagnostic "labels" instead of individual conditions in its analysis. The court listed all of the congenital anomalies for each child and made clear that it was using the term [redacted] "only for expedience." 10/15/13 Opinion at 2.

The Superior Court also examined all of the studies cited by Plaintiffs and determined that the purported associations were lacking an appropriate fit or were otherwise unsupportive of a causal finding—usually because Dr. Frazier could not show a correlative dose or relevant end point. *See* 10/15/13 Opinion at 24-28.

Ninth, Plaintiffs argue that the Superior Court "questions Dr. Frazier's explanation that cleanroom exposures produce multiple adverse outcomes." Supp.

[11] In their latest brief, Plaintiffs do not cite Khattak, which is even more unavailing, as Khattak examined occupations unrelated to semiconductor work (*e.g.*, lab technician, funeral home service, veterinary technician), and there is no reported measure of the widely varying exposure levels for the diverse workers involved in that study. A1274, A1276 & Table 1.

Mem. at 9. After setting up that straw man, they proceed to knock it down, asserting that some chemicals are "well known" to cause multiple diseases or conditions. *Id.* It is not entirely clear what they are challenging, as they yet again fail to cite to the Opinion itself. AMD suspects that Plaintiffs take issue with Judge Silverman's observation that Dr. Frazier "opines that somehow this nondescript exposure caused two substantially different birth defects ***with little attempt to explain the differences***." 10/15/13 Opinion at 18 (emphasis added). The Superior Court was merely pointing out the implausibility of Dr. Frazier's theory that an unspecified mix of chemicals would have caused such disparate birth defects in offspring of parents of different genders—especially in the absence of any published study promoting an analogous theory of causation.

Tenth, the Superior Court did ***not*** reject the animal and other data simply because they are not epidemiological studies. It considered them in proper context:

> Due to the expansive potential sources of data for those analyses, establishing 'fit' for each source is especially important when considering the source's reliability as part of a meta-analysis. That applies in spades here, where the data comes from Taiwanese Fab workers, Dutch house painters, electronics workers, the animal kingdom, and so on.

10/15/13 Opinion at 23. Dr. Frazier never demonstrated that the animals in the studies she referenced received equivalent doses to the working parents here. To the contrary, as to Mr. Ontiveros, she acknowledged that "[t]here are laboratory animal studies that are not directly applicable on a parts million basis which show

cardiac defects." A1411. And as to Mrs. Tumlinson, Dr. Frazier pointed to the Sleet study in which 500 milligrams of a glycol ether was injected into the tail vein of a rat (a very large dose that was intended to induce birth defects, A1413), which, of course, did not happen to Mrs. Tumlinson. A1412. Even more to the point, Dr. Frazier admitted that she never attempted to calculate a human equivalent dose, *id.*, much less correlate it to the purported exposure of Mrs. Tumlinson.

Dr. Frazier also relied on a study involving pregnant rats exposed to various levels of EGME (also known as 2ME)—a chemical that Mr. Ontiveros did not handle or apply. A868; A1505. Out of 283 rat fetuses, only one had [redacted], which is a spontaneous event lacking a dose-response effect. Hanley 1984 (B188). This single rat fetus born to a pregnant, female rat exposed to EGME at levels far beyond those estimated for any AMD employee cannot support a conclusion that a human male's exposure to a "toxic soup" causes [redacted] in humans. *See, e.g.*, *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 144-45 (1997) (finding no abuse of discretion in rejecting experts' reliance on animal studies where experts failed to explain how and why it was permissible to "extrapolate their opinions from these seemingly far-removed animal studies" involving massive doses of PCBs injected directly into the animals); *see also* Maldonado (B181) ("The many animal studies are also insufficient for answering the question of a relationship between glycol ethers and human congenital malformations . . . .).

Eleventh, although Plaintiffs complain that Judge Silverman questioned Dr. Frazier's explanation for disregarding other causative agents, they do not attempt to justify her dismissal of alternative explanations—including idiosyncratic presentation. No one, including the Superior Court, questions that certain diseases can have multiple different causes. But both of the children's conditions at issue in this *Daubert* challenge have a background incidence, meaning that they can occur in the absence of exposure to any chemical, making it incumbent for Dr. Frazier to rule out other possible causes with reasonable certainty. She did not do so. Instead, she ignored well-designed studies of large populations indicating that maternal obesity—in the absence of diabetes—can cause birth defects, like [redacted]. A775; A1451-52. And for her "chemical insult" theory, she relies on studies involving Adriamycin, (a chemotherapy agent known to induce [redacted], but one that Mrs. Tumlinson was never exposed to), *see*, A777-78—though she could not "identify any chemical used at AMD that is known to specifically induce [redacted]." A1411.

Twelfth, Plaintiffs assert that, because the Superior Court accepted Dr. Frazier as qualified to interpret scientific literature, it was then duty-bound to accept her views. They cite no authority for this *ipse dixit* argument, as it is contrary to *Daubert's* gatekeeping principles.

Thirteenth, the Superior Court does in fact identify and analyze a number of analytical gaps in Dr. Frazier's causation opinions—both in its prior *Daubert* opinion and this one.[12] Plaintiffs are the ones who need to demonstrate error in those findings, and their indiscriminate attacks fail to bridge the copious gaps.

Finally, AMD has previously briefed the issues of relevancy under *Daubert* and the role of Texas substantive causation law at this stage and will not restate that argument here, as it exceeds the scope of the remand decision. What is clear is that Dr. Frazier's general and specific causation opinions are deficient under both the reliability and relevance prongs of *Daubert*, and Plaintiffs have failed to show that the Superior Court abused its discretion in so finding. On either basis, AMD respectfully requests that the Superior Court's opinions be affirmed in full.

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[12] Plaintiffs repeatedly challenge the Superior Court's description of the Sung study as not providing odds ratios. *E.g.*, Supp. Mem. at 11 n.9. Sung involves an entirely different industry—electronics—in Taiwan, and as AMD has previously pointed out, Sung, like the Lin studies, relied on official Taiwanese death registries, not live births, and thus had no data from which to calculate a relative risks for birth defects in the children of electronics workers as compared to the general population. A1447.

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Dated: October 30, 2013

CERTIFICATE OF SERVICE

I hereby certify that on this 14th day of November, 2013, a true and correct copy of the foregoing was filed and served via File & Serve Xpress on all counsel of record.

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