EFiled: Nov 06 2013 05:08PM EST Filing ID 54512343
Case Number 672,2012D

## IN THE SUPREME COURT OF THE STATE OF DELAWARE

WENDOLYN TUMLINSON, JAKE ALBERT	)
TUMLINSON, JILLVEH ONTIVEROS and	) No.: 672,2012D
PARIS ONTIVEROS by her mother and next friend	)
JILLVEH ONTIVEROS,	)
Plaintiffs Below, Appellants,	<ul><li>) Appeal from the Superior Court</li><li>) of the State of Delaware in and for</li><li>) New Castle County</li></ul>
-VS	)
ADVANCED MICRO DEVICES, INC.,	) C.A. No. 08C-07-106 FSS )
Defendant Below, Appellee.	)

# PLAINTIFFS BELOW-APPELLANTS' REPLY SUPPLEMENTAL MEMORANDUM IN ACCORDANCE WITH THE DELAWARE SUPREME COURT'S ORDER OF OCTOBER 16, 2013

Date: November 6, 2013

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AMD's Supplemental Memorandum ("DM") is deficient in legal analysis, fails to engage with the full record, distorts those few proofs it does mention, and illustrates the injustice that will occur should this Court affirm.

First, AMD ignores settled *Daubert* jurisprudence that appellate courts conduct *de novo* review to determine whether a motion court has followed *Daubert's* analytical framework, and then conduct an abuse of discretion review to ascertain whether it performed careful and thorough reliability analysis. *See Schultz v. Akzo Nobel Paints LLC*, 721 F.3d 426, 430-31 (7th Cir. 2013) ("Schultz") ("we review *de novo* whether a district court properly followed the framework for determining admissibility of expert testimony"). Invoking a motion courts' discretion under *Daubert* as if it were unbridled license, AMD and the remand court ignore the limited scope of a *Daubert* analysis, and the court abused the discretion that does exist. Appellate courts have not hesitated to reverse decisions that step over those lines.<sup>1</sup>

The following are among the most inaccurate statements contained in the DM:

<sup>&</sup>lt;sup>1</sup> See, e.g., Schultz, (reinstating causation expert noting trial courts must not judge credibility); Milward v. Acuity Specialty Prods. Group, 639 F.3d 11 (1st Cir. 2011) (reversing exclusion of toxicologist's weight of the evidence proof); Hardyman v. Norfolk & W. Ry. Co., 243 F.3d 255 (6th Cir. 2001) (reversing exclusion of differential diagnosis causation proof); Smith v. Ford Motor Co., 215 F.3d 713 (7th Cir. 2000) (reversing exclusion for lack of peer review); Kennedy v. Collagen Corp., 161 F.3d 1226 (9th Cir. 1998) (reversing exclusion for placing excessive emphasis on lack of epidemiological studies where studies would be nearly impossible to perform); Baker v. Dalkon Shield Claimants Trust, 156 F.3d 248 (1st Cir. 1998) (reversing exclusion of differential diagnosis proof of causation).

- 1. Frazier's causation theory is "novel." (p.2) In fact, Dr. Frazier presented no less than 129 peer-reviewed articles (A.740-816), which considered, investigated and made positive findings respecting the theory that chemical exposures of the type encountered in the semiconductor industry cause reproductive harm including birth defects. She also produced scores of peer-reviewed articles which demonstrated that the specific chemicals at issue cause birth defects (A.488-506). AMD and the motion court's claim of "novelty" is flatly inaccurate;
- 2. Plaintiffs' other experts rely on Frazier (p.2, n.4). Plaintiffs' experts each conducted his own independent analysis of the data, was deposed, and reached conclusions agreeing with Frazier (e.g., A. 816-66, 476, 553-64).
- 3. The motion court's analysis was "rigorous" (p.2). To the contrary the decision is long on rhetoric and conclusory assertions. It discusses only *four* from among hundreds of peer-reviewed studies upon which Frazier relied.<sup>2</sup> It is filled with conclusory, unsubstantiated, and false conclusions (*e.g.*, "novelty," "gaps too wide," "matter of first impression," "circular logic"). These are inadequate substitutes for rigorous engagement with proofs that *Daubert* and basic justice demand. *See Schultz*, 721 F.3d at 432 (trial court "must provide more than just conclusory statements about admissibility to show that it properly performed its gatekeeping function").
- 4. Plaintiffs' exposures were not quantified (p.5). Dr. Stewart (A.953-1035), and Scott Reynolds (A.1063-1094) both modeled and quantified exposures. AMD's own contemporaneous monitoring was also available to Dr. Frazier (e.g., A.749-51, 756, 792-98).
- 5. The dose-response relationship between spontaneous abortion and birth defects was based solely on Frazier's "own view" (p.8). In fact, multiple peer-reviewed studies addressing this consensus were provided (A.1234-78).

These are but examples of the liberties with the record infecting AMD's papers and the remand decision. Simply put, an extraordinary failure to engage

<sup>&</sup>lt;sup>2</sup> These studies are: Lin (op. at 25, 28); Sung (op. at 25) Hooiveld (op. at 24) and JHU/IBM (*id.*). Lin aside, the court's erroneous analysis of these three additional studies were presented to this Court. *See* Opening Brief at 6, 9-11, 14, 33-34; Reply Brief at 17-18, and also extensively addressed in the proceedings below, without any expert rebuttal from AMD.

with the record occurred.

Further illustration of the abuse of discretion below and the impropriety of AMD's tactic of proceeding without experts is evidenced by the supplemental appendix and two new studies AMD now references, Maldonado and Wooskie (DM at 6.10). These two outlier studies respecting the semiconductor industry are contradicted by myriad others, including those conducted by the industry itself reaching contrary conclusions (e.g., A.509-50, 627-53, 672-83). Importantly, the motion court never once mentions these studies, let alone explains whether or why it credits them and ignores many others. No scientist for AMD ever told the court that these studies were well done. Yet AMD is asking this Court to infer that somehow the motion court both read and relied upon these studies, and also that it found them so compelling that it might disregard numerous contrary studies. The motion court's failure to engage with the actual record cannot be cured by AMD. This constitutes a failure to follow *Daubert* and is a clear abuse of discretion.

The Lin study has become a focus of the parties' advocacy. Taken at full value, Lin alone destroys the motion court's analysis. Its findings strongly validate the theory that semiconductor exposures cause heart defects in the offspring of male workers. The fit is as near perfect as is likely to ever be encountered: a) same

<sup>&</sup>lt;sup>3</sup> After all AMD offers no expert to justify a rejection of Lin. Plaintiffs' experts insist it is compelling (e.g., A.673-676). Motion courts lack discretion to discredit validated relevant studies. *Schultz*, 721 F. 3d at 433 ("Rule 702 did not require or even permit the district court to choose between studies.").

industry, b) male workers, c) same disease (heart anomalies), d) more than fourfold increase in incidence, e) statistical significance, f) same exposures, g) same time period, h) peer-reviewed. It is difficult to imagine what more is required.

AMD goes to lengths to suggest that Lin is unpersuasive, as does the motion court. In the process, they disregard this Court's instruction that cross-examination and contrary testimony, not preclusion, is the proper way to make that attempt.<sup>4</sup> Moreover, the specific criticisms of Lin are themselves contrived:

- AMD incorrectly claims that Lin and Plaintiffs provide no evidence of comparable exposures to those experienced by Plaintiffs (p.3). In reality, Lin says they experienced "difficulty in carrying out critical exposure assessments" (A.1039) not that they were unable to do so.
- Indeed, Dr. Stewart was a technical consultant to Lin (A.1530-1537), and not an after-the-fact litigation expert as AMD falsely implies (p.4). He was precisely among those who assisted Lin in surmounting the difficulty, by determining that the Taiwanese facilities being studied were substantially similar to American facilities like AMD's.
- Accordingly, Dr. Stewart's opinions on similarity were not conjecture, unconfirmed hypothesis, or litigation driven as AMD posits (p.4). They are conclusions drawn, as part of a peer-reviewed international collaboration of Chinese and United States scientists, for scientific purposes<sup>5</sup> (A.1530-37).
- Further, Frazier explained that the peer-review process concerned itself with the question of similarity, and would have noted dissimilarities between Lin and the industry had there been any (A. 1368-69).
- AMD complains that a different Lin study of female workers produced

<sup>&</sup>lt;sup>4</sup> Tumlinson v. AMD Inc., 2013 Del. LEXIS 399, 17-18 n.52 (Del. Aug. 16, 2013).

<sup>&</sup>lt;sup>5</sup> AMD falsely suggests that Stewart's involvement with Lin post-dates the study. Dr. Stewart consulted with Lin in 2006 (A.1530). The Lin study was published in 2008 (A.1036). The motion court's disregard of this proof was an abuse of discretion.

different results (p.5). This is irrelevant. Female workers, being subjected to miscarriage and stillbirth would be expected to present a distinguishable circumstance. Here too, AMD capitalizes on the fact that it has no experts, who would never endorse its counsel's statements.

• AMD suggests that there were gaps in the data Lin possessed (p.5, n.7). Even if true (and it is not), this is irrelevant. Ample data existed to permit the analysis, pass peer-review, and make reliable findings. The rest is for cross-examination.

AMD incorrectly suggests Frazier has conducted a "meta analysis" (p.1). Meta-analysis is a term of art concerning a type of epidemiological study, distinct from the weight-of-the-evidence, Bradford-Hill evaluation performed. Here too, unencumbered by experts, AMD makes false *ipse dixit* claims by counsel.

Similarly, AMD's praise of the remand court's rigor and attention to detail (p. 1) rings hollow. The remand decision contains numerous scientific and legal assertions without support in the record or the case law. These include asserting that: a) Frazier applies a novel dose-response analysis respecting spontaneous abortion and birth defects (op. 4, *but see*, A.1270-87); b) Frazier is merely an epidemiologist (op. 7, *but see*, A.556-60, documenting her clinical expertise as an occupational medicine physician); c) the JHU/IBM did not find birth defects; d

<sup>&</sup>lt;sup>6</sup> In fact, as Frazier and colleagues explain, the actual data of the JHU/IBM study shows an appalling increase in kidney disease and a neural tube defect (Hirschprung's Disease) among semiconductor offspring, and a three fold increase in birth defects generally (A. 550, 680-681). Jake suffers from both kidney disease and neural tube defect. Thus, the motion court is incorrect in disregarding Frazier's analysis of the data. Instead, it seizes upon "dicta" in the JHU study that excess of birth defects were not observed (A. 899), while ignoring both the data to the contrary, and the JHU/IBM authors' explanation that they did not design the study to look for birth defects

this case is a matter of first impression in Delaware (op. 7, but see, authorities cited Plaintiffs' Opening Brief pp.19-26, Reply Brief pp.7-9, Opening Supplemental Memorandum pp.11-13); e) the necessary detail for a causation opinion increases as established proof of same decreases (op. 10), which is certainly not derived from case law or science; f) Texas case law, Havner and Garza, which depart from Daubert, should be revisited (op. 11) even though this Court asked for a Delaware Daubert analysis only; g) "results requiring a 95% confidence level is appropriate" (op. 14). First, Daubert courts (unlike Texas) have rejected a statistical significance rule, e.g., Matrixx Initiatives Inc. v. Siracusano, 131 S.Ct. 1309, 1312 (2011). Next, the remand court misconstrues the science, further demonstrating inattention to the record. Confidence intervals must have a lower boundary exceeding 1, and p-values must be at .05 to be statistically significant with a 95% likelihood of being non-random (A. 576-77). The motion court confuses the two concepts; h) "specificity speaks to the first and third *Daubert* criteria" (op. 16). This confusing statement has no support in either science or law. The proof before the Court on specificity in science was unequivocal that epidemiologists reject or discount it as a criterion (A. 569, 1375, 1384, 1456). The first and third criteria in Daubert concern whether a technique can be tested (which is true of epidemiologic studies), and whether a technique has a known error rate (which is also true). Here,

<sup>(</sup>A.898, 900). Thus the motion court again abused its discretion in its limited analysis of this study.

the remand court takes leave of *Daubert* altogether; i) Frazier's opinion is untestable for *Daubert* purposes (op. 19). To the contrary, the record is filled with investigations testing whether occupational exposures in this industry cause birth defects (*e.g.*, the Lin study, *see also* A. 713-716 [specifically addressing testability]). Again, the remand court ignores the record and makes statements that are unsupported and incorrect; j) "even the most widely accepted and strongest epidemiology is not a litmus test for toxic tort causation" (op. at 21, citing *Havner*). No *Daubert* court has ever said anything of the sort; and k) Frazier did not explain how she arrived at her opinions. (op. 21). Four days of testimony and hundreds of pages of affidavits, supported by thousands of pages of studies, constitute an adequate explanation by any imaginable standard.

At bottom, the motion court's hostility to Plaintiffs' claims cannot be ignored. Constrained to acknowledge Frazier as "impressive" and qualified in several fields (op. 30, initial op. p.11) it unfairly dismisses that expertise as of no moment (op. 15), and more unfairly, intemperately denigrates her as a scientist (e.g., op. passim). Conclusory and meaningless characterizations dismissing Frazier's data as coming from "Taiwanese Fab workers, Dutch house painters, electronics workers, the animal kingdom, and so on" (op. at 23) demonstrates an attitude in conflict with the proper role of a *Daubert* tribunal.

The remand court goes so far as to acknowledge "cause for [Frazier's] concern about the potential reproductive health effects for men and women working in computer chip manufacturing facilities" (op. at 30-31). It concedes that Lin "links male workers with, potentially, one of Paris Ontiveros's several birth defects" (op. at 31), referring to Paris's heart anomalies, her primary devastating injury.

The remand decision is a miscarriage of justice to gravely injured children who deserve their day in court. This Court should not endorse the motion court's rush to judgment, disregard of settled *Daubert* jurisprudence, disregard of the record, failure to provide a proper analysis on reliability, reliance on inapposite Texas authority, and penchant for asserting unsupported legal and scientific propositions. Endorsement of the numerous errors committed below would have adverse and unjust consequences for the citizens of Delaware.

Appellants respectfully submit that the judgment of the motion court should be reversed and remanded for further proceedings.

Date: November 6, 2013

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