



THE SUPREME COURT OF THE STATE OF DELAWARE

WENDOLYN TUMLINSON, JAKE TUMLINSON,	§	No: 672,2012D
JILLVEH ONTIVEROS and PARIS	§	
ONTIVEROS, by her natural mother and	§	
next friend JILLVEH ONTIVEROS,	§	APPEAL FROM THE SUPERIOR
	§	COURT OF THE STATE OF
Plaintiffs Below,	§	DELAWARE IN AND FOR NEW
Appellants,	§	CASTLE COUNTY
	§	
v.	§	C.A. No.: 08C-07-106-FSS
	§	
ADVANCED MICRO DEVICES, INC.,	§	PUBLIC VERSION
	§	FILED: April 3, 2013
Defendant Below,	§	
Appellee.	§	

DEFENDANT BELOW, APPELLEE'S CORRECTED ANSWERING BRIEF

OF COUNSEL:

FULBRIGHT & JAWORSKI L.L.P.
Stephen C. Dillard
Fulbright Tower
1301 McKinney, Suite 5100
Houston, Texas 77010-3095
Tel: (713) 651-5507
Fax: (713) 651-5246
sdillard@fulbright.com

Stacey A. Martinez
Marcy Hogan Greer
98 San Jacinto Blvd., Suite 1100
Austin, Texas 78701-4255
Tel. (512) 536-5260
Fax. (512) 536-4598
smartinez@fulbright.com
mgreer@fulbright.com

Lisa Horvath Shub
300 Convent St., Ste. 2200
San Antonio, Texas 78205-3792
Tel. (210) 224-5575
Fax (210) 270-7205
lshub@fulbright.com

RICHARDS, LAYTON & FINGER, P.A.
Frederick L. Cottrell III (#2555)
Anne Shea Gaza (#4093)
Elizabeth R. He (#5345)
One Rodney Square
920 North King Street
Wilmington, Delaware 19801
(302) 651-7700
Cottrell@rlf.com
Gaza@rlf.com
He@rlf.com

Attorneys For Defendant,
Appellee Advanced Micro Devices,
Inc.

Dated: April 2, 2013

TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	iv
NATURE OF PROCEEDINGS	1
SUMMARY OF ARGUMENT	2
STATEMENT OF FACTS	5
A. The Manufacture of Semiconductors	5
B. The Tumlinson Plaintiffs	5
C. The Ontiveros Plaintiffs	6
D. Differences Between the Plaintiffs	7
E. Dr. Frazier's Opinions	8
ARGUMENT	10
I. The Superior Court Properly Applied Texas Substantive Law	10
A. Question Presented	10
B. Scope of Review	10
C. Merits of Argument	10
1. Texas Has the Most Significant Relationship to These Claims.....	10
2. The Superior Court Properly Respected the Roles of Daubert and Havner.....	12
(a) Delaware rules provide that only reliable and relevant expert opinions are admissible	12
(b) The substantive requirements of Havner determine what is relevant for purposes of Daubert	13
II. Dr. Frazier's Causation Opinions Were Properly Excluded	17
A. Question Presented	17
B. Scope of Review	17
C. Merits of Argument	17
1. To Be Relevant, the Expert Opinion Must Satisfy Havner.....	17
2. Plaintiffs' Proof Does Not Satisfy Havner or Daubert.....	19
(a) Dr. Frazier's methodology is not supported	19

TABLE OF CONTENTS
(continued)

	Page
(i) "Weight of the evidence" is not a substitute for reliable proof....	19
(ii) Differential diagnosis cannot be used to establish general causation.....	20
(b) The Superior Court properly interpreted Havner	21
(c) Plaintiffs' challenges to the Daubert Opinion are unfounded	22
(i) Correlated exposure levels were entirely lacking.....	22
(ii) The Lin study was fully considered and properly discounted.....	25
(iii) Sung involved very different workers, conditions, and exposures.....	27
(iv) The Superior Court did not ignore relevant studies.....	28
(v) Dr. Frazier had no principled basis for ruling REDACTED REDACTED as a cause of REDACTED REDACTED injuries.....	29
(vi) Studies involving exposures to chemicals in the same family are not probative.....	30
(vii) The reference to "federally approved clean rooms" had no impact on legal analysis.....	31
(viii) Dr. Frazier's extrapolation from the semiconductor studies lacks a sufficiently reliable scientific foundation.....	31
(ix) The Superior Court did consider Plaintiffs' reports as to independent exposures.....	32
(d) Plaintiffs Lack One, Much Less Two, Competent Studies	33
3. Defense Experts Were Not Necessary to Cross-Examine Dr. Frazier.....	34

TABLE OF CONTENTS
(continued)

	Page
III. Dr. Frazier's Opinions Regarding Purported Misconduct Were Neither Admissible Nor Material	35
A. Question Presented	35
B. Scope of Review	35
C. Merits of Argument	35
CONCLUSION	35

TABLE OF AUTHORITIES

	Page(s)
CASES	
<i>Alderman v. Clean Earth</i> , 2007 WL 1334565 (Del. Super. Ct. Apr. 30, 2007), <i>aff'd</i> , 954 A.2d 909 (Del. 2008)	34
<i>Allen v. Pa. Eng'g Corp.</i> , 102 F.3d 194 (5th Cir. 1996)	20
<i>Borg-Warner Corp. v. Flores</i> , 232 S.W.3d 765 (Tex. 2007)	18
<i>Burroughs Wellcome Co. v. Crye</i> , 907 S.W.2d 497 (Tex. 1995)	17
<i>Caraker v. Sandoz Pharms. Corp.</i> , 188 F. Supp. 2d 1026 (S.D. Ill. 2001)	20
<i>Chaplake Holdings, Ltd. v. Chrysler Corp.</i> , 766 A. 2d 1 (Del. Super. Ct. 2001)	14
<i>City of San Antonio v. Pollock</i> , 284 S.W.3d 809 (Tex. 2009)	18, 19
<i>Clinton v. Enterprise Rent-A-Car Co.</i> , 977 A.2d 892 (Del. 2009)	10, 35
<i>Coastal Tankships, U.S.A., Inc. v. Anderson</i> , 87 S.W.3d 591 (Tex. App.—Houston [1st Dist.] 2002, <i>pet.</i> <i>denied</i>)	20
<i>Daubert v. Merrell Dow Pharms., Inc.</i> , 509 U.S. 579 (1993)	<i>passim</i>
<i>Gen. Elec. Co. v. Joiner</i> , 522 U.S. 136 (1997)	12, 15
<i>Estate of George v. Vt. League of Cities & Towns</i> , 993 A.2d 367 (Vt. 2010)	20
<i>Hollander v. Sandoz Pharms. Corp.</i> , 289 F.3d 1193 (10th Cir. 2002)	20
<i>Knight v. Kirby Inland Marine, Inc.</i> , 482 F.3d 347 (5th Cir. 2007)	30
<i>Lee v. Choice Hotels Int'l Inc.</i> , 2006 WL 1148737 (Del. Super. Ct. Mar. 21, 2006)	11

<i>M.G. Bancorporation, Inc. v. Lee,</i> 737 A.2d 513 (Del. 1999)	12, 17
<i>Merck & Co. v. Garza,</i> 347 S.W.3d 256 (Tex. 2011)	<i>passim</i>
<i>Merrell Dow Pharms., Inc. v. Havner,</i> 953 S.W.2d 706 (Tex. 1997)	<i>passim</i>
<i>Milward v. Acuity Specialty Prods. Grp.</i> 639 F.3d 11 (1st Cir. 2011)	19
<i>Siharath v. Sandoz Pharms. Corp.,</i> 131 F. Supp. 2d 1347 (N.D. Ga. 2001), <i>aff'd Rider v. Sandoz Pharms. Corp.,</i> 295 F.3d 1194 (11th Cir. 2002)	20
<i>Smith v. Benjamin Moore & Co.,</i> 2012 WL 2914219 (Del. Super. Ct. July 18, 2012)	23
<i>Transcontinental Ins. Co. v. Crump,</i> 330 S.W.3d 211 (Tex. 2010)	29
<i>Travelers Indem. Co. v. Lake,</i> 594 A.2d 38 (Del. 1991)	10
<i>Wells v. SmithKline Beecham Corp.,</i> 2009 U.S. Dist. LEXIS 21251 (W.D. Tex. Feb. 18, 2009), <i>aff'd,</i> 601 F.3d 375 (5th Cir. 2010)	15
<i>Wells v. SmithKline Beecham Corp.,</i> 601 F.3d 375 (5th Cir. 2010)	<i>passim</i>
<i>Young v. Mem'l Hermann Hosp. Sys.,</i> 573 F.3d 233 (5th Cir. 2009)	16

RULES AND STATUTES

D.R.E. 702	12, 13
------------------	--------

OTHER AUTHORITIES

Bernard D. Goldstein & Mary Sue Henifin, <i>Reference Guide on Toxicology FEDERAL JUDICIAL CENTER, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE</i> 401, 419 (2d ed. 2000)	18
---	----

NATURE OF PROCEEDINGS

This case involves claims that the workplace exposures of two Texas parents to a variety of chemicals caused birth defects in the children. A1682. Plaintiffs asserted claims against the parents' former employer, Defendant-Appellee Advanced Micro Devices, Inc. ("AMD"), for negligence, premises liability, and strict liability. *Id.* The Superior Court ordered that Texas substantive law governs these claims. See Order of July 23, 2010 ("Texas Law Order").

AMD moved to exclude the causation and duty opinions of Plaintiffs' primary causation expert, Linda Frazier, M.D., M.P.H. ("Frazier") as scientifically unreliable. A383. Plaintiffs countered with a "Joint Affidavit" of all four of their causation experts purporting to set forth the epidemiological and other scientific literature that formed the basis of their causation opinions. A470.

In performing its gatekeeping function, the Superior Court held a four-day evidentiary hearing, reviewed thousands of pages of briefing, documentary evidence, and scientific articles, and entered an order, granting AMD's motion to exclude Dr. Frazier. Order of January 6, 2012 ("Daubert Opinion") at 2. All of Plaintiffs' causation experts relied on the same scientific literature. As a result, the Superior Court was likely to exclude the remaining causation experts, which orders would be fatal to all of Plaintiffs' claims. Accordingly, the parties entered into a stipulation that resulted in the entry of a Final Judgment in favor of AMD on all claims. A1683-84. Plaintiffs then took this appeal from the Final Judgment.

SUMMARY OF ARGUMENT

1) Denied. The Superior Court did not err in excluding Plaintiffs' expert opinions on purported misconduct by AMD because Plaintiffs' inability to prove causation is fatal to their claims.

2) Denied. The Superior Court properly analyzed the proposed expert testimony under *Daubert*,¹ taking into account the substantive burden of proof required by Texas law to prove causation under *Havner*.² Plaintiffs' assumption that Texas substantive law has no role in the underlying *Daubert* proceeding because it is procedural in nature is ill-founded. The substantive requirements of Texas law define whether the expert testimony is relevant and thus admissible under *Daubert*. As the Fifth Circuit has recently observed in a similar context: "In finding the evidence scientifically unreliable—and thus insufficient to prove causation under Texas law—it follows that the experts' testimony was also deficient under *Daubert* given its overlap with Texas questions of scientific sufficiency."³ Notably, Plaintiffs cite to the district court opinion in *Wells* as an example of how federal courts should consider such motions because the district court assumed admissibility and granted summary judgment on the lack of causation proof under *Havner*.⁴ But—other than a reference in their citation form—Plaintiffs do not acknowledge that the Fifth Circuit considered an appeal of this district court opinion and upheld the *Wells* district

¹ *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993).

² *Merrell Dow Pharms., Inc. v. Havner*, 953 S.W.2d 706 (Tex. 1997).

³ *Wells v. SmithKline Beecham Corp.*, 601 F.3d 375, 381 (5th Cir. 2010).

⁴ Opening Br. at 31 & n.55.

court's judgment *on Daubert grounds*. This omission is all the more stunning because the Superior Court relied on this Fifth Circuit opinion as the basis for its reasoning that *Havner* provides the standards for considering the expert causation opinions in an exposure case.⁵

3) Denied. Texas unquestionably has the "most significant relationship" to the claims, considering that virtually every aspect of this case is tied exclusively to Texas, including: (i) the alleged injury; (ii) the place of parents' employment and purported exposures; (iii) the alleged misconduct of AMD; (iv) the location where the children were born and received medical care; (v) the residence of all Plaintiffs both at the time of the alleged exposure and currently; and (vi) the place of several of AMD's fabs and business offices. The only connection to Delaware is that AMD is incorporated in Delaware.

4) Denied. The Superior Court did not abuse its discretion in excluding Dr. Frazier's proposed expert causation opinions as being unreliable and irrelevant under *Daubert* and *Havner*. Under Texas law, epidemiological studies may be used to prove that a substance is capable of causing a particular injury, but they must report a doubling of the risk of injury based on a substantially similar exposure.⁶ Further, Texas requires that the results of such a study be

⁵ *Daubert* Opinion at 9 & n.20 (Studies failing *Havner* cannot, as a matter of law, be causation evidence and are "'deficient under *Daubert* given its overlap with Texas questions of scientific sufficiency.'" (quoting *Wells*, 601 F.3d at 381)).

⁶ *Id.* at 717.

replicated in a second study.⁷

In this case involving the diverse exposures of unrelated parents of different genders, Dr. Frazier had to independently support her female-mediated and male-mediated causation theories separately. Thus, she had to identify two *Havner*-compliant female-mediated studies and two *Havner*-compliant male-mediated studies before her causation opinions could be admissible. But **none** of the scientific articles on which she relied satisfied *Daubert* or *Havner*, as they involved very different exposures, myriad classes of chemicals, and divergent end points from the Plaintiffs in this case. The Superior Court did not "overlook[]" these portions of the record, but properly discounted Dr. Frazier's reliance on such inapposite studies—most of which were also discounted by their own authors as insufficient to support anything more than a hypothesis.

After a four-day hearing—during which Dr. Frazier testified at length as to the bases for her causation opinions and responded to questions posed by both sides' counsel and the Superior Court—and following consideration of the voluminous record, the Superior Court determined that Dr. Frazier's methods and analysis lacked the scientific rigor necessary to support the element of causation in any cause of action.⁸ Its opinion was based on a number of considerations, all of which are amply supported by the record in this case. The Court should affirm the Final Judgment in its entirety.

⁷ *Havner*, 953 S.W.2d at 726-27; *Merck & Co. v. Garza*, 347 S.W.3d 256, 267 (Tex. 2011).

⁸ *Daubert* Opinion at 17-18.

STATEMENT OF FACTS

A. The Manufacture of Semiconductors

The semiconductor fabrication process includes oxidation (diffusion), photolithography, etch, and layering/metallization. B0002. Each process includes a series of steps, and each step in each process uses different tools and chemicals. B0003, B0005; B0007. These processes take place in a controlled environment called a clean room or fabrication room ("fab"). B0004, B00021-22. Processes within fabs occur in dedicated areas, frequently called bays, that are often physically separated from other processes by walls, doors, and ventilation devices. B0026-27. Fabs utilize various air handling methods in concert to create a controlled environment. B0028-31.

B. The Tumlinson Plaintiffs

The Tumlinson Plaintiffs' claims are based on the core allegation that REDACTED was born with birth defects as a result of his mother's exposure during pregnancy to an allegedly toxic combination of chemicals while working for AMD. A105, A109-10. This purported "toxic soup" has been described by Plaintiffs and their experts in a variety of ways and with varying ingredients. See, e.g., A1399.

Wendolyn Tumlinson worked in the photolithography area of AMD's Fab 11 in San Antonio, Texas starting in 1986. A884, A886. Photolithography uses light to print circuit patterns onto silicon wafers. B0006-7. The chemical formulations of the photoresist materials used by the photolithography group have changed over time and from facility to facility. B0006, B0009-10; B0019; B0020. Throughout her shift, including cleaning, Ms. Tumlinson wore latex

gloves, safety glasses, a protective hood, a special smock, anti-static shoe covers, and at certain times, a face shield. B0038, B0039.

The chemicals Ms. Tumlinson used were primarily isopropyl alcohol and acetone. B0039, B0041; B0044. She used a spray bottle to apply one or the other of these chemicals to the stepper/aligner tool, which she then wiped down with a lint free cloth. B0041. The whole process took no more than one minute at the beginning and end of her shift. B0041-42. Ms. Tumlinson believes that she also used n-butyl acetate on occasion to clean her tool (B0045) and was familiar with xylene, but she could not recall how she would have used xylene. B0046.

On July 5, 1987, REDACTED was born with a cluster of birth defects

REDACTED

A747;

A777; B0034, B0047; B0054. REDACTED occurs in individuals not associated with the semiconductor industry. A1398. The cause of REDACTED REDACTED is often unknown. *Id.* While she was employed at AMD, Ms. Tumlinson gave birth to another son who does not share REDACTED condition or have any other birth defects. B0035.

C. The Ontiveros Plaintiffs

The Ontiveros' claims are based on the core allegation that REDACTED REDACTED was born with birth defects as a result of her father's exposure to combinations of chemicals at AMD. A105, 110-11; B0068.

Anthony Ontiveros worked in AMD's Fab 14 in Austin, Texas as an etch operator from 1992 to 1995. A105, A869; B0095. Mr. Ontiveros' job was at the "CAROS" sink where he dipped boats of wafers attached to

teflon handles into a sink of sulfuric acid and hydrogen peroxide, which removed hard-baked photoresist from the wafers. B0090, B0092-94.

While handling the acids, Mr. Ontiveros wore latex gloves covered by a second pair of acid resistant gloves that came up past his elbows. B0092. He also wore a face mask, goggles, and an acid resistant apron that covered his chest, lap and legs. B0091-92.

On August 12, 1994, more than seven years after REDACTED was born, REDACTED was born with birth defects, including a form of REDACTED

REDACTED

A105, 110-11; B0068. REDACTED

REDACTED

A786-87. REDACTED

REDACTE occurs in individuals not associated with the semiconductor industry. A1398. The cause of REDACTED is often unknown. Id. During Mr. Ontiveros' employment at AMD, his wife gave birth to a son who does not have any birth defects. B0088.

D. Differences Between the Plaintiffs

The Plaintiff groups have little in common. The children were born more than seven years apart and have radically different birth defects. Their parents worked at different fabs, in different cities, having different physical layouts, utilizing different ventilation systems, in different areas of the plant, performing different processes. B0041; B0092-93; B0007-18; B0028-29; B0032; B100. The parents are different genders, implicating different biological targets of potential exposure and different potential mechanisms of

alleged genotoxicity or embryotoxicity. The parents' job duties required them to use different chemical agents. B0040-43; B0092-93.

E. Dr. Frazier's Opinions

Dr. Frazier is an internist and occupational physician. A740. She considers herself a specialist in environmental reproductive hazards and epidemiology. See, e.g., A740-41. Dr. Frazier proposes to render opinions that REDACTED mother was exposed to "hazardous substances and compounds" while working at AMD in San Antonio that "proximately caused" Jake's birth defects. A745. She acknowledged that the causes for his condition are unknown and REDACTED

REDACTED A1398; A1444-51. She was unable to identify a single chemical used at AMD that is known specifically to induce the birth defects REDACTED has. A1411.

Dr. Frazier likewise opines that REDACTED father was exposed to hazardous substances while working at AMD that "proximately caused" REDACTED birth defects. A785. However, she recognized that REDACTED conditions occur in the absence of chemical exposure and there is no known cause. A1398. Dr. Frazier was also unable to cite a single study showing that the dose of chemicals Mr. Ontiveros received at AMD is capable of causing birth defects like the ones REDACTED has. A1411.

Prior to the *Daubert* hearing, Dr. Frazier would not identify the specific chemical(s), either alone or in combination, that she claimed caused the alleged birth defects. E.g., A1185-87. When pressed at the hearing, Dr. Frazier finally identified **ten** different alleged "causation chemicals" to which Plaintiffs may have been exposed in varying and random combinations. A1399-A1400. But even there,

Dr. Frazier refused to limit the list. *E.g.*, A1399-1400 ("I'll name the 10 chemicals as the most likely candidates. . . ."); A1403-1404.

Dr. Frazier acknowledged significant differences in the way these chemicals might have affected REDACTED -who was allegedly injured through his mother's exposure--and REDACTED -who was allegedly injured through her father's exposure--and she had to analyze them separately. *E.g.*, A1342; A1381; A1391; A1412. For the Tumlinsons, she relied principally on studies that evaluated female workers in other industries and lacked exposure information. A1274,; A1276; A1408-09. The Taiwanese studies she cited for the Ontiveros male-mediated defects likewise lacked dose information and involved different end points and industries. A1036-37; A1041-46. Dr. Frazier also relied heavily on literature including epidemiological studies from the semiconductor industry that evaluated outcomes of spontaneous abortion (miscarriage), decreased fertility, and/or mortality incidence--not incidence of birth defects generally or the specific defects claimed here. See A1435.

ARGUMENT

I. The Superior Court Properly Applied Texas Substantive Law

A. Question Presented

Did the Superior Court err in applying Texas law in excluding Dr. Frazier's expert opinions when Plaintiffs, the AMD facilities, the exposures, and birth defects have at all times been in Texas?

B. Scope of Review

The Superior Court's grant of AMD's Texas Law Motion is subject to a *de novo* standard of review. See *Clinton v. Enterprise Rent-A-Car Co.*, 977 A.2d 892, 895 (Del. 2009).

C. Merits of Argument

1. Texas Has the Most Significant Relationship to These Claims

Delaware courts use the "most significant relationship" test to determine choice of law and attach a strong presumption to the law of the state where the alleged injury occurred, unless another state has a more significant relationship. *Clinton*, 977 A.2d at 896; *Travelers Indem. Co. v. Lake*, 594 A.2d 38, 47 (Del. 1991). In this case, the state where the alleged injury occurred is undeniably Texas. Virtually **every** aspect of this case is tied **exclusively** to Texas:

- Plaintiffs' families have worked and resided in Texas (A105-A106)
- The alleged misconduct occurred in Texas, where AMD employed Wendolyn Tumlinson and Anthony Ontiveros to work at AMD's Texas facilities (A105-A107; B0112)
- The allegedly harmful exposures occurred in Texas (A105-A108)
- The parent Plaintiffs resided in Texas at the time of the alleged misconduct (A105-108)
- The Plaintiff children were born at Texas hospitals and treated in Texas (B00118-19; B0121)
- All four Plaintiffs currently reside in Texas (A104-A05) and

- Defendant AMD has facilities in and does business in Texas (B0036, B0037; B0112; B0122).

In contrast, AMD did not have any manufacturing operations in Delaware and did not have management offices in Delaware. B0115; B0122. The only connection to Delaware is that AMD is incorporated in Delaware.

Clearly, Texas has the most significant relationship to issues of both liability and damages. Texas Law Order at 4, 8. The question is not a close one. See, e.g., *Lee v. Choice Hotels Int'l Inc.*, 2006 WL 1148737, at *2 (Del. Super Ct. Mar. 21, 2006) (holding that the presumption should not be disturbed where place of incorporation is the only factor favoring Delaware).

Plaintiffs suggest generally in their Opening Brief at 2 that California law might alternatively apply, but they appear to focus on Delaware, as they did in the Superior Court. A216. Plaintiffs have not put this Court in a position to consider California substantive law because they have not cited any authorities to demonstrate California's legal standards, much less any conflict with Delaware.⁹

Finally, Plaintiffs' suggestion that Texas' interests would be in having what they believe are less restrictive standards apply in a Delaware court to protect its citizens is nonsensical. *Id.* at 30. Ironically, they seem to be suggesting that Texas has an interest in providing its citizens more favorable treatment in foreign courts than Texas' own judicial system. Under the circumstances, the Superior Court correctly determined that "[t]he parties' relationship is

⁹ Plaintiffs seem to urge the Court to find that Delaware substantive law should apply because California, in their view, has more qualitative contacts with this dispute. Opening Br. at 28-29. They cite no authority for this novel proposition.

completely centered in Texas," Texas Law Order at 7, and concomitantly concluding that Texas substantive law should apply.

2. The Superior Court Properly Respected the Roles of Daubert and Havner

(a) Delaware rules provide that only reliable and relevant expert opinions are admissible

As the Superior Court clearly appreciated, the admissibility of expert opinion is determined by the Delaware Rules of Evidence, including Rule 702, which requires courts to determine if the opinion testimony is reliable. D.R.E. 702; *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 593-94 (1993) (discussing criteria for determining whether the expert's opinion has a reliable basis); *M.G. Bancorporation, Inc. v. Lee*, 737 A.2d 513, 523 (Del. 1999) (extending *Daubert* criteria to Delaware law). There are three key components of the *Daubert* analysis: (i) reliability of the methodology; (ii) a nexus between the data and the opinion proffered; and (iii) relevance.

The nexus requirement ensures that the opinions have a proper fit with the facts. When experts rely upon scientific studies that are "dissimilar to the facts presented," it is proper to reject the experts' reliance on the studies as not providing a sufficiently reliable scientific foundation. See *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 144-46 (1997) ("A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.").

Rule 702 incorporates traditional relevancy analysis by requiring courts to determine if the proposed testimony will assist the jury in deciding a fact in issue. D.R.E. 702; *Daubert*, 509 U.S. at 591. "'Relevant evidence' means evidence having any tendency to make the

existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." D.R.E. 401. As noted, relevancy is determined by Texas law.

(b) The substantive requirements of *Havner* determine what is relevant for purposes of *Daubert*

Plaintiffs conflate the relevance and reliability prongs of the *Daubert* inquiry when they claim that, had the Superior Court applied *Daubert*, "Dr. Frazier's opinions clearly would have been admitted" because they "were relevant to Plaintiffs' claims." Opening Br. at 21. They assert that, as a result of its choice-of-law analysis, "the Superior Court never reached the issue of whether Dr. Frazier's opinions satisfied *Daubert*." Opening Br. at 27. But that is not the case. The Superior Court properly focused on the interplay between *Daubert* and *Havner*, as illustrated in its analysis at the hearing:

Well, we're in Delaware, but in the end this case has to be proved under Texas law. And if the expert doesn't offer an opinion on the point that has to be proved to Texas's satisfaction, then that expert opinion is not going to be helpful to the jury trying to decide whether the Texas standard has been met. So, for example, if we're talking about degrees of competence, an expert who cannot testify with the Texas level of competence is not going to be helpful in the end.

A1680. In its *Daubert* Opinion, the Court further explained that although Texas had "several rigorous standards that must be satisfied, if as here, the expert opinion is based on epidemiological studies":

This conflict is resolved by *Daubert*'s other prong - relevance. An expert's opinion is relevant only if it bears on the proof of a contested fact and it may be considered as evidence of that contested fact. An opinion that is deemed reliable under Delaware law is irrelevant if that opinion will not be given any evidentiary value because it is deemed unreliable under Texas law. . . .

Put another way, AMD cannot be found to be liable in Delaware for a tort allegedly committed in Texas against Texans based on evidence that is unreliable, insufficient, and inadmissible in Texas. *Delaware's evidentiary standards do not create an easier way around the burden of proof in Texas.*

Daubert Opinion at 5-6 (italics in original; other emphasis added). This is consistent with Delaware law. See, e.g., *Chaplake Holdings, Ltd. v. Chrysler Corp.*, 766 A. 2d 1, 5 (Del. Super. Ct. 2001).¹⁰

It is also consistent with the Fifth Circuit's opinion in *Wells*—although, as noted above, Plaintiffs discussed only the district court's decision without alluding to Judge Higginbotham's opinion on appeal. In *Wells*, the Fifth Circuit held that an expert's opinion was inadmissible under *Daubert* because it was not scientifically reliable under *Havner*. *Wells*, 601 F.3d at 381. *Wells* was a federal diversity case involving Texas substantive law and federal procedural law, specifically *Daubert*. 601 F.3d at 377 & n.5. The district court in *Wells* granted summary judgment to the defendant based on its conclusion that the plaintiff's expert testimony did not satisfy *Havner's* proof requirements. See Opening Br. at 31 n.55 (citing *Wells v. SmithKline Beecham Corp.*, 2009 U.S. Dist. LEXIS 21251, at *22 (W.D. Tex. Feb. 18, 2009), *aff'd*, 601 F.3d 375 (5th Cir. 2010)). The Fifth Circuit affirmed the district court's judgment on the alternative basis of inadmissibility under *Daubert*. *Wells*, 601 F.3d at 377.

¹⁰ *Chaplake* may suggest an alternative path to the same conclusion: "The procedural law of a foreign state will, however, be applied when the law of a foreign state is applied to substantive issues [and] **the procedural law of the foreign state is so inseparably interwoven with substantive rights as to render a modification of the foregoing rule necessary, lest a party be thereby deprived of his legal rights.**" (citations and internal quotations omitted) (emphasis added)).

Similar to this case, the plaintiffs' experts in *Wells* were unable to cite statistically significant studies involving the prescription medicine, Requip®, and the injury claimed by the plaintiff, pathological gambling. 601 F.3d at 379-80. Focusing solely on the reliability prong of *Daubert*, the Fifth Circuit reminded that "this court has frowned on causative conclusions bereft of statistically significant epidemiological support." *Id.* at 380 (collecting cases). Only one study rose to the level of statistical significance, but it involved a class of products (dopamine agonists, which included Requip®) and a class of conditions (impulse control disorders, which included pathological gambling). *Id.* The court of appeals held that this study was also an insufficient basis for a reliable causation opinion in part because it involved a class of medications, as opposed to being a controlled test for Requip®. *Id.* Because there was simply "'too great an analytical gap between the data and the opinion proffered,'" *id.* at 380-81 (quoting *Joiner*, 522 U.S. at 146), the court excluded the expert causation opinion under *Daubert*. The Fifth Circuit's description of the effect of that ruling is instructive and fully in line with Judge Silverman's analysis:

Our conclusion that the trial court did not abuse its discretion is an unremarkable sustaining of the district court's gatekeeping role under *Daubert*. In finding the evidence scientifically unreliable - and thus insufficient to prove causation under Texas law - **it follows that the experts' testimony was also deficient under *Daubert* given its overlap with Texas questions of scientific sufficiency.**

601 F.3d at 381 (emphasis added); see also *Young v. Mem'l Hermann Hosp. Sys.*, 573 F.3d 233 (5th Cir. 2009).

Plaintiffs cite a number of decisions from district courts in the Fifth Circuit that predate the 2010 Wells opinion to suggest there is a controversy over the matter. See Opening Br. at 31-32 n.55. In light of Wells, those decisions are of little value here.

It should also be noted that *Havner* follows a line of cases, including *Daubert*, that involve birth defects—although not the conditions of the children in this case—and relied extensively on federal *Daubert* standards. *Havner*, 953 S.W.2d at 709-711, 715-724. Its requirements strike “a balance between the needs of our legal system and the limits of science.” *Id.* at 718. And as Wells points out, that is the same balance struck by *Daubert*: “Wells urges the law to lead science - a sequence not countenanced by *Daubert*. And while the possibilities of the[] relationship [between Requip® and problem gambling] properly spark concerns sufficient to warrant caution, the courts must await its result.” Wells, 601 F.3d at 381. The Superior Court’s application of the substantive standards of *Havner* in determining whether Dr. Frazier’s causation opinions are admissible under *Daubert* was thus entirely correct.

II. Dr. Frazier's Causation Opinions Were Properly Excluded

A. Question Presented

Dr. Frazier was unable to point to a single study, let alone the two studies required by *Havner*, showing a doubling of the risk for either male or female semiconductor workers having a child with birth defects. Instead, Dr. Frazier was required to make unsubstantiated assumptions in an effort to fill a profound analytical gap in the scientific literature on which she relied. Did the trial court properly conclude that Dr. Frazier's opinions on causation as to REDACTED REDACTED and REDACTED vastly different congenital conditions were unreliable and irrelevant and therefore inadmissible?

B. Scope of Review

"[T]he law grants the trial judge broad latitude to determine whether *Daubert's* specific factors are, or are not, reasonable measures of reliability in a particular case. This Court applies an abuse of discretion standard when 'it reviews a trial court's decision to admit or exclude expert testimony.'" *M.G. Bancorporation*, 737 A.2d at 522. This standard "applies on appeals reviewing a ruling on either the reliability of an expert's methodology or the reliability of an expert's ultimate conclusion." *Id.*

C. Merits of Argument

1. To Be Relevant, the Expert Opinion Must Satisfy *Havner*

Under Texas law, causation is an element of each of Plaintiffs' substantive claims. See *Burroughs Wellcome Co. v. Crye*, 907 S.W.2d 497, 499 (Tex. 1995). Testimony failing to meet the criteria stated in

Havner is insufficient to prove causation as a matter of Texas law. See *City of San Antonio v. Pollock*, 284 S.W.3d 809, 820 (Tex. 2009). It is neither competent nor relevant. *Id.* at 816.

Causation in a chemical exposure claim includes both general and specific elements. *Havner*, 953 S.W.2d at 714. General causation questions whether a substance is capable of causing a particular injury or condition in the general population, while specific causation questions whether a substance caused a particular individual's injury or condition. *Id.*

To show general causation in a chemical exposure case, Plaintiffs must offer expert testimony to establish, among other things:

- that the disease at issue can be related to chemical exposure by a biologically plausible theory;
- that the plaintiff was exposed to the chemical in a manner that can lead to absorption into the body; and
- that the dose to which the plaintiff was exposed is sufficient to cause the disease.

Borg-Warner Corp. v. Flores, 232 S.W.3d 765, 771 (Tex. 2007) (quoting Bernard D. Goldstein & Mary Sue Henifin, *Reference Guide on Toxicology*, in FEDERAL JUDICIAL CENTER, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 401, 419 (2d ed. 2000)).

A plaintiff may rely upon epidemiological studies for general causation, but the Texas Supreme Court has imposed a number of requirements on such proof that it considers are necessary to "strike[] a balance between the needs of our legal system and the limits of science." *Havner*, 953 S.W.2d at 714. First, the studies must be properly designed and executed. *Havner*, 953 S.W.2d at 714-15, 719. Isolated case reports and reports lacking the details to permit

scientific evaluation are not supporting evidence. *Id.* at 720. Additionally, the results of the study for that specific injury must be statistically significant. *Havner*, 953 S.W.2d at 723.

Such "[p]roperly designed and executed epidemiological studies" may be some evidence of causation if they report more than a "doubling of the risk" that the exposure is capable of causing the claimed injury. *Id.* at 717. In this case, Plaintiffs had to present two such studies for each of the Plaintiff families because the science relating to female-mediated birth defects does not support causation for male-mediated birth defects, and vice-versa.

Plaintiffs must also satisfy the specific causation requirement, meaning they must show that they were exposed to comparable or higher dose levels as reported in the studies. *Havner*, 953 S.W.2d at 720. And they must rule out other plausible causes of the injury with reasonable certainty. *Id.*; see also *Pollock*, 284 S.W.3d at 819-20.

2. Plaintiffs' Proof Does Not Satisfy *Havner* or *Daubert*

(a) Dr. Frazier's methodology is not supported

(i) "Weight of the evidence" is not a substitute for reliable proof

Plaintiffs' reliance upon the "weight-of-the-evidence methodology," Opening Br. at 21 (citing *Milward v. Acuity Specialty Prods. Grp.*, 639 F.3d 11 (1st Cir. 2011)), is misplaced. In an opinion not cited by Plaintiffs but relied on by the Superior Court, the Supreme Court of Texas flatly rejected "totality of the evidence" methodologies on grounds that would equally apply to "weight-of-the-evidence" methodologies. *Merck & Co. v. Garza*, 347 S.W.3d 256, 268 (Tex. 2011). The court made clear that "[a] plaintiff cannot prove

causation by presenting different types of unreliable evidence." *Id.* Texas is not out of step on the matter—a number of other courts have rejected the "weight of the evidence" approach to establishing causation because it lacks transparency and scientific rigor.¹¹

(ii) Differential diagnosis cannot be used to establish general causation

Plaintiffs also claim that Dr. Frazier's opinions are supported by differential diagnosis. Opening Br. at 21. However, under Texas law, differential diagnosis can be "relevant to show that the chemical caused the illness in the plaintiff (specific causation)," but only **after** "it is proven that a chemical generally causes a particular illness (general causation)." *Coastal Tankships, U.S.A., Inc. v. Anderson*, 87 S.W.3d 591, 608-09 (Tex. App.—Houston [1st Dist.] 2002, pet. denied). Because Dr. Frazier cannot reliably support a general causation finding under *Havner*, any conclusions about specific causation are immaterial and therefore irrelevant.

(b) The Superior Court properly interpreted *Havner*

Plaintiffs attack the epidemiological requirements of *Havner* as mere "*dicta*." Opening Br. at 27. *Garza*—an opinion discussed by the Superior Court at some length (*Daubert* Opinion at 4, 8-10), but not

¹¹ See, e.g., *Hollander v. Sandoz Pharms. Corp.*, 289 F.3d 1193, 1216 n.21 (10th Cir. 2002) ("In our view, this argument is inconsistent with *Daubert*. To suggest that those individual categories of evidence deemed unreliable by the district court may be added to form a reliable theory would be to abandon 'the level of intellectual rigor' of the expert in the field."); *Allen v. Pa. Eng'g Corp.*, 102 F.3d 194, 198 (5th Cir. 1996); *Caraker v. Sandoz Pharms. Corp.*, 188 F. Supp. 2d 1026, 1040 (S.D. Ill. 2001); *Siharath v. Sandoz Pharms. Corp.*, 131 F. Supp. 2d 1347, 1371 (N.D. Ga. 2001), *aff'd* *Rider v. Sandoz Pharms. Corp.*, 295 F.3d 1194 (11th Cir. 2002); *Estate of George v. Vt. League of Cities & Towns*, 993 A.2d 367, 379-380 (Vt. 2010).

cited by Plaintiffs—expressly refutes this argument. In *Garza*, the Texas Supreme Court reiterated that doubling of the risk is required. See *Garza*, 347 S.W.3d at 265-66 (“*Havner* holds, and we reiterate, that when parties attempt to prove general causation using epidemiological evidence, a threshold requirement of reliability is that the evidence demonstrate a statistically significant doubling of the risk.”).

Even if a study meets the threshold doubling of the risk requirement, it is not automatically deemed reliable. *Id.* at 265-66. Rather, it is only after a study satisfies this threshold requirement, that the court conducts a “secondary reliability inquiry.” *Id.* Thus, the fact that Dr. Frazier invoked the Bradford Hill criteria—a form of secondary reliability analysis, see *Havner*, 953 S.W.2d at 718-19 & n.2—in her analysis fails to salvage her conclusions. *Garza*, 347 S.W.3d at 266.

Garza also confirmed that *Havner* requires not just one, but two, statistically significant studies showing at least a doubling of the risk to render an admissible opinion on causation. 347 S.W.3d at 267 (noting that even if the clinical trial could satisfy *Havner*’s threshold requirement, “it cannot do so alone. Another study is still necessary, but lacking here.”).

Garza demonstrates why Dr. Frazier’s scientific literature analysis fails to satisfy *Havner*. *Garza*, 347 S.W.3d at 266-68. A unanimous Texas Supreme Court rejected studies proffered by the plaintiffs’ experts because the experts had attempted to extrapolate from studies finding statistically significant associations “at much higher doses and longer durations” without providing any scientific

basis for that extrapolation. *Id.* at 268. Of particular interest here, the court found that a meta-analysis combining several studies was unreliable because it problematically "combine[d] the results of a number of different studies, with differing dosages, durations, and comparison drugs." *Id.* at 267. *Garza* thus makes clear that Dr. Frazier's extrapolation from, and piecing together of, various studies layered with unsubstantiated assumptions and inferences to form a causation opinion is entirely inadequate.

(c) Plaintiffs' challenges to the Daubert Opinion are unfounded

As to Plaintiffs' litany of claimed "Factual Errors in the Superior Court's Analysis," Opening Br. at 10-15, as demonstrated below, considering the scientific literature and facts presented, the Superior Court did not abuse its broad discretion in concluding that Dr. Frazier's opinions were unreliable and irrelevant.

(i) Correlated exposure levels were entirely lacking

Plaintiffs first claim that the Superior Court failed to credit Dr. Frazier's "meticulous" comparison of exposure levels for each chemical. Opening Br. at 10 ("First"); see also *id.* at 13 ("Eleventh"). However, the assumption that Dr. Frazier analyzed exposure levels for each chemical she asserted to be a potential causal agent is completely unsubstantiated; instead, she assumed substantially equivalent exposures to the studies she considered.

Any assessment of exposure requires an understanding of what chemicals are involved. Dr. Frazier has not identified the particular chemicals she claims are causative agents; she maintains that in

addition to the ten "causation chemicals" she defined at the hearing, there are other unidentified chemicals that could have contributed to a synergistic effect, resulting in the birth defects at issue. See, e.g., A1399-1400. There is thus ample reason for the Superior Court to have concluded that "[t]here is not enough information to say the exact list of other chemicals specifically for each parent." *Daubert* Opinion at 12-12 (quoting A1400); cf. *Smith v. Benjamin Moore & Co.*, 2012 WL 2914219, at *2 (Del. Super. Ct. July 18, 2012) ("Without identifying specific products, Plaintiffs cannot prove the quantity of exposure, i.e., the dose, or show that Defendants' products were a substantial factor in causing [plaintiff's] injury."). Not knowing the chemicals supposedly implicated, it is impossible to correlate a dose.

Next, except to suggest there is a "mix" that is, in her opinion, consistent across all fabs, all semiconductor companies, and all types of workers, Dr. Frazier was unwilling or unable to connect the dots. A1404-A1405;¹² see *id.* at A1400 (testifying that "the proportion of chemicals in the mixture" was the same for Mrs. Tumlinson and Mr. Ontiveros—even though they are different genders, had different jobs, worked in different fabs, and worked with different chemicals). Moreover, although Dr. Frazier insisted that she correlated the doses from the semiconductor studies (see part II.C.2(c)(viii), below) to the exposures of Wendolyn Tumlinson and Anthony Ontiveros, she could not possibly have done so. Notably, Plaintiffs' own expert, James H. Stewart, has acknowledged that the "challenge" in "categoriz[ing] the

¹² Dr. Frazier admitted that the doses in her bar graphs were based only in part on the modeling report of Dr. Stewart. A1405.

study subjects in groups representing different exposures" in the UC Davis study "was substantial . . . in that 14 companies were participating in many different locations with different products being produced." B0125. As also noted in the SIA study Final report:

*Thus, although fabrication rooms have one unifying purpose, the production of wafers with semiconductor chips, these chips have different designs and tolerances and **are produced by different techniques and processes in different companies. This wide range of fabrication room techniques results in exposures of workers that may not necessarily be similar in different companies and locations.***

A938 (emphasis added). Dr. Frazier also admitted that she could not provide the dose of 2-EEA in the Cordier paper, A1408—one of her principal resources for the Tumlinson causation opinion—so she could not possibly correlate the doses reported in that paper to any exposure of Mrs. Tumlinson. Finally, Dr. Frazier admitted to having made some serious calculation errors in her charts. *E.g.*, A1458.

Further undermining Dr. Frazier's exposure assumptions is her reliance on studies involving chemicals in the same family, but not necessarily with the same impacts or toxicities, rendering these materials of questionable probative value here. For example, Dr. Frazier testified that Cordier (A1054) was significant to her analysis of REDACTED maternal-mediated birth defects. But she admitted that only one person in that study—involving 991 cases and 1144 controls—worked with the four glycol ethers included in her 10 "causation chemicals." A1408-1409. The remaining thousands of participants provide no basis for extrapolation or assumption. See, *e.g.*, Garza, 347 S.W.3d at 266-67 (rejecting studies as unreliable

that "combine[d] the results of a number of different studies, with differing dosages, durations, and comparison drugs").

As the Superior Court aptly concluded, "although there have been epidemiological studies here and abroad, none has directly linked [clean] room fab work, even in general terms, with Plaintiffs' birth defects, much less has any study linked the specific work that Tumlinson and Ontiveros did with birth defects." *Daubert* Opinion at 9.

(ii) The Lin study was fully considered and properly discounted

The next set of complaints is that the *Daubert* Opinion improperly slighted the Lin (male) study (A1036-39). See Opening Br. at 10-11 ("Second" through "Fourth"). As noted previously, Dr. Frazier relied on this study as a central piece of her causation theory as to REDACTED REDACTED male-mediated birth defects. A1381-A1382.

This study was based on Taiwanese **mortality** records (not birth records), reporting an association between semiconductor workers and **deaths** from birth defects before age 5. A1036-37. Dr. Frazier conceded that the Lin male study does not report the risk of being born with a birth defect--the researchers did not have any incidence rates for birth defects in the non-exposed population. A1444. The authors of the Lin male study themselves cautioned that "[t]he possible etiological basis needs to be corroborated in further research." A1036.

Another significant limitation on the Lin article for *Daubert/Havner* purposes is that neither the chemicals nor dose were specified for the fathers' possible exposure. As the authors stated, "there is little information on the exact chemicals applied in the manufacturing process." *Id.* Plus, "[o]ne 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." A1039.

Dr. Frazier confirmed that the Lin study did not identify any measurements of exposure, but claimed that she "could get a good idea of dose from the IBM, JHU and the SIA studies." A1369. As noted above in part II.C.2.(c)(i), those studies did not provide dose information. Dr. Frazier has even less support for concluding that exposures at semiconductor facilities in Taiwan were similar to exposures at semiconductor facilities in the United States. To the contrary--the Lin researchers acknowledged their lack of exposure data and cautioned that further research was required. A1036; A1039. Although Plaintiffs attempted a belated effort to fill in this evidentiary hole by having one of their other experts contact the researchers, his non-peer-reviewed opinion that the conditions were "similar" is not sufficient to satisfy the similar exposure requirement of Texas law and *Daubert*.

A separate Lin study on female workers did **not** find a statistically significant association for deaths attributed to birth defects. Dr. Frazier chose not to factor this study in her analysis because she does not agree with the authors' conclusions that there is "**no convincing evidence** that female workers employed during the periconceptional period in the semiconductor industry had higher risks of having adverse birth outcomes." B0128 (emphasis added). Yet the Lin female study's conclusion is consistent with the semiconductor studies that reported on birth defects. In two studies, the final reports indicated frequency of birth defects in pregnancies of female workers

were within the expected rate of 1-4% for the unexposed population. A1386-A1387. Indeed, in the Johns Hopkins report, the authors observed "no adverse effects" on "rates of preterm delivery, low birthweight, birth defects, and infertility or subfertility" associated with maternal or paternal work in the clean rooms. A899.

(iii) Sung involved very different workers,
conditions, and exposures

Plaintiffs next take issue with the Superior Court's characterization of another Taiwanese study examining workers making electronic appliances, Sung (A1041). This study did not involve semiconductor workers, and the chemicals used and exposure levels were not reported, though the authors noted that inspection reports of the electronic facilities studied implied that exposure levels were significantly higher than the exposures in this case. A1045 (noting that Taiwanese plant labor inspectors reported regulatory violations in six out of eight inspections). Like the Lin studies described above, Sung did not find any examples of maladies consistent with

REDACTED , nor did Sung find any instances of REDACTED
or of REDACTED

REDACTED A1044 & Table 2. Again like Lin, the authors cautioned that their work was very preliminary and that "more studies are needed to further corroborate this hypothesis." A1046.

In extrapolating exposures and results from this study, it is noteworthy that Dr. Frazier disagrees with published authors who cautioned against liberal comparisons between the electronics and semiconductor industries. B0133 (cautioning that exposures in the semiconductor fabrication and electronics assembly branches "differ

with the particular technology utilized, the specific manufacturing steps an individual performs, industrial hygiene controls employed, and personal work practices"). For any and all of these reasons, the Sung study is too inconclusive, involves far different exposures and end points, and is too attenuated from Plaintiffs' experience to satisfy the *Havner/Daubert* similarity requirement.

(iv) The Superior Court did not ignore relevant studies

Pointing to the introductory section of the Superior Court's *Daubert* Opinion, Plaintiffs claim that the Superior Court's characterization of "research concerning 'other fields or other places'" means that it did not consider Lin, Gray, Pastides, Schenker, Beaumont, Correa, Swan, and Eskenazi involving semiconductor workers. See Opening Br. at 11-12. Plaintiffs quote a preliminary summary of the voluminous information presented to the Superior Court. It is clear from the transcript of the four-day hearing that the Superior Court heard lengthy testimony and argument—and, in fact, extensively questioned Dr. Frazier and counsel—about these articles. And this was in addition to reviewing the voluminous submissions from Plaintiffs, including the 200-page Joint Affidavit of all Plaintiffs' causation experts. In fact, the Superior Court later specifically references these articles in its more detailed analysis of the scientific evidence. See *Daubert* Opinion at 13-18. This is not a basis for finding fault with the Superior Court.

(v) Dr. Frazier had no principled basis for ruling out REDACTED as a cause of REDACTED injuries

As noted above in part II.c.2(a)(ii), Dr. Frazier's specific causation opinions are irrelevant without admissible opinion testimony of general causation. Plaintiffs nonetheless assert error in the Superior Court's treatment of this evidence, Opening Br. at 12, but there would be none even if specific causation were still at issue.

A differential diagnosis requires a disciplined consideration of all potential causative factors for the condition under review ("ruling in") and a systematic process that "rules out" all other possible causes of the plaintiff's condition. *Transcontinental Ins. Co. v. Crump*, 330 S.W.3d 211, 216 (Tex. 2010). Dr. Frazier "ruled out"

REDACTED as a factor in REDACTED birth defects, and in doing so, dismissed a number of peer-reviewed studies showing that

REDACTED, B0139, based on her assumption that REDACTED and so are inapposite because REDACTED

REDACTED, A1444. Remarkably, at the same time, Dr. Frazier admitted that there were several "studies of really large populations with good generalized ability utilizing excellent study methods that show REDACTED can be associated with birth defects." A1451 (emphasis added). Her strained rationale for discounting the REDACTED reveals the inconsistency (and unreliability) of her methods, rejecting differences in scientific studies that do not support her conclusions, while embracing those

differences when it suits her. Such inconsistent positions highlight the speculative and results-based nature of her opinions.

(vi) Studies involving exposures to chemicals in the same family are not probative

Contrary to Plaintiffs' argument, the Superior Court properly dismissed articles involving chemicals in the same family as not probative of the actual chemicals used at AMD's Texas facilities. See Opening Br. at 13 ("Ninth"). Similar arguments have been rejected by both the Texas Supreme Court and the Fifth Circuit. See *Garza*, 347 S.W.3d at 266-67 (rejecting meta-analysis combining several studies as unreliable involving different products, doses, etc.); *Knight v. Kirby Inland Marine, Inc.*, 482 F.3d 347, 353 (5th Cir. 2007) (upholding rejection of "study focused on organic solvents as a class" that included chemicals to which plaintiffs "were never exposed"). Dr. Frazier also never "quantif[ied] the difference in toxicity levels between the studied chemical and the related chemical" to substantiate her assumption that they would cause the same effects. In sum, "the 'same substance' requirement is lacking." *Daubert* Opinion at 13.

(vii) The reference to "federally approved clean rooms" had no impact on legal analysis

Although Plaintiffs challenge the use of the term "federally approved clean rooms," Opening Br. at 13 ("Tenth"), they fail to show how this reference adversely impacted the *Daubert* analysis.

(viii) Dr. Frazier's extrapolation from the semiconductor studies lacks a sufficiently reliable scientific foundation

In their "Twelfth" through "Fourteenth" points, Plaintiffs claim the Superior Court improperly discounted statistically significant

studies relating directly to semiconductor workers. Opening Br. at 13-14. These articles suggest an association between semiconductor work generally and spontaneous abortion and other fertility issues—not birth defects. A893-952; see also *Daubert* Opinion at 16 & n.35. Despite the fact that those researchers found minor or no increased risk of birth defects, Dr. Frazier supposed that the spontaneous abortions were the result of fetuses with birth defects, assuming that the unspecified mix of chemicals are on a dose-response curve—meaning that, in her view, "if a worker exposed to a lethal dose for a fetus will spontaneously abort, therefore a worker exposed to less than a lethal dose will have a child with birth defects." *Daubert* Order at 17. However, when questioned about the scientific basis for this purported dose-response curve, Dr. Frazier could only point to a chemotherapy agent and the Hiroshima atomic bomb studies—both of which are entirely unrelated to the semiconductor chemicals at issue. A1411. In fact, she could not identify any authority that discussed a dose-response curve with spontaneous abortion and birth defects associated with any of the chemicals at issue. A1353.

Further, and as noted above at part II.C.2(c)(ii), the female Lin study had reviewed prior literature, including the semiconductor studies, observed that more studies were needed "focusing on adverse birth outcomes," and after conducting their research, concluded "no convincing evidence that female workers employed during the periconceptional period in the semiconductor industry had higher risks of having adverse birth outcomes." B0131. If birth defects were

generally assumed to be on a spectrum with spontaneous abortions, then the Lin researchers presumably would have at least mentioned it.

(ix) The Superior Court did consider Plaintiffs' reports as to independent exposures

The claim that Judge Silverman failed to consider Dr. Frazier's isolation of certain chemicals for analysis, Opening Br. at 14 ("Fifteenth"), is unsupported and presents no reason to disturb the Superior Court's decision. As noted above, the Superior Court entertained several days of testimony by Dr. Frazier as to the purported bases for her opinions that the "causation chemicals" either alone or in combination were capable of causing the birth defects at issue. Plaintiffs simply have no such proof.

(d) Plaintiffs Lack One, Much Less Two, Competent Studies

Plaintiffs' alternative argument that they have satisfied Havner's two-study requirement is also specious. As explained above, their expert must present at least two reliable, substantially similar studies reporting a doubling of the risk for **each** child—one set of male-mediated studies and one set of female-mediated. Dr. Frazier attempted to satisfy these requirements by pointing to two male-mediated articles and two female mediated articles, but none of these studies passes muster under *Havner* or *Daubert*.

The male-mediated studies that Plaintiffs claim support Dr. Frazier's causation opinions as to the Ontiveros family, Opening Br. at 33, have been previously discussed at parts II.C.2(c)(ii) & (iii). Both the Lin (male) and Sung studies involve different end points and no information regarding exposures—although there is reason to believe

that the levels of combined-chemical exposures were much higher than anything in Mr. Ontiveros' workspace. The authors of both of these studies recognized their inherent limitations and cautioned against drawing the kinds of causality conclusions that Dr. Frazier has made.

Nor could Dr. Frazier point to a single female-mediated study involving the chemicals or exposures of Mrs. Tumlinson that reports a doubling of risk for birth defects. Although she references Cordier, Opening Br. at 33-34, as noted above at part II.C.2(c)(i), Dr. Frazier ultimately conceded that only one person in that study of thousands actually worked with the four glycol ethers she has identified in her list of ten causation chemicals. A1408-1409. And the Khattak reference is equally 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 this study. A1274, A1276 & Table 1. Finally, Plaintiffs refer again to the semiconductor studies, which have been thoroughly discussed above at part II.C.2.(c)(viii) that the Superior Court properly discounted. See *Daubert* Opinion at 16-17. None of these studies meets the *Havner* standards, and all were properly discounted. See *Garza*, 347 S.W.3d at 268 ("A plaintiff cannot prove causation by presenting different types of unreliable evidence.").

3. Defense Experts Were Not Necessary to Cross-Examine Dr. Frazier

Plaintiffs' repeated complaint that AMD did not bring its own experts to the hearing, e.g., Opening Br. at 23, merits a brief mention. While defense experts may assist a court in understanding

complex subject matter, a Plaintiffs' expert must withstand scrutiny on her own merit and may be properly excluded when she does not. It is clearly the role of the Court in its gatekeeping function—not of the jury or defense experts—to determine whether Dr. Frazier's testimony is admissible. See *Alderman v. Clean Earth*, 2007 WL 1334565, at *2 (Del. Super. Ct. Apr. 30, 2007) (court's sole focus is on the proffered expert), *aff'd*, 954 A.2d 909 (Del. 2008).

III. Dr. Frazier's Opinions Regarding Purported Misconduct Were Neither Admissible Nor Material

A. Question Presented

Did the court err in omitting findings as to Dr. Frazier's "misconduct" opinions after excluding her causation opinions?

B. Scope of Review

This issue presents a matter of law, which is reviewed *de novo*. See *Clinton*, 977 A.2d at 895 (legal issues reviewed *de novo*).

C. Merits of Argument

The Superior Court properly dismissed Dr. Frazier's expert opinions once it ruled that the causation opinions were inadmissible. Plaintiffs cannot show reversible error because of the proof problems with their causation evidence. See part II, *supra*. Plaintiffs' own actions in stipulating to the entry of a Final Judgment based on the exclusion of their causation expert prove the point. A1683-84.

CONCLUSION

For the reasons set forth above, AMD respectfully requests that the Court affirm the Final Judgment in its entirety.

OF COUNSEL:

FULBRIGHT & JAWORSKI LLP
Stephen C. Dillard
Stacey A. Martinez
Marcy Hogan Greer
Lisa Horvath Shub
Fulbright Tower
1301 McKinney, Suite 5100
Houston, Texas 77010-3095
(713) 651-5507

Dated: April 2, 2013

/s/ Frederick L. Cottrell III
Frederick L. Cottrell III (#2555)
Anne Shea Gaza (#4093)
Elizabeth R. He (#5345)
Richards, Layton & Finger, P.A.
One Rodney Square
920 North King Street
Wilmington, Delaware 19801
(302) 651-7700
Cottrell@rlf.com
Gaza@rlf.com
He@rlf.com
Counsel for Defendant Below, Appellee
Advanced Micro Devices, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on this 3rd day of April, 2013, a true and correct copy of the foregoing was filed and served via Lexis Nexis File & Serve and copies of the same were served on counsel of record at the addresses and in the manners indicated below:

VIA E-MAIL & HAND DELIVERY

Ian Connor Bifferato, Esq.
David W. deBruin, Esq.
Thomas F. Driscoll III, Esq.
J. Zachary Haupt
Bifferato LLC
800 N. King Street
Wilmington, Delaware 19801

VIA E-MAIL

Steven J. Phillips, Esq.
Diane Paolicelli, Esq.
Phillips & Paolicelli, LLP
380 Madison Avenue, 24th Floor
New York, New York 10017

VIA E-MAIL

David C. Strouss, Esq.
Thornton & Naumes, LLP
100 Summer Street, 30th Floor
Boston, Massachusetts 02110

/s/ Elizabeth R. He
Elizabeth R. He (#5345)