IN THE SUPERIOR COURT OF THE STATE OF DELAWARE
IN AND FOR NEW CASTLE COUNTY

WENDOLYN TUMLINSON, JAKE TUMLINSON, JILLVEH ONTIVEROS and PARIS ONTIVEROS, by her natural mother and next friend JILLVEH ONTIVEROS	)	
Plaintiffs,	)	C.A. No.: 08C-07-106 FSS
	)	**E-FILED**
v.	)	
ADVANCED MICRO DEVICES, INC.	)	
Defendant.	)	

Submitted: August 31, 2011
Decided: January 6, 2012

ORDER

Upon Defendant's Motion to Exclude Opinion Testimony of Dr. Linda Frazier, M.D., M.P.H. - *GRANTED.*

This is a toxic tort case. Plaintiffs allege chemical exposure at Defendant's semiconductor "clean rooms" caused birth defects that are rare, but seen in the population at-large. To establish causation and breach of duty, Plaintiffs rely on the expert opinion of an epidemiologist, Dr. Linda Frazier, M.D., M.P.H., based on her reviewing assorted scientific studies on lab animals and humans who work in other fields or other places. Defendant moved to exclude Dr. Frazier's opinion evidence, claiming it is unreliable under *Daubert v. Merrell Dow Pharmaceuticals,*

Inc.,[1] as interpreted in both Delaware and Texas. The court held a four day evidentiary hearing and has carefully considered the parties' numerous and voluminous submissions.

Delaware applies the standard announced in *Daubert* to determine expert evidence's admissibility. To satisfy *Daubert*, Plaintiffs must establish that Dr. Frazier's opinions are both relevant and reliable. Evidence is relevant if it helps establish or disprove a disputed fact necessary to the claim. Here, that disputed fact is causation. Texas law emphatically sets a very high threshold for proof of causation in toxic tort claims. Dr. Frazier's opinions do not meet the Texas standard of reliability. As a result, her opinions are not relevant because, as a matter of Texas law, they cannot be accepted as evidence of causation.

I.

Plaintiffs, Texas residents, are two families whose parents worked at Advanced Micro Devices, Inc. semiconductor facilities, and whose children suffered birth defects. Wendolyn Tumlinson worked as a fab operator in AMD's San Antonio, Texas photolithography department beginning in 1986. The facility was a Class 100, federally approved clean room.[2] Tumlinson operated a "stepper/aligner" tool that was

[1] 509 U.S. 579 (1993).

[2] *See* Pls.' Hr'g Ex. 18 at 14 ("Clean Rooms comply with . . . Federal Standard 209-D. [A] clean room [i]s a manufacturing area with particle counts less than or equal to 100 particles per cubic foot (ppcf), of a particle size greater than 0.5 microns.").

cleaned daily with isopropyl alcohol and acetone. There also were other organic solvents, including xylene and glycol ethers, in the tight quarters where Tumlinson worked.

In November 1986, Tumlinson conceived her son, Jake. She operated the stepper/aligner tool through her sixth month of pregnancy, then moved to a non-chemical position until Jake's birth. Jake was born on July 5, 1987, suffering from anal atresia and stenosis, neurogenic bladder, renal agenesis/hypoplasia, imperforate anus, and colo-vesicular fistula. These birth defects, in combination, are referred to as VATER association. As mentioned, VATER association appears, albeit rarely, in the general population. Tumlinson continued to work for AMD after Jake's birth. In 1988, she bore another child, who had no birth defects.

Anthony Ontiveros, Plaintiff Paris Ontiveros's father, worked as an etch operator at AMD's Austin, Texas facility from January 1992 through December 1995. Ontiveros dipped computer parts into baths containing a sulfuric acid-hydrogen peroxide mixture. He then dipped the parts into a hydroflouric acid and ammonium fluoride bath. Ontiveros refilled the chemical baths two or three times per shift. In addition, Ontiveros wiped down AMD's equipment with isopropyl alcohol daily.

Paris was conceived in November 1993, and she was born on August 12,

1994. She suffers from pulmonic stenosis, congenital pulmonary valve atresia, ventricular septal defect, right pulmonary hypoplasia, lower limb reduction defects and situs inversus with dextrocardia. Like VATER association, these defects also appear in the general population, not just in semiconductor industry workers' children. Ontiveros, like Tumlinson, had another child while employed by AMD who had no birth defects.

Plaintiffs' complaint, filed in July 2008, alleges that chemical exposure at the two semiconductor plants caused the birth defects. On December 15, 2010, after discovery closed on the epidemiology issues presented here, AMD moved to exclude Frazier's opinions because they are not scientifically reliable and provide no evidence of causation. The court held a four day evidentiary hearing in April 2011 and the parties submitted proposed findings of fact and conclusions of law in May 2011. In August 2011, the parties submitted *Merck & Co., Inc. v. Garza*.[3]

II.

In July 2010, the court granted AMD's motion to apply Texas substantive law.[4] Evidentiary matters, however, including the admissibility of expert

[3] 347 S.W.3d 256 (Tex. 2011).

[4] *Tumlinson v. Advanced Micro Devices, Inc.,* C.A. No. 08C-07-106 (Del. Super. July 23, 2010) (Silverman, J.).

opinions, are governed by the Delaware Rules of Evidence.[5] This dichotomy, as applied to Dr. Frazier's opinions, may seem to create a conflict because, although both jurisdictions follow *Daubert,*[6] the threshold for admitting expert testimony is significantly higher in Texas than it is in Delaware.

Under *Daubert*, the party offering an expert opinion must satisfy the court that the opinion is both relevant and reliable. Evidence is relevant if it tends to make the existence of a fact that bears on the claim more or less probable.[7] The relevance requirement usually is not seriously disputed, because the point of expert testimony is to provide evidence of causation, defective design, or another essential element of the claim. The focus, instead, is on the reliability of the expert's opinion.

Daubert's non-exclusive criteria for determining reliability include: (1) whether the expert's theory has or can be tested; (2) whether the theory has been subject to peer review; (3) the known or potential error rate associated with the theory; and (4) the extent to which the theory has been generally accepted in the scientific community.[8] Delaware has not set specific requirements for establishing

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[5] *Id.* at 8.

[6] *See M.G. Bancorporation, Inc. v. Le Beau,* 737 A.2d 513, 522 (Del. 1999) ("We hereby adopt the holding[] of *Daubert.*"); *see also E.I. du Pont de Nemours & Co., Inc. v. Robinson*, 923 S.W.2d 549, 556 (Tex. 1995) ("We are persuaded by the reasoning in *Daubert.*").

[7] D.R.E. 401; TX.R. EVID. 401

[8] *Daubert,* 509 U.S. at 593-94.

that an expert opinion satisfies *Daubert*. Texas, by contrast, has several rigorous standards that must be satisfied if, as here, the expert opinion is based on epidemiological studies.

Thus, the same expert testimony might be accepted as reliable in Delaware, and found unreliable in Texas. 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. In the end, then, Texas law on the reliability of an expert opinion governs the *Daubert* analysis under Delaware law.

Put another way, AMD cannot be found 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.

The standard for reliability of an expert opinion in Texas was announced in *Merrell Dow Pharmaceuticals, Inc. v. Havner,*[9] a case involving the alleged toxic effects of Benedictin. *Havner* explained that in toxic tort cases, scientists may not be

[9] 953 S.W.2d 706 (Tex. 1997).

able to determine exactly what caused the plaintiff's injury. But, scientifically reliable epidemiological studies may provide evidence of causation if they establish that exposure to the toxin more than doubles the risk of injury in the general population.[10]

Havner explained clearly how it is if the risk is not doubled the exposure cannot, as a matter of mathematics, be the probable cause of the injury.[11] In addition, the studies must have a confidence interval greater than 1.0,[12] at a 95% confidence level.[13] The expert relying on such studies must prove that: 1) the plaintiff was exposed to the same substance before the injury; 2) the dose levels were the same or greater than those in the studies; 3) the onset of plaintiff's injury was consistent with the studies; and 4) other possible causes are negated with reasonable certainty.[14]

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[10] *Id.* at 716 (Doubling means that "epidemiological evidence must show that the risk of an injury or condition in the exposed population was more than double the risk in the unexposed or control population.").

[11] *Id.* at 717 ("Assume that a condition naturally occurs in six out of 1,000 people even when they are not exposed to a certain drug. If studies of people who did take the drug show nine out of 1,000 contracted the disease, . . . six of the nine incidences would be statistically attributable to causes other than the drug.").

[12] *Id.* at 723 ("A confidence interval shows a 'range of values within which the results of a study sample would be likely to fall if the study were repeated numerous times.'").

[13] *Id.* ("The generally accepted . . . confidence level in epidemiological studies is 95%, meaning that if the study were repeated numerous times, the confidence interval would indicate the range of relative risk values that would result 95% of the time.").

[14] *Id.* at 720.

Finally, the studies should meet Bradford Hill criteria.[15]

Texas reaffirmed *Havner* five months ago in *Merck & Co., Inc. v. Garza*.[16] Quoting *Havner*, *Garza* warned:

> [C]ourts must look beyond the bare opinions of qualified experts and independently evaluate the foundational data underlying an expert's opinion in order to determine whether the expert's opinion is reliable.
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> If the foundational data underlying opinion testimony are unreliable, . . . any opinion drawn from that data is likewise unreliable. Further, an expert's testimony is unreliable even when the underlying data are sound if the expert draws conclusions from that data based on flawed methodology.[17]

Garza also warned, "*Havner* also requires that even if studies meet the threshold requirements of reliability, sound methodology still necessitates that courts examine the design and execution of epidemiological studies using factors like the Bradford Hill criteria."[18] Thus, Bradford Hill criteria should be considered only after analyzing *Havner's* threshold reliability requirements.

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[15] *Id.* at 718 ("The strong consensus among epidemiologists is that conclusions about causation should not be drawn, if at all, until a number of criteria have been considered. One set of criteria widely used by epidemiologists was published by Sir Austin Bradford Hill in 1965.").

[16] 347 S.W.3d 256 (Tex. 2011).

[17] *Id.* at 262-63 (quoting *Havner*, 953 S.W.2d at 711-712, 714).

[18] *Id.* at 266.

Studies failing *Havner* cannot, as a matter of law, be causation evidence[19] and are "deficient under *Daubert* given its overlap with Texas questions of scientific sufficiency.*"*[20] Animal, *in vitro*, *in vivo*, and epidemiology studies may all be considered to determine causation.[21] Epidemiology studies, however, are the most important because animal, *in vitro*, and *in vivo* studies cannot prove causation alone.[22] Therefore, epidemiology studies must meet *Havner's* criteria before other evidence is considered.

Although there have been epidemiological studies here and abroad, none has directly linked cold 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. As discussed below, the American cold room worker studies do not find a link. Thus, *Havner* and *Garza's* holdings are crucial.

This case is what *Daubert* is about. A jury would have to evaluate organic chemistry, biology, teratology, and engineering to properly render its verdict. The evidentiary hearing was a trailer for the trial:

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[19] *City of San Antonio v. Pollock,* 284 S.W.3d 809, 820 (Tex. 2009).

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

[21] *Havner,* 953 S.W.2d at 728.

[22] *Id.* at 729; *See also Brock v. Merrell Dow Pharmaceuticals, Inc.,* 874 F.2d 307, 313 (5th Cir. 1989) (recognizing that animal studies are of very limited usefulness when confronted with questions of toxicity).

> Plaintiffs' Counsel: I can never pronounce, I'm going to ask you to give us the Greek name for?
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> Dr. Frazier: Methoxy acetic acid.
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> Plaintiffs' Counsel: And can it exist that two different chemicals both metabolize into the same toxin?
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> Dr. Frazier: Yes.
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> Plaintiffs' Counsel: Does that exist with respect to the ethylene glycol ethers?
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> Dr. Frazier: Yes, methyl cellosolve, which is 2-ME or EGME, and the ethoxy ethylene glycols, which are Cellosolve acetate, Cellosolve itself, 2-EE, 2-EEA, those are the synonyms. Those all metabolize into methoxy acetic acid, this MAA, toxic metabolite.[23]

The court observes that its juries almost always have a majority with college educations. Usually, there are more jurors with graduate degrees than with less than a high school diploma. Even so, epidemiology poses just the risk of a verdict based on an incorrect appeal to authority, addressed in *Havner*[24] and *Garza*.[25]

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[23] Hr'g Tr. 33-35, Apr. 6, 2011.

[24] *Havner,* 953 S.W.2d at 711 ("An expert's bare opinion will not suffice. The substance of the testimony must be considered.") (internal citations omitted).

[25] *Garza,* 347 S.W.3d at 262 ("[C]ourts must look beyond bare opinions of qualified experts and independently evaluate the [underlying] foundational data. . . to determine reliab[ility].").

III.

Dr. Frazier's credentials are impressive. She is an internist, board certified in occupational medicine. She also has a master's degree in public health, concentrating in epidemiology. Dr. Frazier has extensive experience studying epidemiology and occupational reproductive hazards. Currently, she is conducting reproductive epidemiology research at the University of Kansas School of Medicine - Wichita.

Dr. Frazier is the lead editor of a medical textbook, *Reproductive Hazards of the Workplace*, the only textbook providing in-depth toxicological information about chemicals hazardous to reproduction and fetal development. She has edited articles and book chapters on the health effects of industrial and environmental chemicals. In addition, Dr. Frazier has been a peer reviewer for several academic journals, including Journal of Toxicology and Environmental Health, Maternal and Child Health Journal, and Applied Occupational and Environmental Hygiene.

In short, Dr. Frazier possesses the knowledge, skill, experience, training and education to assist a trier of fact to understand the evidence in this case. Her primary expertise includes the fields of internal medicine, occupational or industrial medicine, epidemiology, reproductive health and hazard assessment. Dr. Frazier is

competent to interpret and explain the meaning of data, reports and studies in those fields.

IV.

Dr. Frazier opines that there is a causal relationship between each child's birth defects and the two parents' work exposure to ten, named chemicals as well as other, unidentified, toxic chemicals.[26] She states that the chemicals are reproductive toxicants, and that the timing and level of the parents' exposure to the chemicals are consistent with causation. In addition, Dr. Frazier says that she considered and ruled out alternative explanations for the birth defects. Dr. Frazier relies on numerous peer reviewed epidemiological studies as well as animal studies, government findings and industry statements.[27]

Nevertheless, Dr. Frazier's opinions do not meet the *Havner* standards for several reasons. First, *Havner* requires that the substances evaluated in the epidemiological studies be the same as the substances that allegedly harmed the children. Dr. Frazier identified ten causative chemicals, but she repeatedly stated that there were other, unidentified chemicals that contributed to the children's birth defects. For example:

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[26] Pls.' Joint Aff. at 4-5.

[27] *See* Pls.' Opp'n to Def.'s Mot. to Dismiss Ex. A, Tables 1- 14.

> Defendant's Counsel: Did the mixture of chemicals that caused Jake Tumlinson's and Paris Ontiveros's birth defects have other chemicals in the recipe other than the 10 you've mentioned?
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> Dr. Frazier: Yes.
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> Defendant's Counsel: And were those other chemicals the same for Mrs. Tumlinson as they were for Mr. Ontiveros?
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> Dr. Frazier: There is not enough information to say the exact list of other chemicals specifically for each parent.[28]

Moreover, she relied on studies involving other chemicals in the same family as the ten AMD chemicals.[29] Dr. Frazier explained that, if one chemical causes congenital malformations, it is probable that another chemical in the same family also causes congenital malformations.[30] Even if she is correct, there is nothing quantifying the difference in toxicity levels between the studied chemical and the related chemical. Thus, the "same substance" requirement is lacking.

Second, *Havner* requires that the parents' level of exposure be the same

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[28] Hr'g Tr. 83-84, Apr. 7, 2011.

[29] *See, e.g.,* Sylvaine Cordier, et al., *Congenital Malformations and Maternal Occupational Exposure to Glycol Ethers*, Epidemiology 355 (1997); Sohail Khattak, et al., *Pregnancy Outcome Following Gestational Exposure to Organic Solvents: A Prospective Controlled Study,* JAMA 1106 (1999).

[30] Hr'g Tr. 148-150, Apr. 6, 2011.

or greater than the exposure levels in the studies. Dr. Frazier did not analyze the exposure level of each chemical. Instead, she relied on an AMD Total Volatile Organic Chemical (TVOC) measurement. Most of the studies she relied on, however, did not address exposure levels.[31] For those studies, the "same or greater dose levels" requirement is lacking.

Third, *Havner* requires that other possible causes be ruled out with reasonable certainty. Tumlinson was obese, and there are studies showing an association between obesity and birth defects. Dr. Frazier ruled out obesity, nonetheless, because Tumlinson did not have diabetes. Yet, Dr. Frazier acknowledged that there are several well-controlled studies of large populations showing an association between obesity and birth defects, without a diagnosis of diabetes. She considered those studies and ruled them out on the theory that the obese people in those studies had undiagnosed diabetes or elevated blood sugar levels. Dr. Frazier did not confirm her theory, and without that confirmation it cannot be said that Dr. Frazier ruled out obesity with reasonable certainty.

Fourth, many of the studies forming the basis for Dr. Frazier's opinions involved different environments, tested for different outcomes, and/or reported no

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[31] *See, e.g.,* Khattak, et al., *supra* note 29. *See also* Ching-Chun Lin, et al., *Increased Risk of Death With Congenital Anomalies in the Offspring of Male Semiconductor Workers,* Int. J. Occup. Health 14:112 (2008).

increased risk.[32] For example, the 2008 Lin study addressed mortality rates for Taiwanese semiconductor workers' children. Dr. Frazier considered this study a major factor in her causality opinion with respect to Ontiveros. But the Lin study did not address birth defects, it lacked adequate exposure measurements, and it involved a Taiwanese workplace – which may or may not mirror the AMD workplace.

Another example is the 2006 Hooiveld study, which evaluated congenital malformations in children of male painters exposed to glycol ethers and other solvents. The chemicals in the Hooiveld study were organic solvents, but they were not the same chemicals used by semiconductor workers. Moreover, neither parent in this case worked as a painter, and there is no discernable relationship between the two work environments.

The 2009 Sung study, likewise, studied a different population – electronics workers – and it failed to quantify those workers' exposure level to the

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[32] *See, e.g.,* M. Hooiveld, et al., *Adverse Reproductive Outcomes Among Male Painters with Occupational Exposure to Organic Solvents,* Occupational and Environmental Medicine 63:538-544 (2006) (examining birth defects in Dutch carpenters and painters); Tzu-I Sung, et al., *Increased Risks of Infant Mortality and of Death Due to Congenital Malformation in the Offspring of Male Electronics Workers,* Birth Defects Research (Part A): Clinical and Molecular Teratology 85:119-124 (2009) (examining death from cardiac defects); G-Y Hsieh, et al., *Prolonged Menstrual Cycles in Female Workers Exposed to Ethylene Glycol Ethers in the Semiconductor Manufacturing Industry,* Occupational and Environmental Medicine 62:510-516 (2005) (examining menstrual cycles); Adolfo Correa, et al., *Ethylene Glycol Ethers and Risks of Spontaneous Abortion and Subfertility,* American Journal of Epidemiology, 143:7 707-717 (1996) (examining spontaneous abortion and subfertility).

chemical solvents. In fact, the authors state, "we cannot be certain that the observed excess risks are entirely attributable to exposure to organic solvents. In this study, we were not able to identify any specific types of solvents responsible for the elevated risks."[33] Dr. Frazier testified, "Sentences describing inadequate ventilation tells me that the concentrations exceeded the current regulatory levels."

The Sung study also does not report an odds ratio or relative risk regarding electronic workers' children being born with birth defects.[34] Defense counsel asked Dr. Frazier, "So, we have no odds ratio that lets us calculate the relative risk as compared to the general population for being born with birth defects?" Dr. Frazier responded, "Correct."

There were three studies of semiconductor workers in the United States – DEC, JHU/IBM, and SIA.[35] The DEC Final Report found only minor differences in the number of birth defects in the exposed and unexposed populations.[36] The authors of the JHU/IBM report state that they "observed no adverse effects on birth

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[33] Sung, et al., *supra* note 32, at 123.

[34] *Id.* at 122.

[35] Harris Pastides, et al., *Spontaneous Abortion and General Illness Symptoms Among Semiconductor Manufacturers,* Journal of Occupational Medicine, 30:7 543-551 (1988); *The Johns Hopkins University Retrospective and Prospective Studies of Reproductive Health Among IBM Employees in Semiconductor Manufacturing* (1993); Marc C. Schencker, *Final Report to the Semiconductor Industry: Epidemiologic Study of Reproductive and Other Health Effects Among Workers Employed in the Manufacture of Semiconductors* (1992);

[36] Pastides, et al., *supra* note 35, at 547.

weight or gestational maturity, and no increased risk of birth defects or childhood neoplasms associated with either maternal or paternal work in the Clean Room Areas.[37] The SIA study reports on spontaneous abortion, not birth defects.[38]

The court accepts Dr. Frazier's assurance that the dose-response curve is a "well-known" concept in epidemiology. Nevertheless, the way Dr. Frazier has applied it to the studies showing spontaneous abortion is untested and vague. Dr. Frazier did not propose a shape for the curve when applied to the causation chemicals. She opines that 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. That may be true in theory, but Dr. Frazier does not tie the dose response to what happened here, except in an *a fortiori* fashion.

These examples demonstrate that Dr. Frazier's opinions are not reliable as a matter of Texas law. Although Dr. Frazier considered a large number of scientific articles and studies, the data they provided did not satisfy the *Havner* requirements in one or more respects.

Dr. Frazier makes a case for concern that working in a clean room, even a federally approved one, poses an increased risk of birth defects. Her testimony

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[37] *See* Pls.' Hrg. Ex. 18 at 182.

[38] *See* Schenker, et al, *supra* note 35, at 1 ("The major objective of this study was to test the hypothesis that female semiconductor industry employees working in silicon wafer manufacturing have an increased for spontaneous abortions.").

supports researchers in this field's call for more studies.[39] That, however, is not the same as scientifically proving that the risk to Plaintiffs here was twice that of the general population.

V.

For the foregoing reasons, Advanced Mirco Devices, Inc.'s motion to exclude is **GRANTED.**

IT IS SO ORDERED.

/s/ Fred S. Silverman
Judge

cc: Prothonotary (Civil)
pc: Ian Connor Bifferato, Esquire
David W. deBruin, Esquire
Kevin G. Collins, Esquire
J. Zachary Haupt, Esquire
Steven Phillips, Esquire
Nancy A. Perry, Esquire
David C. Strouss, Esquire
Brad J. Mitchell, Esquire
Anne Shea Gaza, Esquire
Frederick L. Cottrell, III, Esquire
Elizabeth R. He, Esquire
Stacey A. Martinez, Esquire
Lisa Horvath Shub, Esquire
Robert G. Newman, Esquire
C. Ashley Callahan, Esquire
Jennifer O'Sullivan, Esquire
Kim F. Tyson, Esquire

[39] *See id.* at 386 ("Further work is needed to confirm these findings, and to evaluate the individual exposures and work processes suggested as risk factors. In particular, attention should be focused on women working in the etching and photolithography areas, and those handling glycol ethers or other photoresist solvents.").