UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
AT LOUISVILLE

DARLENE GIBSON PLAINTIFF

v. CIVIL ACTION NO. 3:07CV-192-S

SANOFI-AVENTIS U.S., LLC DEFENDANT

MEMORANDUM OPINION

This matter is before the court on motions of the defendant, sanofi-aventis U.S., LLC ("sanofi"), to exclude the causation opinions of experts Dr. George C. Rodgers and Dr. Rukmaiah Bhupalam (DN 44), and for summary judgment (DN 43). This accident arose from a motor vehicle accident allegedly resulting from an occurrence of "sleep-driving," a purported side-effect of the sleeping pill, Ambien®.

A party moving for summary judgment has the burden of showing that there are no genuine issues of fact and that the movant is entitled to summary judgment as a matter of law. *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 151-60, 90 S. Ct. 1598, 16 L. Ed. 2d 142 (1970); *Felix v. Young*, 536 F.2d 1126, 1134 (6th Cir. 1976). Not every factual dispute between the parties will prevent summary judgment. The disputed facts must be material. They must be facts which, under the substantive law governing the issue, might affect the outcome of the suit. *Anderson v. Liberty Lobby, Inc.*, 106 S. Ct. 2505, 2510 (1986). The dispute must also be genuine. The facts must be such that if they were proven at trial, a reasonable jury could return a verdict for the non-moving party. *Id.* at 2510. The disputed issue does not have to be resolved conclusively in favor of the non-moving party, but that party is required to present some significant probative evidence which makes it necessary to resolve the parties' differing versions of the dispute at trial. *First National Bank of Arizona v. Cities Service Co.*, 391 U.S. 253, 288-89 (1968). The evidence must be construed in a

light most favorable to the party opposing the motion. *Bohn Aluminum & Brass Corp. v. Storm King Corp.*, 303 F.2d 425 (6th Cir. 1962).

The plaintiff, Darlene Gibson ("Gibson"), fifty-eight, resides in Louisville.[1] On the evening of March 12, 2006, she returned to Louisville from a trip to Indianapolis, Indiana. She picked up her dog from a friend's house, and returned home for dinner. Between 7:00 and 8:00 p.m. Gibson took an Ambien® sleeping pill[2] and began preparing herself for bed. She applied a cosmetic facial mud mask and put curlers in her hair. At 8:19 p.m. she was involved in an automobile accident in which she struck a utility pole approximately one mile from her home. At the time of the accident, she was dressed for bed, was not wearing her glasses, and was wearing the mud mask and hair curlers. She was unbelted, and suffered various injuries in the collision. Gibson was transported to University Hospital for treatment.

Gibson reported to hospital personnel that she had taken two Ambien®, and that the accident occurred while she was driving herself to Southeast Hospital because she was experiencing chest pain and shortness of breath. She was treated for injuries related to the accident, and was evaluated for cardiac symptoms. The evaluation did not reveal any cardiac anomalies. Among her injuries was a serious injury to her foot which has rendered her unable to return to her employment as a teacher with the Jefferson County Board of Education.

Gibson has stated that she has no recollection of events prior to the accident or of speaking to the doctors or nurses at University Hospital, and that she did not know why she was there. Dr. Matthew D. McCullough, a physician who treated Gibson at the hospital, concluded that she had been driving herself to the hospital for cardiac symptoms and fell asleep at the wheel due to her earlier ingestion of two Ambien®.

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[1]These facts have been taken principally from Gibson's responsive briefs.

[2]She reported to medical personnel after the accident that she had taken two Ambien®, but she now denies ever having done so.

Gibson contends that although she has no recollection of any of the events, she is sure that she would not have driven herself voluntarily without her glasses and in a state of readiness for bed. She alleges that she suffered an occurrence of "sleep-driving," an involuntary activity. She also notes that no "Southeast Hospital" exists in Louisville, and that she was not driving in the direction of Southwest Hospital. Gibson had been taking Ambien® from July 2001 until the time of the accident in 2006. She was prescribed ten milligrams per day for insomnia by her primary care physician, Dr. Kathy Neider.

Gibson related in an April 4, 2006 office visit with Dr. Neider that she began experiencing vertigo after a car accident in October, 2005. She related that she was involved in a second car accident in March, 2006 and that she was directed by the hospital to follow up with her primary care physician. Gibson indicated to Dr. Neider that she had no recollection of getting into her car prior to the accident in March, and did not know why she was going to the hospital on that occasion except maybe because of vertigo.

Ambien®, manufactured by sanofi, is the most widely prescribed sleep aid in the United States. Its generic name is zolpidem tartrate. It is classified as a non-benzodiazepine sedative hypnotic. Ambien® is indicated for the short-term treatment of insomnia. Ambien® has been approved for use in Europe since 1987 and in the United States since 1992.

In his report, Dr. Rodgers explained his basis for concluding that it is "medically probable" that Gibson's accident "was sleep-driving caused by Ambien® ingestion:"

> Like many sedative hypnotics, the use of Ambien has been linked to various parasomnias, that is, undesirable events occurring during sleep. One example of parasomnia is somnambulism, or sleep walking. A subset of somnambulism is sleep-driving. There are several reports in the medical literature of somnambulism associated with Ambien use, although none detail sleep-driving specifically. Sleep-driving has, in fact, been rarely reported in the medical literature. It came to particular attention in 2006 when a well publicized auto accident was blamed on Ambien use. Since then there have been several anecdotal reports on the internet. Reports of sleep-driving in conjunction with Ambien use has been reviewed by both the FDA and Sanofi Aventis. It is clear that there have been numerous other cases, most reported through MedWatch. A report to the FDA by Sanofi Aventis (dated

> April 24, 2006) identified 19 potential cases of sleep-driving associated with Ambien. Of these[,] 7 were medically confirmed and 12 were not systematically investigated. This review included cases reported through January 31, 2006. My review of reports to Sanofi Aventis from March through August 2006 identified an additional 32 likely cases. The data provided to the FDA led this agency to request a change in labeling for Ambien and twelve other sedative hypnotics to include a specific warning about sleep-driving as well as other complex sleep behaviors, such as preparing and eating food and making telephone calls.

Rodgers Report, p. 2.

The original labeling for Ambien® listed somnambulism as a rare event. Since its approval for use, the Physician's Desk Reference has contained specific warnings to "use extreme care while doing anything that requires complete alertness such as driving a car, operating machinery, or piloting aircraft." *1994 Physician's Desk Reference*, p. 2192. Under "Safe Use of Sleeping Medicines," the warning states: "Do not take Ambien® or any other sleep medicine unless you are able to get a full night's sleep before you must be active again...Do not increase the prescribed dose of Ambien® or any other sleep medicine unless instructed by your doctor...Ambien® works very quickly. You should only take Ambien® right before going to bed and are ready to go to sleep." *Id.*, pp. 2189-2192. A March 2007 letter disseminated by sanofi informed physicians that the prescribing information for Ambien®, Ambien® CR and other sedative hypnotic drug products had been revised, pursuant to FDA initiative, to include, in part, a precaution for patients concerning reported incidents of "sleep-driving" and other complex behaviors after taking sedative hypnotic medication.

Dr. Rukmaiah Bhupalam, stated in his report that

> Per records provided to me, it suggests that she did go to bed or taking [sic] Ambien and had no recollection of getting into car and her car hit a telephone pole. Per review, as above, Ambien has been linked to complex activity such as sleepwalking, sleep-eating, sleep-driving, and the patient may not be aware of having any of these complex activities. It is highly probable that her accident was related to taking Ambien, causing sleep-driving. After several reports such as this, FDA has changed black box warning. I feel it is highly probable that her sleep driving and accident on March 12, 2006 was due to taking Ambien.

Bhupalam Report, p. 2.

In her complaint, Gibson alleges negligence, strict product liability, breaches of express and implied warranties, negligent misrepresentation, and violation of the Kentucky Consumer Protection Act in sanofi's manufacture and sale of Ambien®.

In *Larkin v. Pfizer, Inc.*, 2001 WL 34065029 (W.D.Ky. Feb. 8, 2001), *aff'd*, 122 Fed.Appx. 263 (6th Cir. 2005), the court stated:

> Plaintiffs have brought product liability claims for strict liability, negligence, and breach of warranty. While Kentucky recognizes product liability claims under each theory, a common element of each is demonstration that a product was defective or unreasonably dangerous. *Montgomery Elevator Co. v. McCullough*, 676 S.W.2d 776, 780-82 (Ky. 1984)...Kentucky has adopted the Restatement (Second) of Torts. Zithromax and Daypro are the types of desirable but unavoidably unsafe products described by the Restatement (Second) of Torts, § 402A, comment k. The evidence demonstrates that Plaintiffs' claims are most appropriately considered in that context. Comment k provides:
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> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment for rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician...The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk...

Id. at *3. Upon certification of the issue to the Kentucky Supreme Court, the Restatement (Third) of Torts: Products Liability § 6(d)(duty to warn of possible side effects satisfied if adequate warning given to patient's health care provider, subject to exceptions) was adopted, without exceptions. *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 770 (Ky. 2004). This principle, known as the learned intermediary doctrine, applies here. Both Dr. Rodgers and Dr. Bhupalam testified that they were not asked to render nor were they rendering opinions concerning the adequacy of the warning in the

Ambien® labeling at the time of the accident. The FDA issuance of revised labeling for all sedative hypnotics in 2007 does not alone establish inadequacy in the prior labeling. Gibson has not offered any evidence suggesting that the warning in 2006 was inadequate. The labeling warned of rare occurrences of somnambulism. The activity of "sleep-driving" is said to be a particular manifestation of somnambulism, in addition to preparing and eating food, making phone calls, and having sex. *see*, sanofi-aventis March 2007 letter to physicians (changes in warnings). Thus the warning concerning somnambulism has always been included in the product literature. Additionally, Dr. Neider testified in her deposition that she would have prescribed Ambien® for Gibson under either version of the Ambien® labeling. Further, Gibson testified that she did not read any product materials which accompanied her Ambien® prescriptions. In the absence of any evidence that the 2006 labeling was inadequate, Gibson cannot succeed on any of her claims relating to the manufacture and marketing of this drug. *Larkin, supra.*

Gibson urges that the Ambien® was defective because she would not have had the automobile accident but for the Ambien® causing her to "sleep-drive." For a number of reasons, the doctrine of *res ipsa loquitur* is inapplicable to this case.

First, in order to succeed in establishing "but for" causation, Gibson must rule out all other possible causes of the accident but the alleged involuntary act. "The doctrine of *res ipsa loquitur* 'is only to be applied when the nature of the accident itself not only clearly supports the inference of negligence but excludes all others...'" *Frank Fehr Brewing Company v. Corley*, 96 S.W.2d 860 (Ky. 1936). The evidence in the case supports more than one possible cause of the accident. As there were no witnesses besides Gibson herself, she has no recollection of the events immediately prior to the accident, and she has provided two versions of the incident - one immediately following the accident and one retrospectively adduced from the circumstances - the facts herein are ill-suited to application of the principle of "but for" causation. *Enlow v. St. Jude Medical, Inc.*, 327 F.Supp.2d 738 (W.D.Ky. 2003).

Gibson herself explained at the hospital that she was attempting to drive herself to the hospital, as she was experiencing chest pain and shortness of breath. This explanation is inconsistent with an inference that Ambien® induced Gibson to "sleep-drive." If Gibson's statement to hospital personnel that she took two Ambien® before leaving the house is credited, abuse of the drug (ingestion of twice the prescribed amount) could not be eliminated as a possible cause. Gibson attempts to "tilt the balance" from possible to probable cause of the accident with the expert reports of Dr. Rodgers and Dr. Bhupalam. As noted in *Enlow*, 327 F.Supp.2d at 741,

> A lack of knowledge as to the cause of the accident does not call for application of the doctrine [of *res ipsa loquitur*]. The separate circumstances of each case must be considered and from them *it must first be decided whether according to common knowledge and experience of mankind, this accident could not have happened if there had not been negligence.*

Id. (emphasis added).

This first hurdle cannot be overcome by Gibson. In looking at the circumstances of this case, Gibson cannot establish that this accident could not have happened but for a drug-induced involuntary action. At best, Gibson urges that she would not voluntarily drive without her glasses, with a mud mask on her face, and with curlers in her hair. However, she admits that she has no recollection of the events before the accident. Directly contrary to her contention after the fact that she would not voluntarily leave the house as she did, Gibson stated at the hospital that she did so because she was driving herself to the hospital with cardiac symptoms.[3] The application of *res ipsa loquitur* simply does not apply here, as other possible causes of the accident clearly exist.

The court explained in *Enlow, supra*., that

> Although the jury may draw reasonable inferences from the evidence of a defect in manufacturing, it is incumbent on the plaintiff to introduce evidence that will support a reasonable inference that the defect was the 'probable' cause of the [injury] as distinguished from a 'possible' cause among other possibilities; otherwise the jury

[3]We recognize that Gibson contends that she was in an involuntary Ambien-induced state when she gave this explanation. She seeks simply to discredit one statement with another. She cannot, however, establish that in the experience of mankind, this explanation is impossible.

> verdict is based upon speculation or surmise...There must be sufficient proof to tilt the balance from possibility to probability...Thus, defendants invariably receive a judgment...as a matter of law in Kentucky where plaintiffs are unable to isolate one cause, either by direct evidence, or...by eliminating other possible causes."

Enlow, 327 F.Supp.2d at 741, *quoting, Gray v. General Motors Corp*, 133 F.Supp.2d 530, 534 (E.D.Ky. 2001); *Midwestern V.W. Corp. v. Ringley*, 503 S.W.2d 745 (Ky. 1973).

As Gibson cannot isolate one cause by direct evidence, she attempts to "tilt the balance" by offering expert testimony that it is "medically probable" (Rodgers Report) or "highly probable" (Bhupalam Report) that the accident was caused by Ambien-induced "sleep-driving."

Sanofi has filed a separate motion to exclude the causation opinions of Gibson's experts. We conclude that the motion to exclude is well taken.

There is no question that Gibson had ingested Ambien® shortly before she drove her car into a utility pole. The precise causation question, however, is whether Gibson was in an Ambien-induced somnambulistic state when she drove her vehicle. The parties agree that there are no clinical studies linking the ingestion of Ambien® to the behavior of "sleep-driving." Indeed, there is no recognized medical diagnosis of "sleep-driving." Rather, it is a term used to describe a particular complex motor activity engaged in while in a state of somnambulism. The experts based their conclusions that Gibson was probably "sleep-driving" on anecdotal reports of a number of other "sleep-driving" experiences. There is nothing "expert" about such a conclusion. This conclusion does not rely on a matter of scientific, technical, or other specialized knowledge which would assist the trier of fact to understand the evidence or determine a fact in issue. Fed.R.Evid. 702. The trier of fact could count the number of reported "sleep-driving" incidents if called upon to do so. However, this calculation does not establish a medical probability that "sleep-driving" occurred in this instance. The experts conclude that Gibson must have been in a somnambulistic state because at the time of the accident she had a mud mask on, curlers in her hair, and was not wearing her glasses. This is not a finding of medical causation, but rather sheer speculation void of any scientific basis. It has not been shown that "sleep-driving" induced by a prescribed dose of

Ambien® is any more probable than the emergency room physician's conclusion that she had fallen asleep at the wheel.

The complete absence of reliable evidence of medical causation is fatal to Gibson's claims. It is irrelevant in this analysis that sanofi acknowledged to the FDA that serious methodological constraints exist in the development of clinical studies of the reported phenomenon of "sleep-driving."

Dr. Rodgers testified that a causal relationship between Ambien® and "sleep-driving"could be discerned clinically if sufficient epidemiological evidence were available. However, Dr. Rodgers is not an epidemiologist. He is a pediatrician and toxicologist. He has no experience in the area of sleep medicine. He did not perform any sort of systematic epidemiological evaluation of statistical data. Rather, he reviewed a collection of case reports and focused on the fact that the FDA concluded that specific warnings concerning these reports should be included in labeling of sedative hypnotics in 2007. This basis is wholly inadequate and does not constitute admissible evidence of medical causation in this case.

Dr. Bhupalam's report fares no better. Dr. Bhupalam's finding of "highly probable" cause was based upon only scant review of a number of case reports. When questioned in his deposition, he could not identify the five or six reports he reviewed, and he could not state whether any of the reported events were similar to those surrounding Gibson's accident. There is no record evidence of medical causation established through any reliable scientific method. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993); *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999). Therefore, the expert opinions on medical causation offered in this case are inadmissible.

In light of the conclusions herein that Gibson has failed to come forward with admissible evidence of medical causation, evidence of defect or inadequate warning, sanofi is entitled to summary judgment as a matter of law. *Nelson v. Tennessee Gas Pipeline Co.*, 243 F.3d 244 (6th Cir. 2001). A separate order will be entered this date in accordance with this opinion.

IT IS SO ORDERED.

October 27, 2009

Charles R. Simpson III, Judge
United States District Court