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Supreme Court of Texas.
Merck and Co., Inc., Petitioner,
v.
Felicia Garza, et al., Respondents.
No. 09-0073.
January 20, 2010.

Oral Argument

Appearances:Stephen G. Tipps, Baker Botts LLP, Houston, TX, for petitioner.

Kevin Dubose, Alexander Dubose & Townsend, Houston, TX, for respondents.

Before:

Chief Justice Wallace B. Jefferson, Justice Nathan L. Hecht, Justice Harriet O'Neill, Justice Dale Wainwright, Justice David M. Medina, Justice Paul W. Green, Justice Phil Johnson.

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MARSHALL: Oyez, oyez, oyez. The Honorable, the Supreme Court of Texas, all persons having business before the Honorable, the Supreme Court of Texas are admonished to draw near and give their attention for the Court is now sitting. God save the State of Texas and this Honorable Court.

CHIEF JUSTICE WALLACE B. JEFFERSON: Thank you. Be seated, please. Good morning. The Court has three matters on its oral submission docket today in the order of their appearance. They are Docket No. 09-0073, Merck and Company vs. Felicia Garza, et al, from Starr County and the Fourth Court of Appeals District. Justice Willett and Justice Guzman are not sitting on that cause. Docket No. 08-1044 in the matter of BW from Harris County and the First Court of Appeals District. And 09-1005, Transcontinental Insurance Company vs. Joyce Crump from Fort Bend County and the Fourteenth Court of Appeals, and Justice Guzman is not sitting in that case. The Court has allotted 20 minutes per side for each of these arguments and we will take a brief recess between the arguments. These proceedings are being recorded and a link to the argument should be posted on the Court's website by the end of the day today. The Court is now ready to hear argument in the first cause, Merck & Company vs. Felicia Garza.

MARSHALL: May it please the Court, Mr. Stephen G. Tipps will present argument for the Petitioner. The Petitioner has reserved five minutes for rebuttal.

ORAL ARGUMENT OF STEPHEN G. TIPPS ON BEHALF OF THE PETITIONER

ATTORNEY STEPHEN G. TIPPS: May it please the Court, this case presents at least three important questions concerning the Court's landmark Havner opinion. First, was the totality of the evidence review, mentioned on page 720 of the opinion, intended by the Court to override the specific requirements for epidemiological studies that the Court had painstakingly established in the preceding five pages. We submit that the answer to that question is no, because a totality of the evidence review makes sense only if the plaintiff first has satisfied the minimum requirements established in Havner for using epidemiological studies to prove causation. Second, are clinical trials among the epidemiological studies covered by Havner's requirements? We submit that the answer to that question is yes, because clinical trials are simply one form of epidemiological study all of which address only the question of whether or not there is an increase in the risk of a disease associated with a particular drug, and like all epidemiological evidence they can satisfy this State's more likely than not burden of proof only if they show a relative risk greater than 2.0. And third, do the studies identified by the Garzas in this case, which now number an even dozen, satisfy Havner's requirements? We submit that the answer to that question is no. The chart filed late yesterday afternoon by the Garzas notwithstanding, not only can the Garzas not point to two such studies, which is what Havner requires, they cannot point to even one. Let me first address the question of whether Havner establishes minimum requirements. With its opinion in this case, the San Antonio Court of Appeals has placed itself in a distinct minority among Texas intermediate appellate courts in its interpretation of Havner. Virtually all of the other Courts of Appeals that have addressed this question, including two other panels of the San Antonio Court, have held either explicitly or by implication that Havner established minimum requirements for epidemiological studies.

JUSTICE HARRIET O'NEILL: But now when they talk about those studies, they were talking about observational studies.

ATTORNEY STEPHEN G. TIPPS: The studies at issue in Havner were observational studies, but the --

JUSTICE HARRIET O'NEILL: And you would agree that clinical trials are more reliable than observational studies.

ATTORNEY STEPHEN G. TIPPS: Clinical trials are more reliable than observational studies, but the Havner opinion established the requirements for all epidemiological studies. Epidemiological studies are divided by scientists into two categories, either experimental studies or observational studies. Clinical trials are an example of experimental epidemiological studies, and the significant thing about the Court's opinion is that what the Court did was contrast a controlled scientific experience which can prove a direct cause and effect relationship with epidemiological studies that can only show an increase in risk. And clinical trials, just like observational studies do nothing more than show an increase in risk.

JUSTICE HARRIET O'NEILL: But now clinical trials are what Merck relies on to get this product to market. Isn't that right?

ATTORNEY STEPHEN G. TIPPS: Clinical trials are what Merck relies upon and what any drug manufacturer relies upon.

JUSTICE HARRIET O'NEILL: Well, then why shouldn't that enhance the reliability behind clinical trials as opposed to observational studies?

ATTORNEY STEPHEN G. TIPPS: It should, and that's where the Court's totality of the evidence review comes into play. As I read Havner, as most of the Courts of Appeals have read Havner, as at least three District Courts sitting in Texas have read Havner, Havner establishes minimum requirements for all epidemiological studies, and if a plaintiff seeking to rely upon epidemiological studies to prove causation cannot show that there are at least two statistically significant studies that show more than a doubling of the risk at the same dose and duration and also satisfy Havner's exclude other causes requirement, then the plaintiff has not met Havner's requirements and has not established the necessary causation. At that point, if the plaintiff though has met those requirements, what the Court said in Havner is that that's not enough, that the gatekeeper, the trial court as the gatekeeper still needs to look at the totality of the evidence, and it is at that point that a Court should give more weight to clinical trials than to observational studies. For example, if all a plaintiff had were two observational studies showing a relative risk or odds ratio of 2.01, that might not be enough because all of the other factors, the Bradford Hill factors, the Henley Cook postulates, all of those other factors might not satisfy the gatekeeper that the studies are scientifically reliable. On the other hand, if the epidemiological studies upon which the plaintiff has relied to meet the minimum requirements are clinical trials, then presumably a relative risk of 2.01 might well be satisfactory. But the problem with, or one of several problems with the San Antonio Court's opinion is that it suggests that clinical trials should not be subjected to Havner's minimum requirements and yet it offers nothing as an alternative. And basically says that the Court simply is to look at all of the -- if there are clinical trials, the Court is to look at all of the evidence and if in its judgment, its subjective judgment, the studies are scientifically reliable, then that's enough. I mean that is the very ipse dixit regime that this Court addressed and changed in Havner. And I think also a simple reading of the Court's opinion in Havner should lead the Court to the opinion that Havner established minimum requirements. The totality of the evidence language is in the final or the next to the last paragraph of Section 4 of the opinion. Section 4 of the opinion is the section in which the Court undertook, quote, “To consider the use of epidemiological studies and the more likely than not burden of proof.” And the Court then went on in that section to say that one of the requirements is to show a more than doubling of the risk, that the Court should apply the Bradford Hill factors, the Court should look at the design and execution of the studies, the Court should look at the dose and duration and make sure that it's comparable to what the plaintiff experienced and the Court should see if other plausible causes were excluded with a reasonably certainty. When read in that context, it seems to me and it seems to other Courts that have interpreted this Court's opinion, that the Court is to undertake a totality of the evidence review only if those minimum requirements have been met. And quite frankly, it seems to me that it would make no sense for the Court to have wasted all the time and effort to establish those minimum requirements if at the end of the day the issue was to be left to the Trial Judge in his or her discretion.

CHIEF JUSTICE WALLACE B. JEFFERSON: You said that notwithstanding the chart

that was submitted by the plaintiffs yesterday that those requirements have not been met. How do you distinguish this chart that they have given to us yesterday and on the bench today?

ATTORNEY STEPHEN G. TIPPS: Well, we of course have a battle of charts. We submitted a charge early in the day and they submitted a chart later in the day. And simply put, if you look through the 11 studies that the Garzas have identified on their chart, you will not find one that shows a more than doubling of the risk, that is to say a relative risk of greater than 2.0 that is statistically significant at this dose which is 25 milligrams, and this duration which is less than 30 days. There is not one such study. I would submit that probably the study on their list that comes the closest, which ironically is not even a study, is VIGOR [Ph.]. And they rely with regard to VIGOR on an item that they've attached as Tab B of their handout, that is nothing more than an email with regard to a study that was never completed, that expressed some preliminary findings. And one of the tests said no statistical significance; one said statistical significance at a relative risk of greater than 3.0. But when the Court established requirements for epidemiological studies in Havner, I don't think it intended to mean that a plaintiff can prove causation indirectly by submitting an email setting forth preliminary findings in an epidemiological study that was never completed. Preliminary findings change, the evidence in the record is that this is not something that scientists would rely upon, and the final point is that we objected to testimony by their expert concerning this very chart that's attached as Tab B to their handout and the Court sustained the objection.

JUSTICE DAVID M. MEDINA: Mr. Tipps, can there ever be a situation where the risk factor is slightly less than 2, so 1.8, 1.9, when there's other evidence to boost this doubling of the risk factor, or maybe not boost it, support it? Can that ever be considered by the trier of fact, or is it 2.0 period? If you don't meet that threshold, the case is over?

ATTORNEY STEPHEN G. TIPPS: Well, this Court of course identified that as an issue in Havner and did not, specifically did not address it. The Court cited to the Ninth Circuit's opinion in Dobert 2 [Ph.], which is the Ninth Circuit's reconsideration of Dobert when it was sent back by the Supreme Court, and Judge Kosinsky [Ph.] in that case included a footnote in which he hypothesized that in a case -- he made the assumption of a case in which someone was suing for a birth defect claiming that his mother was a smoker and smoking caused the birth defect, and he hypothesized a situation in which there was one study with regard to smokers that showed a 1.5 relative risk and one study with regard to drinkers that showed a 1.8 relative risk, and he speculated that perhaps an expert might come in and reanalyze that data. And he made the assumption that the mother in question was not a drinker, that she was a tee-totaling smoker. And so that drinking would be a confounding factor. And he speculated that perhaps if a study like that could be reanalyzed, maybe it would come up with 2.0. There are a handful of courts around the country that have talked about this. Some courts have mentioned that maybe if the plaintiff had a specific genetic factor that predisposed him or her to a particular condition that that might be enough. But I would suggest that the Court should be very wary of allowing that kind of exception for the simple purpose that according to the Court's analysis in Havner, a relative risk of greater than 2.0 is necessary to satisfy this State's more likely than not burden of proof. And as the Court cited in its example in Havner, if you have a situation in which six out of a thousand people will have a disease for natural causes, and you have a study that shows that in the study nine of the thousand had the disease, well, you would conclude that

it's not more likely than not that any one of those persons contracted the disease because of the drug. It's more likely that they had it for natural causes, and it's only if more than 12 of the thousand who have taken the drug contract the disease that you satisfy the more likely than not burden of proof.

JUSTICE DAVID M. MEDINA: So what guidance can we give to a trial judge who tries these cases which are so difficult because there's always a battle of the experts and he's trying to weigh this evidence, and they're given this great authority to be the gatekeeper of this evidence, and if it's close, if they exclude it, then they take away the case from the plaintiff, if you let it in, then the jury is going to help decide these issues, and maybe we evaluate there. What guidelines can we give them on these type of cases that are so close?

ATTORNEY STEPHEN G. TIPPS: Well, I think the Court established good and clear guidelines in Havner, which include that there be at least two studies that show a more than doubling of the risk.

JUSTICE DAVID M. MEDINA: But reasonable minds do differ. I mean you have a trial judge in the same jurisdiction deciding the same case one way, exclude the evidence, and a judge right down the hall would allow this evidence. I mean these cases are that case.

ATTORNEY STEPHEN G. TIPPS: That can be true, but a study either has a relative risk of more than 2.0 or it does not. A study either is statistically significant or it's not. If the confidence interval includes 1.0 it's not statistical significant.

JUSTICE DAVID M. MEDINA: That seems like an easier case to decide there.

ATTORNEY STEPHEN G. TIPPS: Well, I mean those are the standards that the Court gave trial judges in Havner, and I think those standards can be applied by trial judges; they are applied by trial judges all across the State of Texas.

JUSTICE DAVID M. MEDINA: Who controls these clinical studies when they're done?

ATTORNEY STEPHEN G. TIPPS: Typically the clinical study in a prescription drug case is commissioned by the drug manufacturer, but the study is done by doctors, scientists, researchers. I don't think there's any -- I mean these are legitimate scientific studies, they are published in journals, they are peer reviewed which, of course, is one of the factors under Robinson. But I mean I think the regime that the Court established in Havner is a good one that courts have been following, that this Court failed to follow in this case, because as I pointed out before, if there were two studies that met the Havner requirements the Garzas would be up here telling you these are the two studies. Now, maybe Mr. Dubose for the first time is going to come up and say, “Well, I found three,” which they are. But we don't have that. We have, they keep pointing to 12 different studies, not one of which satisfies the requirements of Havner.

CHIEF JUSTICE WALLACE B. JEFFERSON: When did the trial occur? When was the trial?

ATTORNEY STEPHEN G. TIPPS: I think it was in early 2005.

CHIEF JUSTICE WALLACE B. JEFFERSON: Have there been studies, if you know, post trial that would satisfy the doubling of the risk?

ATTORNEY STEPHEN G. TIPPS: There have been studies that have come out post trial. I do not believe that there has been any study that would satisfy Havner's requirements in this case at this dose and this duration. And I think it's very important for the Court to focus on the fact that this case is really only about short term use of Vioxx, 25 milligrams, less than 30 days, and I don't believe that there's any study that would suggest that that can cause heart attacks.

JUSTICE DALE WAINWRIGHT: In their brief, Respondents say that a Merck employee, Shapiro, prepared a cardiovascular meta-analysis about Vioxx that showed a 95 percent confidence interval and a doubling of the risk. Address that one.

ATTORNEY STEPHEN G. TIPPS: First of all, no expert for the plaintiffs ever mentioned the Shapiro study.

JUSTICE DALE WAINWRIGHT: Was it mentioned at trial?

ATTORNEY STEPHEN G. TIPPS: Not mentioned at trial. So no opinion was expressed with regard to the Shapiro study, number one. Number two, the Shapiro study is a meta-analysis in which you look at multiple studies, including the VIGOR Study. The VIGOR Study was a large study, at 50 milligrams, nine months use. The VIGOR results heavily influenced the Shapiro results. And as we have pointed out in the chart that we filed with the Court and directed the Court to the particular parts of the record, if you exclude VIGOR from the Shapiro meta-analysis, the relative risks are like 1.09 or 1.19 and not statistically significant.

CHIEF JUSTICE WALLACE B. JEFFERSON: Further questions? Thank you, Mr. Tipps.

ATTORNEY STEPHEN G. TIPPS: Thank you, Your Honor.

CHIEF JUSTICE WALLACE B. JEFFERSON: The Court is ready to hear argument now from the Respondents.

MARSHALL: May it please the Court, Mr. Kevin Dubose will present argument for the Respondent.

ORAL ARGUMENT OF KEVIN DUBOSE ON BEHALF OF THE RESPONDENT

ATTORNEY KEVIN DUBOSE: May it please the Court, in the Havner opinion this Court said the law must balance the need to compensate those who have been deeply injured by the wrongful actions of another, with the concept deeply embedded in our jurisprudence that a defendant cannot be found liable for an injury unless the preponderance of the evidence supports cause in fact.

JUSTICE HARRIET O'NEILL: Let me just ask you.

ATTORNEY KEVIN DUBOSE: Sure.

JUSTICE HARRIET O'NEILL: This 2.0 threshold, does your case rise and fall on that? When I read your response, it seemed to me like you were producing numbers that yielded what Havner, the other side, argues would require. I

mean do you win or lose on that basis?

ATTORNEY KEVIN DUBOSE: It depends on how you apply that 2.0 standard. If you isolate each test by itself and say it has to meet every one of these standards, then I think there are two of our tests that we rely on that do that. One is the VIGOR Study that was mentioned a while ago which had the required statistical significance, the 95 percent confidence level greater than 2 percent, greater than double the risk, and events began to occur immediately. In the bench exhibit that we filed, Tab B, is the report from the VIGOR Study and it says several significant things. First of all, even though that study was discontinued because of another study where the results were so bad that Merck said, “We better pull this drug off the market and discontinue VIGOR,” but in the first paragraph of that report and under Tab B they say, “Here are the preliminary results, but we don't expect these results to change.” The other thing about that study is if you look at the chart, it shows the occurrence of serious cardiovascular events, and they start occurring immediately.

JUSTICE PHIL JOHNSON: Mr. Dubose, was that into evidence?

ATTORNEY KEVIN DUBOSE: Yes, Your Honor.

JUSTICE PHIL JOHNSON: Okay. On page 2 of opposing counsel's chart it shows that VIGOR is not in evidence and not yet published at trial.

ATTORNEY KEVIN DUBOSE: It's Plaintiff Exhibit 111, Your Honor.

JUSTICE PHIL JOHNSON: Okay.

ATTORNEY KEVIN DUBOSE: And it was admitted. So the VIGOR Study we think has all the elements. The other thing is the Shapiro meta-analysis that Merck was just talking about. It's not a clinical study, it is a meta-analysis, but that's where Merck asked one of its own employees --

JUSTICE HARRIET O'NEILL: But that wasn't introduced at trial?

ATTORNEY KEVIN DUBOSE: No, it was introduced at trial.

JUSTICE PAUL W. GREEN: It says it was relevance evidence; a relevance objection was sustained from that chart. So was it actually admitted?

ATTORNEY KEVIN DUBOSE: It was, Your Honor. Let me, first of all, it was admitted as Exhibit 130, Plaintiffs' Exhibit 132. Here is the story regarding the --

JUSTICE DALE WAINWRIGHT: This doesn't seem to be a hard question. Was the exhibit admitted at trial?

ATTORNEY KEVIN DUBOSE: Yes, yes, Your Honor, and Plaintiffs' Exhibit 132, it was admitted at trial. There was never any objection to the admission of the exhibit. In the discussion of the exhibit, at one point Counsel for Merck made an objection to relevance and the Court said, “I'm inclined to agree with you, Counsel. Counsel, please move on to something else.” But it was discussed by the experts. There was one objection, it was not ruled on one way or the other and certainly there was not an objection to this Exhibit 132 and it was admitted into evidence.

JUSTICE HARRIET O'NEILL: But her study was not an epidemiological study?

ATTORNEY KEVIN DUBOSE: It was not an epidemiological; it was a meta-analysis which scientists do rely upon. It was commissioner by Merck and it studied all of the existing evidence at that time about Vioxx, both clinical trials and epidemiological studies.

JUSTICE HARRIET O'NEILL: If you have to have an epidemiological study, then your case rises or falls on the VIGOR Study?

ATTORNEY KEVIN DUBOSE: The VIGOR Study is the best one we have. As I said, there is no point where Havner says you have to apply all of these considerations to every single test and if they fail one, they suddenly become no evidence. It's kind of like in the Dobert Robinson analysis where you have the six nonexclusive factors that this Court has said you consider. It has never said, “If you lose on one of these, then it's no evidence.” It just said, “These are considerations, these are indicia of reliability.” And that's what Havner talks about in the Havner opinion, it never says, “We are setting out a mathematical formula.” In fact, there are numerous places where the Court specifically says we're not doing that.

JUSTICE DALE WAINWRIGHT: Counsel, before you go into that in detail, let me just be clear. Assuming that the Havner standards required to meta-analyses, clinical trials, of course epidemiological studies, are you saying there are two that satisfy the Havner requirements?

ATTORNEY KEVIN DUBOSE: That satisfy all of the requirements, that's right, Your Honor.

JUSTICE DALE WAINWRIGHT: Okay. VIGOR and the meta-analysis?

ATTORNEY KEVIN DUBOSE: The Shapiro meta-analysis, right.

ATTORNEY KEVIN DUBOSE: In the Havner opinion itself, the Court talks about these scientific considerations, but after doing so, and the Court -- as I said, we're not coming up with this language on our own and the Court didn't, the Court turned to the field of science in an effort to meld the scientific and the legal analysis, and it said that, “We do not hold, we do not hold that a relative risk of more than 2.0 is a litmus test. Other factors must be considered. The strong consensus among epidemiologists is that conclusions about causation should not be drawn until a number of criteria have been considered.” In another place the opinion says, “There are a number of reasons why reliance on a relative list on 2.0 as a bright-line boundary would not be in accordance with sound scientific methodology.”

JUSTICE HARRIET O'NEILL: But the context of that discussion in Havner seemed to be that, you know, if you prove 2.0 that doesn't establish liability either. I mean that seemed to be the tone that that was written in, that just because you meet 2, doesn't mean you've established it.

JUSTICE NATHAN L. HECHT: Well, not just the tone, but a sentence or two before that it says, “We also note that some of the literature indicates it must consider a relative risk of less than 3 to indicate a weak association.” It seems that in that paragraph, as Justice O'Neal suggests, that 2 is a minimum rather than a maximum.

ATTORNEY KEVIN DUBOSE: If I can direct you to one other place in the opinion,

Justice Hecht, at 718, the Court says, “There may be in fact no causal relationship even if the relative risk is high, likewise even if a particular study reports a low relative risk, there may in fact be a causal relationship.” The Court really -- it said the fact that you've got over 2.0 doesn't guarantee that it's reliable, the fact that you're under doesn't mean it's necessarily unreliable, that you consider all of these factors. And at the end of all of these discussions about the factors you consider the Court said, “We emphasize that Courts must make a determination of reliability from all the evidence. Courts should allow a party, plaintiff or defendant, to present the best available evidence, assuming it passes muster under Robinson” -- and that's not a challenge in this case -- “and only then should a Court determine from a totality of the evidence, considering all of the factors affecting the reliability of particular studies whether there is legally sufficient evidence to support a judgment.”

JUSTICE DALE WAINWRIGHT: One other such factor is disproving other possible causative factors. Was that done here? The Petitioners make a point of explaining how, unfortunately Mr. Garza was advanced in age, obese, smoked for 40 years, smoked at that time several packs a day, had high blood pressure issues, had cholesterol issues, had a quadruple bypass and other facts in the record, and they say that just the advance of those cardiac conditions and the other medical conditions is what caused his untimely death. Were those addressed, disproven?

ATTORNEY KEVIN DUBOSE: They certainly were, Your Honor. And you have to look at two things. First of all, you have to look at Mr. Garza's condition shortly before his heart attack, and then you have to look at the findings from the autopsy about what caused the heart attack. In terms of his condition, this case is somewhat unusual in that exactly at the point when he started taking Vioxx, he had a full cardiac workup, and that told us several things. His cardiologist concluded based on that workup that he had a stable cardiac status. There was a very small area of diminished blood flow at the very tip of his heart which wasn't anywhere close to where the fatal clots occurred. They did a carotid Doppler test showing minimum plaquing, no flow obstructing lesions and the arteries were not life threatening. They showed a 60 percent ejection fraction, which means every time the heart pumps, 60 percent of the blood empties and flows back in, which sounds kind of scary to me, but they said that's actually a good number for ejection fraction, and it is a good predictor of staying alive longer. And his blood pressure was normal, his cholesterol was under control, he had cut back his smoking to two or three packs a day. So that's the picture you have just before he had his heart attack. And there was a statistical study that the expert relied on from Circulation Magazine, a medical journal, showing 5,000 patients that said, “For someone with a history of a heart attack,” which he had, “and a mildly abnormal thallium scan,” which he had, “there is a 1.4 to 2.0 chance of dying from a heart attack within the next year.” So in contrast to those facts about his condition just before it happened, we have the autopsy that shows that the cause of his heart attack was two fresh occlusions, and the experts testified that that means they did not exist at the time he started to take Vioxx, a drug known to cause clots. And that he probably had the clot for the first time on the day when he had the heart attack. But these two, there were two clots that developed in two different arteries and the experts on both said this was rare or unusual to have two heart clots develop at once. The chance of a fatal clot over the next year being 1 percent to 2 percent, the fact that it would happen twice at the same time is extremely rare. And you add to that fact that the only thing that had changed about his treatment between the time of his stable cardiac status and his heart attack

is that he started taking Vioxx, a drug known to cause clots. So what the Havner opinion requires is that we negate causes with reasonable certainty, and based on the expert evidence, we did do that, we negated that cause with reasonable certainty.

JUSTICE NATHAN L. HECHT: Back to the studies, Chief Justice asked opposing counsel whether there have been any studies since this trial. What's your answer to that?

ATTORNEY KEVIN DUBOSE: I know that I've read about some. Your Honor, I haven't bothered to study them because I didn't want to go outside the record, but I can't really answer that, I just know that I remember seeing some.

JUSTICE NATHAN L. HECHT: And what is the status of the Vioxx litigation around the country?

ATTORNEY KEVIN DUBOSE: I know that there was a class action on Vioxx that was settled, but I don't know the terms and I don't know if there are any other pending cases.

JUSTICE NATHAN L. HECHT: Or whether there's ongoing litigation in other --

ATTORNEY KEVIN DUBOSE: I'm just not aware, Your Honor, sorry.

CHIEF JUSTICE WALLACE B. JEFFERSON: Or other Texas Courts, do you know? Or other appellate courts?

ATTORNEY KEVIN DUBOSE: I'm just not aware, Your Honor. With regard to the suggestion that this is the only Court that has ever interpreted Havner in the way that it has, I beg to differ with that. Another San Antonio Court of Appeals case called Texas Workers' Compensation vs. Lopez, 21 SW2d 358, said that our reading of Havner does not reveal a clear indication that a doubling of the risk is necessary for statistical significance. In Havner there were 30 studies that had all concluded that Bendectin, did not cause birth defects. Against this backdrop, the Supreme Court criticized the Havner scientific evidence and set a high standard for the use of epidemiological studies in the face of contrary scientific belief. In the present case, the scientific evidence is overwhelmingly in favor of the Lopez proposition. That's what we've got in this case, and that's why it's so different from Havner. In Havner there were 30 published peer review studies that said Bendectin did not cause this particular heart attack, so these few epidemiological studies that the experts were relying on, unpublished, not peer reviewed. In each of the studies the experts relied upon, the author of the study had reached the opposite conclusion of what the experts said. Whereas in our case, every one of the studies that we've shown shows that there is an increased risk of heart attack with Vioxx.

JUSTICE DALE WAINWRIGHT: But none show causation? They show an association, right? You can't get to causation with epidemiological studies, right?

ATTORNEY KEVIN DUBOSE: The Third Restatement that just recently came out, Your Honor, addresses that and it talks about a difference between epidemiological studies and clinical trials, and it says that all scientific proof of causation is based at some level on inference, and there's a question of at what level do you tolerate the inference and what you don't. Clinical trials are the gold standard, you could call them, the highest level

of reliability of scientific tests as opposed to epidemiological studies. So what we think the Court should do is consider a number of indicia of reliability, one of which is whether it's a clinical trial or an epidemiological study, the clinical trial being much more reliable. I also think you should look at where the study comes from, what the chances are for bias. And most of the studies we rely on were done by Merck. It's not junk science; it's Merck science that we're relying on.

JUSTICE DAVID M. MEDINA: Well, I think it's very relative, having experienced a myocardial infarction a couple of years ago. There's a drug, Zetia, that was recently talked about in some scientific journal as leading or may contribute to heart attacks. In this instance my wife's doctor prescribed that to me and I read this article and I quit taking it, but then I read that the company behind it is their competitor. So how does the trial judge or whoever is reviewing these studies, how do they determine that these studies are indeed reliable? That seems to be another issue outside the framework of Havner.

ATTORNEY KEVIN DUBOSE: Well, it is another level of indicia that you should consider, is the course of the study. And again that's one of the things that makes this case easier because most of the studies came from Merck. We're not relying on a competitor or some rogue scientist as in Havner, but Merck studies themselves that reach these conclusions.

JUSTICE HARRIET O'NEILL: It seems to me that the main contest is not so much that this drug can cause cardiovascular events, it's just at this dosage and this duration, and I think you would have a much easier case over a longer period of time. So there, it would be helpful to look at the actual studies in terms of relative dose and duration.

ATTORNEY KEVIN DUBOSE: In terms of dose, Your Honor, almost all the studies we rely on are the same dose, 25 milligrams. There's one, the first one, VIGOR, was at 50 milligrams, and I think there's one at 12.5, but most of them are 25 milligrams. In terms of duration -- well, first of all let me point this out, almost none of these studies were undertaken for the purpose of determining whether Vioxx caused an increase in cardiovascular risk. They were taken to study other things, and a number of cardiovascular events kind of jumped out at the people doing the study and so they commented on them, but most of the studies were not under -- the scientists say “they were now powered for duration,” which means they were not undertaken or to prove how long it would take. Some of the studies were a three-year study and what we know is at the end of three years, this is the number of events there were. But we rely on several studies: The Protocol 90 Study was a six-week study; the Junie [Ph.], another meta analysis published in The Lancet, a British medical journal, said it didn't matter how long the patients were on it, even a short duration was able to demonstrate the affect; the Soloman Study, which we talked about, says the results were observable throughout the study period regardless of how long the drug had been taken; and then the VIGOR Study, which is in Tab B of your bench exhibit, has the chart that shows when the serious cardiovascular events started to occur and it's immediately. So are there any studies saying taking 25 milligrams for 23 days double the risk? Well, no, because there's no study, and all we have is what Merck has done.

JUSTICE HARRIET O'NEILL: But you're saying if you take pieces of different studies, then you get the significance that the effects start immediately?

ATTORNEY KEVIN DUBOSE: That's right.

JUSTICE HARRIET O'NEILL: And the other studies have the 25 milligram?

ATTORNEY KEVIN DUBOSE: Right.

JUSTICE HARRIET O'NEILL: And nothing in Havner says it has to be one study?

ATTORNEY KEVIN DUBOSE: That is exactly right, Your Honor. And the way that Vioxx works and the reason it causes cardiovascular risk is there are these two kinds of enzymes, there's one that causes clots and one that breaks up clots. And with Vioxx, you let the enzyme go that causes clots, but you suppress that enzyme that breaks up clots, and so that's why it creates a danger and that could happen at any time. Just as the drugs say, “They're fast acting, provide fast-acting pain relief, they also immediately start to have that effect. And it's different in different people, but at some point in a lot of people it's going to cause a clot and suppress the enzyme that breaks up the clots, and there's no reason why that wouldn't begin until 18 or 30 months later.

CHIEF JUSTICE WALLACE B. JEFFERSON: Did Garza have no history of clots before this event?

ATTORNEY KEVIN DUBOSE: Yes, Your Honor, but none for several years before this. The last procedure he had was in '98 and his heart attack occurred in 2001. And so I say he has a history of clots, I don't know that that's true. He had coronary artery disease, which causes a narrowing of the arteries, but I don't know that he ever had any history of clots, come to think of it.

JUSTICE DAVID M. MEDINA: How does the fact that he had a previous myocardial infarction before this come into play? Is that something for the gatekeeper to consider?

ATTORNEY KEVIN DUBOSE: I don't think it's a gatekeeper issue, it's one of the factors that you consider in terms of causation, but I would hate to see the Court adopt a rule that says, “Anybody who has ever had a heart attack of any sort can never again sue for heart attack and prove causation.” You mentioned you had one, Your Honor, and I had a heart attack myself four years ago, and I don't think that means that I can never take a drug that will cause me to have a heart attack.

JUSTICE HARRIET O'NEILL: Is Vioxx on the market today?

ATTORNEY KEVIN DUBOSE: It's not, Your Honor. It was removed from the market I believe in 2004, maybe 2005.

JUSTICE DAVID M. MEDINA: And how should that play in this analysis, the fact that it's been removed from the market?

ATTORNEY KEVIN DUBOSE: I'm sorry. Oh, how should that play in this analysis? I think that's some evidence that Merck knew that they had a problem with Vioxx. I don't think it's necessarily conclusive, but that's one of the factors the Court should consider.

JUSTICE DAVID M. MEDINA: That's post trial evidence, though, right?

ATTORNEY KEVIN DUBOSE: No, no. It was removed from the market before trial and it was discussed at trial, and it was because of a Merck clinical trial,

the approved study that Merck made a decision to take it off. Even though it was the most profitable drug in the history of Merck, they took it off the market because of concerns about cardiovascular risk.

JUSTICE HARRIET O'NEILL: Do you make much of the fact that Merck did not include patients with histories of cardiovascular events in the studies? Can you elaborate on that just a little bit?

ATTORNEY KEVIN DUBOSE: I can, Your Honor, because the studies might have been more helpful in terms of whether Vioxx causes problems for people with a history of cardiovascular disease, if they had included people that had those. But there were some internal emails that were introduced in evidence where someone said, “Why don't we allow everybody to participate in the study?” And the interim email said, “Oh, no, that would probably generate bad results for cardiac events and would skew the studies and would cause us to look bad,” so they didn't, but it would have been a more accurate picture. Even if you exclude people with a history of heart disease, they still had these studies that show an increased risk.

JUSTICE HARRIET O'NEILL: So would you say that excluding them would have any affect on the 2.0 factor, doubling of the risk factor?

ATTORNEY KEVIN DUBOSE: It's really impossible to determine. In retrospect, Your Honor, I think if they had been included there's a much better chance the numbers would have been higher, but I think it's difficult to say in retrospect that we can project a higher number based on that.

JUSTICE DALE WAINWRIGHT: If you're successful on your causation argument at this Court, the case goes back for retrial; is that correct?

ATTORNEY KEVIN DUBOSE: That's exactly right, [inaudible].

JUSTICE DALE WAINWRIGHT: Because of the jury issue, misconduct issue?

ATTORNEY KEVIN DUBOSE: It was remanded by the San Antonio Court of Appeals because of a juror misconduct issue, which we chose not to challenge.

CHIEF JUSTICE WALLACE B. JEFFERSON: Justice Hecht?

JUSTICE NATHAN L. HECHT: No, thank you.

CHIEF JUSTICE WALLACE B. JEFFERSON: Are there any other questions? Thank you, Counsel. The Court will hear rebuttal.

REBUTTAL ARGUMENT OF STEPHEN G. TIPPS ON BEHALF OF PETITIONER

ATTORNEY STEPHEN G. TIPPS: I'd like to use my five minutes to address three questions: First, the current status of the Vioxx litigation; second, a few comments on the studies; and third the question of excluding other causes. Most of the Vioxx litigation has been settled. If the Court wants to learn about the settlement, it can look at the Merck website. The settlement was announced in November 2007. Certain cases were excluded from the settlement. This case was excluded from the settlement because the settlement required that cases meet certain standards, one of which was 30 days Vioxx use documented, and this case had only seven days of Vioxx use documented and so it didn't qualify for the settlement. There's one other Vioxx case in the Texas system. It's coming out of the Fourteenth Court of Appeals, the Court

may or may not file a petition for review, I'm not sure, but most of the Vioxx litigation is over. Second, with regard to the studies, I think it's important for the Court in thinking about this to take into account the fact that in 2005 the FDA reviewed all of these studies, all of the hundred clinical trials that have been conducted with regard to Vioxx and concluded a number of things, one of which was there does not appear to be any risk associated with short-term Vioxx use. So it's in that context that here we are in this case, in which the plaintiffs have over the course of the case identified 12 such studies and now today we hear the two that they claim satisfy Havner. And again, neither of those two studies satisfies Havner. First, with regard to --

JUSTICE HARRIET O'NEILL: Well, is there anything in Havner that says it has to be one study that hits all the requirements? Because some of these studies appear to show that these effects can happen immediately, and so if you've got studies that establish that and meets the requirements of statistical significance, and you have other studies that show at 25 milligrams you can have an effect, why can't you combine those?

ATTORNEY STEPHEN G. TIPPS: Havner specifically says you can't pick and choose parts of studies. Havner talks about, Havner establishes the requirements for an epidemiological study that a plaintiff seeks to use to prove causation. And those requirements are more than doubling the risk, statistical significance at the same dose and duration. It has to be a single study, and then Havner goes on and says that one study would not be enough. And that's why the Courts have said, well, there have to be at least two studies. But yes, Havner does require that and Havner specifically says that you can't choose one part of a study over another part of a study.

JUSTICE HARRIET O'NEILL: Well, I can understand not being able to build a quilt, but it seems like if the study shows that the effects are immediate and that's not really disputed, and other studies show 25 milligrams, then --

ATTORNEY STEPHEN G. TIPPS: Well, no, it is hotly disputed, and we tried to make this clear in our chart, but there is no study that, no study that's in evidence that any expert talked about that shows that a statistically significant finding of more than doubling of the risk that incidents begin immediately. The objection to the email containing the VIGOR conclusions was an objection to the very chart that Mr. Dubose has represented to the Court shows that these effects begin immediately. And the objection was that whatever the chart shows, if the study is not statistically significant, then the Court should not consider it. And that objection was sustained. But there is no study that shows a more than doubling of the risk, a statistically significant more than doubling of the risk at this dose, 25 milligrams, and this duration, less than 30 days.

JUSTICE PHIL JOHNSON: Counsel, opposing counsel referenced the Shapiro Study, and they give here Plaintiffs' Exhibit 132. That has dosage at various, including 25 milligrams, and duration, various, including less than 30 days. Can you address that study? That's one that they rely on specifically.

ATTORNEY STEPHEN G. TIPPS: Shapiro is a meta-analysis in which the investigator relied upon multiple studies, one of which was the VIGOR Study. That was the biggest study in the Shapiro Meta Analysis.

JUSTICE PHIL JOHNSON: This is not a separate independent study, it is an analysis of multiple studies?

ATTORNEY STEPHEN G. TIPPS: Yes, yes.

JUSTICE PHIL JOHNSON: And just as they say here, duration was various but was not limited to a short duration, and was not -- and it had various dosages, including greater than 25 milligrams?

ATTORNEY STEPHEN G. TIPPS: Yes, it included VIGOR. The VIGOR Study, 41 percent, and I've given the Court the reference to the record, I did the math, the division to get 41 percent, but you can look at the chart and see that 41 percent of the patient years in the Shapiro Meta Analysis are attributable to VIGOR. VIGOR was 50 milligrams, twice the dose involved here, and the duration was nine months. If you take out VIGOR, and that's in our chart as well, the relative risk drops to like 1.1 and the finding becomes statistically insignificant. Moreover, if you look at another place in Shapiro, and this is in our chart as well, and see what the result is if you compare Vioxx to placebo, you again get no doubling of the risk and no statistical significance. And so if you look at the relevant part of Shapiro, it doesn't satisfy Havner and doesn't support the plaintiffs' case. I think I'm out of time unless the Court -- I didn't get to all my points.

CHIEF JUSTICE WALLACE B. JEFFERSON: Justice Wainwright?

JUSTICE DALE WAINWRIGHT: The third point, can you address that briefly?

ATTORNEY STEPHEN G. TIPPS: I can. The plaintiffs make two points with regard to excluding other probable causes. The first is they say that Mr. Garza had a stable cardiac status. They overlook the fact that the stress test that he had just been given revealed an abnormality, an apical ischemia, which Dr. Posada, his treating physician, said justified a cardiac catheterization, which Dr. Simonini testified if Dr. Posada recommended a cardiac catheterization, then Mr. Garza was at risk of having a heart attack. So that's the first point.

JUSTICE HARRIET O'NEILL: But I understood the response to that was it was in a different part, it was in a different area of the heart, and so it couldn't have been the area where these clots formed.

ATTORNEY STEPHEN G. TIPPS: Well, I don't think that's supported by the record. But it is clear that if he had had a cardiac catheterization, it would have revealed the blockage in these bypass arteries that were discovered on pathology. And the other point, Justice Wainwright, is that the primary effort that the plaintiffs made to exclude other causes was their expert's testimony that it was very rare that there were two clots. And he's relying upon the autopsy report. Three quick responses. Number one, the expert offered no scientific basis for his bare opinion that it's rare to have two clots in a heart attack event. Number two, there is no evidence anywhere in this record that Vioxx tends to cause multiple clots, that multiple clotting is a signature of a Vioxx heart attack. And number three, the only pathologist to testify, Dr. Wheeler, and the only person to look at these slides under high magnification concluded that they were not clots, but rather they were hemorrhages within the plaque, and no one claims that Vioxx causes hemorrhages within the plaque. And we submit that under City of Keller, the Wheeler testimony should be credited because it demonstrates that the assumption that Simonini made and that the coroner made that these were clots is simply false, and that this is a situation in which testimony that might appear to be competent becomes incompetent when you look at the

scientific evidence. So that's the quick response on that.

CHIEF JUSTICE WALLACE B. JEFFERSON: Any further questions? Thank you, Counsel. The cause is submitted and the Court will take a brief recess.

[End of proceedings.]

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