UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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:
KARLENE HOGAN,
06 CV 260
Plaintiff,
-against- :
United States Courthouse
Brooklyn, New York
NOVARTIS PHARMACEUTICALS CORPORATION,
Defendant. :
May 23, 2011
- - - - - - - - - - - - - - - - X 9:30 o'clock a.m.

TRANSCRIPT OF TRIAL
BEFORE THE HONORABLE BRIAN M. COGAN
UNITED STATES DISTRICT JUDGE, and a jury.

APPEARANCES:

For the Plaintiff: OSBORN LAW, P.C.
295 Madison Avenue
New York, N. Y. 10017
BY: DANIEL OSBORN, ESQ.
PHILIP J. MILLER, ESQ.

BEINS, GOLDBERG & HENNESSEY
Chevy Chase Metro Building
Chevy Chase, Maryland 20815
BY: JOHN J. BEINS, ESQ.

VALAD & VECCHIONE, PLLC
3863 Plaza Drive
Fairfax, Virginia 22030

For the Defendant:
RIVKIN RADLER, LLP
926 RXR Plaza
Uniondale, New York 11556
BY: JESSE J. GRAHAM, ESQ.

HOLLINGSWORTH, LLP
1350 I Street
Washington, D.C. 20005
BY: BRUCE J. BERGER, ESQ.
ROBERT E. JOHNSTON, ESQ.

Court Reporter: Henry R. Shapiro
225 Cadman Plaza East
Brooklyn, New York
718-613-2509

Proceedings recorded by mechanical stenography, transcript produced by computer.

THE COURT: Good morning.

Be seated please. Thank you all for the weekend reading.

Do I need to hear anymore on the motions. Anything further from the defendant?

MR. BERGER: Your Honor, I think our brief lays it out as clearly as you lay it out. I don't think there is anything in the opposition that deserves a response.

THE COURT: No reason to be insulted.

MR. BERGER: It's not necessary to respond to the plaintiff's opposition.

THE COURT: Deserves as a moral connotation for it.

Anything further, Mr. Osborn?

MR. OSBORN: I will let Mr. Beins handle that.

MR. BEINS: The only thing I would point out something that we didn't address in the brief. The Olshansky case from Rhode Island talked about a breach of implied warrantee, slightly differently than it talked of the standard for negligence and strict liability.

In this case they relaxed the causation element of the plaintiff's proof.

Thank you, your Honor.

THE COURT: First of all, I'm ruling on this motion against the backdrop of some pretty clear Second Circuit law as to what I am to do with these kinds of motions. The Second

Circuit has expressed an interest in efficient of judicial administration that it suggested in all but cases that are really, really clear. I go ahead, at least, where the defendant's case will be relatively brief as it is here and let the jury hear the rest of the case and then determine whether the defendant is entitled to judgment as a matter of law.

At this point the technical standard I have to find that a reasonable jury could not arrive at a verdict in favor of the plaintiff or that any such verdict would be the result of sheer surmise and conjecture. If the jury returns a verdict for the plaintiff, I'm going to revisit the defendant's arguments, but at this point I will deny the motion and my reasons are as follows.

First of all, after the learned intermediary doctrine, that has been adopted by over two dozen jurisdictions and, I think, Rhode Island would adopt it as well.

I see nothing in Rhode Island case law, including the Castrugnano case, to suggest that Rhode Island would require direct patient warning in pharmaceutical drug cases. Just because 4024 A of the second restatement says nothing about the learned intermediary doctrine doesn't bother me. There are a lot of states that adopted both.

If Rhode Island doesn't accept the doctrine in the

way that most courts have, then it's likely it's going to look to the third restatement, which requires direct warnings when the manufacturer has reason to know that the health care provider will not be in a position to reduce the risk to the patient.

Unlike the mass inoculation vaccine scenario that the restatement mention in one of its comments, Zometa is a very serious therapy that is commenced after consultation with doctors.

Plaintiff has admitted in the joint pretrial order that Zometa is admitted at infusion centers and the patient sees the package or gets any written information about it.

Plaintiff doesn't despite Zometa's successful bone manufacturer, even if it can lead to ONJ. As intended there Zometa is a type of drug learned intermediary doctrine encourages a doctor-patient dialogue.

Zometa does not fall within the exception of the restatement and I, therefore, find a direct warning to Mr. Hogan was not required.

Now, in terms of the heating presumption, I don't think the plaintiff fully understands what the function of the presumptions are, either on motion for summary judgment, or on a motion for a directed verdict.

What is really going on is the jury doesn't get instructed on the heating presumption. The heating

presumption the Court considers if it's going to apply it in determining whether plaintiff has made a prima facie case. In other words, let assume that there is a total of absence of evidence as to proximate cause from a plaintiff. A court could say, I'm going to let it go to the jury anyway because of the heating presumption in plaintiff's favor. That satisfies plaintiff's prima faca case. It's not as if the jury gets instructed on the heating presumption. This to me is no different than, I don't know if the parties are familiar with this area of law, in the employment discrimination area you have what is known as the McDonald-Douglas burden shifting test that the courts use on summary judgment and basically the plaintiff has to demonstrate by showing certain factors on a prima facie case and then if it does then the defendant has to come forward with legitimate business justification for the employment action and if it does that then the Court looks at all the facts and determines whether there is a jury issue.

That is the same thing with the heating presumption, reasons the plaintiff can either get to the jury because of the presumption, or it can get there because the plaintiff has adduced sufficient facts as to a proximate cause. I'm not deciding now whether I'm letting the case go to the jury based on the heating presumption or based on the evidence that the plaintiff has submitted. I will note, as the

defendant has put forth, evidence that may rebut any such presumption, even if there is a heating presumption, it's obviously rebuttable.

The defendant has shown that or at least offered evidence that Dr. Przygoda would have proceeded and Dr. Brown would have extracted Mr. Hogan's teeth when he did because of the impending stem cell transplant and the necessity of starting soon. The plaintiff has put in evidence that Dr. Brown has changed his practice requiring an informed consent to undergo dental procedures for patients taking the drugs and informing them about the alleged risk of ONJ.

If the jury does infer that adequate warnings would have led one of Mr. Hogan's doctors to change the course of events that led to his jaw condition, I will then revisit the role of the heating presumption, but I don't need to determine that now because I'm letting the case go to the jury. I will not rule on it right now.

Now, as to the failure to warn plaintiff himself, I think the plaintiff has submitted evidence based on which a jury could conclude that Novartis Pharmaceuticals should have warned about the dangers of ONJ in 2003, at least, under the standard that the Second Circuit has suggested that I evaluate these motions. For example, Dr. Marks testified about the textbook, which predates the therapy, and which arguably Novartis Pharmaceuticals overlooked. It's an