

Novartis Gets Punitive Damages Barred In Bone Drug Suit

By Juan Carlos Rodriguez

Law360, New York (May 12, 2014, 4:06 PM EDT) -- A North Carolina federal judge overseeing a trial over jaw injuries allegedly caused by Novartis Pharmaceutical Corp.'s bone drugs Zometa and Aredia on Friday said the company can't be held liable for punitive damages because there isn't enough evidence to prove its executives acted wrongfully.

Plaintiffs Jimmy and Patricia Earp have alleged that Novartis is liable for punitive damages under North Carolina law because Zometa caused him to develop osteonecrosis of the jaw. The suit is one of a multitude over the drug. But U.S. District Judge James Dever III said in a transcript provided to Law360 that the Earps failed to meet the standard to prove punitive damages are appropriate in this case.

The judge said if the jury finds the Earps are entitled to compensatory damages, it also may award them punitive damages only if they prove, "by clear and convincing evidence," that fraud, malice or willful or wanton conduct was related to his osteonecrosis of the jaw. And the Earps also must prove that Novartis' officers, directors or managers participated in or condoned the conduct constituting the aggravating factor.

North Carolina's punitive damages statute defines malice as "a sense of personal ill-will towards the claimant that activated or incited the defendant to perform the act or undertake the conduct that resulted in harm to the claimant," and also includes a fraud component, Judge Dever said, but he said the Earps have conceded that malice and fraud are not at issue in this case.

"Rather, Mr. Earp alleges that Novartis' officers, directors or managers acted willfully or wantonly, or condoned willful or wanton conduct, and that such willful malice, likewise the fraud reference or wanton conduct is related to his osteonecrosis of the jaw," the judge said.

He said that under North Carolina law, willful or wanton conduct means "the conscious and intentional disregard of and indifference to the rights and safety of others, which the defendant knows or should know is reasonably likely to result in injury, damage or other harm."

But based on the evidence in the case, Judge Dever said, the Earps have not presented sufficient evidence to allow a rational jury to find willful or wanton conduct on the part of Novartis' officers, directors or managers by clear and convincing evidence.

"Moreover, based on the evidence presented, and viewing the evidence in the light most favorable to

Mr. Earp, no rational jury could say, without hesitancy, that Novartis' officers, directors or managers participated in or condoned the requisite willful or wanton conduct and that they knew or should have known that such conduct was reasonably likely to result in injury," the judge said.

He granted Novartis a directed verdict on the issue of punitive damages.

The company has also filed a motion for judgment as a matter of law, saying the Earps failed to prove by a preponderance of the evidence that Novartis' warnings were inadequate.

It also said the Earps failed to prove that a different warning would have altered the prescribing doctors' decisions and prevented Jimmy Earp's injury. And it said the Earps failed to prove that Jimmy Earp's ONJ was caused by Aredia and Zometa.

That motion was pending on Monday.

Counsel for the Earps were not immediately available for comment Monday.

The Earps are represented by Samuel Ranchor Harris of Girardi Keese, Lyn Broom of Teague Rotenstreich Stanaland Fox & Holt, John Vecchione of Valad & Vecchione PLLC, and Elizabeth Odette of Lockridge Grindal Nauen PLLP.

Novartis is represented by William J. Cople III and Buffy J. Mims of Hollingsworth LLP and Susan P. McWilliams of Nexsen Pruet LLC.

The case is Jimmy Earp et al. v. Novartis Pharmaceuticals Corp., case number 5:11-cv-00680, in the U.S. District Court for the Eastern District of North Carolina.

--Additional reporting by Kurt Orzeck. Editing by Jeremy Barker.