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Fosamax Ruling Puts Preemption In Play For Branded Drugs

By **Greg Ryan**

Law360, New York (July 02, 2013, 8:14 PM ET) -- A New Jersey federal judge's ruling Thursday that claims related to Merck & Co. Inc.'s Fosamax are preempted by federal law will likely inspire other brand-name drug makers to mount the defense, which companies have forsaken following an unfavorable U.S. Supreme Court decision four years ago.

The decision marks one of the few times since the high court's decision in Wyeth v. Levine that a brand-name drug company has secured a favorable preemption ruling. In that landmark 2009 ruling, the Supreme Court had held that a plaintiff could pursue failure-to-warn and other claims against a brand-name drug maker unless there was clear evidence the FDA would have rejected a label change.

But in the Merck case, U.S. District Judge Joel Pisano did find clear evidence the U.S. Food and Drug Administration would not have approved a stronger warning about Fosamax's link to femur fractures.

Before Thursday, the best-known exception to Wyeth v. Levine had been a 2011 Oklahoma federal court ruling in a suit over the antidepressant Effexor — a decision known as Dobbs.

"This decision, along with Dobbs, may make some companies pursue a preemption motion where they wouldn't have in the past," Bowman and Brooke LLP partner Randall Christian said.

The Fosamax ruling may be more encouraging for brand-name drug makers than Dobbs was, because the FDA likely scrutinized Fosamax's safety less closely than it did that of selective serotonin reuptake inhibitors like Effexor, according to Christian. Even with less evidence about the agency's thinking on a proposed label change, the court still determined the evidence was "clear."

"I think this one lays out that if the FDA's analyzing a particular drug and particular adverse event ... those activities can constitute clear evidence it would have rejected a proposed labeling request," Christian said.

The Fosamax ruling also struck new ground on the place of prior approval supplements in preemption battles over brand-name drugs. A company must submit a PAS to the FDA when it wants to make a major change to a drug.

Merck had submitted a supplement proposing to add language about femur fractures to Fosamax's precaution and adverse reaction labeling, but the FDA rejected the changes to the precaution labeling.

The plaintiff in the case, Bernadette Glynn, argued that Merck could have instead made a "changes being effected" submission to the agency to strengthen the femur fracture warning, since a CBE submission is approved after a label change is made, rather than being preapproved. In Wyeth v. Levine, the Supreme Court had ruled in the plaintiff's favor under the reasoning that Wyeth could have submitted a CBE regarding the drug Phenergan's risks, and there was no evidence the FDA would have rejected such a change.

But Judge Pisano ruled that since the FDA did not approve the PAS, it ultimately would not have approved the CBE either.

The Fosamax ruling suggests to brand-name drug makers "they don't have to file a CBE if they've filed a PAS and it's rejected," said Frommer Lawrence & Haug LLP partner Elizabeth Leff. "They can assume that's 'clear evidence.'"

The decision could even affect how drugmakers behave before they are engaged in litigation. Since it cited the FDA's rejection of Merck's proposed label change as the clear evidence the drugmaker needed for preemption, the ruling may prompt other brand-name drug makers to be more proactive in submitting proposed labeling changes to the FDA, according to Blackwell Burke PA partner Peter Goss.

"By putting the information out there and making a proposal the FDA rejects, that's exactly what you need for 'clear evidence' under Levine to get preemption," Goss said.

At the very least, the decision makes preemption in the post-Levine world a little less rare, according to Goss. That alone can benefit drugmakers facing failure-to-warn claims, he said.

"There haven't been a lot of courts willing to stick their necks out there post-Levine and say, 'This is what the court meant by clear evidence,'" Goss said. "Once you get a well-reasoned opinion out there, it makes the argument a lot more viable for the next case."

Glynn is represented by Paul Pennock, Edward Braniff and Jonathan Sedgh of Weitz & Luxenberg PC and Donald Ecklund of Carella Byrne Cecchi Olstein Brody & Agnello PC.

Merck is represented by Chilton Varner and Andrew Bayman of King & Spalding LLP, Karen Confoy of Fox Rothschild LLP and Steve Marshall of Venable LLP.

The case is Glynn v. Merck Sharp & Dohme Corp., case number 3:11-cv-05304, in the U.S. District Court

for the District of New Jersey.

--Editing by Kat Laskowski and Katherine Rautenberg.