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BLOG

Zantac MDL Narrowed by Two Preemption-Based Dismissal Orders

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In re: Zantac (Ranitidine) Product Liability Litigation[1] is a coordinated multi-district litigation (MDL) centralized in the Southern District of Florida. The MDL involves allegations (which the defendants deny) that the active ingredient in Zantac (a heartburn medication) and its generic formulations are potentially carcinogenic because ranitidine can transform into the cancer-causing molecule NDMA. On 2020's final day, the Court issued two dismissal orders that, on federal preemption grounds, eliminated (1) innovator liability claims under 35 jurisdictions' laws against the prescription *brand* manufacturers by individuals who took *generic* formulations of those brand manufacturers' products; and (2) all misbranding claims against the prescription generic manufacturers by individuals who took those generic manufacturers' products.[2]

Decision 1: The innovator liability claims under 35 jurisdictions' laws

Certain plaintiffs who were prescribed *generic* versions of Zantac sued the *brand* manufacturers under 35 jurisdictions' laws with a theory known as innovator liability.[3] Innovator liability is, simply stated, "holding a brand-name manufacturer liable for injuries from a [generic] product it did not make, sell, or distribute" because the generic product is allegedly just a generic version of the branded product that the brand manufacturer invented, created, and first marketed. [4] In this case, the plaintiffs sought to hold the brand manufacturers liable for injuries plaintiffs alleged were caused by the generic versions of branded Zantac. The generic-prescribed plaintiffs claimed that they could utilize innovator liability against Zantac's brand manufacturers, and that innovator liability had not been definitively rejected by the highest courts in any of the 35 jurisdictions those plaintiffs were from.

To decide the motion to dismiss, the Court conducted an analysis under *Erie R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938), which requires federal courts sitting in diversity to predict how the highest court of a jurisdiction would rule when that jurisdiction has not definitively ruled on an issue.[5] The Court did an *Erie* analysis for each of the 35 jurisdictions. This was no small task. The Court documented its *Erie* analysis in a separate appendix exceeding 50 pages.[6]

Ultimately, the Court "predict[ed]" that none of the highest courts of the 35 jurisdictions would recognize Plaintiffs' theory of [innovator] liability." [7] All of the claims based on the theory of innovator liability were dismissed.

Decision 2: The warning and design defect claims against the generic manufacturers

Plaintiffs did not only assert claims against branded pharmaceutical companies, they also pursued redress for injuries alleged to have been caused by generic ranitidine by suing generic manufacturers directly. However, in a separate order that same day, the Court found plaintiffs' claims were preempted. Specifically, the Court addressed whether plaintiffs who were prescribed generic formulations of Zantac could sue the generic manufacturers for misbranding under federal law, and particularly because the generic manufacturers allegedly failed to warn about carcinogens and did not formulate the products without carcinogens.[8] The Court began by citing two Supreme Court decisions—*PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011) and *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472 (2013)—which held that warning and formulation claims against generic drug manufacturers are preempted because they cannot remedy design defects or provide additional warnings while remaining in compliance with federal law.[9] Under that federal law, they can only sell their products using the same federally-approved labels as the brand manufacturers, and they can only sell those products using the same formulations as the branded manufacturers. [10] Similar and additional categories of preempted claims include, without limitation, failure to communicate information to consumers or medical providers, failure to conduct testing of generic products, misrepresentation, fraud, violation of state consumer protection statutes, and breach of express and implied warranties.[11]

The Plaintiffs alleged that their claims did not fall into any of these categories because they were based on violations of the federal misbranding laws that prohibited the introduction of misbranded and mis-formulated drugs into interstate commerce.[12] For that reason, argued Plaintiffs, the claims were not preempted because they were not suing based on claims that *differed* from federal law, but rather their claims were "*parallel* to federal misbranding requirements."[13]

To address Plaintiffs' argument, the Court first, buttressed by many other federal court opinions, explained that "federal courts presented with claims that generic drug manufacturers had distributed misbranded drugs rejected such claims as preempted" under *Mensing* and *Barrett*.[14] The Court went on to explain that, while federal law prohibits misbranding, the misbranding law does not grant a private civil right to sue.[15] But in addition, the misbranding allegations were essentially based on allegations that the generic products were sold with warning and design defects.[16] Thus, "[i]f Plaintiffs' position were accepted, a plaintiff could avoid preemption simply by asserting, for example, that a drug's labeling was false or misleading."[17] That would "render the vast body of preemption caselaw in the drug context, including binding Supreme Court decisions, meaningless."[18] And the Court "cannot adopt a position that would render preemption case law meaningless."[19]

> The court summarized its ruling as follows:
>
> Plaintiffs' claims based on alleged defects in ranitidine products, product labeling, or other communications that Generic Manufacturer Defendants could not independently change while remaining in compliance with federal law are pre-empted. This includes, but is not limited to, claims based on allegations that ranitidine products were defectively designed because they break down into NDMA and claims based on failure to warn consumers that the products contained NDMA or could break down into NDMA when ingested.[20]

These two decisions were noteworthy because they occurred in the same litigation and involved questions of potential liability for both brand and generic pharmaceutical manufactures in connection with the sale of generic drug products. Thus, we have summarized them here.

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[1] Case No. 20-md-02924 (S.D. Fla.)

[2] The Court issued order orders on the various pending motions to dismiss. This addresses just the two orders discussed herein.

[3] There were 52 potential "jurisdictions": all 50 U.S. states plus Puerto Rico and the District of Columbia. ECF No. 2516, at 3-4. Defendants conceded innovator liability was a valid theory in two states: California and Massachusetts. *See id.* at 7 fn.5. Plaintiffs conceded innovator liability was not valid in four states: Alabama, Iowa, West Virginia, and Florida; and they declined to pursue claims under any of the other remaining eleven jurisdiction: Georgia, Idaho, Indiana, Kansas, Kentucky, Louisiana, New Jersey, Ohio, Tennessee, Texas, and Washington. *Id.*

[4] *Id.* at 9.

[5] *Id.* at 10.

[6] *Id.* at 25-79.

[7] *Id.* at 15; *see also id.* at 11-14.

[8] ECF No. 2512.

[9] *Id.* at 6.

[10] *Id.*

[11] *Id.* at 17-19.

[12] *Id.* at 20.

[13] *Id.*

[14] *Id.* at 24.

[15] *Id.* at 28.

[16] *Id.*

[17] *Id.*

[18] *Id.*

[19] *Id.*

[20] *Id.*

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