Client Alert

November 6, 2014

"Generic" Logic Helps Branded Drug Achieve Dismissal

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A federal district court has held that design defect claims against a brand pharmaceutical manufacturer are preempted by federal law. *Booker v. Johnson & Johnson*, No. 3:12 oe 40000, 2014 WL 5113305 (N.D. Ohio Oct. 10, 2014).

SETTING THE STAGE – *MUTUAL V. BARTLETT*

In 2013, the United States Supreme Court held that federal law preempts failure-to-warn design defect claims against generic drug manufacturers. *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013). The Supreme Court based its *Bartlett* decision in part on *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), which held that federal law prohibited generic manufacturers from implementing unilateral label changes, and therefore preempted state-law requirements (through statutes or juries) that a drug company strengthen its warnings. Of particular relevance, the Supreme Court also stated in *Bartlett* that the drug at issue—a single-molecule drug—was "chemically incapable of being redesigned." 133 S. Ct. at 2475. However, the Supreme Court fell short of holding that design defect claims against brand manufacturers were preempted, setting the stage for the *Booker* case, decided last month.

BACKGROUND

Booker arose out of the Ortho Evra MDL pending in the Northern District of Ohio. The plaintiff sued on behalf of her deceased daughter, who allegedly died from a pulmonary embolism after using Ortho Evra, a branded birth control patch.

Defendants moved for summary judgment on plaintiff's design and manufacturing defect claims, subsequent to the court's ruling that the package insert adequately warned of increased risk of blood clots and pulmonary embolism.[1]

DESIGN DEFECT UNDER GEORGIA LAW

The court evaluated the alleged design defect under Georgia law. Like many states, Georgia follows the Restatement (Second) of Torts, section 402A, comment k. Under comment k, pharmaceutical products, "properly prepared, and accompanied by proper directions and warnings, [are] not defective, nor [are they] unreasonably dangerous."[2] To assert comment k as an affirmative defense under Georgia law, the defendant must show that "(1) the product is properly manufactured and contains adequate warnings; (2) its benefits justify its risks; and (3) the product was at the time of the manufacture and distribution incapable of being made more safe."[3]

Because the court had already determined the warnings were adequate as a matter of law, the only remaining

1 Defendants had successfully moved for summary judgment on the failure-to-warn claim, among others. Defendants had also unsuccessfully moved for judgment on the pleadings on the design and manufacturing defect claims, and re-raised those arguments here on a motion for summary judgment.

2 *Booker*, 2014 WL 5113305, at *3 (quoting *Bryant v. Hoffman-La Roche, Inc.*, 585 S.E.2d 723, 728 (Ga. Ct. App. 2003)).

3 *Id.* (quoting *Bryant*, 585 S.E.2d at 728).

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issues were whether the benefits of the product outweighed its risks and whether the product was incapable of being made more safe.

ALTERNATIVE DESIGN PROHIBITED BY FEDERAL LAW

In weighing the risks against the benefits of any design, Georgia law focuses on "whether an alternative design would have made the product safer than the original design and was a marketable reality and technologically feasible."[4] The *Booker* court found that plaintiff made a prima facie case of design defect because she alleged that birth control pills and intrauterine devices were two alternative designs available at the time decedent was prescribed Ortho Evra. The court then stated clearly that under Georgia law, defendants' motion for summary judgment for design defect would be denied.

But the court went on to grant the motion because of preemption. The court relied primarily on the language from *Bartlett* that single-molecule drugs are incapable of redesign: "state-law design defect claims . . . that place a duty on manufacturers to render a drug safer by either altering its composition or altering its labeling are in conflict with federal laws that prohibit manufacturers from unilaterally altering drug composition or labeling."[5] The *Bartlett* case discussed only generic drugs and the inability of generic drug manufacturers to change the chemical composition of their products due to the sameness requirements of the Hatch-Waxman Amendments. The Supreme Court also found that a "simple" drug is "chemically incapable of being redesigned." Although technically dicta, this language was correctly interpreted by the *Booker* court as applying with equal weight to *any* pharmaceutical manufacturer, whether brand or generic. In doing so, the court applied *Bartlett* to preempt design defect claims against brand manufacturers—even when those claims do not sound in failure to warn.

IMPACT OF *BOOKER*

The reasoning underlying the *Booker* court's holding would extend to all single-molecule drugs, which comprise virtually all prescription drugs that are not biologics. Any molecule constituting an active pharmaceutical ingredient could not be "redesigned" and still be an FDA-approved drug. If other courts follow suit, pharmaceutical manufacturers would finally be able to rely on FDA approval as a defense to design defect claims.

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4 *Id.* (quoting *Banks v. BCI Ams.*, 450 S.E.2d 674 (Ga. 1994)).

5 *Id.* (quoting *Bartlett*, 133 S. Ct. at 2479).

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