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New Pharma Co. Defenses For 'Innovator Liability' Claims

JULY 10, 2020

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Under a theory known as "innovator liability," a handful of states have permitted plaintiffs who only ingested a generic medication to sue the pharmaceutical company that manufactured the branded form of the medication. Although they represent a minority,[1] courts in California,[2] Massachusetts,[3] Vermont,[4] and Illinois[5] have recognized some form of innovator liability.

Plaintiffs using the innovator liability theory can avoid federal law preempting failure-to-warn claims against generic manufacturers by instead filing their claims against the branded manufacturer—even though they never ingested the brand medication.[6] In these cases, plaintiffs usually argue that because the branded manufacturer controls the label, and the label contained the allegedly inadequate warning, the branded manufacturer is liable.

Assuming that this theory remains good law, and that plaintiffs will try to expand its reach, what defenses are available to branded manufacturers? Below, we review three defense strategies that manufacturers have successfully employed to avoid innovator liability in recent cases.[7]

Lack of Personal Jurisdiction

To bring a lawsuit, a plaintiff must establish that the court has personal jurisdiction, either specific or general, over the defendant.[8]

General jurisdiction over a corporation is typically found in the state "where it is incorporated or has its principal place of business."[9] Specific jurisdiction is found where the subject of the suit "arises out of or relates to the defendant's contacts with the forum."[10]

Plaintiffs in innovator liability cases have a significant problem with personal jurisdiction where general jurisdiction is unavailable. In particular, while the plaintiff may have specific jurisdiction over the generic manufacturer in the state where the plaintiff ingested the medication, since the plaintiff did not ingest the brand's medication at all, it cannot

establish specific jurisdiction through that channel.

The plaintiff may claim that the brand's other contacts with the state are sufficient to confer specific jurisdiction, but recent court decisions have cast doubt on this theory. The U.S. District Court for the Eastern District of California recently recognized this very issue in *Henry v. Angelini Pharma Inc.*, dismissing an innovator liability case for lack of personal jurisdiction.[11]

There, the plaintiff—a California resident who took the generic formulation of trazadone hydrochloride, a drug used to treat insomnia, in California—claimed that he suffered significant resulting injuries.[12] Because federal preemption barred failure-to-warn claims against the generic manufacturer, the plaintiff sued the brands (Angelini Pharma and Endo Ventures), claiming that they were "involved 'in some meaningful way'" with the brand-name extended-release formulation of the drug.[13]

The defendants moved to dismiss for lack of personal jurisdiction, and the court agreed.[14] First, with respect to general jurisdiction, the court noted that neither defendant was at home in California, as both parties were incorporated outside of California and also maintained principal places of business elsewhere.[15]

Second, as to specific jurisdiction, the court concluded that "there is nothing that ties Plaintiff's claim to Defendants' activities in California."[16] In the court's view, to the extent that either defendant marketed their brand drug in California and misrepresented the side effects, "there is no indication that [the] conduct had any effect on how" the generic manufacturer "eventually labeled the trazodone product that allegedly harmed Plaintiff."[17]

Following Henry, drug manufacturers should carefully consider preserving and making personal jurisdiction arguments where general jurisdiction is not established.

How Federal Courts May Lead the Way

When sitting in diversity, federal courts are required to apply the substantive law of the forum state—or the appropriate state as governed by the applicable choice of law rules.[18] In the context of multidistrict litigation, a district court may be faced not only with the task of predicting the outcome of an unresolved issue of the forum state's law, but also with the laws of many states based on the transferred cases.

Faced with such a challenge, some judges have refused to expand the doctrine.[19] Recognizing federalism concerns, many courts of appeals have directed trial courts to avoid expanded liability in diversity cases where state law is unclear.[20]

For example, in affirming a district court's refusal to expand innovator liability, the U.S. Court of Appeals for the Sixth Circuit said: "When given a choice between an interpretation … which reasonably restricts liability, and one which greatly expands liability, we should choose the narrower and more reasonable path."[21]

The U.S. District Court for the District of Delaware's recent opinion in *Trower v. Janssen Pharmaceuticals* presents a model case highlighting this issue.[22] There, the plaintiff took risperidone—a generic version of Risperdal—for mental health issues, and sued Janssen, the maker of the branded drug, alleging that he developed gynecomastia as a result of taking the drug.[23]

The court granted summary judgment for the defendant. After surveying other states' laws and relevant Delaware authority, the court concluded that "Delaware law does not support imposing liability on a brand name defendant for a generic manufacturer's product."[24]

Notably, addressing federalism concerns, the court went even further, explaining: "[E]ven if Delaware law provided some basis for imposing liability for failure to warn on brand name manufacturers, it would be imprudent for me to extend Delaware's law to that point while sitting in diversity."[25]

In view of these cases, branded drug makers who find themselves fighting against a novel expansion of state law in federal court may raise federalism concerns and the large collection of relevant authority urging federal judges to resist expanding state law.

No Liability for Former Drugs Where Harm Was Previously Unknown

One element of all claims sounding in negligence is that the defendant must have breached a duty to the plaintiff. Even assuming that a branded drug manufacturer owes a general duty to generic users, what about brands who no longer make a drug, and were not aware of a risk when the drug was still on the market?

The Second District of the California Court of Appeals considered just that situation, and concluded there is no liability.[26] In a coordinated action, plaintiffs had alleged that talcum powder products manufactured by Johnson & Johnson, and Johnson & Johnson Consumer Inc., or JJCI, caused them to develop ovarian cancer.[27]

Following a bellwether trial on the plaintiffs' failure to warn theory, the jury found for the plaintiffs, awarding $68 million in compensatory damages and $340 million in punitive damages against Johnson & Johnson, and additional damages against JJCI.[28] The trial court granted the defendants' motions for judgment notwithstanding the verdict and motion for new trial for a number of reasons, including insufficiency of the evidence and excessive damages.[29]

On appeal, the Court of Appeals affirmed the judgment notwithstanding the verdict with respect to Johnson & Johnson, determining that it owed no duty to the plaintiffs. After concluding that Johnson & Johnson stopped manufacturing talcum powder in 1967, and that there was no evidence of the defect at least until 1982,[30] the court refused to apply innovator liability.[31]

The court observed that whereas *T.H. v. Novartis Pharm. Corp.*, the California Supreme Court case that established innovator liability, pertained to "liability for a negligent failure to warn in labeling that occurred prior to a manufacturer divesting itself of the rights to the drug," there was "no substantial evidence that Johnson & Johnson negligently failed to warn prior to 1967, when it was manufacturing Johnson's Baby Powder."[32]

Thus, the court held that because Johnson & Johnson owed no duty to the plaintiffs, judgment notwithstanding the verdict was proper.[33]

In light of the Johnson & Johnson talcum powder cases, drug manufacturers sued for drugs that they no longer produce should carefully consider the extent to which they had reason to know of a defect while the drug was still in production.

Looking Forward: Likely Plaintiff Strategies

Given federal preemption and states' reticence to adopt innovator liability, what can branded and generic manufacturers expect to happen?

Two recent trends have emerged: Plaintiffs are (1) attempting to expand innovator liability against branded companies where it does not yet exist, and (2) trying to assert claims against generic companies in an effort to make an end-run around longstanding and powerful preemption defenses under federal law.

A recent case in the U.S. District Court for the Western District of Texas, *Johnson v. Novartis Pharmaceuticals Corporation*, shows both strategies at work—though they were ultimately unsuccessful.[34] There, the plaintiff sued a number of branded and generic companies for alleged harms arising out of his use of generic versions of the drugs minocycline and carbamazepine.[35]

The plaintiff alleged that both drugs caused him to experience symptoms of Peyronie's disease.[36] As a result, he asserted a number of claims against the various defendants, including strict liability, negligent manufacturing, negligent failure to warn/fraudulent representation, breach of express and/or implied warranty, and loss of consortium.[37]

All defendants moved to dismiss.[38] The court first considered whether the two branded companies could be held liable under an innovator liability theory, and determined that they could not be.[39] Evaluating recent federal court decisions, including the U.S. Court of Appeals for the Fifth Circuit's decision in *Eckhardt v. Qualitest Pharmaceuticals Inc.*,[40] the court determined that under Texas law, "brand name manufacturers do not owe a duty to consumers of generic drugs."[41]

Thus, the court concluded that because the "[p]laintiff's original and amended complaint admits that he did not ingest [the branded defendants'] products, his claims against them must be dismissed."[42] The court granted the motion to dismiss, with prejudice.

Turning to the plaintiff's claims against the generic manufacturers, although the court noted that the plaintiff had "assert[ed] multiple causes of action," the court determined that "each of the ... causes of action center[s] around a products liability claim based on Defendants' alleged failure to warn."[43]

Accordingly, the court decided to "treat Plaintiff's causes of action as a failure to warn claim," and ultimately concluded that the claims failed under state law because they were not subject to any of the five exceptions to the presumption of U.S. Food and Drug Administration preemption that are codified in Texas.[44] The court also determined, in the alternative, that the claims were preempted under federal law.[45]

Although the court in Johnson did not separately consider the plaintiff's claim for negligent manufacturing, many other courts have considered and rejected such a tactic. The U.S. District Court for the Central District of California's comment rejecting a negligent manufacturing claim in what was otherwise a failure to warn case provides an apt description of the problem:

Plaintiffs have not attempted to state a manufacturing defect claim against any of the "Pharma Defendants"—and understandably so, since their theory of the case is that [the drug itself] (rather than a specific batch that [decedent] was prescribed) is unreasonably dangerous for teenagers.[46]

In sum, branded and generic drug manufacturers should consider defenses based on personal jurisdiction, federalism and the specific allegations when faced with a plaintiff's creative attempt to expand liability.

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[1] See In re Darvocet, Darvon, & Propoxyphene Prod. Liab. Litig., 756 F.3d 917, 938 (6th Cir. 2014) ("[A]n overwhelming majority of courts, in at least fifty-five decisions from twenty-two states" have rejected innovator liability); Johnson v. Novartis Pharms. Corp., et al., 2020 WL 2300139, at *3 (W.D. Tex. May 7, 2020) (rejecting innovator liability under Texas law).

[2] T.H. v. Novartis Pharm. Corp., 407 P.3d 18, 47-48 (Cal. 2017).

[3] Rafferty v. Merck & Co., 92 N.E. 3d 1205, 1209 (Mass. 2018).

[4] Kellogg v. Wyeth, 762 F. Supp. 2d 694, 705-09 (D. Vt. Oct. 20, 2010).

[5] Garner v. Johnson & Johnson et al., 2017 WL 6945335, at *7 (C.D. Ill. Sept. 6, 2017).

[6] See Novartis, 407 P.3d at 24.

[7] The U.S. Court of Appeals for the Tenth Circuit's opinion in Schrock v. Wyeth Inc., 727 F.3d 1273, 1285 (10th Cir. 2013), provides a helpful survey of the reasons courts cite in declining to recognize innovator liability.

[8] Goodyear Dunlop Tires Operations SA v. Brown, 564 U.S. 915, 919 (2011).

[9] Daimler AG v. Bauman, 571 U.S. 117, 137 (2014).

[10] Id. at 127 (quotations and citation omitted).

[11] Henry v. Angelini Pharma Inc., 2020 WL 1532174 (E.D. Cal. March 31, 2020).

[12] Id. at *1.

[13] Id.

[14] Id. at *3-4.

[15] Id. at *3.

[16] Id. at *4.

[17] Id.

[18] See Erie R.R. Co. v. Tompkins, 304 U.S. 64, 78 (1938); see also Klaxon Co. v. Stentor Elec. Mfg. Co., 313 U.S. 487, 496 (1941) (applying Erie to choice of law).

[19] Darvocet, 756 F.3d at 939 ("After conducting a state-by-state Erie analysis, we conclude that the highest courts in each of the 22 implicated states would not recognize Plaintiffs' misrepresentation claims under their respective state laws"); Strayhorn v. Wyeth Pharm. Inc., 737 F.3d 378, 406 (6th Cir. 2013) (declining to extend innovator liability); Trower v. Janssen Pharm. Inc., 2019 WL 1571834, at *4 (D. Del. April 11, 2019) (same).

[20] See, e.g., Del Webb Communities Inc. v. Partington, 652 F.3d 1145, 1154 (9th Cir. 2011) ("Federal courts should hesitate prematurely to extend the law in the absence of an indication from the state courts or the state legislature that such an extension would be desirable") (quotations and citation omitted); Werwinski v. Ford Motor Co., 286 F.3d 661, 680 (3d Cir. 2002) (when deciding between "two competing yet sensible interpretations of [state] law," a court "should opt for the interpretation that restricts liability, rather than expands it"); Todd v. Societe Bic SA, 21 F.3d 1402, 1412 (7th Cir. 1994) (en banc) ("When given a choice between an interpretation of [state] law which reasonably restricts liability, and one which greatly expands liability, we should choose the narrower and more reasonable path"); see also Guar. Tr. Co. of N.Y. v. York, 326 U.S. 99, 105 (1945) ("Congress never gave, nor did the federal courts ever claim, the power to … create substantive rights denied by State law").

[21] Darvocet, 756 F.3d at 937.

[22] Trower, 2019 WL 1571834.

[23] Id. at *1.

[24] Id. at *4.

[25] Id.

[26] Johnson & Johnson Talcum Powder Cases, 37 Cal. App. 5th 292, 297 (Ct. App. 2019), review denied (Oct. 23, 2019).

[27] Id. at 296-97.

[28] Id. at 297.

[29] Id. at 313.

[30] Id. at 315.

[31] Id. at 317.

[32] Id.

[33] Id. at 320. Separately, the court reversed the judgment notwithstanding the verdict as to liability for JJCI, but affirmed it as to punitive damages. See id. at 339.

[34] Johnson v. Novartis Pharmaceuticals Corp., 2020 WL 2300139 (W.D. Tex. May 7, 2020).

[35] Id. at *1.

[36] Id.

[37] Id.

[38] Id. at *5.

[39] Id. at *2.

[40] Eckhardt v. Qualitest Pharmaceuticals Inc., 751 F.3d 674 (5th Cir. 2014).

[41] Novartis, 2020 WL 2300139 at *3.

[42] Id.

[43] Id. at *3.

[44] Id. at *3-4; see id. at *4 (explaining that Tex. Civ. Prac. & Rem. Code § 82.007(b)(1)-(5) establishes that a plaintiff can rebut the presumption of federal preemption by pleading: "(1) 'fraud on the FDA'; (2) the product was sold after the FDA ordered the product removed from the market; (3) if the manufacturer promoted the product for a use not approved by the FDA; (4) off-label prescriptions; and (5) bribery of a public official").

[45] Id. at *4.

[46] Patton v. Forest Labs. LLC, 2018 WL 5270476, at *18 (C.D. Cal. May 10, 2018), aff'd, 793 F. App'x 608 (9th Cir. 2020).

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