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Teva Parenteral Meds., Inc. v. Dist. Court, 137 Nev. Adv. Op. 6 (Mar. 4, 2021)

Mia Bacher

Teva Parenteral Meds., Inc. v. Dist. Court, 137 Nev. Adv. Op. 6 (Mar. 4, 2021)[1]

CONSTITUTIONAL LAW: PREEMPTION

Summary

The Court held that plaintiffs' strict product liability, breach of implied warranty, and deceptive trade practices claims against propofol drug manufacturers were preempted by federal law because it would have been impossible for them to comply with federal law and avoid state tort liability. The plaintiffs' negligence claim, however, was not preempted because the manufacturers could have avoided state liability without violating of federal law.

Background

In 1989, the FDA approved the anesthetic, propofol (also known as Diprivan). The FDA granted Petitioners Teva Parenteral Medicines, Inc., Baxter Healthcare Corporation, and McKeeson Medical-Surgical, Inc. permission to manufacture generic propofol and distribute it in 20mL, 50mL, and 100mL vials. The labels on each vial clearly indicated that they were for single-patient use.

Petitioners all sold propofol to Dr. Depak Desai for his endoscopy centers in Las Vegas.[2] Contrary to the warning on the labels, Dr. Desai used the 50mL vials for multiple patients. He was subsequently criminally charged for these actions. Due to this criminal use of single-patient vials on multiple patients, his patients all received letters from the CDC and SNHD warning them of a possible risk of infection with Hepatitis B, Hepatitis C, and HIV. Plaintiffs in this action are a group of approximately 800 of Dr. Desai's patients who received these letters. All plaintiffs had the recommended tests, and all their tests came back negative.

In their complaint, plaintiffs alleged claims of strict product liability, breach of implied warranty of fitness for a particular use, negligence, violation of Nevada Deceptive Trade Practices Act, and punitive damages. Plaintiffs specifically alleged that petitioners knew or should have known that selling 50mL vials, *not* 20mL vials, of propofol to an ambulatory surgical center with high patient turnover is unsafe because it entices doctors to use a single vial on multiple patients, thereby increasing the risks of contamination. They sought to obtain compensation for the testing costs and pain and suffering while awaiting test results.

Petitioners filed a motion to dismiss, alleging that plaintiffs' claims conflicted with federal law, namely the Drug Price Competition and Patent Term Restoration Act of 1984.[3] The district court denied the motion, finding plaintiffs' claims were not preempted by federal law. Petitioners then filed a writ of mandamus with the Supreme Court of Nevada.

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[1] By Mia Bacher.

[2] Dr. Desai is now deceased and is not a party in this action.

[3] Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

Discussion

Entertaining the petition

Writs of mandamus can be used to compel performance of an act required by law or to control an arbitrary or capricious discretionary action.[4] Generally, the Nevada Supreme Court will refuse to consider writs on a district court's ruling on a motion to dismiss, but it will exercise its discretion to consider one when "an important issue of law needs clarification and considerations of sound judicial economy and administration militate in favor of granting the petition."[5]

Here, the Court decided that whether or not plaintiffs' claims are preempted under the Hatch-Waxman Act is an important issue of law that needs clarification. Given the early stage of litigation and the great number of plaintiffs involved, the Court decided to entertain the petition.

Preemption

Preemption is an issue that the Court reviews de novo, without any deference to the district court's findings.[6] The doctrine of preemption comes from the US Constitution's Supremacy Clause, which provides that federal law supersedes state law.[7] There are two types of preemption: express and implied. Express preemption occurs when Congress specifically declares a statute will preempt state law. Implied preemption occurs if federal law dominates a particular area of law (field preemption) or conflicts with state law (conflict preemption).

Petitioners argued conflict preemption applied here because it is impossible for them to comply with the Hatch-Waxman Act and also avoid state tort law. They relied on *PLIVA Inc. v Mensing*[8] and *Mutual Pharmaceutical Co. v. Bartlett*[9] to make their argument. In *Mensing*, a group of plaintiffs sued a drug manufacturer, arguing the drug manufacturer knew or should have known that it had a duty under state law to warn of the severe neurological disorder their drug could cause with long-term use.[10] The Supreme Court held that the state claims were preempted because the manufacturer's duty under state law conflicted with their duty under the Hatch-Waxman Act.[11] This conflict occurred because federal law required generic labels to match those of the name brand labels while the state law required there to be additional protections listed on generic brands, thus it would be impossible for manufacturers to comply with both laws.[12] The

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[4] NEV. REV. STAT. § 34.160 (2017); Int'l Game Tech. v. Second Jud. Dist. Ct., 124 Nev. 193, 197, 179 P.3d 556, 558 (2008).
[5] City of Mesquite v. Eighth Jud. Dist. Ct., 135 Nev. 240, 243, 445 P.3d 1244, 1248 (2019).
[6] Nanopierce Techs., Inc. v. Depository Tr. & Clearing Corp., 123 Nev. 362, 370, 168 P.3d 73, 79.
[7] U.S. CONST. art. VI, cl. 2.
[8] PLIVA Inc. v. Mensing, 564 U.S. 604 (2011).
[9] Mutual Pharmaceutical Co. v. Bartlett, 570 U.S. 472 (2013).
[10] *Mensing*, 564 U.S. at 610.
[11] *Id.* at 618.
[12] *Id.*

Court rejected the argument that manufacturers could have asked the FDA to help strengthen warnings to avoid conflict preemption.[13] A similar situation occurred in *Bartlett*, but there the Court rejected the argument that the drug manufacturer could have simply stopped selling their drug in the state to avoid the preemption.[14]

Read together, these cases hold that the Hatch-Waxman Act imposes a duty of "sameness" between generic and name brand drug labels. A state law that imposes a duty on generic drug manufacturers to alter their label or design makes it impossible for these manufacturers to comply with federal law and avoid state liability.

Analysis of state- and federal-law duty

Petitioners argued that plaintiffs' claims are preempted because their cause of action would impose a duty on them (the manufacturers) to alter the 50mL vial, change its warning labels, or stop selling the drug in Nevada. To determine whether this is the case, the court identified the duties under state law and compared those to the duties under federal law.[15] Plaintiffs conceded that their strict liability and breach of implied warranty claims are preempted under *Mensing* and *Bartlett*, but contended that their negligence and deceptive trade practice claims were not preempted because they were not premised on the labeling or design of the drug.

Plaintiffs' deceptive trade practices claim alleged that petitioners made false representations and omitted facts about the 50mL vial. However, the only representations identified in their complaint were of those contained in the FDA-approved label. Petitioners thus could not have changed the alleged misrepresentations without violating federal law. Therefore, plaintiffs' deceptive trade practices claim was preempted.

Plaintiffs' negligence claim alleged that petitioners owed a duty "to distribute, market, and packages the propofol in safe single use vials that are not conducive to multi-dosing" and that they should have known that distributing 50mL to high-turnover ambulatory clinics would encourage such multi-dosing. In short, they argued that petitioners had a duty not to sell to Dr. Desai's ambulatory surgical clinics. Plaintiffs' negligence claim was preempted to the extent that they alleged improper warnings.

Plaintiffs' claim that petitioners had a duty not to sell the 50mL vials was not preempted, as petitioners have not been able to establish that this would conflict with federal law. Here, petitioners argued that to avoid liability they would have either (1) had to stop selling 50mL vials to Dr. Desai or (2) alter the size of the vials. The first option is not precluded by *Mensing* or *Bartlett* because petitioners did not demonstrate that they had a duty under federal law to continue selling 50mL vials to clinics they should have known were misusing the product. This does not conflict with *Bartlett* because it would not require manufacturers to stop selling entirely in the State of Nevada, it would only require them to stop selling to clinics that they knew were

[13] *Id.* at 620–24.
[14] *Bartlett*, 570 U.S. at 475–76.
[15] *See id.* at 480.

misusing the drug. In the alternative, the manufacturers could sell just the 20mL vials, which are also FDA approved, without having to alter the design of the 50mL vial. Thus, the claim of negligence was not preempted.

Conclusion

The petition for writ of mandamus was denied as it pertained to the negligence claim but was granted as it pertained to the strict product liability, breach of implied warranty, and deceptive trade practices claims.