IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WISCONSIN

ESTATE OF TERI CASSEL, TERRY CASSEL, and ROBERT RODNEY CASSEL-GEBHARD,

Plaintiffs,

v.

ALZA CORPORATION and JANSSEN PHARMACEUTICALS, INC.,

Defendants.

ORDER

12-cv-771-wmc

Teri Cassel passed away in 2009 while wearing two Duragesic patches, which are meant to deliver the drug fentanyl through the skin. Ms. Cassel's estate and two sons filed this action against the patch designer and manufacturer, Alza Corporation, and the patch distributor, Janssen Pharmaceuticals, Inc., alleging that manufacturing, marketing and design defects caused Ms. Cassel's accidental and lethal overdose of fentanyl. Defendants have since moved for partial summary judgment on the design defect claims under the doctrine of "impossibility preemption," a species of conflict preemption recently addressed by the Supreme Court in *PLIVA, Inc. v. Mensing*, 564 U.S. ---, 131 S. Ct. 2567 (2011), and *Wyeth v. Levine*, 555 U.S. 555 (2009). More specifically, defendants argue that plaintiffs' state law claims based on defective design are preempted by FDA regulations preventing defendants from changing the design of Duragesic patches to meet state standards. In response, plaintiffs maintain that this motion is premature and ask for a six-month stay of briefing so that they can complete substantial discovery.[1]

[1] This case is one of many parallel Duragesic patch lawsuits around the country. Both

In turn, defendants oppose a stay, contending that their summary judgment motion can be decided without further discovery because it hinges entirely upon a question of law: the applicability of "impossibility preemption."

As articulated in *PLIVA, Inc. v. Mensing* and *Wyeth v. Levine*, defendants are correct in asserting that the "impossibility preemption" doctrine can be invoked as a pure matter of law. This is only possible when the law on its face prevents compliance with state tort law duties. Such is not the case here or, at least, defendants have not proven it to be so. The doctrine can also be invoked upon a factual showing of "clear evidence" that federal regulators would have prevented compliance with state tort law, but plaintiffs will be allowed further discovery before any such facts can be considered. A stay of further briefing on defendants' partial summary judgment motion will, therefore, be allowed.

OPINION

The Supremacy Clause states that federal law "shall be the supreme Law of the Land . . . anything in the Constitution or laws of any State to the contrary notwithstanding." U.S. Const. art. VI, cl. 2. State law cannot be applied, because of what is known as "conflict preemption," where (1) "compliance with both federal and state regulations is a physical impossibility" or (2) "state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 98 (1992) (internal quotations and marks omitted).

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sides are cooperating to coordinate discovery around a master schedule established by a court in California.

The United States Supreme Court's approach to so-called "impossible" conflicts between state and federal law is discussed in *Wyeth v. Levine*, 555 U.S. 555 (2009) and *PLIVA, Inc. v. Mensing*, 564 U.S. ---, 131 S. Ct. 2567 (2011). Both cases involved seemingly incompatible duties regarding the content of drug warning labels under FDA regulations and state tort law. In *Levine*, the plaintiff was injured by a Phenergan, the brand-name version of an anti-nausea drug. Having had the drug administered by direct injection into her arm, the plaintiff argued that the drug label violated Vermont tort law in failing to warn about the dangers of injecting Phenergan, even though the language on the label had been reviewed and expressly approved by the FDA. 555 U.S. at 559-60. The Supreme Court agreed, finding that it was possible for the defendant to comply with state tort law *and* FDA rules simultaneously. *Id.* at 568-69. This was so, the Court explained, because the drug maker was *not* legally prohibited from unilaterally improving the warning label without prior FDA approval. *Id.* In the absence of an express legal prohibition on making a change to the label, the "impossible" defense did not facially apply. The ruling did not preclude the defendant from establishing federal preemption of state law by "clear evidence" that the FDA regulators would not have approved a label meeting Vermont's tort law standards. *Id.* at 571.

In *Mensing,* the plaintiffs alleged injury because of inadequate drug labeling of generic metoclopramide (brand name Reglan) in violation of Louisiana and Minnesota laws, which required the defendants to update product labels with newly-discovered risks of harm. 131 S.Ct. at 2572-73. Because the drug was sold as generic metoclopramide, it was subject to different legal standards than governed brand-name manufacturer Wyeth

in *Levine*. A generic drug manufacturer may obtain approval of a drug from the FDA simply by showing equivalence to a brand-name drug that had undergone clinical trials and been approved for sale. *See* 21 U.S.C. § 355(j)(2)(A). In exchange for this exemption from regulatory scrutiny, federal law demands generic drug manufacturers act just like their brand-name counterparts with respect to the approved drug, including (among other requirements) insuring that "generic drug labels be the same at all times as the corresponding brand-name labels." *Mensing*, 131 S.Ct. at 2578. *See also* 21 U.S.C. §§ 355(j)(2)(A)(v) & (j)(4)(G). This is known as the "duty of sameness." *Mensing*, 131 S.Ct. 2576.

At some point before the plaintiffs' injuries, the defendants in *Mensing* learned of their obligation under state tort law to update the warning label with new information, but concluded that they were not free to unilaterally change the label because of the federal "duty of sameness." Accordingly, the Court found that FDA law preempted any state law duty the defendants had to update the drug label. Under these relatively narrow circumstances, the Court also found that it need not consider whether the FDA would have rejected the necessary labeling change had defendants proposed it, since the conflict between state and federal law was apparent on its face.

Taken together, the *Levine* and *Mesnsing* decisions suggest a three-part test to determine whether a state law tort claim is preempted by FDA law or, for that matter, by the law of any other federal regulatory body. First, the court must identify the steps a defendant should have taken to avoid liability under state tort law. Next, the court must determine as a matter of law whether federal law expressly *prohibited* the defendant from

taking these steps. If the answer to this second question is "No," the court must determine whether the defendant has presented "clear evidence" that the regulatory agency would have stepped in and exercised its discretionary authority to prohibit the defendant from taking the necessary steps under state law.[2]

Defendants argue that the present case resembles *Mensing*, where federal law facially prohibited generic drug makers from improving their label and thus avoiding state law liability. In other words, they say that further discovery is unnecessary because the inquiry should stop with the second step of the test as a pure question of law. This court disagrees.

Taking the steps in order, plaintiffs have alleged that defendants designed the patches improperly – so improperly, in fact, that they were unreasonably dangerous for use and did not satisfy the necessary duty of care owed to users. To avoid liability under state law, the court will accept for now that defendants should have designed the patches differently from the start or should have re-designed and replaced the patch before it reached the plaintiff. Because this design problem arguably could have been fixed even before the patch was submitted for FDA approval, FDA law does not appear to bar

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[2] In *Bartlett v. Mutual Pharmaceutical Co.*, 678 F.3d 30, 34 (1st Cir. 2012), the First Circuit Court of Appeals considered preemption in a case much like this one, involving drug design tort claims and FDA law. The First Circuit cabined *Levine* and *Mensing* to their unique facts (drug labeling instead of drug design) and pursued a different analysis altogether. *Id.* at 37-38. The court found that drug and device manufacturers have never faced truly conflicting obligations under federal law and state tort law, because manufacturers can *always* satisfy both by pulling their product from the shelves. *Id*. While the *Bartlett* opinion is noteworthy, its reasoning remains in question while an appeal is pending in the Unites States Supreme Court. (The Court heard oral argument on the appeal on March 19, 2013. *See* http://www.supremecourt.gov/Search.aspx?FileName=/docketfiles/12-142.htm.)

defendants from avoiding any state tort liability. Defendants make much of the fact that they could not have unilaterally fixed the flaws in the patch after receiving FDA approval because this would have been an unauthorized "major change" under 21 C.F.R. § 314.70(b). But this would only matter if defendants' tort lies solely in failing to redesign the patch *after* FDA approval. Unlike the defendants in *Mensing*, who never had control over the label on their generic drug, at least at this stage of the lawsuit, it appears defendants had ample opportunity to unilaterally fix their mistake before FDA approval.

This brings the court to step three in the test, which asks whether the FDA would (somehow) have prevented defendants from redesigning the patch before it approved the patch design that allegedly killed Ms. Cassel. Since this is a factual question and defendants bring a facial challenge, there is obviously no evidence before the court currently to find that the FDA would have done so. At the very least then, it would appear inappropriate to rule on the question without granting both sides an opportunity for some additional discovery. Accordingly, plaintiffs' motion for a stay will be granted.

ORDER

IT IS ORDERED that plaintiffs' motion to stay briefing on defendants' summary judgment motion (dkt. #22) is GRANTED. Plaintiffs' response to that motion will now be due October 28, 2013, and defendants' response will be due November 8, 2013.

Entered this 3rd day of May, 2013.

BY THE COURT:

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WILLIAM M. CONLEY
District Judge