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Mich. Drug Companies Now Less Immune Under Tort Reform

Law360, New York (February 11, 2014, 5:20 PM ET) -- In a decision of critical importance for any pharmaceutical or medical device company doing business in Michigan, on Jan. 21, 2014, the U.S. Court of Appeals for the Sixth Circuit reversed the dismissal of a fentanyl patch lawsuit, ruling that manufacturers and sellers of "combination products" are not statutorily immune from liability under Michigan's Tort Reform statute. (Miller v. Mylan Inc., No. 12-2502 (6th Cir. Jan. 21, 2014)).

That statute, before now, provided drug companies with nearly absolute immunity from suit in Michigan, except in cases of fraud or bribery to secure federal approval:

In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer is not liable, if the drug was approved for safety and efficacy by the [U.S. Food and Drug Administration], and the drug and its labeling were in compliance with the [FDA]'s approval at the time the drug left the control of the manufacturer or seller. (Mich. Comp. Laws § 600.2946(5)).

[A drug] does not include a medical appliance or device. (Mich. Comp. Laws § 600.2945(b)).

As the Sixth Circuit commented, Michigan is the only state that provides immunity for drug makers and sellers in this fashion. Since tort reform, pharmaceutical litigation has been virtually unheard of in the state. If the majority opinion carving out this exception stands, the decision is the first chink in the armor in almost 20 years.

Beth Ann Kelly died after allegedly receiving an overdose of fentanyl from the transdermal patch system manufactured by the defendant Mylan Pharmaceuticals Inc. Kelly's estate representative sued Mylan in state court alleging strict liability, negligence, negligent misrepresentation, fraud, warranty and violation of the Michigan Consumer Protection Act. Mylan removed the case to federal court where the district court dismissed it as barred under the Michigan Tort Reform statue.

The Sixth Circuit, however, disagreed, concluding that "the district court's analysis was incomplete and that a factual question remains as to whether the fentanyl patch was a 'combination product.'" Citing to 1990 amendments by Congress to the Food, Drug and Cosmetic Act in which "combination products" became fully recognized as a third category of regulated products (along with drugs and devices), the majority held that the lower court failed to "take full account of the statutory scheme governing federal drug regulation" in making an "either/or" distinction between drugs and medical devices.

The court stated that "[a]t best, Michigan law is ambiguous as to whether the manufacturer of a

combination product should be immune from suit." Because the Michigan legislature did not explicitly immunize manufacturers of combination products from tort liability, the majority refused to construe the statute to automatically and broadly exempt manufacturers of such products from liability.

The question then became: Is the fentanyl patch a "combination product?" The Miller plaintiff carefully worded her complaint to allege that it is the manner in which the patch system delivers fentanyl, and not the fentanyl itself, that makes the product defective and unreasonably dangerous. Kelly likewise emphasized the manner in which the patch delivers fentanyl as the basis for her negligence and other claims.

Michigan looks to federal law for the definition of a "drug" and leaves the term "medical device" undefined. (Mich. Comp. Laws § 600.2945(b)). The Food, Drug, and Cosmetic Act defines "drug" to include "articles (other than food) intended to affect the structure or any function of the body of man or other animals" as well as "articles intended for use as a component of" a drug. (21 U.S.C. § 321(g)(1)). "Combination products," in contrast, are defined to include "product[s] comprised of two or more regulated components, i.e., drug/device … that are physically, chemically or otherwise combined or mixed and produced as a single entity." (21 C.F.R. § 3.2(e)(1)).

The Sixth Circuit rejected the lower court's conclusion that the patch was akin to a time-release capsule that qualified as an "article intended for use as a component" of fentanyl, making the fentanyl patch a "drug" under the federal regulatory definition. It distinguished between inactive ingredients, such as "coatings, binders, and capsules," and products like a patch "that appear[] to have a mechanical (rather than chemical) effect on the human body."

Nevertheless, the appeals court refused to decide categorically that the fentanyl patch was a combination product. Instead it concluded that the issue posed "a question of fact that we are unprepared to answer in the first instance," and remanded the case to the lower court with instructions to decide that question. It is apparent from the opinion, however, that the Sixth Circuit favors a narrow definition of the term "drug" as that term is used in the Michigan statute.

If it stands, the Miller decision provides a powerful weapon for plaintiffs in any case in which a product arguably contains a mechanical component like a patch. This could have far-reaching effect in Michigan where, since tort reform in the mid-1990s, pharmaceutical manufacturers and sellers of FDA approved drugs have generally been immune from liability.

In a lengthy and well-reasoned dissent, Judge David W. McKeague examined the FDA regulations and limited case law to argue that the fentanyl patch is indeed a "drug," not a "combination product." McKeague observed that the only evidence in the record showed that the FDA had designated the fentanyl patch as a "drug."

The dissent questioned why the majority "appears to give little or no deference to the FDA's designation, instead" instructing "courts to make an independent evaluation of whether a product is a 'drug,' 'device,' or 'combination product,'" which inevitably "leads to courts second-guessing the FDA's designation of a given product."

But absent reconsideration of the majority decision, the opinion stands and opens a loophole in the broad immunity previously enjoyed by drug manufacturers and sellers in Michigan. It is the first published ruling to do so.

It is the Michigan Supreme Court, of course, and not the Sixth Circuit, which has the ultimate authority to interpret Michigan statutes. But state courts may find Miller persuasive, and it represents a significant victory for plaintiffs in that it provides a road map for drafting potentially viable complaint allegations against combination product manufacturers and sellers doing business in Michigan.

Mylan has the option of seeking a rehearing en banc, but if the Sixth Circuit's opinion stands, whether Michigan state courts adopt Miller's reasoning and how the trial court decides the combination product factual inquiry bear close monitoring.

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