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Important Product Liability Practice Trends To Watch In 2022

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It's time to take stock of the product liability climate, and venture predictions for the year ahead. The last year has seen several important legal developments relevant to product liability, including in the areas of personal jurisdiction, preemption and class action procedure. This year promises interesting developments in these same subject areas.

Personal Jurisdiction

Battles over whether a court can assert jurisdiction over a product seller often embody a clash between the general notion that plaintiffs have the ability to choose a forum for their product claims, and the limits, under due process, on their ability to drag a defendant into court in a forum with which it has insufficient contacts.

Venerable U.S. Supreme Court precedents considering general and specific jurisdiction are challenged, conceptually, by modern means of marketing products — and, practically, by increasingly aggressive forum shopping by product liability claimants. Litigation tourism is one form of travel that the pandemic has not reduced.

In its 2014 decision in Daimler AG v. Bauman, the Supreme Court clarified that only those corporate defendants "at home" in a jurisdiction can be sued there.[1] This typically means that general personal jurisdiction is limited to those states where a corporation is incorporated, or has its principal place of business.[2]

Then, in 2017, in Bristol-Myers Squibb Co. v. Superior Court of California, the Supreme Court relied on what it termed "settled principles of specific jurisdiction" to hold that there must be a sufficient affiliation between the forum and the underlying controversy. Otherwise specific jurisdiction is lacking, regardless of a defendant's unconnected activities in the state.[3]

In Bristol-Myers Squibb, the mere fact that other plaintiffs were prescribed and ingested the drug in the forum state did not allow the state court to assert specific jurisdiction over the nonresidents' claims.

In March 2021, the high court clarified the reach of Bristol-Myers Squibb — and reiterated its restrictions on forum shopping by nonresidents whose product use and injuries occurred elsewhere —

in Ford Motor Co. v. Montana Eighth Judicial District Court.[4]

The court rejected the argument that the state court had jurisdiction only if the company's conduct in the state had given rise to the plaintiff's claims — i.e., had designed, manufactured or sold in the state the particular product used by the plaintiff.

Specific jurisdiction, the court asserted, may still exist when the defendant has "systematically served a market," such as by advertising, selling and servicing the product models for many years.[5] But the court reinforced its Bristol-Myers Squibb holding regarding plaintiffs who were not residents of the state, did not purchase the product in the state and had not sustained their injuries in the state.[6]

Looking ahead on personal jurisdiction, we foresee increasingly high-stakes fights on the theory that a corporate defendant consents to jurisdiction merely by registering to do business in a state. Such cases raise not only questions of statutory construction under the various state registration statutes, but also serious issues of constitutional interpretation.

Since the court in Daimler expressed reservations about expanding jurisdiction beyond those states where a company could be considered at home, the exercise of general jurisdiction over an out-of-state defendant based solely on a business registration raises significant due process questions.

Moreover, a law requiring consent to general jurisdiction in exchange for the privilege of doing business in the state might implicate the commerce clause of the U.S. Constitution — or create an unconstitutional condition if it forces companies to choose between renouncing their due process right to not be sued where they are not at home, and foregoing the benefit of doing business in the state.

In Chavez v. Bridgestone Americas Tire Operations LLC, issued in November 2021, the Supreme Court of New Mexico rejected the theory that corporate registration to do business constitutes consent to personal jurisdiction.[7] In contrast, in September 2021, the Supreme Court of Georgia held in Cooper Tire & Rubber Co. v. McCall that corporate registration is consent to general jurisdiction, and that this does not violate federal due process.[8]

The Supreme Court of Pennsylvania most recently considered the issue in Mallory v. Norfolk Southern Railway Co., in December 2021.[9] Pennsylvania's long-arm statute provided that qualification to do business as a foreign corporation constituted a sufficient basis to enable Pennsylvania courts to exercise general personal jurisdiction over the foreign corporation.

The state court found this scheme eviscerates the U.S. Supreme Court's general jurisdiction framework set forth in Daimler, and violates federal due process notions of fair play and substantial justice.[10] Finally, the court concluded that a foreign corporation's registration to do business in Pennsylvania does not constitute voluntary consent to general jurisdiction but, rather, compelled submission by legislative command.[11]

Ford was decided in a venerable product distribution context; as Justice Samuel Alito stated in his concurring opinion, "there is nothing distinctively 21st century about the question in the case now before us."[12] But practitioners should note that at least some members of the high court may be ready to tackle thorny issues of internet-based product sales and other modern marketing techniques — including Justice Alito, who said:

[T]here are also reasons to wonder whether the case law we have developed since that time is well suited for the way in which business is now conducted.[13]

The jurisdiction by registering to do business notion is likely to wind up in the Supreme Court, given the split of authority and the statutes' impact on modern marketing techniques.

Preemption

The Supreme Court clarified important aspects of the preemption doctrine in 2019 in Merck Sharp & Dohme Corp. v. Albrecht, holding that preemption was a legal issue for the court to decide, including any subsidiary factual disputes that are part of the broader legal question.[14]

In prescription drug products cases in which a defendant asserts that federal law preempts a state warning law, the Merck court held there must be clear evidence that shows that the drug manufacturer fully informed the U.S. Food and Drug Administration of the justifications for the warning required by state law — and that the FDA, in turn, made clear that it would not approve a change to the drug's label to include that warning.

This rule was applied by the U.S. District Court for the District of Massachusetts in June 2021 in In re: Zofran (Ondansetron) Products Liability Litigation, where the plaintiffs alleged that the former manufacturer of prescription Zofran should have added warning language about the alleged risk of birth defects if the drug was taken by pregnant women.[15]

In assessing the defense, the court stated that, first, all the information that the plaintiffs alleged was withheld from the FDA had been provided to the agency by 2020: "Based on the undisputed evidence, the FDA was 'fully informed' of the justifications for the warning label that plaintiffs contend was required by state law."[16]

Next, the court observed that the current manufacturer of the drug had discussed with the FDA possible warnings concerning the use of Zofran during pregnancy, based on the possibility of fetal injury. The FDA rejected the proposed changes, stating that the available data did not support a recommendation to avoid Zofran in pregnancy.

Instead, the FDA approved a new label that did not include warnings concerning use during pregnancy.[17] Accordingly, it was apparent that the FDA would not approve the label that the plaintiffs alleged was required by state law.[18]

The Massachusetts district court also addressed some key subsidiary issues. First, the outcome was no different because the current drugmaker, not the original manufacturer, was the party to which the FDA rejection was directed. Preemption, the court said, "does not depend on whether the defendant manufacturer is the one who asked for the changes, or to which the FDA explicitly communicated its decision."[19]

The court also recognized that the FDA might react to proposed label changes when raised in a citizen's petition, in a unilateral change of an existing label by the manufacturer under the "changes being effected" regulations, and/or by a prior approval supplement requesting revisions to the label, which the FDA must approve before implementation:

Finally, the FDA has an independent duty imposed by statute to require label changes if it becomes aware of new information that it determines should be included in the drug's label.[20]

As the case law develops in light of Albrecht, a multidistrict litigation proceeding to watch in 2022 is In re: Taxotere (Docetaxel) Products Liability Litigation, pending in the U.S. District Court for the Eastern District of Louisiana.[21] Three manufacturers of a generic form of a name-brand chemotherapy drug, Taxotere, have filed motions for summary judgment on preemption grounds.

The defendants argue that they did not have the newly acquired information that was needed to justify a label change to add the allegedly missing warnings. Lacking that newly acquired information, they say, the manufacturers procedurally could not have invoked the changes being effected pathway to unilateral label changes.

The MDL court will need to analyze these issues under the new Albrecht regime. Interestingly, the motions also raise preemption issues that have not been fully explored. The defendants' products were approved through the FDA's Section 505(b)(2) pathway, which is a hybrid pathway that shares characteristics of both abbreviated new drug applications and stand-alone new drug applications.

The defendants emphasize that their approval applications relied on the FDA finding that the listed/branded drug is safe and effective. The plaintiffs argue that the defendants should have acted more like new drug application holders, and unilaterally updated their labels in light of new alleged risks.

As preemption case law continues to develop, practitioners will want to assess the optimal timing of preemption motion practice, with the judge now deciding all issues and a traditional summary judgment approach no longer the default. There may also be options for increased creativity in the manner in which the court decides any underlying disputed "brute" facts, with focused discovery, and evidentiary or Markman-like hearings.[22]

As the preemption doctrine arises in more product MDLs, the picture may come into focus reflecting how MDL preemption decisions are procedurally severable, so as to enable interlocutory appeals.

Multiplaintiff Procedures — Class Actions

The U.S. Court of Appeals for the Eighth Circuit decided Johannessohn v. Polaris Industries Inc. in August 2021, a putative class action against an ATV manufacturer, for allegedly failing to disclose defects that artificially inflated the price of the ATVs.[23] The appellate court affirmed the denial of class certification on predominance, superiority and manageability issues, with the theme being that both parties' evidence must be assessed in deciding these issues.

Rule 23(b)(3)'s predominance requirement mandates that courts ask whether the aggregation-enabling common issues in the case are more prevalent than the aggregation-defeating individual issues. Claims of fraudulent representations concerning the product require individualized findings on whether the plaintiffs actually relied on the alleged misrepresentation — evidence that will often come in the defendant's rebuttal case.

For example, some of the named plaintiffs apparently bought new ATVs despite earlier experiences with the alleged defect. Some owners apparently tried to sell their ATVs to third parties, stating they were in excellent condition — without mentioning the alleged defect — thus likely making for multiple mini-trials within the class action.[24]

The appellate court also rejected the plaintiffs' attempt alternately to certify several statewide classes. The proposed classes failed the superiority element because:

> [T]he proposed classes would still require application of the laws of four different states to 43 different vehicle configurations, including at least four different engines, with changing exhaust standards through the years, and various attempts by [the defendant] to remedy the problems.[25]

The plaintiffs argued that they could solve these problems with expert testimony, but, observed the Eighth Circuit, "cases are not tried on the evidence of one party."[26]

Practitioners should take note of the Johannessohn decision's clear reminder of the need to adequately address at the certification stage the case management challenges associated with many putative class actions. Issues such as choice of law, use of multiple products and distinguishable plaintiffs can create insurmountable practical difficulties.

Merely assuming the case will settle following certification, or vague assurances that some procedure can later be devised, is not an adequate showing of manageability to justify certification of a product-based class.

On another important class issue, in Prantil v. Arkema Inc., the U.S. Court of Appeals for the Fifth Circuit addressed in January 2021 whether, when the "cementing of relationships" on issues of classwide liability or damages turns on scientific evidence, a court should insist that Federal Rule of Evidence 702 — also known as the "Daubert hurdle" — be cleared when that scientific evidence is relevant to the decision to certify.[27]

The Fifth Circuit answered in the affirmative, holding that if an expert's opinion would not be admissible at trial, it should not pave the way for certifying a proposed class.[28] As the district court hesitated "to apply Daubert's reliability standard with full force," the class certification was vacated.[29]

The Fifth Circuit stated it was aligning with the U.S. Court of Appeals for the Third Circuit, the U.S. Court of Appeals for the Seventh Circuit and the U.S. Court of Appeals for the Eleventh Circuit on this important class issue. The Eighth Circuit and the U.S. Court of Appeals for the Ninth Circuit, however, call for a more limited application of Rule 702 at the certification stage.

The Ninth Circuit, for example, holds that expert testimony's admissibility is merely a factor in determining the weight to be accorded at the class certification stage.[30] The Supreme Court may well need to make a more definitive statement than its dicta from 2011 in Wal-Mart Stores Inc. v. Dukes,[31] expressing "doubt" at the proposition "that Daubert did not apply to expert testimony at the certification stage of class-action proceedings."

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[1] Daimler AG v. Bauman, 571 U.S. 117, 134 S.Ct. 746 (2014).

[2] Id. at 760-61.

[3] Bristol-Myers Squibb Co. v. Superior Court, 137 S.Ct. 1773, 198 L.Ed.2d 395 (2017).

[4] Ford Motor Co. v. Montana Eighth Jud. Dist. Ct., 141 S.Ct. 1017, 1028, 209 L.Ed.2d 225 (2021).

[5] Id. at 1028.

[6] Id. at 1031.

[7] Chavez v. Bridgestone Ams. Tire Operations LLC et al., __P.3d__, 2021 WL 5294978 (N.M. Nov. 15, 2021) (focusing on statutory construction but predicting Supreme Court action).

[8] Cooper Tire & Rubber Co. v. McCall, 863 S.E.2d 81, 90 (Ga. 2021).

[9] Mallory v. Norfolk S. Ry. Co., __A.3d __, 2021 WL 6067172 (Pa. Dec. 22, 2021).

[10] Id. at *17 (citing International Shoe Co. v. Washington, 326 U.S. 310, 66 S.Ct. 154, 90 L.Ed. 95 (1945)).

[11] Id. at *20.

[12] Ford Motor Co., 141 S. Ct. at 1032 (Alito, J. concurring).

[13] Id.; see also id. at 1025 n.2 ("Fair enough").

[14] Merck Sharp & Dohme Corp. v. Albrecht, 139 S.Ct. 1668, 1680, 203 L.Ed.2d 822 (2019).

[15] In re Zofran (Ondansetron) Prod. Liab. Litig., MDL No. 1:15-md-2657-FDS, 2021 WL 2209871 (D. Mass. June 1, 2021).

[16] Id. at *30.

[17] Id.

[18] Id. at *33.

[19] Id.

[20] Id. at *3.

[21] In re: Taxotere (Docetaxel) Prods. Liab. Litig., Case 2:16-md-02740 (E.D. La.).

[22] Markman v. Westview Instruments Inc., 517 U.S. 370 (1996).

[23] Johannessohn v. Polaris Industries Inc., 9 F.4th 981 (8th Cir. 2021).

[24] Id. at 984-85

[25] Id. at 986.

[26] Id.

[27] Prantil v. Arkema Inc., 986 F.3d 570, 575 (5th Cir. 2021)

[28] Id. at 576.

[29] Id.

[30] See Sali v. Corona Reg'l Med. Ctr., 909 F.3d 996, 1006 (9th Cir. 2018); see also In re Zurn Pex Plumbing Prod. Liab. Litig., 644 F.3d 604, 611-12 (8th Cir. 2011).

[31] Wal-Mart Stores Inc. v. Dukes, 564 U.S. 338, 354, 131 S. Ct. 2541, 2554, 180 L. Ed. 2d 374 (2011).