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ARTICLE

Clinical Trials and Specific Jurisdiction After Bristol-Myers

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What clinical activities are sufficient to establish specific jurisdiction over drug and medical device manufacturers? In the wake of the U.S. Supreme Court's decision in *Bristol-Myers Squibb Co. v. Superior Court of California*,[1] this has become an increasingly important question that can determine where a company is forced to litigate.

Forum selection can have an outsized effect in any litigation by determining critical factors such as statute of limitations,[2] permissive tort theories of recovery like innovator liability[3] or expansive strict liability regimes,[4] and the availability of punitive damages.[5] Whether a company's clinical and research activities in a particular state satisfy specific jurisdiction requirements is, therefore, an inquiry that can have broad ramifications for overarching litigation strategies.

The Supreme Court's Holding

The Supreme Court in BMS clarified the circumstances under which courts may find specific jurisdiction. In BMS, plaintiffs brought suit against Bristol-Myers Squibb and a distributor, McKesson Corporation, in California state court after allegedly sustaining injuries from Bristol-Myers' blood-thinning drug, Plavix.[6]

Of the 678 plaintiffs that were consolidated before the County of San Francisco Superior Court, 592 were residents of states other than California.[7] Bristol-Myers moved to quash service on the grounds that the Superior Court lacked personal jurisdiction with respect to the claims of the 592 nonresident plaintiffs.[8]

In support of its motion, Bristol-Myers noted that none of the nonresident plaintiffs' injuries occurred in California and that Bristol-Myers is incorporated in Delaware, is headquartered in New York and maintains substantial operations in New Jersey, with over 50% of its domestic workforce based in either New York or New Jersey.[9] Bristol-Myers also averred that the development of Plavix did not take place in California, nor was any regulatory or marketing strategy work relating to Plavix performed in the state.[10]

The Superior Court denied Bristol-Myers' motion, concluding that the company's research facilities in California (none of which were involved with the development of Plavix) and sales representatives employed in the state were

"sufficiently extensive to subject it to the general jurisdiction of the state courts."[11]

After a lengthy appeals process, the California Supreme Court held on review that while California lacked general jurisdiction over Bristol-Myers,[12] it did have specific jurisdiction over the nonresident plaintiffs' claims on the basis that Bristol-Myers' "extensive contacts with California establish minimum contacts based on a less direct connection between [its] forum activities and plaintiffs' claims than might otherwise be required."[13]

In support of its finding, the court employed a sliding scale approach to specific jurisdiction and pointed to Bristol-Myers' California-based research and development facilities, along with its "sizeable revenues from the sales of its product here," as sufficient to establish a substantial connection to the state.[14]

On appeal, the Supreme Court reversed, finding that "[t]he State Supreme Court found that specific jurisdiction was present without identifying any adequate link between the State and the nonresidents' claims," and had instead engaged in an approach that "resemble[d] a loose and spurious form of general jurisdiction."[15] The court emphasized that "[f]or a court to exercise specific jurisdiction over a claim there must be an 'affiliation between the forum and the underlying controversy, principally, [a]n activity or an occurrence that takes place in the forum State.'"[16]

In reaching this conclusion, the court found relevant that the nonresident plaintiffs "were not prescribed Plavix in California, did not purchase Plavix in California, did not ingest Plavix in California, and were not injured by Plavix in California."[17] And importantly, the court noted that it was not "sufficient—or even relevant—that BMS conducted research in California on matters unrelated to Plavix."[18] Thus, California lacked jurisdiction over the nonresident plaintiffs' claims due to the lack of "a connection between the forum and the specific claims at issue."[19]

The Post-BMS Legal Landscape Regarding Clinical Trials and Personal Jurisdiction

Post-BMS, plaintiffs have argued that specific jurisdiction exists over drug and medical device companies in any state where they have maintained clinical trials for the drug or device in question. They often point to the court's observation that Bristol-Myers "did not develop Plavix in California, did not create a marketing strategy for Plavix in California, and did not manufacture, label, package, or work on the regulatory approval of the product in California," and contend that these factors, including research and clinical activities, provide a "blueprint for establishing personal jurisdiction over a nonresident plaintiff's claim."[20]

A Majority of Courts Reject Clinical Trials as a Basis for Specific Jurisdiction

Superior Court of California

After the Supreme Court's BMS ruling, the Superior Court of California has on two occasions held that it lacked specific jurisdiction over defendant drug companies where the requisite connection to the forum state was based on clinical test sites.[21] In these cases, nonresident plaintiffs brought suit against Boehringer Ingelheim et al., Bayer Healthcare Pharmaceuticals Inc. and Janssen Pharmaceuticals Inc., alleging failure to disclose and warn of certain adverse side effects associated with taking the drugs Pradaxa and Xarelto.

In re Pradaxa, plaintiffs argued that the court had specific jurisdiction over BI primarily because the company had collected and analyzed data from clinical trials conducted in California, which ultimately gave rise to plaintiffs' claims.[22] Relying on the court's ruling in BMS, the Superior Court granted Boehringer Ingelheim's motion to dismiss after concluding that "[t]he Non-California Plaintiffs failed to demonstrate how any of BI's activities with respect to the RE-LY trials, much less the RE-LY trials in California, give rise or sufficiently relate to the specific failures to warn alleged in the Complaints."[23]

Thus, the connection between Boehringer Ingelheim's clinical activities in California and the non-resident plaintiffs' claims was "too attenuated to support the exercise of specific jurisdiction over BI."[24]

In the case of In re Xarelto, the Superior Court for the same reason quashed nonresident plaintiffs' motion to compel further jurisdictional discovery into activities such as "specific clinical studies concerning Xarelto"[25] and granted Bayer and Janssen's motion for protective order after concluding that it lacked personal jurisdiction over

defendants.[26] The court held that the proposed discovery "seeks information on, at best, merely tenuous contact between the Defendants and California" and further noted that "[t]he fact that Xarelto clinical trials were conducted in California is not sufficient to establish personal jurisdiction."[27]

Eastern District of Missouri

In a series of cases, the Eastern District of Missouri held that clinical test sites, along with certain marketing activities, did not support specific jurisdiction over Bayer with respect to the claims of non-Missouri plaintiffs regarding Bayer's permanent birth-control device, Essure.[28]

The most recent case, *Moore v. Bayer Corp.*, is illustrative. In Moore, plaintiffs argued that the court had specific jurisdiction over Bayer because the company held clinical trials in Missouri[29] However, the court noted that "[t]he non-Missouri plaintiffs were not prescribed Essure in Missouri, they did not have the device implanted in Missouri, and they were not injured in Missouri."[30]

The court also observed that the nonresident plaintiffs neither participated in the clinical trials at issue nor did they "personally [review] or [rely] on the resulting data."[31] Thus, after rejecting similar arguments regarding Bayer's Missouri marketing campaign, the court granted Bayer's motion to dismiss, holding that "the connections between Missouri and the non-Missouri plaintiffs' claims against Bayer are too attenuated for this court to exercise personal jurisdiction over Bayer."[32]

Southern District of Illinois

In *BeRousse v. Janssen Research & Development LLC*,[33] non-Illinois plaintiffs brought suit against Janssen Research & Development LLC for alleged injuries from the prescription blood-thinner drug Xarelto. The nonresident plaintiffs argued that the court had specific jurisdiction because Janssen had "purposefully targeted Illinois as the location for multiple clinical trials which formed the foundation for Defendants' Xarelto [FDA] application."[34]

The court rejected this argument, however, and instead found the "instant matter is analogous to BMS" where California "did not retain specific personal jurisdiction over non-resident defendant pharmaceutical companies, for non-resident plaintiff claims not arising out of or relating to defendant's contacts with California."[35]

Similar to BMS, "the non-Illinois plaintiffs failed to allege ingestion of Xarelto in Illinois, or [suffer] from injuries caused by Xarelto in Illinois."[36] Accordingly, the court granted Janssen's motion to dismiss for lack of personal jurisdiction, as "[u]nder these facts—in regard to the non-Illinois plaintiffs' allegations—there is no connection between Illinois and the underlying Xarelto controversy."[37]

Limited Rulings That Clinical Trial Sites Support Exercise of Specific Jurisdiction

Pennsylvania Superior Court

In *Hammons v. Ethicon Inc.*, a nonresident plaintiff alleged that she was injured by Prolift—a pelvic mesh device manufactured by Ethicon and Ethicon's parent company, Johnson & Johnson.[38] The plaintiff argued that Pennsylvania had jurisdiction over defendants because they developed a defective design in the forum state, which ultimately caused her injury.[39]

On appeal from the jury verdict, the Pennsylvania Superior Court concluded that defendants' supervising "the design and manufacturing process of pelvic mesh in Pennsylvania" supported the trial court's exercise of specific personal jurisdiction.[40] The court noted that the connection between Ethicon and Pennsylvania was "considerably stronger than the connection between Bristol-Myers and California," due in part to Ethicon relying "heavily on an Allentown, Pennsylvania gynecologist," who was retained as an investigator for "three important clinical studies" for Prolift and was compensated "over $1.7 million for his services in Pennsylvania."[41]

The court also noted that Ethicon "provided all material specifications for the weaving of the mesh," delivered product materials, produced and tested the product and communicated on issues related to mesh design and development in Pennsylvania.[42] The court thus concluded that the trial court's exercise of personal jurisdiction was proper.

Northern District of California
Only a week after the Supreme Court's BMS decision, the Northern District of California issued two substantively identical opinions in *Dubose v. Bristol-Myers Squibb Co. et al.*, and *Cortina v. Bristol-Myers Squibb Co. et al.*[43]

In both cases, the court denied defendants AstraZeneca AB and Bristol-Myers' motion to dismiss for lack of personal jurisdiction with respect to nonresident plaintiffs' claims that defendants failed to warn about the risks for their type 2 diabetes drug, Saxagliptin (marketed under Onglyza and Kombiglyze XR), and engaged in "inadequate clinical trials, testing and study, and inadequate reporting regarding the results of the clinical trials, testing and study."[44]

Applying the U.S. Court of Appeals for the Ninth Circuit's "but for" test "to determine whether a claim arises out of the defendant's forum-related activities," the court concluded that the nonresident plaintiffs' injuries "would not have occurred but for [Defendants'] contacts with California because the Saxagliptin clinical trials conducted here were part of the broken chain of events leading to [plaintiffs'] alleged [injuries]."[45]

While the court noted that the existing case law "provides no basis for imposing an arbitrary cut-off … to the exercise of its jurisdiction" with respect to the percentage of clinical trials "conducted in a given jurisdiction," it observed that unlike in BMS, plaintiffs alleged here that "nearly every pivotal clinical trial necessary for NDA approval involved studying of the Saxagliptin drugs throughout the State of California," and "but for the pre-NDA development of the Saxagliptin drugs within the State of California, the drugs would not have been sold and marketed throughout the U.S. and not ingested by Plaintiff[s]."[46]

Importantly though, the precedential value of Dubose and Cortina remains unclear. The Superior Court of California subsequently declined to follow Dubose and its progeny In re Xarelto, stating that "Dubose is not binding, and is not persuasive in light of the holding in BMS and the cases applying it."[47]

Risks Remain and Caution Is Advised
While the post-BMS legal landscape indicates that a majority of courts view the place of clinical activities as largely immaterial to specific jurisdiction analysis in standard product liability actions, a risk remains that aggregation of clinical trials in a single state could subject drug and medical device manufacturers to litigation in unexpected venues. It would be prudent, therefore, for companies to closely assess the locations of their clinical and research operations in connection with their overall litigation strategy.

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[1] 137 S. Ct. 1773 (2017).

[2] Lambert, W., Focusing on Fulfilling the Goals: Rethinking How Choice-of-Law Regimes Approach Statutes of Limitations, 65 Syracuse L. Rev. 491, 528 (2015) ("When statutes of limitations are characterized as procedural, a plaintiff may go to a state that has a favorable statute of limitations and bring his claim there, despite no longer being able to bring his claim in the state under whose law the cause of action arises because the statute of limitations has run in that state.").

[3] See, e.g., T.H. v. Novartis, 4 Cal.5th 145, 156 (Cal. 2017) (holding that under California law, "a brand-name drug manufacturer owes a duty of reasonable care in ensuring that the label includes appropriate warnings, regardless of whether the end user has been dispensed the brand name drug or its generic bioequivalent."); *Rafferty v. Merck & Co., Inc.*, 479 Mass. 141, 157 (Ma. 2018) (similarly recognizing recovery against brand-name drug manufacturer by consumers prescribed with generic under Massachusetts law).

[4] See, e.g., *Jones v. SmithKline Beecham Corp. et al.*, 2008 WL 11340340, at *3 (Aug. 19, 2008) (observing that California imposes strict liability in tort "on all of the participants in the chain of distribution of a defective product," including distributors) (emphasis added).

[5] Borchers, Patrick J., Punitive Damages: Forum and the Conflict of Laws, 70 La. L. Rev. 529, 536 (2010) (noting that with respect to punitive damages, some courts "treat their availability as a procedural issue subject to forum law.").

[6] *Bristol-Myers Squibb Co. v. Superior Court*, 1 Cal.5th 783, 789 (Cal. 2016).

[7] Id.

[8] Id. at 790.

[9] Id.

[10] Id.

[11] Id. at 790-91.

[12] Id. at 799.

[13] Id. at 806.

[14] Id. at 805-06.

[15] BMS at 1781.

[16] Id. (citing *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 564 U.S. 915, 919 (2011)).

[17] Id.

[18] Id.

[19] Id.

[20] *Moore v. Bayer Corp.*, 2018 WL 4144795 at *14 (E.D. Mo. Aug. 29, 2018).

[21] In re Pradaxa, 2019 WL 1177510 (Cal. Super. Ct. Jan. 31, 2019); In re Xarelto Cases, 2018 WL 809633 (Cal. Super. Ct. Feb. 6, 2018).

[22] In re Pradaxa, 2019 WL 1177510, at *3.

[23] Id. at *3.

[24] Id. at *3.

[25] In re Xarelto, 2018 WL 809633, at *9.

[26] Id. at *13.

[27] Id. at *10.

[28] *Moore v. Bayer Corp.*, 2018 WL 4144795 (E.D. Mo. Aug. 29, 2018); *Hinton v. Bayer Corp.*, 2018 WL 3725776 (E.D. Mo. July 27, 2018); *Johnson v. Bayer Corp.*, 2018 WL 999972 (E.D. Mo. Feb. 21, 2018); *Schaffer v. Bayer Corp.*, 2018 WL 999980 (E.D. Mo. Feb. 21, 2018); *Jordan v. Bayer Corp.*, 2018 WL 837700 (E.D. Mo. Feb. 13, 2018); *Dyson v. Bayer Corp.*, 2018 WL 534375 (E.D. Mo. Jan. 24, 2018).

[29] *Moore v. Bayer Corp.*, 2018 WL 4144795, at *5.

[30] Id. at *4.

[31] Id. at *5.

[32] Id. at *1.

[33] 2017 WL 4255075 (S.D. Ill. Sept. 26, 2017).

[34] Id. at *4.

[35] Id.

[36] Id.

[37] Id.

[38] *Hammons v. Ethicon, Inc.*, 190 A.3d 1248, 1255–56 (Pa. Super. Ct. June 19, 2018).

[39] Id. at *1263.

[40] Id.

[41] Id. at *1263-64.

[42] Id at *1263.

[43] *Dubose v. Bristol-Myers Squibb Co.*, 2017 WL 2775034 (N.D. Cal. June 27, 2017); *Cortina v. Bristol-Myers Squibb Co.*, 2017 WL 2793808 (N.D. Cal. June 27, 2017).

[44] Dubose, 2017 WL 2775034, at *1; Cortina, 2017 WL 2793808, at *1.

[45] Dubose, 2017 WL 2775034 at *3; Cortina, 2017 WL 2793808 at *3.

[46] Id.

[47] In re Xarelto, 2018 WL 809633, at *20.

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