The Biomaterials Access Assurance Act

An Underused Tool Against Forum Shopping

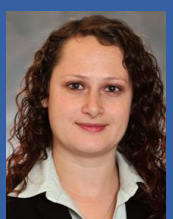
By James F. Murdica and Jenya Moshkovich

The Biomaterials Access Assurance Act can be a valuable tool to protect biomedical suppliers from baseless civil suits.

The Biomaterials Access Assurance Act (BAAA) was enacted in 1998 to protect biomaterial suppliers of implanted medical devices from the expenses of defending baseless civil suits. 21 U.S.C. §§1601-1606. The BAAA is a valuable and underused tool for medical device defendants because it provides a mechanism for swiftly dismissing defendants that supplied medical device parts or materials but that did not design, manufacture, test, or label the devices. The act has practical applications that can prevent forum shopping through fraudulent joiner of in-state materials suppliers and can in some cases provide a complete defense against liability to a supplier.

Background

In the early 1990s, many suppliers of component parts and raw materials used in implantable medical devices were pulling out of the U.S. medical device market due to litigation costs. *See* H.R. Rep. 105-549 at 10 (1998); J.D. Kerouac, A *Critical Analysis of the Biomaterials Access Assurance Act of 1998 as Federal Tort Reform Policy,* 7 B.U. J. Sci. & Tech. 330–31 (2001). Biomaterials that were withdrawn or that suppliers threatened to withdraw included fluorinated carbon, surgical stainless steel, fluorpolymers, resins and film products, silicone and silicone adhesives, polyethylene, nickel and titanium memory metals, and many others. *See* H.R. Rep. 105-549 at 10. Although these suppliers were rarely ultimately found liable when sued due to the "bulk supplier" and "learned intermediary" doctrines, litigation costs far outweighed the suppliers' profits. *Id.* One report referenced in the BAAA legislative history found that 75 percent of suppliers that provided biomaterials required for implantable medical devices had banned sales to U.S. device manufacturers due to concerns regarding litigation exposure. Kerouac, *supra,* at n.13 (citing H.R. Rep. 105-549, pt. 2, at 11 (1998)). Another report exemplified the problem with the case of DuPont, a company that supplied Teflon to Vitek, a



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jaw implant manufacturer. After numerous lawsuits were filed alleging that the implant materials fragmented, Vitek declared bankruptcy. Plaintiff attorneys then sued DuPont, despite the fact that each implant contained only a few cents worth of DuPont's Teflon and the final implant sold for over *fifty dollars.* A.M. Murphy, *The Biomaterials Access Assurance Act of 1998 and Supplier Liability: Who You Gonna Sue?*, 25 Del. J. Corp. L. 715 (2000); Kerouac *Critical Analysis* at n.14 (citing *Kealoha v. E.I. DuPont de Nemours & Co.*, 844 F. Supp. 590, 592 n.5 (1994)). DuPont eventually prevailed, but not before spending $26 million and five years litigating more than 650 lawsuits. Murphy, *supra,* at 716, 728–30.

Congress enacted the BAAA to safeguard the availability of life-saving and life-enhancing medical devices by clarifying the permissible scope of liability for biomaterial suppliers and minimizing litigation expenses by providing "expeditious procedures to dispose of unwarranted suits against" them. 21 U.S.C. §§1601(8), (15).

BAAA Substance

The BAAA applies to any civil action in federal and state court "on the basis of any legal theory, for harm allegedly caused, directly or indirectly, by an implant." 21 U.S.C. §1603(b)(1). The BAAA protects "biomaterials suppliers" that supply either raw materials or component parts for medical implants from the expenses of litigation for implant failure by providing "expeditious procedures to dispose of unwarranted suits against the suppliers" in the form of motions to dismiss or for summary judgment. 21 U.S.C. §1601(15)(B). Once a motion is filed, no discovery is permitted except the discovery necessary to determine the pending motion or a motion to dismiss for lack of jurisdiction. 21 U.S.C. §1605(c)(1). Unlike a standard motion to dismiss, which must be decided based on the four corners of the complaint, the BAAA permits the parties to submit affidavits supporting their positions. 21 U.S.C. §1605(c)(2). If successful, a dismissal under the BAAA is with prejudice, except a court may later rejoin the dismissed supplier if future evidence reveals a basis for contribution or indemnification. 21 U.S.C. §§1605(e), 1606(a).

To prevail on a BAAA-related motion, the moving party must demonstrate that it (1) is a "biomaterials supplier," (2) is not a manufacturer of the failed implant, (3) is not a seller of the failed implant, and (4) did not provide raw materials or component parts that failed to meet applicable contractual requirements or specifications. 21 U.S.C. §1605(a)(1)–(3). S*ee also Mattern v. Biomet*, 2013 U.S. Dist. Lexis 44054, at *5 (D.N.J. Mar. 28, 2013).

Defining a "Biomaterials Supplier"

As defined by the BAAA, a "biomaterials supplier" is an entity that directly or indirectly "supplies a component part or raw material for use in the manufacture of an implant." 21 U.S.C. §1602. A "component part" is "a manufactured piece of an implant" and includes "a manufactured piece of an implant that (i) has significant non-implant applications" and "(ii) alone, has no implant value or purpose, but when combined with other component parts and materials, constitutes an implant." 21 U.S.C. §1602(3). A "raw material" is "a substance or product that… (A) has a generic use; and (B) may be used in an application other than an implant." 21 U.S.C. §1602(8).

Defining a "Manufacturer"

A biomaterial supplier may be liable as a "manufacturer" if it

> has or should have registered with the Secretary pursuant to section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) and the regulations issued under such section; and (ii) included or should have included the implant on a list of devices filed with the Secretary pursuant to section 510(j) of such Act (21 U.S.C. 360(j)) and the regulations issued under such section.

21 U.S.C. §1604(b)(2)(A). This essentially means that a supplier may be liable if it is required to register as a manufacturer with the U.S. Food and Drug Administration (FDA). A biomaterial supplier may also be liable if it failed to do either of the two things mentioned in 21 U.S.C. §1604(b)(2)(A) quoted above, and it is "the subject of a declaration issued by the Secretary" stating that it was required to have done so. 21 U.S.C. §1604(b)(2)(B).

Defining a "Seller"

A biomaterial supplier may be liable as a "seller" only if it "held title to the implant and then acted as a seller of the implant after its initial sale by the manufacturer" or "acted under contract as a seller to arrange for the transfer of the implant directly to the claimant after the initial sale by the manufacturer of the implant." 21 U.S.C. §1604(c)(1). A "seller" as defined by the act means "a person who, in the course of a business conducted for that purpose, sells, distributes, leases, packages, labels, or otherwise places an implant in the stream of commerce." 21 U.S.C. §1602(10).

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A biomaterial supplier may also be liable as a manufacturer or seller if it is "related by common ownership or control to a person meeting" these requirements, and a court finds that the related manufacturer or seller "lacks sufficient financial resources to satisfy any judgment that the court feels it is likely to enter should the claimant prevail." 21 U.S.C. §§1604(b)(2)(C), (c)(2).

Failing to Meet Contractual Specifications

Under the act, a biomaterials supplier may "be liable for harm to a claimant caused by an implant if the claimant in an action shows, by a preponderance of the evidence," that the biomaterial supplier

"fail[ed] to meet applicable contractual requirements or specifications." 21 U.S.C. §1604(d). The failure to meet contractual specifications must also be "an actual and proximate cause of the harm to the claimant." 21 U.S.C. §1604(d)(2).

Application of the BAAA

Between 1998 and 2013, only two published opinions relied on these BAAA provisions—both successfully.

Marshall v. Zimmer, the first BAAA product liability case, involved a hip implant. 1999 U.S. Dist. Lexis 23594, at *1–2 (S.D. Cal. Nov. 4, 1999). The plaintiff initially named only Zimmer, an orthopedic product manufacturer, as a defendant, but later moved to amend the complaint by adding additional defendants, including four suppliers of raw materials and components. Citing the BAAA, Zimmer opposed the amendment, arguing that adding these defendants would be futile. *Id*. at *4. The plaintiff responded that the argument was premature. *Id*. at *6. The court sided with Zimmer, finding that although the immunity statute was raised in the context of a motion to amend, there was no reason to allow amended pleadings that would be subject to dismissal: the BAAA "is quite clear that the suppliers can provide affidavits to demonstrate that they are not subject to litigation for their minimal contribution to a medical device ultimately designed, made, and sold by the manufacturer." *Id*. at *6–7.

In *Whaley v. Morgan*, the second BAAA product liability action, which also involved a hip implant, the plaintiff sued DePuy Orthopedics, Inc., the primary implant manufacturer, as well as Morgan Advanced Ceramics, the manufacturer of a femoral head—one of the components of the hip implant system. *Whaley v. Morgan Advanced Ceramics, Ltd.*, 2008 U.S. Dist. Lexis 29918, at *5–7 (D. Colo. Mar. 31, 2008). The court dismissed Morgan in accordance with the BAAA, finding that Morgan, as a biomaterials supplier, could not be liable for the harm allegedly caused by the implant because it was not the manufacturer or the seller of the implant and did not furnish raw materials or components that failed to meet contractual requirements or specifications. *Id*. at *8–9.

The BAAA recently reemerged in some defendants' efforts to defeat forum shopping by removing cases from state to federal courts on the basis of fraudulent joinder. Plaintiffs preferring to litigate in state court often name local, minimally involved suppliers as defendants in an attempt to defeat diversity with the "forum defendant" rule. According to this rule, a state court action that could have been brought initially in a federal court under 28 U.S.C. §1332 is "removable only if none of the parties in interest properly joined and served as defendants is a citizen of the State in which such action is brought." 28 U.S.C. §1441(b). Over the past year, a number of defendants have removed cases to federal court by arguing that a forum defendant was a fraudulently joined biomaterials supplier that was subject to dismissal under the BAAA. Some succeeded, some did not, and some still await decisions.

The first case to argue fraudulent joinder based on the BAAA was *Mattern v. Biomet*, 2013 U.S. Dist. Lexis 44054 (D. N.J. Mar. 28, 2013). In *Mattern*, the plaintiffs sued Biomet in the New Jersey state courts over a hip implant and named Biomet Fair Lawn LLC, a New Jersey company, as a defendant. Biomet removed the case to federal court, arguing that Biomet Fair Lawn was fraudulently joined and subject to dismissal as a biomaterials supplier under the BAAA. No. 2:12-cv-04931-ES-SCM, Dkt. 1 (D.N.J. Aug. 6 2012). Biomet Fair Lawn also filed a concurrent motion to dismiss on the same grounds along with an affidavit, as permitted by 28 U.S.C. §1605, explaining that Biomet Fair Lawn is a casting manufacturer whose only role in the manufacturing process was to shape a raw piece of metal that would eventually become an implant and further explaining that Biomet Fair Lawn did not market, sell, distribute, lease, or package the implants; it did not develop or publish the package inserts, labels, or marketing materials; and it did not have any involvement with warnings or instructions. 2013 U.S. Dist. Lexis 44054, at *6–7, 10. The affidavit also explained that Biomet Fair Lawn is not registered and is not required to be registered with the Secretary of the U.S. Department of Health and Human Services and is not required to list and has never listed a Biomet hip implant, or any other Biomet device, on a 21 U.S.C. §360(j) device list. *Id*. at *9. The court dismissed Biomet Fair Lawn, finding that it was a biomaterials supplier under the BAAA and that it was not the manufacturer or seller of the implants and that it did not furnish raw materials or component parts that failed to meet contractual requirements or specifications. *Id*. at 6–12. Using the same argument, Biomet removed numerous cases to federal court, and in all except *Mattern*, the plaintiffs eventually agreed to dismiss the supplier forum-defendant without prejudice, enabling the cases to remain in federal court. *See, e.g,. Benson v. Biomet, Inc. et al*., 2:12-cv-03618-WJM-MF, Dkt. No. 15 (D.N.J. July 25, 2012); *Hanson v. Biomet, Inc. et al*., 2:12-cv-03359-SRC-CLW, Dkt. No. 17 (D.N.J. July 25, 2012); *Anker v. Biomet, Inc. et al*., 2:12-cv-03414-ES-CLW, Dkt. No. 12 (D.N.J. July 30, 2012); *Abourjilie v. Biomet, Inc. et al*., Dkt. No. 8 (D.N.J. July 30, 2012).

A subsequent case, *In re Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, involved thousands of pelvic mesh cases consolidated in a multidistrict litigation (MDL) in the U.S. District Court for the Southern District of West Virginia. 2013 U.S. Dist. Lexis 178317 (S.D. W. Va. Dec. 19, 2013). A group of plaintiffs preferring to litigate their cases in the plaintiff friendly Mass Tort Division of the Court of Common Pleas of Philadelphia County named Secant, a Pennsylvania company, as a defendant. *Musewicz et al. v. Ethicon, Inc. et al*., 2:13-cv-04087, Dkt. No. 1 (E.D. Pa. July 12, 2013); *Hammons v. Ethicon, Inc. et al*., 2:13-cv-04086, Dkt. No. 1 (E.D. Pa. July 12, 2013); *Delacruz et al. v. Ethicon, Inc. et al*., 2:13-cv-04088, Dkt. No. 1 (E.D. Pa. July 12, 2013). Ethicon removed the cases to federal court, arguing that Secant is a biomaterials supplier that should be dismissed in accordance with the BAAA along with affidavits explaining that Secant did not produce the final meshes at issue in the case. *Id*. Dkt. 1, 1–2. Rather, the affidavits explained that Ethicon supplies Secant with spools of polypropylene filament, which Secant knits into rolls of mesh and sends on to the next steps of the manufacturing process. *Id*. \

The plaintiffs moved to remand, arguing that Secant is not a BAAA-protected supplier because it played a significant role in designing and manufacturing the meshes. 2013 U.S. Dist. Lexis 178317, at *8. The court remanded the cases, determining that Ethicon had not met its heavy burden of establishing fraudulent joinder because

it only demonstrated that the BAAA *may* bar the plaintiffs' claim against Secant. The court concluded that the evidence presented by the plaintiffs that the BAAA may apply to Secant, "along with the dearth of case law interpreting the B.A.A.A., make it difficult to determine whether the B.A.A.A. is applicable to Secant," and the fact that "the defendants may ultimately be successful in dismissing Secant from the case does not change this analysis." *Id*. at *9.

In a related action, the U.S. District Court for the Southern District of West Virginia also rejected the argument that the BAAA creates federal question jurisdiction. *See Wilson v. Ethicon Women's Health & Urology*, 2014 U.S. Dist. Lexis 65516 (S.D. W. Va. May 13, 2014). Having been remanded to state court, Ethicon can renew its arguments for Secant's dismissal under the BAAA there, and if the state court grants it, remove the cases again if they become removable with a year of the initial filing.

Similar to Ethicon, Boston Scientific Corporation (BSC) is also defending an MDL involving pelvic mesh products in the U.S. District Court for the Southern District of West Virginia that some plaintiffs hoped to avoid by filing cases in the Indiana state courts and naming an in-state defendant, MedVenture, whose involvement in the manufacturing process is limited to cutting and cauterizing the mesh material in accordance with BSC's specifications. Similar to Biomet and Ethicon, BSC removed *Bocock v. BSC*, along with seven similar cases, on the basis of fraudulent joinder, explaining MedVenture's limited role in an affidavit submitted by MedVenture's president and CEO. *Bocock v. MedVenture Tech. Corp.*, 2013 U.S. Dist. Lexis 135086, at *19 (S.D. Ind. Sept. 20, 2013). The court declined to rule on the plaintiffs' remand motion, reasoning that by submitting an affidavit, BSC went beyond merely challenging the pleadings entirely on their face, and the court should allow the plaintiffs to engage in some discovery to test MedVenture's factual assertions in the interest of fairness. *Id*. at *20–21.

Rather than engaging in discovery, the plaintiffs, hoping for a decision before the cases were transferred to the MDL stipulated that the questions at issue were legal in nature and they did not need discovery to file a motion to remand. 4:13-cv-00109-SEB-WGH, Dkt. Nos. 33, 36 (S.D. Ind.). The court did not rule on the remand motion before the transfer, despite the plaintiffs' emergency motion to expedite the ruling. 4:13-cv-00109-SEB-WGH, Dkt. Nos. 51 (S.D. Ind.). The plaintiffs renewed their motion to remand in the MDL, which remains pending. 2:13-cv-32576, Dkt. No. 61 (S.D. W. Va. Apr. 11, 2014). For the time being at least, the BAAA successfully defeated forum shopping by having these cases removed to federal court and transferred to the MDL on the basis of fraudulent joinder.

In summary, the BAAA can be a valuable tool in defeating forum shopping by swift dismissal of a local, minimally involved biomaterials supplier. FD