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Product Liability

Using the Biomaterials Access Assurance Act as a Sword and a Shield

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Imagine a familiar scenario: Your client is an implantable medical device manufacturer who has been sued by multiple plaintiffs alleging harm after implantation of its product. The plaintiffs are bringing suit in State X state court but hail from various states throughout the United States, including State X. Your client is not a citizen of State X or any other state in which the plaintiffs are citizens. Thus, you assume that diversity jurisdiction exists and that you can remove the case to federal court. But not so fast—plaintiffs have destroyed diversity jurisdiction in this case by also suing a State X entity whose only involvement in the manufacturing process of your medical device was to provide you with component parts or raw materials. Are there any other options for securing federal jurisdiction at this point?

This article will explore a medical device manufacturer's removal strategy based on a federal statute, the Biomaterials Access Assurance Act ("the BAAA"), 21 U.S.C. § § 1601-1608, designed to address the exact scenario above. The BAAA is used by medical device suppliers as a shield for protection against product liability claims. And in doing so, medical device manufacturers may also use the Act as a sword in ultimately obtaining federal jurisdiction where it should have been appropriate from the outset of the case.

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I. What is the BAAA?

Although the BAAA does not apply to product liability claims brought against a medical device manufacturers, it is important to understand how it works to ultimately land in federal court. The BAAA protects "biomaterials suppliers" from liability in personal liability litigation involving an implantable medical device.[1] It is grounded in the principle that the manufacturer of a product is the proper defendant in a personal injury lawsuit arising from the alleged defective nature of the

[1] 21 U.S.C. § § 1601, 1603(b)(1).

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product not a mere supplier along the production chain.[2] To protect biomaterials suppliers of implants in personal injury lawsuits, Congress created a unique procedural mechanism allowing biomaterials suppliers to seek dismissal at the earliest possible opportunity so as to prevent them from being subjected to costly discovery.[3]

II. How to Obtain Dismissal and Establishing Immunity Under the BAAA

A. Motion to Dismiss

The BAAA attempts to prevent gamesmanship by providing a simple procedure by which biomaterials suppliers may establish immunity and obtain dismissal. The Act provides step by step requirements for a biomaterials supplier defendant in filing a motion to dismiss. Once a motion to dismiss is filed, the Court must rule solely on the pleadings and any affidavits submitted under Sections 1605(c)(2)(A) and (B).[4] Of note, discovery is generally not permitted and only allowed to shed light on a narrow set of allegations while a motion to dismiss is pending.[5] If the court finds that the movant qualifies for immunity under the BAAA, the court is required to enter an order dismissing the claims against the movant with prejudice.[6]

B. Step One: Qualify as a "Biomaterials Supplier"

For a successful motion to dismiss under the BAAA, the movant must first establish that it is a "biomaterials supplier."[7] Specifically, the movant must have "directly or indirectly supplie[d] a component part or raw material for use in the manufacture of an implant."[8] Courts have interpreted component parts and raw materials to include items such as pieces of metal that require further manufacturing in order to become implants[9] as well as polypropylene mesh material[10] or femoral hip heads that combine with other components to constitute a hip implant.[11] It is important to focus on whether the product is a finished, implantable device. If the product was not implantable at the time it left the biomaterials supplier's hands, it should arguably qualify as a component part or raw material.[12] Establishing a movant's status as a biomaterials supplier is oftentimes the most difficult step to overcome but is the most critical in achieving immunity: the BAAA specifically states that "a biomaterials supplier . . . *shall not be liable* for harm to a claimant caused by an implant . . . ."[13]

In qualifying as a biomaterials supplier, the movant must also show that it does not meet any exceptions to the rule. Specifically, Section 1604(a) states that the biomaterials supplier can be held liable if it is *also* "(1) a manufacturer of the implant . . .; (2) as a seller of the implant . . . ; or (3) for furnishing . . . component parts for the implant that failed to meet applicable contractual requirements or specifications . . . ."[14]

C. Step Two: Negate Liability as a "Manufacturer"

After a movant establishes that it is a biomaterials supplier, it must negate that it is also a "manufacturer" or "seller," or that it could be liable for failing to meet "applicable contractual requirements or specifications."[15] Under the Act, a biomaterials supplier may be liable as a manufacturer if it is registered or required to be registered with the Secretary of Health and Human Services pursuant to 21 U.S.C. § 360, *and* included the implant on a list of devices filed with the Secretary pursuant to 21 U.S.C. § 260(j). It may also be liable if it was required but failed to comply with either one of those requirements[16] or if it is related to the manufacturer of the device by common ownership.[17] Importantly, "any person" may petition the Secretary to issue a declaration that the biomaterials supplier must register its device.[18] And to determine whether the movant has registered, a party can search the public database on the FDA's website. The parties are also permitted to submit affidavits to support or negate the status of a movant as a manufacturer of the finished medical device.[19]

In most cases, a movant's status and therefore its protection under the BAAA comes down to registration—whether or not the entity is registered with the FDA as a manufacturer or contract manufacturer. Consequently, prior to filing a motion to dismiss, it is important to ensure that the entity is not registered as to the device at issue.

D. Step Three: Negate Liability as a "Seller"

A movant must also negate that it is liable as a "seller" as defined by the BAAA. A biomaterials supplier is a "seller" if it (1) acted as a seller of the implant after its sale by the manufacture; or (2) arranged for the transfer of the implant directly by the claimant after its initial sale by the manufacturer.[20] Alternatively, a biomaterials supplier may be held liable as a seller if it is "related by common ownership or control to a person meeting" the requirements of the BAAA, and if the related manufacturer does not have "sufficient financial resources to satisfy any judgment that the court feels it is likely to enter should the claimant prevail."[21] Thus, if

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[2] *See id.*

[3] *Id.* § § 1605(a), 1605(c) (Congress' intent was to "create expedited procedures for determining whether a biomaterials supplier defendant is protected" from liability.).

[4] *Id.* § 1605(c)(3).

[5] *Id.* § 1605(d)(2)-(3) (discovery only permitted on the question of whether the biomaterials supplier may be liable for failure to meet the device manufacturer's contractual specifications); *Mattern v. Biomet*, Civ. A. No. 12-4931, 2013 BL 82144 (D.N.J. Mar. 28, 2013).

[6] 21 U.S.C. § 1605(e).

[7] *Id.* § 1604(a).

[8] *Id.* § 1602(1)(A); *see also Mattern*, 2013 BL 82144, at *2-4 (dismissing products liability claims against "casting manufacturer whose sole role in the manufacturing process is to shape a raw piece of metal that will eventually become an implant").

[9] *Mattern*, 2013 BL 82144, at *2.

[10] *In re: Pelvic Mesh Litigation*, No. 1402829, 2014 WL 4188104 (Pa. Com. Pl. Aug. 25, 2014).

[11] *Whaley v. Morgan Advanced Ceramics, Ltd.*, Civ. No. 07-cv-00912-REB-CBS, 2008 BL 78014 (D. Colo. Mar. 31, 2008).

[12] *See* 21 U.S.C. § 1602(3)(B)(ii) (a component part is a manufactured piece of an implant that "alone, has no implant value or purpose").

[13] *Id.* § 1604(a) (emphasis added).

[14] *Id.*

[15] *Id.*

[16] *Id.* § 1604(b)(2)(B).

[17] *Id.* § 1604(b)(2)(C).

[18] *Id.* § 1604(b)(3).

[19] 21 U.S.C. § 1605(c)(2).

[20] *Id.* § 1604(c)(1).

[21] *Id.* § 1604(c)(2).

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a movant ever acted as a seller of the device or maintains common ownership with the seller, the BAAA will not protect it from immunity.

E. Step Four: Negate Liability for Failure to Meet Contractual Requirements

Further, the BAAA recognizes liability by a movant where it has failed to meet its contractual requirements with respect to the product at issue. Specifically, a biomaterials supplier may be liable under Section 1604(d) of the BAAA if it supplied raw materials or a component part that either (1) did not constitute the product described in the contract or (2) failed to meet contractual specifications.[22] The failure to meet contractual requirements must have been ''an actual and proximate cause of the harm to the claimant.''[23]

The language of the BAAA suggests that a biomaterial supplier's failure to meet contractual requirements would be based on a claim by the manufacturer of the device, and not the claimant.[24] The Act discusses that ''the main defendant in th[e] action [i.e., the manufacturer] . . . has a strong incentive to pass any blame for the alleged defects in its medical device on to any supplier who failed to comply with the contract or whose product may have contributed to [the plaintiff's] injury.''[25] Thus, if there is no breach of contract crossclaim by the manufacturing defendant in the case, there should not be a related basis for plaintiff to negate the BAAA's protection.

F. Securing Dismissal Pursuant to the BAAA

The most practical way to establish that an entity is a biomaterials supplier, and does not meet any exception to protection under the BAAA, is by affidavit in support of its motion to dismiss. Once done, the biomaterials supplier should be dismissed from the lawsuit with prejudice, leaving the medical device manufacturer defendant as the sole defendant in the case.[26]

III. Establishing Diversity of Citizenship and Removal to Federal Court

As the biomaterials supplier defendant is moving for dismissal, the medical device manufacturer defendant should be contemplating possibilities for removal to federal court. Although plaintiffs may have attempted to destroy federal diversity jurisdiction by naming the biomaterials supplier as a defendant, the BAAA can be used as a sword by the co-defendant medical device manufacturer to thwart plaintiff's attempts. Based on the requirements set forth in the BAAA, if it appears that the Act applies to the home-state supplier defendant, the medical device manufacturer has two removal options: (1) removing the case prior to a finding of immunity based on a fraudulent joinder argument, or (2) removing after a finding of immunity.

A. Option 1: Removal Before Dismissal of the Biomaterials Supplier

Any attempt to remove the case to federal court while the non-diverse biomaterials supplier defendant is still a party requires an argument that the citizenship of the non-diverse defendant should be ignored.[27] To ignore the citizenship of a party, the manufacturer can argue that the non-diverse defendant has been fraudulently joined.[28] ''[J]oinder is fraudulent if 'there is no reasonable basis in fact or colorable ground supporting the claim against the joined defendant, or no real intention in good faith to prosecute the action against the defendant or seek a joint judgment.' ''[29] Further, a court must find that the ''plaintiff cannot establish a claim against the non-diverse defendant even after resolving all issues of fact and law in the plaintiff's favor.''[30] Upon a finding of fraudulent joinder, the court may disregard the citizenship of the nondiverse defendants, ''assume jurisdiction over a case, [and] dismiss the nondiverse defendants. . . .''[31]

Establishing fraudulent joinder may be a difficult task, however, as courts do not find fraudulent joinder ''simply because plaintiff has a weak case against a non-diverse defendant.''[32] Instead, parties are generally required to prove fraudulent joinder by clear and convincing evidence.[33] The defendant's burden is heavy, and the standard for establishing fraudulent joinder ''is even more favorable to the plaintiff than the standard ruling on a motion to dismiss under Fed. R. Civ. P. 12(b)(6).''[34] To defeat a claim of fraudulent joinder, a plaintiff is only required to demonstrate that it has a ''slight possibility of a right to relief.''[35]

With these standards in mind, the difficultly of establishing that a biomaterials supplier has been fraudulently joined will depend on whether the biomaterials supplier is clearly immune under the Act. If there is a legitimate argument that the biomaterials supplier does not qualify for immunity under the Act, a court will be less inclined to find that the biomaterials supplier has been fraudulently joined. In cases in which an entity

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[22] *Id.* § 1604(d)(1)

[23] *Id.* § 1604(d)(2).

[24] This is true unless the plaintiff can offer proof that the component part or raw material did not meet accepted legal standards, published standards, standards submitted to the Secretary, or standards including in the submission for premarket approval. This is the only section of the BAAA on which discovery is permitted. 21 U.S.C. § § 1605(c)(1)(B), 1605(d)(2)-(3).

[25] *Marshall v. Zimmer*, Civ. No. 99-0973-E, 1999 WL 34996711, *3 (S.D. Cal. Nov. 4, 1999).

[26] Dismissal is required in all federal and state courts: the BAAA contains an express preemption provision that bars any finding of liability under state law where the BAAA precludes it. 21 U.S.C. § 1603(c)(1).

[27] *See* 28 U.S.C. § 1332(a)(1); 28 U.S.C. § 1441(b)(2).

[28] *Burden v. General Dynamics Corp.*, 60 F.3d 213 (5th Cir. 1995).

[29] *In re Briscoe,* 448 F.3d 201, 217 (3d Cir. 2006) (quoting *Abets v. State Farm Fire & Cas. Co.,* 770 F.2d 26, 32 (3d Cir. 1985)).

[30] *Mayes v. Rapoport*, 198 F.3d 457, 464 (4th Cir. 1999).

[31] *In re Briscoe,* 448 F.3d at 216 (citation and quotation marks omitted).

[32] *Nele v. TJX Cos., Inc.,* No. 11–7643, 2013 BL 175219 (E.D. Pa. July 1, 2013).

[33] *Id.* (citing *Nobers v. Crucible, Inc.*, 602 F. Supp. 703, 705 (W.D. Pa. 1985)).

[34] *Mayes*, 198 F.3d at 464 (quoting *Hartley v. CSX Transp., Inc.*, 187 F.3d 422, 424 (4th Cir. 1999)).

[35] *Id.* at 466 (quoting *Hartley*, 187 F.3d at 426); *see also Marshall v. Manville Sales Corp.*, 6 F.3d 229, 232-33 (4th Cir. 1993) (holding that defendants failed to meet the heavy burden of proving that plaintiffs had no possibility of establishing a cause of action against the non-diverse defendant).

has supplied a piece of an implant to a manufacturer which unquestionably qualifies as a ''component part'' or ''raw material,'' the entity cannot be considered a ''manufacturer'' or ''seller'' under the BAAA, and the manufacturer does not allege that the biomaterials supplier deviated from contractual specifications,[36] the device manufacturer has a strong argument that the non-diverse biomaterials supplier was fraudulently joined. Conversely, if there is a question as to whether the biomaterials supplier's product at issue qualifies as a ''raw material'' or ''component part,'' or if the supplier could be held liable as a ''seller'' or ''manufacturer,'' a federal court will be reluctant in finding fraudulent joinder.

Prior to determining whether to remove a matter to federal court by utilizing a fraudulent joinder argument based on the BAAA, a device manufacturer should conduct a thorough BAAA analysis to ensure that the biomaterials supplier is unquestionably immune from liability under the BAAA. If this is the case, the biomaterials supplier's citizenship should be ignored, and diversity jurisdiction in federal court should be proper. If the question of immunity is closer, however, the device manufacturer may wish to consider waiting to remove until after the biomaterials supplier obtains a dismissal in state court.

B. Option 2: Removal After Dismissal of the Biomaterials Supplier

If the device manufacturer would rather wait until after a finding of immunity under the BAAA, the manufacturer must consider any obstacles. Specifically, the ''voluntary/involuntary'' rule is a potential obstacle that may hinder removal.

The voluntary/involuntary rule is a judicially created doctrine that allows federal courts to exercise jurisdiction over a case that was not initially removable only when diversity was created by a voluntary action of the plaintiff. For example, if the case became removable when the plaintiff voluntarily dismissed the non-diverse defendant, then the case passes the ''voluntary/involuntary'' test and is properly removable.[37] If, however, the event upon which removal was based was not a voluntary act of the plaintiff, federal courts cannot exercise jurisdiction and are required to remand. Courts consider the grant of a motion to dismiss as an involuntary act, and may apply the voluntary/involuntary rule to prohibit a device manufacturer from removing after the biomaterials supplier is dismissed under the BAAA.[38] As such, a device manufacturer must be prepared to argue that the rule should not apply.

1. Overcoming the voluntary/involuntary rule with fraudulent joinder

Device manufacturers may avoid the voluntary/involuntary rule by arguing fraudulent joinder of the biomaterials supplier. Fraudulent joinder has been accepted by courts across the country as an exception to the rule.[39] While the same standard should be applied to a fraudulent joinder analysis *after* the dismissal of the biomaterials supplier as would be applied to a fraudulent joinder analysis *before* the biomaterials supplier is dismissed, a court may be more likely to find fraudulent joinder after a state court has ruled that the biomaterials supplier is immune from liability. Accordingly, the device manufacturer should argue that the voluntary/involuntary rule does not apply because the biomaterials supplier was fraudulently joined—it was clearly not an appropriate party at the time the lawsuit was filed as it is immune from liability under the BAAA. And, in this instance, federal jurisdiction is thus appropriate.

2. The voluntary/involuntary rule has been statutorily abrogated

Device manufacturers may also avoid the application of the voluntary/involuntary rule based on the recent amendments to the removal statute, 28 U.S.C. § 1446. Specifically, device manufacturers can argue that the voluntary/involuntary rule has been statutorily abrogated and thus, is no longer good law. While this argument is novel, it garners support from both documented congressional intent as well as common sense: because the amendment to Section 1446 forbids courts from looking beyond the plain language of the statute to deprive defendants of rights to removal, the voluntary/involuntary rule is no longer viable.

By way of background, any removal based upon the dismissal of a biomaterials supplier under the BAAA would be made pursuant to 28 U.S.C. § 1446(b)(3). Congress amended Section 1446 in 2011 to expressly provide that the *only exceptions* to a Section 1446(b)(3) removal (hereinafter referred to as an ''other paper'' removal) provided for under Section 1446(b)(3) are those set forth in subsection (c). More specifically, Congress amended Section 1446 in 2011 by adding the *emphasized language* to the beginning of subsection (b)(3):

> (b)(3) *Except as provided in subsection (c),* if the case stated by the initial pleading is not removable, a notice of removal may be filed within thirty days after receipt by the defendant, through service or otherwise, of a copy of an amended pleading, motion, order or other paper from which it may first be ascertained that the case is one which is or has become removable.[40]

Subsection (c), which contains a list of detailed exceptions to a removal authorized by subsection (b)(3), does not include any reference to the voluntary/involuntary rule.

Because Congress did not include the voluntary/involuntary rule in subsection (c) among the specific statutory exceptions to an ''other paper'' removal, defendants in an involuntary dismissal situation have a strong argument that the voluntary/involuntary rule is no longer viable.[41] Indeed, the continued application of

[36] *See* Section II.B. *supra*.

[37] *See* footnote 34, *supra*.

[38] *See, e.g., Farley v. Argus Energy, LLC*, No. 2:08-CV-00818, 2008 BL 149245 (S.D. W. Va. July 16, 2008).

[39] *Arthur v. E.I. DuPont*, 798 F. Supp. 367, 369 (S.D. W. Va. 1992); *see also Knudson v. Systems Painters, Inc.*, 634 F.3d 968, 977 (8th Cir. 2011); *Crockett v. R.J. Reynolds Tobacco Co.*, 436 F.3d 529 (5th Cir. 2006).

[40] 28 U.S.C. § 1446(b)(3) (emphasis added).

[41] *See TRW Inc. v.Andrews*, 534 U.S. 19, 28 (2001) (''Where Congress explicitly enumerates certain exceptions to a general prohibition, additional exceptions are not to be implied, in the absence of evidence of a contrary legislative intent.'').

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the voluntary/involuntary rule would effectively nullify the 2011 Congressional amendments.[42]

Further, the voluntary/involuntary rule should not be considered an exception to ''other paper'' removals permitted in 28 U.S.C. § 1446(b)(3). Subsection (c) of amended Section 1446 expressly provides *the only exceptions* to an ''other paper'' removal otherwise authorized by subsection (b)(3) and the voluntary/involuntary rule is not listed. Thus, upon removal of a case in which an in-state or non-diverse biomaterials supplier has been dismissed under the BAAA, the manufacturer may attempt to avoid the application of the voluntary/involuntary rule by arguing that it has been unequivocally abrogated by the 2011 amendments.[43]

IV. Conclusion

Though there may be obstacles on the route to federal court, the BAAA can provide medical device manufacturers with the necessary tools to get there. As more and more state and federal courts are asked to interpret the plain language and simple dismissal procedures of the BAAA, it will become even more obvious to practitioners that the Act can be used by both the biomaterials supplier defendant and the medical device manufacturer defendant. In addition, federal courts will be more willing to maintain jurisdiction based on a finding of fraudulent joinder (whether removing before or after the biomaterials supplier has been found immune). Thus, while biomaterials suppliers should continue using the BAAA to shield themselves from liability, medical device manufacturers can begin to pursue removal strategies by using the BAAA as their weapon.

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[42] *See Lee v. Carter-Reed Co.*, No. 2:06-CV-1173, 2006 BL 123298 (D.N.J. Dec. 5, 2006) (holding that the ''voluntary/involuntary rule should not be expanded to the point it would nullify an act of Congress'').

[43] It is worth noting that the 2011 amendments also added language that could be helpful in allowing a defendant to beat yet another potential obstacle to removal, the ''one year'' rule. While 28 U.S.C. § 1446 prevents ''other paper'' removals when they are filed over one year after the commencement of an action, the amendments provide an important exception to this rule: if the district court ''finds that the plaintiff has acted in bad faith in order to prevent a defendant from removing the action,'' then the one year rule does not apply. 28 U.S.C. § 1446(c)(1). While a manufacturer should attempt to remove prior to the expiration of one year after the case is commenced, if that is not possible, it may argue that the plaintiff's bad faith prevented removal.