A Potentially Far-Reaching Effect

Connell v. Lima Corporate and the Biomaterials Access Assurance Act

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In key respects, the impact of the Ninth Circuit's expansive construal of the term "biomechanical supplier" remains open; in others, it simply depends upon perspective.

Since 1998, the Biomaterials Access Assurance Act ("BAAA"), 21 U.S.C. §1601, *et seq.*, has protected certain manufacturers of medical implant components from liability in personal injury suits. Though significant in some cases, the BAAA has played a minor role in medical device litigation generally. This February, however, the Ninth Circuit Court of Appeals expansively construed the BAAA's key term ("biomaterials supplier") and immunized the manufacturer of a near-complete hip implant "component." *See Connell v. Lima Corporate*, 988 F.3d 1089 (9th Cir. 2021). In doing so, the Ninth Circuit enshrined a controversial desire of Congress: that plaintiffs should center litigation on end-product manufacturers.

This article examines the significance of *Lima* and the BAAA to medical device litigation and to indemnity and contribution arrangements in the medical device industry. The authors are indebted to and continue the efforts of two helpful DRI predecessors: P.J. Cosgrove & Joshua A. Klarfeld, ***A Legislative Response to Shotgun Litigation***, For The Defense 54 (Feb. 2014) ("explor[ing] the bases of raising motions under the BAAA" and early caselaw), and James F. Murdica & Jenya Moshkovich, ***An Underused Tool Against Forum Shopping***, For The Defense 20 (Sept. 2014) (providing overview of BAAA-based fraudulent joinder caselaw).

The BAAA in Its First Two Decades

Congress enacted the BAAA in 1998 to prevent international manufacturers of medical implant components from exiting



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the American medical device market. *See* Murdica & Moshkovich, *supra*, at 20. At the time, even helpful common law defenses (like "the 'bulk supplier' and 'learned intermediary doctrines'") could not offset crippling litigation exposure. *See id.* at 20–21. To assure America's access to these components, the BAAA authorized prediscovery dismissal procedures for "biomaterials suppliers" complying with contractual specifications. *See id.* at 21.

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Once passed, the BAAA saw little substantive application; by early 2013, only "three cases cit[ed] the BAAA's motion to dismiss provision for a substantive purpose." Cosgrove & Klarfeld, *supra*, at 55. Indeed, the BAAA's utility quickly shifted to a procedural preoccupation: fraudulent joinder. *See* Murdica & Moshkovich, *supra*, at 22; *see also Quinn v. Ethicon, Inc.*, No. 2:19-cv-05462, 2020 WL 977326, at *3–4 (E.D. Pa. Feb. 27, 2020) (surveying recent BAAA-based fraudulent joinder decisions in the consolidated pelvic mesh litigation).

To be sure, the BAAA's legacy thus far lies in removal litigation. Yet, the Ninth Circuit Court of Appeals' recent analysis of the BAAA—the first ever by a federal appellate court—may forecast a wider impact.

Connell v. Lima Corporate – Background

In *Connell v. Lima Corporate*, the Ninth Circuit Court of Appeals held that the BAAA protected the Italian manufacturer of a three-part modular revision hip stem sold to an American company for sterilization and packaging and later combined with a femoral head for surgical implantation. *Lima*, 988 F.3d 1089.

Lima is an Italian manufacturer of "modular revision hip stems," *id.* at 1094—orthopedic products for use in "total joint replacement systems." *See Connell v. Lima Corp.*, No. 1:16-cv-00456-CWD, 2019 WL 403855, at *2 (D. Idaho Jan. 30, 2019). Lima's hip stems are composite: they contain (1) a femoral stem for placement in the femoral canal, (2) an angled neck for attachment to a femoral head, and (3) a set screw attaching the stem and neck. *See Lima*, 988 F.3d at 1094–95. During implantation, surgeons connect the hip stem to a separate femoral head, liner, and shell manufactured by a different company. *See id.* at 1095.

Lima sold the at-issue hip stem to an American orthopedics manufacturer: Encore Medical L.P. (d/b/a DJO Surgical). *Id.* at 1093–94. The parties' "Supply Agreement" identified Lima (the "Seller") as a manufacturer of "Components… for use in, among other things, total joint replacement systems." *Lima*, 2019 WL 403855, at *2. It identified DJO Surgical (the "Purchaser") as a manufacturer of "joint prosthesis systems." *Id.* Lima agreed to provide DJO Surgical with "parts developed and/or manufactured by [Lima] and designed for incorporation into joint prosthesis systems"—including "Revision Modular Stems"—according to DJO Surgical's specifications. *Id.*

One such Revision Modular Stem (connected to a shell, a liner, and a DJO-brand femoral head) was implanted in plaintiff Jeffrey Connell in "a total hip revision surgery." *Id.* at *1; *Lima*, 988 F.3d at 1095. Lima sold it to DJO Surgical pursuant to their agreement. *Lima*, 2019 WL 403855, at *1–3. DJO Surgical, in turn, sold it to a distributor, and the distributor sold it to the hospital at which Plaintiff underwent surgery. *Id.* at *1.

Connell v. Lima Corporate: Summary Judgment and Denial of Impleader

Years after implantation, the "femoral stem portion" of the plaintiff's implant fractured. *Id.* He and his wife sued (as relevant here) both Lima and DJO Surgical in the United States District Court for the District of Idaho. *Id.* Almost two years after filing, the plaintiffs settled with and dismissed DJO Surgical. *Id.*

The plaintiffs' settlement with DJO Surgical left Lima the lone defendant. *Id.* Lima later moved for summary judgment under the BAAA as an immunized "biomaterials supplier of component parts for the DJO Surgical Revision Femoral Hip System." *Id.* at *4. The plaintiffs rejected this designation; they countered that Lima itself "was the manufacturer of the hip system and that DJO was merely a distributor or seller." *Id.*

Summary Judgment for Lima as a "Biomaterials Supplier"

The District of Idaho found that "the BAAA applie[d] to preempt Plaintiffs' product liability claims," and it granted summary judgment for Lima. *Id.* at *7. The court first assessed the applicability of the BAAA to Lima, and then the inapplicability of the BAAA's three exceptions. *Id.* at *4–7.

"The BAAA defines a 'biomaterials supplier' as 'an entity that directly or indirectly supplies a component part… for use in the manufacture of an implant.'" *Id.* at *5 (original brackets omitted) (quoting 21 U.S.C. §1602(1)(A)). Surveying BAAA caselaw and the Lima-DJO Surgical Supply Agreement, the district court deemed Lima "a biomaterials supplier of component parts used by DJO for its Revision Femoral Hip System." *Id.* at *5–6. In large part, the district court's decision turned on the following observation: "when the distal stem and femoral neck arrived from Italy in Austin, Texas, at DJO's facility, the parts were not ready for implantation into a human being—a crucial characteristic of an implant under the BAAA." *Id.* at *6. Rather, upon receipt, DJO Surgical undertook "numerous additional steps necessary to ready all three components of the hip system for commercial distribution"—including inspection, packaging, labeling, and sterilization. *Id.* What's more, "[t]itle to the Components passed to DJO at the place of shipment[,]

and DJO was responsible for inspecting and conducting performance testing to ensure the Components were in conformity with its specifications." *Id.* DJO Surgical further maintained "sole responsibility for obtaining all FDA clearances to sell its products in the United States," and even "held itself out as the manufacturer of the 'DJO Modular Revision Femoral Hip Stem' in its 510(k) application to the FDA." *Id.*

Yet, the district court did not end its inquiry there. *Id.* at *7. It then addressed three potential exceptions to BAAA immunity, asking if Lima "acted (1) as manufacturer of the implant; (2) as seller of the implant; or (3) furnished raw materials or component parts for the implant that failed to meet applicable contractual requirements or specifications." *Id.* (citing 21 U.S.C. §1604(a)). The court quickly disposed of the latter two exemptions. *Id.* No evidence suggested that Lima sold the plaintiffs' implant. *Id.* And no evidence suggested "that DJO's inspection upon receipt noted any deviation or that the stems in the shipment failed to meet the specifications"; in fact, "quality assurance records" from Lima's factory revealed that "no abnormalities were noted for the production lot of stems including the stem eventually implanted in [Plaintiff]." *Id.*

Thus, the district court narrowed its focus to the first exemption—"whether Lima, as a biomaterials supplier, [could] nevertheless be considered the manufacturer of the implant." *Id.* (citing 21 U.S.C. §1604(a)(1)). This exemption "applies only in three situations": (1) "if Lima registered or was required to register with the Secretary of Health and Human Services and included or was required to include the implant on a list of devices filed with the Secretary"; (2) "if Lima was subject to a declaration issued by the Secretary that stated Lima was required to so register and list the implant but failed to do so"; or (3) "if Lima was related by common ownership or control to an entity meeting th[ose] requirements." *Id.* (citing 21 U.S.C. §1604(b)(2)(A)–(C)). Because the plaintiffs "d[id] not assert that any of these situations appl[ied] to exclude Lima from the BAAA's preemption protections for biomaterials suppliers," the court found "no facts that dispute[d] or introduce[d] any doubt as to Lima's representations regarding the inapplicability of this exemption." *Id.*

Accordingly, the district court granted Lima summary judgment. *Id.* at *8. Seven months later it doubled down, denying the plaintiffs' motion to alter or amend its decision. *See Connell v. Lima Corp.*, No. 1:16-cv-00456-CWD, 2019 WL 5873456 (D. Idaho Aug. 23, 2019). Indeed, though the court admittedly mistook the hip stem screw (manufactured by Lima) as the product of *another* company in its prior decision, that mistake "was not determinative of the Court's ruling." *Id.* at *2, *2 n.3, *3. What's more, in the period between the court's summary judgment order and its refusal to alter, the plaintiffs had unsuccessfully petitioned the FDA "on the issue of whether Lima was required to register with the FDA or list the modular revision hip system at issue." *Id.* The FDA determined that "Lima was a seller of components for the modular revision hip system and that Lima was exempt from the FDA's registration and listing requirements"; Lima simply "manufactured devices for another party who both initiate[d] the specifications and commercially distribute[d] the device." *Id.* at *1, *3.

Denial of Impleader

Separately, the district court denied the plaintiffs' "motion to implead Lima under 21 U.S.C. §1606(a)" after summary judgment in Lima's favor. *Lima*, 988 F.3d at 1096. In certain circumstances, the BAAA permits "[s]ubsequent impleader of [a] dismissed biomaterials supplier." *See* 21 U.S.C. §1606. Specifically, it allows plaintiffs to "implead a dismissed biomaterials supplier" "within 90 days after entry of a final judgment in an action by the claimant against a manufacturer" upon the court's findings that "the negligence or intentionally tortious conduct of the dismissed supplier was an actual and proximate cause of the harm" and that the plaintiff "is unlikely to be able to recover the full amount of its damages from the remaining defendants." *Lima*, 988 F.3d at 1105 (original emphasis omitted) (quoting 21 U.S.C. §1606(a)). The district court made no such findings. *Id.* It simply denied impleader "because there was no 'final judgment' against DJO, the 'manufacturer'"; the court did not view "the settlement agreement resulting in a voluntary dismissal with prejudice of the claims against DJO" as "an adjudication on the merits." *Id.* at 1096.

Connell v. Lima Corporate – Appeal

On appeal to the Ninth Circuit Court of Appeals, the plaintiffs challenged both summary judgment for Lima and denial of their impleader motion. *Id.* at 1096. The appellate court affirmed both rulings. *Id.* at 1110–11.

Critically, the court of appeals found that Lima's hip stem "[wa]s a 'piece' of an implant as a separate part of a larger whole, unable to function on its own"; even the plaintiffs acknowledged that it could not "be implanted or function without a separate compatible femoral head.

Summary Judgment for Lima as "Biomaterials Supplier" Affirmed

First, the court of appeals examined Lima's status as an immune "biomaterials supplier"—a "question of first impression in the courts of appeal." *Id.* at 1097. Applying 21 U.S.C. §1602(1)(A), the court queried "whether Lima met the[] elements of (1) supplying a 'component part' (2) 'for use in the manufacture of an implant.'" *Id.* at 1098. In the court's view, Lima's hip stem was a "component part" under the BAAA—*i.e.*, "a manufactured piece of an implant." *Id.* (quoting 21 U.S.C. §1602(3)(A)). Critically, the court of appeals found that Lima's hip stem "[wa]s a 'piece' of an implant as a separate part of a larger whole, unable to function on its own"; even the

plaintiffs acknowledged that it could not "be implanted or function without a separate compatible femoral head." *Id.* at 1099.

Yet, the plaintiffs argued that Lima's hip stem was not a "component part because it [wa]s *itself* an implant." *Id.* (emphasis added). This circular argument forced the court to define "implant" while defining "component part." *See id.* at 1098–1101.

Acknowledging its expansive definition of "biomaterials supplier," the court explained "that Congress meant for plaintiffs to recover from either the statutory manufacturer or the direct seller of an implant"—not component part suppliers.

Analyzing the BAAA's definition (26 U.S.C. §1602(5)), the court identified "two major elements to the definition of implant: [1] 'medical device' and [2] 'intended by the manufacturer… to be placed' in a body cavity." *Id.* at 1100. Lima's hip stem met the first element—it was a "medical device." *Id.* But it did not meet the second, and "the definition of 'implant' hinge[d] decisively on the second element…" *See id.* at 1100–01. The court of appeals' narrow construal of this second element, described below, expands the BAAA's reach significantly.

The court of appeals identified two approaches to the manufacturer-intent element of an "implant," as the phrase "'intended by the manufacturer… to be placed' in a body cavity" "could be read in one of two ways." *Id.* at 1100. Narrowly, "[i]t could be read to apply only when the device is ready to be placed into a body cavity by itself." *Id.* Broadly, "it could be read to apply when a manufacturer anticipates that an item could ever be inserted into a body, even if it must first be combined with other items to become implant-ready." *Id.* The court endorsed the narrow view as "better supported by the statutory context and stated purpose" of the BAAA. *Id.* at 1101. After narrowly defining "implant," the court of appeals also rejected the plaintiffs' argument "that a component part must have 'significant non-implant applications'" under 28 U.S.C. §1602(3)(B). *Compare id.* at 1102, *with Daley v. Smith & Nephew Inc.*, 321 F. Supp. 3d 891, 897–98 (E.D. Wis. 2018) (assessing BAAA immunity of machinist of femoral neck hip implant component and clarifying that it "used a piece of titanium… as the base material to machine the femoral neck" and that "[t]itanium has many uses other than medical device manufacturing"); *Wilson v. Ethicon, Inc.*, No. 19-1905, 2019 WL 6880472, at *2 (E.D. Pa. Dec. 16, 2019) (assessing BAAA immunity of mesh manufacturer and clarifying that its "polypropylene filament" knitted into mesh "has other uses"); *Mattern v. Biomet, Inc.*, No. 12-4931 (ES), 2013 WL 1314695, at *2 (D.N.J. Mar. 28, 2013) (assessing BAAA immunity of casting manufacturer and clarifying that it "use[d] raw chromium and cobalt metals *(which have many uses other than medical device manufacturing)* to create the metal castings that later become parts of the Device" (emphasis added)).

The court of appeals thus considered the following issue "determinative": "[w]hether the manufacturer DJO intended the Hip Stem to be implanted as it was received from Lima." *Lima*, 988 F.3d at 1101. Because "DJO did not intend the Hip Stem to be implanted by itself when it was received from Lima," "the Hip Stem was not an implant under the BAAA" but "a component part." *Id.* Indeed, "the only device intended to be placed in a body cavity alone as-is" was the ultimate "hip implant, complete with all component parts including the Hip Stem, femoral head, shell, and liner." *Id.*

Satisfied that Lima's hip stem was a "component part," the court then addressed the second requirement of a "biomaterials supplier"—*i.e.*, that Lima supplied that "component part" "'for use in the manufacture' of an implant." *Id.* at 1104 (citing 21 U.S.C. §1602(1)). Despite its narrow reading of the manufacturer-intent element, the court broadly read the "use" requirement. *See id.* In its view, "Lima need[ed] only to have supplied the Hip Stem, a prepared material, to be applied in a new form, quality, or combination to produce a complete hip implant." *Id.* Because DJO Surgical "sterilized, packaged, and combined" Lima's hip stem "with other component parts to form a complete hip implant," Lima met "the second element of the definition of 'biomaterials supplier.'" *Id.* at 1104–05 (warning, however, "that if the Hip Stem had *only* been sterilized and packaged before being implanted into a body, that may not have been enough")

Taken together, Lima met all elements of a "biomaterials supplier": (1) its hip stem was a "component part," (2) for "sterilizing, packaging, and combining" by DJO Surgical, into (3) "the final complete hip implant." *See id.* at 1105. Acknowledging its expansive definition of "biomaterials supplier," the court explained "that Congress meant for plaintiffs to recover from either the statutory manufacturer or the direct seller of an implant"—not component part suppliers. *See id.*; *see also Daley*, 321 F. Supp. 3d at 898 ("Congress apparently sought to insulate component suppliers and place all the risk on device manufacturers for the failure of the implant, whether caused by a flaw in the entire implant or one of its component parts…. [T]he BAAA forces [the implant manufacturer] to shoulder the risk that [the component manufacturer] might make a mistake in producing a component of the [device]"). Though the plaintiffs themselves suffered under this ruling, "future plaintiffs are now on notice that[,] absent negligence or intentionally tortious conduct, recovery from an entity that provides *part* of an implant will not be available." *Lima*, 988 F.3d at 1105.

Denial of Impleader Affirmed

The court of appeals also affirmed the district court's denial of impleader, albeit on different grounds. *Id.* at 1105–11. Indeed, though it declined to decide "whether a voluntary dismissal pursuant to a mutual settlement agreement" was appealable and thus final, it reasoned that, at the time of Lima's dismissal, "there were no 'remaining defendants' besides Lima." *Id.* at 1106. And in the court of appeals' view, "[t]he

statutory text, context, and purpose" of 21 U.S.C. §1606(a)(2)(B) "require[d] a defendant—other than the biomaterial supplier—to remain in the litigation after the biomaterials supplier [wa]s dismissed" for impleader. *Id.* at 1107. More specifically, it deemed 21 U.S.C. §1606(a)(2)(B) to require "remaining defendants" "to be remaining at the time of the biomaterials supplier's dismissal." *See id.* at 1108.

Connell v. Lima Corporate – Takeaways

At this point, the effect of *Lima* is unclear but potentially far-reaching. Does it expand application of the BAAA beyond "component" manufacturers, as traditionally conceived? The defense bar may have competing intuitions on whether the *Lima* product is best characterized as a "near-complete" device.

More to the point, does *Lima* help or harm end-product manufacturers? It ultimately may do both. On the one hand, *Lima* charges plaintiffs to pursue (and effectively discourages settlement with) end-product manufacturers. Yet, this charge could indirectly strengthen end-product manufacturers' relationships with upstream supply chain participants—giving confidence that the American judicial system will not outweigh engagement with American end-product manufacturers. In either case, however, the BAAA partially tempers its impact: it "provides a safety valve by which either manufacturers or claimants may implead negligent suppliers who have been dismissed back into the action." *Id.* at 1105 (citing 21 U.S.C. §1606). Specifically, "the BAAA provides that[,] where the manufacturer of the device can prove a certain level of component part manufacturer fault, the manufacturer may implead the component part manufacturer to obtain some type of contribution after the court enters final judgment on the issue." *Sadler v. Adv. Bionics, LLC*, No. 3:11-cv-00450-TBR, 2013 WL 1636374, at *3 (W.D. Ky. Apr. 16, 2013) (citing 21 U.S.C. §1606). However, the BAAA imposes a hurdle to post-dismissal impleader of biomaterials suppliers on end-product manufacturers: the court must find, "based on the court's independent review of the evidence contained in the record of the action, that under applicable law… the negligence… of the dismissed supplier was an actual and proximate cause of the harm to the claimant; and… the manufacturer's liability for damages should be reduced in whole or in part because of such negligence…." 21 U.S.C. §1606(a).

In key respects, then, the impact of *Lima* remains open; in others, it simply depends upon perspective. Nevertheless, *Lima* offers one universal takeaway: the importance of contractual arrangements between end-product manufacturers and their component suppliers. In giving plaintiffs "no direct means of obtaining recovery from the component part manufacturer when the BAAA applies," *Sadler*, 2013 WL 1636374, at *3, the BAAA (and *Lima*) redirects focus from the verdict form to the indemnity clause. Under *Lima*, even a contract's minor details (such as the designations "Seller" and "Purchaser") inform the BAAA's applicability; all the more so a contract's important provisions—*e.g.*, its title passage clause, its assumption of risk clause, and its conformity to specifications clause. *See Lima*, 2019 WL 403855, at *2–3; *see also Lima*, 988 F.3d at 1094.

In highlighting the importance of contractual arrangements between component part suppliers and end-product manufacturers, *Lima* is not alone. Almost a decade ago, the Western District of Kentucky found that the BAAA's "specific remedial scheme akin to joint and several liability" "is irreconcilable with Kentucky's adoption of several liability in all tort actions" and thus rejected a jury instruction on apportionment to a component part manufacturer on this and another ground. *See Sadler*, 2013 WL 1636374, at *2–3; *see* Michael K. Steenson *et al.*, 27 Minn. Prac. Products Liability Law §16.23 (Aug. 2020 Update) (explaining *Sadler*). *Sadler* synthesized the BAAA's instructions simply: "Plaintiffs are to sue the manufacturer, and the manufacturer may then, where appropriate, implead the component part manufacturer for contribution or indemnity." *Sadler*, 2013 WL 1636374, at *3. Paired with *Lima*, the *Sadler* decision demonstrates the dangers of an inadequate indemnity arrangement. For example, an unsuspecting end-product manufacturer could suffer surprise at the early dismissal of (what it deems) a near-complete product supplier; it could suffer worse at the inability to apportion fault at trial. And without a favorable "independent" court review post-final judgment, a careful indemnity provision might provide the best reliable offset for an unfavorable personal injury verdict.

Accordingly, *Lima* warrants medical device attorneys' attention. By inviting expansion of BAAA immunity, it may leave unwary medical device attorneys and in-house counsel with BAAA issues in unexpected cases. Alternatively, it may strengthen supply chain relationships. In any event, we encourage medical device attorneys unfamiliar with the BAAA and *Lima* to incorporate them into initial case assessments for personal injury actions. As explained above, the BAAA may give comfort or concern (depending on the circumstances) throughout the lifecycle of a case. Initially, it may provide grounds for removal based on fraudulent joinder, *see generally* Murdica & Moshkovich, *supra*, and it may provide early disposition of claims against biomaterials suppliers. *See generally* Cosgrove & Klarfeld, *supra*. Later, it may affect discovery strategy, *see* 21 U.S.C. §1605(c)(1) & (d), §1606(c), and may inform third-party actions, dispositive motions, and opening or closing arguments. *See id.* §1606(a)(1). And ultimately, it should come to mind at the "entry of a final judgment," as the end-product manufacturer's 90-day clock to move to implead a dismissed biomaterials supplier then commences. *See id.* §1606(a).

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