FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

JEFFREY D. CONNELL; JANET CONNELL, *Plaintiffs-Appellants*, v. LIMA CORPORATE; LIMA USA, INC., an Indiana corporation, *Defendants-Appellees*, DJO GLOBAL, INC., a Delaware corporation; ENCORE MEDICAL LP, a Delaware corporation, *Defendants-Intervenors.*	No. 19-35797 D.C. No. 1:16-cv-00456-CWD OPINION

Appeal from the United States District Court
for the District of Idaho
Candy W. Dale, Magistrate Judge, Presiding

Argued and Submitted August 10, 2020
Anchorage, Alaska

Filed February 17, 2021

Before: Johnnie B. Rawlinson, Mary H. Murguia, and Ryan D. Nelson, Circuit Judges.

Opinion by Judge R. Nelson

SUMMARY*

Biomaterials Access Assurance Act

The panel affirmed the district court's summary judgment in favor of Lima Corporate in a diversity action alleging product liability and negligence claims relating to a hip implant.

The panel held that in light of the statutory text, context, and stated purpose, Lima Corporate was a biomaterials supplier of its Hip Stem – a "component part" supplied "for use in the manufacture of an implant." *See* the Biomaterials Access Assurance Act ("BAAA"), 21 U.S.C. § 1602(1)(A). The panel concluded that Lima Corporate was immune from liability under the BAAA and, under the circumstances of this case, could not be impleaded under 21 U.S.C. § 1606.

COUNSEL

Eric S. Rossman (argued) and Erica S. Phillips, Rossman Law Group PLLC, Boise, Idaho; George E. McLaughlin, Warshauer McLaughlin Law Group, Denver, Colorado; for Plaintiffs-Appellants.

Stephen R. Thomas (argued) and Andrew J. Rosholt, Hawley Troxell Ennis & Hawley LLP, Boise, Idaho; Brian J. Hurst, Baker McKenzie, Dallas, Texas; for Defendants-Appellees.

* This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

OPINION

R. NELSON, Circuit Judge:

We are presented with a question of first impression: who qualifies as a biomaterials supplier under the Biomaterials Access Assurance Act ("BAAA"), 21 U.S.C. § 1601 *et seq.* We conclude, in light of the statutory text, context, and stated purpose, that Lima Corporate ("Lima") is a biomaterials supplier of its Hip Stem—a "component part" supplied "for use in the manufacture of an implant." *See id.* § 1602(1)(A). Therefore, Lima is immune from liability under the BAAA and, under the circumstances here, cannot be impleaded under § 1606.

I

A

Encore Medical L.P., doing business as DJO Surgical ("DJO"), manufactures and sells orthopedic hip, knee, and shoulder devices. DJO purchases medical devices from suppliers such as Lima, an Italian company, to sell in the United States. One of Lima's products is a modular revision hip stem ("Hip Stem") which consists of: (1) a femoral stem, which the surgeon inserts into a channel in the patient's femoral canal; (2) an angled neck, also called a proximal body; and (3) a set screw, which holds the stem and neck together.

Lima supplied the Hip Stem to DJO for sale in the United States. The Supply Agreement between Lima and DJO described the Hip Stem (referred to as the "Revision Femoral Stem") as comprising two parts—the stem and the neck—but included pictures of the screw holding them together. The Supply Agreement also mentioned compatible hip

implant product components not included in the Hip Stem, such as acetabular plates, acetabular cups, polyethylene liners, femoral heads, and bone screws. DJO agreed to obtain regulatory certifications permitting sale of the Hip Stem, such as the required United States Food and Drug Administration ("FDA") clearance letters and 510(k) notifications, in DJO's name. Lima agreed to produce the Hip Stem according to DJO's specifications.

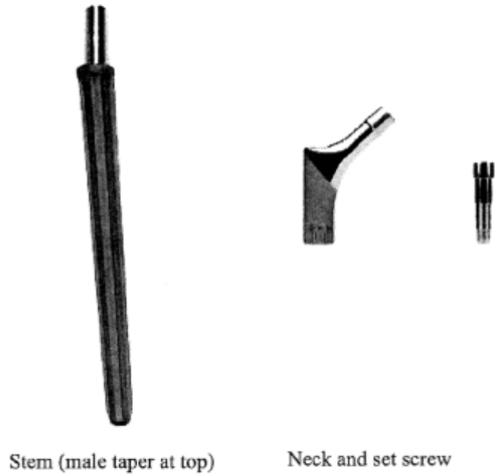

Image 1. Image of the Hip Stem.

DJO submitted a 510(k) notification to the FDA seeking preclearance for the Hip Stem (calling it the "Modular Revision Hip Stem"). DJO described its methods for "steriliz[ing] and packaging" the Hip Stem before labeling and redistribution. DJO also developed and provided instructions for use of the Hip Stem. Lima had provided DJO with access to testing data and results from its European operations and a copy of Lima's "Instructions for Use" for

the Hip Stem used in other countries. Lima was not required by law to register or list the Hip Stem it sold to DJO. DJO obtained clearance from the FDA to market the Hip Stem in the United States.

The Hip Stem sold by DJO was essentially identical to the Hip Stem supplied by Lima. DJO's 510(k) notification specified a list of separate "Compatible Components" previously cleared by the FDA, including various femoral heads, acetabular shells, and liners. DJO's "Instructions for Use" noted the Hip Stem may be used with DJO's "CoCr" brand of femoral heads or ceramic heads, separate pieces that could be paired with the Hip Stem but were not manufactured or supplied by Lima and approved under separate 510(k) notifications. DJO's surgical technique specified that the Hip Stem cannot be implanted or function without a separate compatible femoral head. The surgeon was instructed to attach various component parts with the Hip Stem "in situ," meaning inside the patient's body during surgery.

B

In 2011, Jeffrey Connell underwent left hip revision surgery in Boise, Idaho. The orthopedic surgeon implanted a dual mobility acetabular shell, polyethylene liner, and a DJO CoCr metal femoral head connected to the Hip Stem.

Image 2. A dual mobility acetabular shell, liner, and ceramic femoral head.

Image 3. The Hip Stem attached to a shell, liner, and ceramic femoral head.

Three years after surgery, Mr. Connell had gained weight and the femoral stem portion of Mr. Connell's implant fractured. The failed hip prosthesis was removed, discarded, and replaced. Because the explanted products were not returned, DJO did not determine a definitive root cause for the fracture.

Mr. Connell and his wife filed this action against DJO and Lima for product liability, negligence, breach of warranties, and negligent infliction of emotional distress.

After discovery, DJO and the Connells settled and the district court dismissed the claims against DJO with prejudice on November 16, 2018.

Lima then moved for summary judgment as a "biomaterials supplier" entitled to immunity under the BAAA. The district court held the Connells' claims against Lima were preempted by the BAAA and granted summary judgment on January 30, 2019. The district court reasoned that the pieces supplied by Lima were not ready for implantation when they arrived at DJO's facility and thus were not an implant under the BAAA. The district court also noted, incorrectly as it turned out, that the screw used in the Hip Stem was not provided by Lima and, therefore, Lima supplied only two of the three pieces of the Hip Stem.

The Connells timely requested reconsideration under Rule 59(e) noting the district court's misunderstanding that Lima did not provide the screw and arguing the district court erroneously interpreted the BAAA. The Connells separately sought to implead Lima back into the action pursuant to 21 U.S.C. § 1606(a)(2), which provides that under specific circumstances a claimant may implead a dismissed biomaterials supplier within 90 days after a "final judgment in an action by the claimant against a manufacturer."

The district court denied reconsideration, explaining that who manufactured the screw was not dispositive because the Hip Stem was not ready for implantation when DJO received it. DJO still had to complete several steps before the Hip Stem was ready for commercial distribution. The district court also held that Lima was not a manufacturer of the Hip Stem under the BAAA given the FDA's determination pursuant to 21 C.F.R. § 807.20 that Lima "was exempt from FDA's registration and listing requirements as an entity that manufactured 'devices for another party who both initiates

the specifications and commercially distributes the device.'" The district court declined to consider new arguments or evidence regarding the other two exceptions to preemption of liability for a biomaterials supplier under the BAAA, which the Connells had not previously raised.

The district court also denied the Connells' motion to implead Lima under 21 U.S.C. § 1606(a), because there was no "final judgment" against DJO, the "manufacturer." The district court held that the settlement agreement resulting in a voluntary dismissal with prejudice of the claims against DJO was not an adjudication on the merits and thus not an appealable judgment. The Connells timely appealed the district court's grant of summary judgment and denial of the Connells' motions for reconsideration and impleader, and we have appellate jurisdiction under 28 U.S.C. § 1291.

II

"We review the district court's order granting summary judgment de novo." *Guenther v. Lockheed Martin Corp.*, 972 F.3d 1043, 1052 (9th Cir. 2020) (citation omitted). A party is entitled to summary judgment only when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c).[1] We view all facts in the light most favorable to the non-moving party. *Guenther*, 972 F.3d at 1052.

[1] Lima argues that Congress provided for an alternative standard to Rule 56 in the BAAA. Under the BAAA, a "biomaterials supplier shall be entitled to entry of judgment without trial if the court finds there is no genuine issue of material fact for each applicable element set forth in paragraphs (1) and (2) of section 1604(d)." 21 U.S.C. § 1605(d)(1)(A). The statutory language limits the BAAA's standard for summary judgment to cases dealing with § 1604(d). Because § 1604(d) is not at

The denial of a Rule 59(e) motion is reviewed for abuse of discretion. *389 Orange St. Partners v. Arnold*, 179 F.3d 656, 661 (9th Cir. 1999). We review the denial of a motion to implead under Federal Rule of Civil Procedure 14 for abuse of discretion, *Stewart v. Am. Int'l Oil & Gas Co.*, 845 F.2d 196, 199 (9th Cir. 1988), and assume the same standard of review applies by analogy to impleader under § 1606, which is permissive. *See* 21 U.S.C. § 1606(a) ("A court . . . *may implead* a biomaterials supplier who has been dismissed from the action . . ." (emphasis added)). Lastly, we review issues of statutory interpretation de novo. *United States v. Schmidt*, 947 F.2d 362, 370 (9th Cir. 1991).

III

We begin by interpreting the language of the BAAA. Whether a company like Lima is immune from liability as a "biomaterials supplier" under the BAAA is a question of first impression in the courts of appeal. But our de novo review is guided by well-established rules of statutory interpretation. We "begin[] with the statutory text, and end[] there as well if the text is unambiguous." *BedRoc Ltd., LLC v. United States*, 541 U.S. 176, 183 (2004). "[W]hen the statute's language is plain, the sole function of the courts . . . is to enforce it according to its terms." *Lamie v. U.S. Tr.*, 540 U.S. 526, 534 (2004) (citations omitted). "[U]nless otherwise defined, words will be interpreted as taking their ordinary, contemporary, common meaning" existing "at the time Congress enacted the statute." *Perrin v. United States*, 444 U.S. 37, 42 (1979) (citation omitted).

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issue in this appeal, the BAAA's standard for summary judgment does not apply.

"[B]ecause the statute contains an express pre-emption clause, we do not invoke any presumption against pre-emption but instead focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent." *Puerto Rico v. Franklin Cal. Tax-Free Tr.*, 136 S. Ct. 1938, 1946 (2016) (internal quotation marks and citations omitted). We also analyze the scope of a preemption statute using a "fair understanding of congressional purpose," *see Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485–86 (1996) (citation and emphasis omitted), and using "the ordinary meaning of the words used," *Richards v. United States*, 369 U.S. 1, 9 (1962).

We determine if a statute's meaning is plain or ambiguous by looking to "the language itself, the specific context in which that language is used, and the broader context of the statute as a whole." *Robinson v. Shell Oil Co.*, 519 U.S. 337, 341 (1997). "In construing a statute we are obliged to give effect, if possible, to every word Congress used," *Reiter v. Sonotone Corp.*, 442 U.S. 330, 339 (1979), without rendering words "superfluous, void, or insignificant," *Young v. United Parcel Serv., Inc.*, 135 S. Ct. 1338, 1352 (2015) (internal quotation marks and citations omitted). If we find the language ambiguous, "we are left to resolve that ambiguity" and find the interpretation that is "more consistent with the broader context" and "primary purpose" of the statute. *Robinson*, 519 U.S. at 345–46.

A

We begin, as we must, with the text of the Biomaterials Access Assurance Act. Pub. L. No. 105-230, 112 Stat. 1519 (1998) (codified at 21 U.S.C. §§ 1601–06). At its core, the BAAA preempts liability for "biomaterials supplier[s]" with

certain exceptions. 21 U.S.C. § 1604(a).[2] This liability preemption "applies to any civil action brought by a claimant, whether in a Federal or State court, on the basis of any legal theory, for harm allegedly caused, directly or indirectly, by an implant." *Id.* § 1603(b)(1). It "supersedes any State law regarding recovery for harm caused by an implant and any rule of procedure applicable to a civil action to recover damages for such harm only to the extent that [the BAAA] establishes a rule of law applicable to the recovery of such damages." *Id.* § 1603(c)(1). Thus, if a defendant satisfies the definition of a biomaterials supplier, it may "raise any exclusion from liability" as provided in the statute and move for dismissal or summary judgment. *Id.* § 1603(a)(1).

Congress included a statement of findings in the BAAA that clarified its purpose in immunizing biomaterials suppliers. *Id.* § 1601; *see United States v. Turkette*, 452 U.S. 576, 589 (1981) (applying the statutory statement of findings as "the declared purpose of Congress"). It sought to "assure the continued supply of materials for lifesaving medical devices" without protecting "negligent suppliers." 21 U.S.C. § 1601(17). Though "raw materials and component parts suppliers d[id] not design, produce, or test a final medical device," *id.* § 1601(7), they were nevertheless targeted by costly and often meritless litigation deterring them from providing component parts for use in

[2] Three exceptions exist under which biomaterials suppliers may be held liable: if the supplier (1) is a "manufacturer" as defined in § 1604(b); (2) is a "seller" as defined in § 1604(c); or (3) "furnish[es] raw materials or component parts for the implant that fail[] to meet applicable contractual requirements or specifications," as described in § 1604(d). 21 U.S.C. § 1604(a). On appeal, the Connells only argue that Lima is not a "biomaterials supplier," not that any of these exceptions apply.

medical devices, *id.* § 1601(8); *see also id.* § 1601(11). This "unavailability of raw materials and component parts" would "lead to unavailability of lifesaving and life-enhancing medical devices." *Id.* § 1601(9). Of particular concern was that "suppliers . . . in foreign nations [were] refusing to sell raw materials or component parts" in the United States. *Id.* § 1601(10). Thus, Congress enacted the BAAA "to clarify the permissible bases of liability for suppliers of raw materials and component parts for medical devices" and "provide expeditious procedures to dispose of unwarranted suits against the suppliers . . . to minimize litigation costs." *Id.* § 1601(15).

Whether Lima is immune from liability hinges on the BAAA's definition of "biomaterials supplier," defined as "an entity that directly or indirectly supplies a *component part* or raw material *for use in the manufacture of an implant*." *Id.* § 1602(1)(A) (emphases added). We turn to whether Lima met these elements of (1) supplying a "component part" (2) "for use in the manufacture of an implant." *Id.* The definition of "component part" in the first element incorporates the definition of "implant," contained in the second element. As discussed below, the definition of "implant" is key to our holding that Lima is immune as a "biomaterials supplier."

B

1

We first analyze whether Lima's Hip Stem was a component part. The BAAA defines a "component part" as "a manufactured piece of an implant." *Id.* § 1602(3)(A). We hold the Hip Stem meets the definition of a component part under the BAAA.

The Hip Stem meets the first element of the definition of "component part" according to the plain, ordinary meaning of "manufactured." Congress did not define the word "manufactured" in the BAAA, though it defined "manufacturer" in great detail as:

> any person who, with respect to an implant—
>
> (A) is engaged in the manufacture, preparation, propagation, compounding, or processing (as defined in section 360(a)(1) of this title) of the implant; and
>
> (B) is required—
>
> (i) to register with the Secretary pursuant to section 360 of this title and the regulations issued under such section; and
>
> (ii) to include the implant on a list of devices filed with the Secretary pursuant to section 360(j) of this title and the regulations issued under such section.

Id. § 1602(6). A "manufacturer" explicitly engages in activities beyond just the "manufacture" of the implant: specifically, "preparation, propagation, compounding, or processing." *Id.* This statutory distinction suggests "manufacturer" and "manufactured" are not mere variations of the same definition. If Congress had intended the meaning of "manufactured" to be the same as its definition of "manufacturer," it could have easily done so by defining the term "manufactured." It did not. We read this omission to be intentional. *See Barnhart v. Sigmon Coal Co.*, 534 U.S.

438, 452–54 (2002). Since the statute does not "clearly express[] an intention to the contrary," we read "manufactured" according to its "ordinary meaning." *See United States v. Price*, 980 F.3d 1211, 1218 (9th Cir. 2019) (as amended) (internal quotation marks and citation omitted). And the Hip Stem satisfies the first element of a component part under the ordinary meaning of "manufactured." *See Manufacture*, *Black's Law Dictionary* 964–65 (6th ed. 1990) (defining "manufactured" items as "nearly all such materials as have acquired changed conditions or new and specific combinations . . . from . . . direct action of the human hand, . . . chemical processes . . . , or . . . machinery").

Moreover, the Hip Stem is a "piece" of an implant as a separate part of a larger whole, unable to function on its own. *See Piece*, *Oxford English Dictionary* (2d ed. 1989) (defining "piece" as a "separate or detached portion, part, bit, or fragment of anything"); *see also Part*, *Black's Law Dictionary* 1117 (6th ed. 1990) (defining "part" as "[a]n integral portion, something essentially belonging to a larger whole"). The Connells acknowledge that the Hip Stem cannot be implanted or function without a separate compatible femoral head. DJO's 510(k) notification, surgical technique for inserting the Hip Stem, and Instructions for Use all clarify that the Hip Stem cannot be implanted alone. To function, it must be combined with a separate compatible femoral head, acetabular shell, and liner—all separate parts not supplied by Lima. *See*, *e.g.*, Image 1, *supra* at 4; Image 2, *supra* at 6; Image 3, *supra* at 6. Thus, the Hip Stem is a "manufactured piece" of the larger whole of Mr. Connell's hip implant, which also incorporates a shell, liner, and DJO CoCr femoral head.

Finally, the Hip Stem is a manufactured piece of an "implant" and therefore a "component part." The definition of "implant" is the crux of the determination that Lima constitutes a biomaterials supplier. The Connells contend that the Hip Stem cannot be a component part because it is itself an implant. But the BAAA's definition of "implant" clarifies the difference between an implant and a component part.

The BAAA defines "implant" as:

> (A) *a medical device that is intended by the manufacturer . . .*
>
> (i) *to be placed into a surgically or naturally formed or existing cavity of the body for a period of at least 30 days;* or
>
> (ii) *to remain in contact with bodily fluids or internal human tissue through a surgically produced opening for a period of less than 30 days; and*
>
> (B) suture materials used in implant procedures.

21 U.S.C. § 1602(5) (emphases added). There are two major elements to the definition of implant: "medical device" and "intended by the manufacturer . . . to be placed" in a body cavity. The parties both conflate "medical device" with "implant," likely because of the BAAA's circular definition of "device." But the definition of "implant" hinges decisively on the second element of "intended by the manufacturer . . . to be placed" in a body cavity. And the complete hip implant (*not* the Hip Stem) was the only

medical device intended to be implanted by DJO, the manufacturer, into Mr. Connell. Thus, the Hip Stem was only a component part comprising "a manufactured piece" of the complete hip implant.

It is true that both the Hip Stem component part and Mr. Connell's complete hip implant satisfy the first element of the "implant" definition—a "medical device." A "medical device" is "a device, as defined in section 321(h) of this title, and includes any device component of any combination product as that term is used in section 353(g) of this title."[3] *Id.* § 1602(7). Section 321(h) broadly and circularly defines "device" as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . intended to affect the structure or any function of the body of man or other animals." *Id.* § 321(h). The Hip Stem is a device or "similar or related article" "intended to affect the structure" of the human body. And Mr. Connell's complete hip implant (incorporating the Hip Stem, shell, liner, and femoral head) is also a medical device under this definition. Therefore, the broad definition of "medical device" is not determinative.

The Hip Stem can be both a "medical device" and a "component part" because these statutory definitions are not mutually exclusive. The definition of "medical device" cross-referenced in § 1602(7) includes "any component, part, or accessory." *Id.* § 321(h). Though Congress chose an inartful and circular definition of "medical device," its expansive choice of wording is clear. *Lamie*, 540 U.S. at 534 ("The statute is awkward . . . but that does not make

[3] 21 U.S.C. § 353(g) does not provide any additional relevant definitions.

it ambiguous on the point at issue."). The definition of "medical device" "is worded broadly" and "[i]ts plain text prevents us from reading it" to mean that a component part cannot also be a medical device. *See United States v. Nader*, 542 F.3d 713, 721 (9th Cir. 2008).

Instead, the parties' main disagreement, and the key to defining "implant," centers on the second element of the definition: "intended by the manufacturer . . . to be placed" in a body cavity. 21 U.S.C. § 1602(5). This phrase could be read in one of two ways. It could be read to apply only when the device is ready to be placed into a body cavity by itself. Alternatively, 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. Here, Lima argues that the Hip Stem was not intended to be implanted by itself; thus, it was a component part. But the Connells assert that because the Hip Stem was intended to be inserted into a body at some point (albeit with other parts attached), it is more properly classified as an implant, not a component part. Lima's interpretation is better supported by the statutory context and stated purpose.

The text of the BAAA differentiates a component part from the final implant. *See, e.g.*, *id.* § 1601(2)–(5); *id.* § 1602(3), (5). If an "implant" were anything that could eventually make its way into a body in some form or another, then every component part of a final implant would be an implant. The Connells' interpretation of "implant" ignores the statutory distinction between "component part" and "implant," rendering it superfluous. *See Young*, 135 S. Ct. at 1352. Further, Congress's statement of findings states the BAAA's overriding purpose is to preclude liability for suppliers of component parts that did not manufacture the final implant. *See generally id.* § 1601. Both Lima and the

Connells agree, as do we, that the BAAA is meant to immunize those lacking control over the final implant. Thus, it makes more sense to read "implant" as the final device ready and intended for implantation, not as a device merely intended to form a piece of some broader implant.

In light of the statutory context and purpose, we read the words "intended . . . to be placed" in § 1602(5) to mean intended for implantation by itself, according to the limitations in § 1602(5)(A)(i)–(ii). *See Robinson*, 519 U.S. at 345–46; Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 63 (2012) ("A textually permissible interpretation that furthers rather than obstructs the document's purpose should be favored."). A "component part" is not an "implant" because it does not meet the second element of the definition, being intended for implantation by itself, even if it meets the first element, being a medical device.

Whether the manufacturer DJO intended the Hip Stem to be implanted as it was received from Lima is therefore determinative. DJO is indisputably the statutory "manufacturer" of the Hip Stem under § 1602(6) of the BAAA because DJO, not Lima, was required to register with the FDA. And DJO made clear that the Hip Stem, as supplied by Lima, could not be implanted and function by itself. In fact, DJO processed, sterilized, labeled, and packaged the Hip Stem and included Instructions for Use requiring it to be combined with other component parts before implantation. DJO did not intend the Hip Stem to be implanted by itself when it was received from Lima.

Therefore, the Hip Stem was not an implant under the BAAA. It was instead a component part. Common parlance might refer to any item inserted into a body as an implant. But the BAAA lays out a specific two-part definition for our

purposes here—medical device, and manufacturer's intent for implant. 21 U.S.C. § 1602(5). A device not intended to be implanted by itself would not be an "implant" under the BAAA, even if a supplier may intend it to be part of an implantable medical device sometime down the road. The hip implant, complete with all component parts including the Hip Stem, femoral head, shell, and liner, was the only device intended to be placed in a body cavity alone as-is.[4]

2

Besides their main argument regarding the definition of "implant," the Connells cursorily assert that a component part must have "significant non-implant applications" if it has no implant value in itself, citing § 1602(3)(B). Section 1602(3)(B) states under the subheading "Certain components" that "[s]uch term includes a manufactured piece of an implant that . . . has significant non-implant applications; and . . . alone, has no implant value or purpose, but when combined with other component parts and materials, constitutes an implant." The Connells' argument would require § 1602(3)(A) to generally define "component part," and for § 1602(3)(B) to narrow the definition to only include "certain components." However, the alternative reading that § 1602(3)(B) merely lists a nonexclusive example additionally defining "certain components" is the only reading that makes sense in light of the statutory text, context, and purpose.

[4] The manufacturer's intent requirement in the component part definition addresses any concerns that companies could "launder" a final medical device to achieve immunity. A company could not be immune as a biomaterials supplier by merely sending a final medical device to a third party for repackaging because the manufacturer would intend it to be inserted without combination with other component parts.

Section 1602(3)(B)'s choice of wording is key. After component part is defined, § 1602(3)(B) states "[s]uch term includes" parts of implants with "significant non-implant applications" and no implant value alone. The word "includes" shows § 1602(3)(B) is illustrative and a non-exclusive listing of one type of component part, not defining all parts. *See Fed. Land Bank of St. Paul v. Bismarck Lumber Co.*, 314 U.S. 95, 100 (1941) ("[T]he term 'including' is not one of all-embracing definition, but connotes simply an illustrati[on.]"). So § 1602(3)(A) defines "component part," whereas § 1602(3)(B) clarifies that definition to expansively also include "certain components" with non-implant applications and no separate implant value or purpose.

The statutory context reinforces this interpretation. *See United States v. Morton*, 467 U.S. 822, 828 (1984) ("We do not . . . construe statutory phrases in isolation; we read statutes as a whole."). Congress could have written a limited definition in the same way it wrote limited definitions elsewhere in § 1602, but did not. *See, e.g.*, 21 U.S.C. § 1602(2)(D) (titled "Exclusions" and stating "[s]uch term does not include" certain items); *see also United States v. Philip Morris USA Inc.*, 566 F.3d 1095, 1115 (D.C. Cir. 2009) (holding that the verb "include" is non-limiting where the "most obvious way" to limit a definition would be to write it the way Congress wrote other limited definitions nearby). Congress did not title § 1602(3)(B) "Exclusions," as it did § 1602(2)(D). Nor did Congress state that the component part definition is limited to items with significant non-implant applications and no implant value or purpose alone. Instead, it titled § 1602(3)(B) "Certain components," defining *that* term, not "component part," with the text in § 1602(3)(B). *See Almendarez-Torres v. United States*, 523 U.S. 224, 234 (1998) ("[T]he title of a statute and the

heading of a section are tools available for the resolution of a doubt about the meaning of a statute." (internal quotation marks and citations omitted)). Thus, we read § 1602(3)(B) as non-limiting; it does not require component parts to have "significant non-implant applications."

Moreover, the Connells' interpretation of § 1602(3)(B) raises superfluity problems, as little would differentiate the definitions of "component part" and "raw material." If a component part requires significant non-implant applications, it would be virtually identical to a raw material, which is a "substance or product that . . . has a generic use; and . . . may be used in an application other than an implant." 21 U.S.C. § 1602(8). Yet "raw material" and "component part" are used distinctively throughout the entire BAAA; reading them similarly means reading them impermissibly as "superfluous." *See Young*, 135 S. Ct. at 1352.

The Connells argue, though, that Congress's statement of findings dictates that most medical devices be "made with raw materials and component parts that . . . are not designed or manufactured specifically for use in medical devices." 21 U.S.C. § 1601(3). They note that the statement of findings states that "raw materials and component parts also are used in a variety of nonmedical products" and only "small quantities of the raw materials and component parts are used for medical devices . . . ." *Id.* § 1601(4)–(5). This, they urge, means the Hip Stem cannot be a component part because it was designed for exclusive use in a medical device.

This argument fails for two reasons. First, when reading a preemption statute, we rely on its "plain wording" which "necessarily contains the best evidence of Congress' pre-emptive intent." *Puerto Rico*, 136 S. Ct. at 1946 (cleaned up). Immunity under BAAA preemption hinges on the

statutory definition of "biomaterials supplier." 21 U.S.C. § 1604. And we have explained how the operative language here—the definition of "biomaterials supplier"—covers those who supply component parts for manufacture in an implant, regardless of whether those parts are also used in nonmedical products. Though the statement of findings may explain the impetus for the BAAA, we analyze Lima's status and the Hip Stem according to the BAAA's substantive provisions. *See District of Columbia v. Heller*, 554 U.S. 570, 578 n.3 (2008) ("[T]he preamble cannot control the enacting part of the statute in cases where the enacting part is expressed in clear, unambiguous terms." (citation omitted)).

Second, even if considered, the statement of findings does not support the Connells' argument. The findings explain the facts that existed at the time of enactment; they do not limit the scope of preemption. When Congress passed the BAAA, it was concerned precisely *because* "small quantities of the raw materials and component parts are used for medical devices." 21 U.S.C. § 1601(5). Congress sought to fix the problem of this dwindling market for raw materials and component parts in medical devices. *Id.* § 1601(5)–(17). Indeed, the fact that entities such as Lima are creating component parts specifically for use in the manufacture of implants evidences the BAAA's success in encouraging the component part market. Accepting the Connells' reading would punish those suppliers like Lima that undertake the very thing Congress meant to encourage—providing "sources of supply for the full range of threatened raw materials and component parts for medical devices." *Id.* § 1601(10). The Connells' selective quotations of isolated findings do not square with the overall substance of the findings. *See, e.g.*, *id.* § 1601(10)–(11) (highlighting the need to convince foreign suppliers to export component parts to the United States).

The Connells concede that the statute immunizes a supplier who supplies a component part, such as a screw or stem. That is the case here. The level of processing, testing, advertising, and assembly needed to produce Lima's component part is irrelevant. Lima supplied a component part—the Hip Stem—and did not supply the other required shell, liner, and femoral head component parts. It matters not that Lima's component part itself comprised three divisible pieces (the femoral neck, stem, and attachment screw). Whether Lima provided one or three component parts, Lima's Hip Stem could not function alone and was not intended to be implanted alone. It was *not* an entire hip implant as the Connells claim. The final medical device—Mr. Connell's entire hip implant—necessarily combined a shell, liner, and femoral head in addition to the Hip Stem.[5]

[5] Various district courts addressing component parts of hip implants under the BAAA have come to similar conclusions. A femoral head was held to be a component part where, as here, it was used in a broader final hip implant consisting of several components: a "femoral sleeve," a "femoral stem," a "femoral hip head," an "acetabular cup," and a "liner." *Whaley v. Morgan Advanced Ceramics, Ltd.*, No. 07-cv-00912, 2008 WL 901523, at *2 (D. Colo. Mar. 31, 2008). A defendant was held to be a biomaterials supplier because it made "femoral necks" that "were not completed medical devices and could not be implanted into a human being without additional components and numerous other manufacturing steps and quality checks . . . ." *Daley v. Smith & Nephew Inc.*, 321 F. Supp. 3d 891, 897–98 (E.D. Wis. 2018). And a biomaterials supplier providing a hip stem for use in a hip implant, Def.'s Mem. Opp. Pl.'s Mot. Am. Compl. 5, was held likely immune under the BAAA, *Marshall v. Zimmer*, No. 99-0973-E, 1999 WL 34996711, at *3 (S.D. Cal. Nov. 4, 1999).

District courts addressing other types of implants have reached similar conclusions. *See, e.g.*, *Cavanaugh v. Ethicon Inc.*, No. 19-2014, 2019 WL 6883752, at *2–3 (E.D. Pa. Dec. 16, 2019) (holding defendants were "biomaterials suppliers" because "the mesh they created was a

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Lima must also meet the second element of the definition of "biomaterials supplier" to be immune under the BAAA. That is, Lima must have supplied the Hip Stem component part "for use in the manufacture" of an implant. 21 U.S.C. § 1602(1). We hold that Lima satisfies this element under the plain, ordinary meaning of "manufacture."

First, as explained above, we read the phrase "for use in the manufacture" by its ordinary meaning. "Use" means "application" or "employ[ment] for . . . a given purpose." *Use*, *Black's Law Dictionary* 1541 (6th ed. 1990). The noun "manufacture" means "[t]he production of articles for use from raw or prepared materials by giving such materials new forms, qualities, properties or combinations." *Manufacture*, *Black's Law Dictionary* 965 (6th ed. 1990). Putting these two together, Lima needs 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. This it did. After Lima supplied the Hip Stem, it was then sterilized, packaged, and combined with other component parts to form a complete hip implant. Thus, Lima meets the second element of the definition of "biomaterials supplier."

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component part used in the manufacture of the pelvic mesh devices underlying th[e] litigation"); *Mattern v. Biomet, Inc.*, No. 12-4931, 2013 WL 1314695, at *2 (D.N.J. Mar. 28, 2013) (holding supplier who shaped metal for implants was a biomaterials supplier because "[t]he castings . . . are not completed medical devices and could not be implanted into a human being without additional manufacturing steps and quality checks"); *Jones v. Blackstone Med., Inc.*, No. 6:07-cv-455, 2009 WL 10677484, at *2 (E.D. Tex. Apr. 13, 2009) ("[T]he literal language of [§ 1604(a)(3)] envisions the situation where a manufacturer of a medical device contracts with another manufacturer to produce a specific component part that will be incorporated into a medical device.").

Note that if the Hip Stem had *only* been sterilized and packaged before being implanted by itself into a body, that may not have been enough to give it "new forms, qualities, properties or combinations." As we have explained, Congress evidently chose to list "manufacture" as a noun distinguished from "preparation, propagation, compounding, or processing." 21 U.S.C. § 1602(6). Thus, merely sterilizing and packaging an item might not necessarily cause it to be supplied for "use in the manufacture" of an implant. But here the Hip Stem *was* given a "new . . . combination[]" by being assembled with other component parts, in addition to being sterilized and packaged with instructions created by DJO. Together, this was enough to cause the Hip Stem to be "use[d] in the manufacture" of the final complete hip implant.

* * *

Altogether, Lima meets the elements of the definition of a biomaterials supplier under § 1602(1) by (1) supplying a "component part"—the Hip Stem—(2) "for use in the manufacture of"—the sterilizing, packaging, and combining the Hip Stem with three other component parts—(3) "an implant"—the final complete hip implant.[6]

We recognize that defining "biomaterials supplier" expansively may limit recovery for plaintiffs like the Connells. But given the limited case law and the strong statutory indications that Congress intended to broadly preempt liability for those supplying raw materials and

[6] Because we affirm the grant of summary judgment de novo, we also affirm the denial of the Rule 59 motion. The district court did not abuse its discretion in denying reconsideration because the district court properly determined that Lima is immune from liability as a biomaterials supplier.

component parts, we believe this result is consistent with both the text and purpose of the BAAA. In addition, this expansive definition of "biomaterials supplier" has the benefit of providing a clearer rule to litigants—if an entity has provided a part that must be combined with other items to create a final, independently functional "implant," that entity is a "biomaterials supplier" and only liable according to the exceptions in 21 U.S.C. § 1604(b)–(d). In such a case, it appears that Congress meant for plaintiffs to recover from either the statutory manufacturer or the direct seller of an implant instead. Although the Connells settled previously with the statutory manufacturer here, DJO, 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. Further, the statute provides a safety valve by which either manufacturers or claimants may implead negligent suppliers who have been dismissed back into the action. *See* 21 U.S.C. § 1606. We now turn to the contours of this particular statutory provision.

IV

Even if a defendant has immunity as a "biomaterials supplier," a complainant may implead a dismissed biomaterials supplier as follows:

> A court, *upon motion by* a manufacturer or *a claimant* within 90 days after *entry of a final judgment in an action by the claimant against a manufacturer* . . . may implead a biomaterials supplier *who has been dismissed from the action* . . . if . . .
>
> (2) the claimant has moved to implead the supplier and the court finds . . .

> (A) the negligence or intentionally tortious conduct of the dismissed supplier was an actual and proximate cause of the harm to the claimant; and
>
> (B) the claimant is unlikely to be able to recover the full amount of its damages from *the remaining defendants*.

Id. § 1606(a) (emphases added).

Prior to the district court's order, no court had interpreted § 1606(a). The district court concluded impleader was not available because there was no "final judgment" against the manufacturer—DJO—after DJO's voluntary settlement with the Connells. According to the district court, the voluntary dismissal entered after that settlement was not a "judgment" under Federal Rule of Civil Procedure 54 because a voluntary settlement is not appealable. Because we "affirm the district court's decision on [an] alternative ground," *Myers v. U.S. Parole Comm'n*, 813 F.2d 957, 959 (9th Cir. 1987), we do not decide whether a voluntary dismissal pursuant to a mutual settlement agreement is appealable. Instead, the statutory text, context, and purpose support reading § 1606(a) to foreclose impleader here because there were no "remaining defendants" besides Lima, the biomaterials supplier, when Lima was dismissed from the action.

As a threshold matter, the grant of summary judgment for Lima qualifies as an "entry of a final judgment in an action by the claimant against a manufacturer," 21 U.S.C. § 1606(a). The limiting phrase "against a manufacturer" applies to the "action by the claimant," not the "entry of final judgment." *See Barnhart v. Thomas*, 540 U.S. 20, 26 (2003)

("[A] limiting clause or phrase . . . should ordinarily be read as modifying only the noun or phrase that it immediately follows.").

And "an action by the claimant against a manufacturer" refers to the action *as a whole*, not a subsidiary claim. *Compare Action*, *Black's Law Dictionary* 28 (6th ed. 1990) (defining "action" as "all the formal proceedings in a court of justice attendant upon the demand of a right"), *with Claim*, *Black's Law Dictionary* 247 (6th ed. 1990) (defining "claim" as a "cause of action"); *see also* Fed. R. Civ. P. 54(b) ("[A]ny order . . . that adjudicates fewer than all the *claims* . . . does not end the *action*.") (emphases added).[7] The language in § 1606 contemplating a separate "entry of judgment on the *claim*" against the biomaterials supplier underlines these distinct concepts. 21 U.S.C. § 1606(b)(1) (emphasis added).

Thus, there is "an action by the claimant against a manufacturer" under the BAAA if the manufacturer was

[7] In *Pedrina v. Chun*, we discussed the "interpretation of the word 'action' in Rule 41(a)(1), and whether it refers to the entire controversy against *all* the defendants, or to the entirety of claims against any single defendant." 987 F.2d 608, 609 (9th Cir. 1993). We concluded that Rule 41(a)(1), which provides for dismissal of an "action," "[p]ermitt[ed] a plaintiff to dismiss fewer than all of the named defendants" because it was "consistent with th[e] purpose" of Rule 41(a)(1). *Id.* at 610. That interpretation of "action" as the claims against a particular defendant was cabined to Rule 41(a)(1). *See id.*; *see also* 9 Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 2362 (4th ed. 2008, October 2020 Update) (stating it is "unnecessary" to read Rule 41(a)(1) literally because "[t]he power to drop some plaintiffs or defendants from the suit plainly exists, either explicitly in the Federal Rules or in the district court's inherent power"). *Pedrina* does not govern our reading of "action" as used in § 1606(a).

ever a defendant in the lawsuit. Here, the action was brought against the manufacturer, DJO.

We now move on to "final judgment." The "final judgment" must be the judgment disposing of the claimant's entire action brought against a manufacturer. *See Riley v. Kennedy*, 553 U.S. 406, 419 (2008) ("A final judgment is 'one which ends the litigation on the merits and leaves nothing for the court to do but execute the judgment.'" (quoting *Catlin v. United States*, 324 U.S. 229, 233 (1945))). The voluntary settlement and dismissal of DJO with prejudice was not a final judgment on the action as a whole, because the action continued with Lima as a defendant.[8] Thus, before us is "an action by the claimant [the Connells] against a manufacturer [DJO]," and a "final judgment" was entered upon summary judgment for Lima disposing of the action as a whole. So far, so good for the Connells.

But the crux of the motion to implead here turns on the language, context, and purpose of § 1606(a). Starting with the statutory language, a claimant's motion to implead a biomaterials supplier back into the action is permitted *only* when it is "unlikely to be able to recover the full amount of its damages from *the remaining defendants*." 21 U.S.C. § 1606(a)(2)(B) (emphasis added). Lima argues that there were no "remaining defendants" at the time Lima was dismissed, because DJO had already been dismissed from the action months earlier. The Connells do not address

[8] Were the voluntary settlement a final judgment, the motion to implead would have been untimely. The settlement was signed July 13, 2018, and effective June 29, 2018, and the order dismissing DJO with prejudice was entered November 16, 2018. The motion to implead was filed April 29, 2019—well beyond the statutorily permitted 90 days of either the settlement's effective date or the order dismissing DJO with prejudice.

Lima's statutory argument, instead urging us to treat DJO as a remaining defendant notwithstanding the statutory language. The statutory language is imprecise to be sure and either interpretation is plausible. The statutory text, context, and purpose, however, better support interpreting § 1606 to require a defendant—other than the biomaterials supplier—to remain in the litigation after the biomaterials supplier is dismissed.

The plain text of § 1606(a)(2)(B) connotes there must be defendants remaining in the action for a claimant to implead a dismissed biomaterials supplier. Congress specified the claimant may implead only if "*the* remaining defendants" are unlikely to provide the full amount of damages, requiring there be defendants remaining. Qualifying "defendants remaining" with the article "the," as opposed to "any" or "if any," suggests there must be at least one defendant remaining. *See Hernandez v. Williams, Zinman & Parham PC*, 829 F.3d 1068, 1074 (9th Cir. 2016) ("[T]he definite article 'the' 'particularizes the subject spoken of' . . . ." (quoting *The*, *Black's Law Dictionary* 1647 (4th ed. 1968))); *see also Gates & Fox Co. v. Occupational Safety & Health Rev. Comm'n*, 790 F.2d 154, 156 (D.C. Cir. 1986) ("[T]he definite article suggest[s] that some specific [item] is referred to . . . ."); Scalia & Garner, *supra*, at 122–23 (explaining the "wording of the lead-in may be crucial to the meaning" by distinguishing the phrases "*the* following" and "*any* . . . of the following" (emphases added)).

And "remaining" requires that other defendants continue in the action after the biomaterials supplier is dismissed. *See Remaining*, *Oxford English Dictionary* (1989) (defining "remaining" as "[t]hat remains, in various senses"); *see also Remain*, *Oxford English Dictionary* (1989) (defining

"remain" as "[t]o be left after the removal or appropriation of some part, number or quantity").

The Connells essentially urge this court to read the statute as "remaining defendants, *if any*" and add an implied exception. *Cf. Ali v. Fed. Bureau of Prisons*, 552 U.S. 214, 227–28 (2008) (contrasting the "unmodified, all-encompassing" use of the word "any" with other more limited modifiers). Yet "[a] casus omissus does not justify judicial legislation." *Ebert v. Poston*, 266 U.S. 548, 554 (1925). "It is our judicial function to apply statutes on the basis of what Congress has written, not what Congress might have written." *Hooks v. Kitsap Tenant Support Servs., Inc.*, 816 F.3d 550, 562 (9th Cir. 2016) (quoting *United States v. Great N. Ry. Co.*, 343 U.S. 562, 575 (1952)) (alteration removed).

Congress could have written § 1606(a)(2)(B) to explicitly allow a claimant to implead a dismissed biomaterials supplier when there are no remaining defendants. But "Congress did not write the statute that way," which is "strong affirmative evidence" supporting our interpretation of § 1606. *See United States v. Naftalin*, 441 U.S. 768, 773 (1979). Reading "the remaining defendants" to require other defendants to be remaining thus gives "effect . . . to all [§ 1606's] provisions, so that no part will be inoperative or superfluous, void or insignificant." *Corley v. United States*, 556 U.S. 303, 314 (2009) (citation omitted).

Acknowledging that the statutory text supports a requirement that defendants must be remaining then raises the question of precisely at *which point* there must be defendants remaining. We see three potential ways to read this provision: that there must be defendants remaining at (1) the time of the biomaterials supplier's dismissal; (2) the

time of final judgment; or (3) the time the motion to implead is filed. We conclude that the statutory text, context, and purpose support reading "the remaining defendants" to require defendants to be remaining at the time of the biomaterials supplier's dismissal.

The use of the word "remaining" refers directly to the point in time when there was "removal or appropriation of some part, number or quantity"—*i.e.*, when the biomaterials supplier was dismissed. *See Remaining*, *Oxford English Dictionary* (1989); *Remain*, *Oxford English Dictionary* (1989). Congress did not use a different qualifying phrase, such as "any other" defendants, which would suggest that other defendants only had to be part of the action at some prior point. Rather, Congress specifically used "remaining," which by its own terms ties directly to the point in time of "removal" of the biomaterials supplier. This "strong affirmative evidence" supports our interpretation of § 1606(a). *Naftalin*, 441 U.S. at 773.

And the text of § 1606(a) explicitly states that a manufacturer or claimant may only implead a biomaterials supplier "who has been *dismissed from the action*." § 1606(a)(2) (emphasis added). This language suggests that an action continues to exist after the biomaterials supplier has been dismissed. The action itself cannot have been disposed of in the dismissal. Thus, the biomaterials supplier must *first* be dismissed from the action, which *then* continues to be litigated between at least two other parties until the action has been resolved in a final judgment. Reading "the remaining defendants" to apply at time of final judgment or when the motion was filed would not be possible because there would be no action continuing after dismissal. Thus, the statutory language points us towards reading § 1606(a)

to require at least one other defendant to be remaining at the time of the biomaterials supplier's dismissal.

Applying "the remaining defendants" at the time the impleader motion is filed may seem to be a more natural reading, but in context it would read the phrase to be "void," *Young*, 135 S. Ct. at 1352. Filing a motion after final judgment necessarily means there are no remaining defendants—the action has already been finally resolved. Thus, in cases where a plaintiff moves to implead after a judgment with respect to the manufacturer, it is impossible to read "remaining defendants" to apply at the time the impleader motion is filed without violating the "cardinal rule of statutory interpretation that no provision should be construed to be entirely redundant." *Brewster v. Sun Tr. Mortg., Inc.*, 742 F.3d 876, 879 (9th Cir. 2014) (internal quotation marks and citation omitted). The only way to salvage reading "the remaining defendants" to apply at the time the impleader motion is filed is by reading the provision as "any other defendants" instead, which we have already rejected. *See supra*, at 31–32. Our reading applying "the remaining defendants" to apply at the time of the biomaterials supplier's dismissal makes more sense in light of the statutory context and purpose.

Sections 1606(b) and (c) further support requiring "remaining defendants" at the time the biomaterials supplier is dismissed, not at final judgment or when the motion to implead is filed. Section 1606(b)(1) allows an impleaded biomaterials supplier to "supplement the record of the proceeding that was developed prior to the grant of the motion for impleader." And § 1606(c) clarifies that nothing in § 1606 "shall give a claimant or any other party the right to obtain discovery from a biomaterials supplier at any time prior to grant of a motion for impleader beyond that allowed

under section 1605" of the BAAA. Section 1606 thus explicitly contemplates that the biomaterials supplier was dismissed at an early stage before the record of the proceeding had been developed or discovery had occurred. Section 1606 does *not* similarly address the situation here, where the manufacturer has been dismissed and the biomaterials supplier has undergone full discovery, won on final judgment, and then is impleaded back into the case. This statutory presumption that the biomaterials supplier was dismissed at an early stage further supports our interpretation of § 1606.

The BAAA's statutory context reinforces our interpretation. Permitting a motion to implead in this case would effectively insert an unwritten third ground for finding a biomaterials supplier liable into § 1604(d), as the Connells essentially urge. As written, § 1604(d) includes only two exceptions to biomaterials supplier immunity for failure to meet contractual requirements or specifications. Congress could have written the provisions of § 1606(a)(1) and (2) regarding negligent or intentionally tortious harmful conduct and damages into § 1604(d), but did not. Thus, we assume that Congress intended only the two exceptions listed in § 1604(d) to exist and the impleader section to function as a process different from a third exception. *See Duncan v. Walker*, 533 U.S. 167, 173 (2001) ("[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." (citations omitted)).

Moreover, § 1605 imposes strict limitations on discovery regarding biomaterials suppliers. For summary judgment motions, discovery is "limited solely to

establishing whether a genuine issue of material fact exists" as to the § 1604(d) exceptions for biomaterials supplier immunity. 21 U.S.C. § 1605(d)(2). And any discovery permitted is cabined "solely to the extent permitted by the applicable Federal or State rules for discovery against nonparties." *Id.* § 1605(d)(3). As with §§ 1606(b) and (c), § 1605 allows limited discovery with the presumption that the biomaterials supplier will be dismissed early, unless it is liable under §§ 1604(b), (c), or (d). The BAAA does not contemplate the situation here where a biomaterials supplier not liable under § 1604 undergoes full discovery, is dismissed, and then is immediately impleaded back.

The BAAA also generally requires a claimant to name the manufacturer as a party. *Id.* § 1605(b); *see also id.* §§ 1605(a)(4), (c)(3)(C). In only two limited scenarios, a manufacturer need not be a party: (1) where the manufacturer was not subject to service of process where the biomaterials supplier was domiciled or subject to service of process, and (2) where an "applicable law or rule of practice" bars a claim against the manufacturer. *Id.* § 1605(b). So Congress knew how to specify when an action could proceed without a manufacturer in § 1605(b), but chose not to do so in § 1606(a). *See Sigmon Coal Co.*, 534 U.S. at 452–54. And even if § 1606(a) could apply in the two limited scenarios listed in § 1605(b) where the manufacturer is not a party, neither scenario is present here where the Connells and DJO entered a voluntary settlement to dismiss DJO with prejudice. Thus, impleader is not available.

To the extent this result might be seen to permit biomaterials suppliers to insulate themselves from liability by waiting until the claimant reaches a settlement with a manufacturer to assert immunity under the BAAA, as the Connells suggest, it seems unlikely that suppliers who are

potentially immune under the BAAA would persist in costly litigation and discovery with the aim to avoid liability later.

Finally, the statutory purpose also supports our reading of § 1606. Congress created "expeditious procedures to dispose of unwarranted suits against the suppliers in such manner as to minimize litigation costs." 21 U.S.C. § 1601(15)(B). These procedures were meant to protect biomaterials suppliers. And though the BAAA's "protections do not protect negligent suppliers," *id.* § 1601(17), the BAAA does "clarify the permissible bases of liability for suppliers of raw materials and component parts for medical devices," *id.* § 1601(15)(A). These bases of liability apply only through certain procedural processes.

Claimants must first show a biomaterials supplier is liable under one of the bases of liability in §§ 1604(b), (c), or (d). If not, a biomaterials supplier is dismissed and the action proceeds against "the remaining defendants." The claimant can only implead a biomaterials supplier back into the action if the biomaterials supplier was negligent or intentionally tortious and "the remaining defendants" still in the action are unable to cover the full amount of damages. *Id.* § 1606.

Reading § 1606(a)'s plain text, together with its statutory context and purpose, leads to the conclusion that a motion to implead under § 1606(a) is permitted only when there is a defendant, other than the biomaterials supplier, remaining in the action after the biomaterials supplier is dismissed. Although this result could limit plaintiffs' recovery in some cases, we understand this result to be consistent with Congress's purpose in enacting the BAAA—broadly limiting liability for biomaterials suppliers while maintaining avenues for plaintiffs to recover from the statutory manufacturer. Here, after the manufacturer, DJO,

was dismissed with prejudice from the lawsuit, § 1606(a) did not permit the Connells to implead Lima after Lima, the only defendant, was later dismissed on summary judgment.

V

We hold Lima is a biomaterials supplier of the Hip Stem under the BAAA and thus immune from liability. We also hold that § 1606(a) does not permit the Connells to implead Lima here.

AFFIRMED.