IADC Committee Newsletter

PRODUCT LIABILITY

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IN THIS ISSUE

Component parts manufacturers of medical devices have a sharp tool to use in their defense arsenal in products liability cases. Sarah Cronan, with assistance from Jessie Zeigler, explains the existence and use of this tool.

A Twist on Component Supplier Liability in Medical Device Cases

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Component part and raw material suppliers can avoid liability if their product is not defective and if the supplier played no role in the design, testing, or manufacture of the final product. Section 5 of the Restatement (Third) of Torts reflects the law as it developed after the introduction of Section 402A of the Restatement (Second) of Torts in 1964. The good news for suppliers of components and raw materials incorporated into medical devices is that additional protection from liability exists under the Biomaterials Access Assurance Act of 1998, 21 U.S.C. §§ 1601-1606.[1]

Component Supplier Liability under the Restatement

Historically, a component part or material supplier was subject to strict liability like any other product seller. Section 402A of the Restatement (Second) of Torts imposes strict liability on sellers of "any product" if sold "…in a defective condition unreasonably dangerous to the user or consumer…". As long as the seller expected the product to reach the consumer without substantial change in the condition in which it was sold, it does not matter that the seller used reasonable care in the preparation and sale of the product.[2]

In the Third Restatement, the American Law Institute clarified the liability of commercial sellers of product components to reflect the holdings in existing case law:

> One engaged in the business of selling or otherwise distributing product components who sells or distributes a component is subject to liability for harm to persons or property caused by a product into which the component is integrated if:
>
> (a) the component is defective in itself, as defined in this Chapter, and the defect causes the harm; or
>
> (b) (1) the seller or distributor of the component substantially participates in the integration of the component into the design of the product; and
>
> (2) the integration of the component causes the product to be defective, as defined in this Chapter; and
>
> (3) the defect in the product causes the harm.[3]

To date, almost every court to consider the issue of component supplier liability has adopted or cited Section 5 of the Third Restatement.[4]

[1] This article does not address Section 6 of the Restatement (Third) of Torts: Products Liability pertaining to liability for harm caused by defective prescription drugs and medical devices.

[2] Restatement, Second, Torts § 402A.

[3] Restatement Third, Torts: Products Liability § 5.

[4] *See Cipollone v. Yale Indus. Prods.*, 202 F.3d 376, 379 (1st Cir. 2000); *White v. ABCO Eng'g Corp.*, 221 F.3d 293, 306 (2nd Cir. 2000); *Port Auth. Of N.T. and N.J. v. Arcadian Corp.,* 189 F.3d 305, 314 (3rd Cir. 1999); *Cimino v. Raymark Indus.*, 151 F.3d 297, 299, 332-334 (5th Cir. 1998); *In re Silicone Gel Breast Implants Prods.*, 996 F.Supp.1110, 1113-14, 1116-17 (N.D. Ala. 1997), *rev'd in part*, *United States v. Baxter Int'l, Inc.*, 345 F.3d 866 (11th Cir. 2003); *Wagner v. General Motors Corp.*, 258 S.W.3d 749, 755-756 (Ark. 2007); *Davis v. Goodyear Tire & Rubber Co.*, No. 4:09CV00030 JMM, 2010 U.S. Dist. LEXIS 40820, at *6, 8 (E.D. Ark. 2010); *Arena v. Owens Corning Corp.*, 74 Cal.Rptr.2d 580, 589 (Cal. App. 1998);

Artiglio v. General Elec. Co., 71 Cal.Rptr.2d 817, 821-22, 824 (Cal. App. 1998); *Jimenez v. Superior Court*, 58 P.3d 450, 454, 458 (Cal. 2002); *Tellez-Cordova v. Campbell-Hausfeld/Scott Fetzger Co.*, 129 Cal.App.4th 577, 582 (Cal. App. 2004); *Gonzalez v. Autoliv ASP, Inc.*, 64 Cal.Rptr.3d 908, 914-16 (Cal. App. 2007); *Taylor v. Elliott Turbomachinery Co.*, 90 Cal. Rptr.3d 414, 429-31, 434 (Cal. App. 2009); *O'Neil v. Crane Co.*, 53 Cal.4th 335, 346 (2012); *Maxton v. Western States Metals*, 203 Cal. App. 4th 81, 88-89 (Cal. App. 2012); *Fallon v. The Matworks*, 918 A.2d 1067, 1077 (Conn. Super. Ct. 2007); *Scheman-Gonzalez v. Saber Mfg. Co.*, 816 So.2d 1133, 1141 (Fla. Dist. Ct. App. 2002); *Kohler Co. v. Marcotte*, 907 So.2d 596, 598-99 (Fla. Dist. Ct. App. 2005); *Union Carbide Corp. v. Aubin*, 97 So.3d 886, 893 (Fla. Dist. Ct. App. 2012); *Baley v. Fed. Signal Corp.*, 2012 Ill. App. 093312, at *P55 (Ill. App. Ct. 2012); *Del Signore v. Asphalt Drum Mixers*, 182 F.Supp.2d 730, 745 (N.D. Ind. 2002); *Bergfeld v. Unimin Corp.*, 226 F.Supp.2d 970, 980 (N.D. Iowa 2002); *Gray v. Badger Mining Corp.*, 676 N.W.2d 268, 275, 280, 281 (Minn. 2004); *Zaza v. Marquess and Nell, Inc.*, 675 A.2d 620, 629, 633, 638 (N.J. 1996); *Boyle v. Ford Motor Co.*, 942 A.2d 850, 853-54, 860-61 (N.J. 2008); *Mathews v. University Loft Co.*, 903 A.2d 1120, 1128 (N.J. Super. Ct. 2006); *Sawyer v. A.C. & S., Inc.*, 938 N.Y.S.2d 230, 230 (N.Y. App. Div. 2011); *Buonanno v. Colmar Belting Co.*, 733 A.2d 712, 715-19 (R.I. 1999) (including thorough discussion of §5); *Ruzzo v. La Rose Enterprises*, 748 A.2d 261, 266-67 (R.I. 2000); *Guilbeault v. Reynolds Tobacco Co.*, 84 F.Supp.2d 263, 277-278 (D.R.I. 2000); *Gray v. Derderian*, 365 F.Supp.2d 218, 225, 235, 237 (D.R.I. 2005); *Davis v. Komatsu America Industries Corp.*, 42 S.W.3d 34, 35, 38, 40-43 (Tenn. 2001) (listing cases from other jurisdictions that favorably cited §5); *Toshiba Intern Corp. v. Henry*, 152 S.W.3d 774, 779, 781-84 (Tex. App. 2004); *Brocken v. Entergy Gulf States, Inc.*, 197 S.W.3d 429, 435-36 (Tex. App. 2006); *Ranger Conveying & Supply Co. v. Davis*, 254 S.W.3d 471, 480-85 (Tex. App. 2007); *Smith v. Robin America, Inc.*, 773 F.Supp.2d 708, 714 (S.D. Tex. 2011); *Sepulveda–Esquivel v. Central Machine Works, Inc.*, 84 P.3d 895, 899 (Wash. App. 2004); *Schreiner v. Wieser Concrete Products, Inc.*, 720 N.W.2d 525, 530 (Wis. App. 2006); *Godoy ex rel. Gramling v. E.I. du Pont de Nemours and Co.*, 743 N.W.2d 159, 163, 164 (Wis. App. 2007); *Industrial Risk Insurers v. American Engineering Testing, Inc.*, 769 N.W.2d 82, 99, 100 (Wis. App. 2009).

The rationale cited for this rule of law is that component parts are often integrated into other products, and it would be unjust to impose liability on the parts supplier because the integrated product uses the component in a manner that renders the integrated product defective.[5] In other words, sellers of component parts and raw materials should not have to scrutinize every product into which their parts or materials are being integrated.[6]

Liability is appropriate when the components part or raw material is defective in its design, manufacture, or warning.[7] In addition, if the component seller substantially participates in the design of the integrated product, then liability may be warranted.[8] "Substantial participation" does not include design of a component pursuant to the manufacturer's specifications; nor does the provision of mechanical or technical service or advice concerning the component.[9] Even if the component seller substantially participates in the integration of the component into the finished product, liability should not be imposed unless the harm caused by the defect is related to the component.[10]

Protection Afforded by the BAAA

At the same time as the Third Restatement came out, Congress enacted The Biomaterials

[5] Restatement Third, Torts: Products Liability § 5, cmt. a.
[6] *Id.*
[7] *Id.* at § 5, cmt. b.
[8] *Id.* at § 5, cmt. b.
[9] *Id.* at § 5, cmt. e.
[10] *Id.* at § 5, cmt. f.

Access Assurance Act ("BAAA" or "Act").[11] The BAAA protects suppliers of component parts and raw materials used in implantable medical devices from liability for harm to claimants. Specifically, the BAAA clarifies permissible bases of liability against biomaterials suppliers and provides expeditious procedures to dispose of unwarranted suits against these suppliers to minimize litigation costs.[12]

The rationale cited by Congress in the BAAA is "to assure the continued supply of materials for lifesaving medical devices."[13] In the wake of litigation involving the Dalkon Shield, silicone breast implants, and Proplast, biomaterials suppliers stopped sales to medical device manufacturers due to concern about the risks and costs of products liability litigation. Congress responded by enacting the BAAA finding "a threatened shortage of raw materials and component parts for lifesaving medical devices." Congress determined that immediate action "in the national interest" was necessary notwithstanding that "States and their courts are the primary architects and regulators of our tort system."[14]

While exceptions exist, such as when a supplier manufactures or sells the implant or the implant fails to meet applicable specifications, the BAAA shields suppliers from liability for harm to claimants.[15] "Claimants" include persons bringing an action for harm caused by an implant, as well as executors of estates and minors or incompetents through a parent or guardian who allege such harm.[16] A person alleging injury from silicone gel or the silicone envelope in a breast implant is excluded from the definition of "claimant" as are other entities.[17]

The Act applies to "any civil action brought by a claimant, whether in Federal or State court, on the basis of any legal theory, for harm allegedly caused, directly or indirectly, by an implant."[18] Moreover, the Act preempts any State law allowing for recovery of damages for harm caused by an implant.[19] Procedures related to the recovery of such damages are also preempted to the extent any Federal or State procedure conflicts with those set forth in the Act.[20]

If a claimant files suit against a biomaterials supplier for harm due to an implant, the supplier can move to dismiss or seek summary judgment based upon the liability exclusion set forth in Section 1604 of the BAAA. The Act details the procedures for the filing of such motions, including the grounds for the motion and limits on discovery related to the motion.[21] These procedures also direct the Court how to rule upon such motions (*e.g.*, court shall rule on motion to dismiss based solely on the pleadings and affidavits and shall grant the motion unless…).[22]

A dismissal pursuant to this section shall be with prejudice.[23] If a post-judgment

[11] 21 U.S.C. §§ 1601-1606 (1998).
[12] 21 U.S.C. § 1601 (15).
[13] 21 U.S.C. 1601 (17).
[14] 21 U.S.C. § 1601 (15), (16).
[15] *See* 21 U.S.C. § 1604 ("…a biomaterials supplier shall not be liable for harm to a claimant caused by an implant unless such supplier is liable" 1) as a manufacturer; 2) as a seller of the implant; or 3) fails to meet contractual requirements or specifications).
[16] 21 U.S.C. §1602(2).
[17] *See* 21 U.S.C. § 1002 (D)(ii).
[18] 21 U.S.C. § 1603(b).
[19] 21 U.S.C. § 1603(c).
[20] *Id*.
[21] 21 U.S.C. § 1605.
[22] *Id*.
[23] 21 U.S.C. § 1605(e); *see also Whaley v. Morgan Advanced Ceramics, Ltd.*, 2008 U.S. Dist. LEXIS

interpleader is filed, however, the court must conduct an independent review of the evidence of record and determine under the applicable law: 1) if the dismissed supplier was negligent or intentionally tortious; 2) if the dismissed supplier's negligence or intentionally tortious conduct was an actual and proximate cause of the harm to the claimant; and 3) if the manufacturer's liability for damages should be reduced in whole or part; or 4) if the claimant is unlikely to recover the full amount of damages from the remaining defendants.[24]

The BAAA in Practice

A recent decision from the Western District of Kentucky illustrates a novel application of the BAAA and its impact on a manufacturer's liability. In *Sadler v. Advanced Bionics v. Astro Seal*, case no. 3:11-cv-450 (W.D. KY 2013), the plaintiffs obtained a jury verdict against Advanced Bionics, the manufacturer of a cochlear implant, for $7.2 million dollars. Advanced Bionics manufactured the cochlear implant, which was implanted into the Sadlers' minor child in January 2006. The cochlear implant incorporated a component made by Astro Seal pursuant to the manufacturer's specifications.

During discovery, Advanced Bionics filed a third party complaint against Astro Seal seeking contribution, apportionment, and indemnity. The Third-Party Complaint alleged that the hermetically sealed feedthru component manufactured by Astro Seal allowed moisture to leak into the device. Astro Seal moved to dismiss the third party complaint due to lack of personal jurisdiction, and the Court granted the motion.

During trial, Advanced Bionics sought to apportion fault to Astro Seal in accordance with Kentucky statute, KRS § 411.182, which provides in relevant part:

> (1) In all tort actions, including product liability actions, involving fault of more than one (1) party to the action, including third-party defendants and persons who have been released under subsection (4) of this section, the court, unless otherwise agreed by all parties, shall instruct the jury to answer interrogatories or, if there is no jury, shall make findings indicating:
>
> (a) The amount of damages each claimant would be entitled to recover if contributory fault is disregarded; and
>
> (b) The percentage of the total fault of all parties to each claim that is allocated to each claimant, defendant, third-party defendant, and person who has been released from liability under subsection (4) of this section.
>
> (2) In determining the percentage of fault, the trier of fact shall consider both the nature of the conduct of each party at fault and the extent of the causal relation between the conduct and the damages claimed.

Plaintiffs objected to any apportionment of fault as to Astro Seal arguing that as a component supplier, Astro Seal could not be liable to plaintiffs, and it was immune from suit under the BAAA.[25] The District Judge

29918 (D. Colo. March 31, 2008) (noting dismissal must be with prejudice notwithstanding the potential statutory remedy of post-judgment impleader pursuant to 21 U.S.C. § 1606.

[24] 21 U.S.C. § 1606.

[25] Plaintiffs also argued that apportionment was improper because, as a component supplier, Astro Seal owed no duty to plaintiffs under Kentucky law. In

adopted plaintiffs' argument holding that an apportionment instruction was improper.[26] Relying on *CertainTeed v. Dexter*, 330 S.W.3d 64,74 (Ky. 2010), the Court determined that Advanced Bionics could not demonstrate that Astro Seal legally caused the plaintiffs' injuries.[27] Specifically, Advanced Bionics could not prove that Astro Seal is liable to Plaintiffs given the "shield from liability the BAAA confers upon Astro Seal."[28]

A second ground cited by the Court for denying apportionment is the express preemption provision in the BAAA at 21 U.S.C. §1603(c).[29] The District Judge held that Kentucky's remedial scheme for tort liability, KRS § 411.182 which eliminated joint and several liability in favor of several liability, could not be reconciled with the remedial scheme of the BAAA – to protect component part suppliers from liability because "suppliers of materials do not design, test or produce medical devices, so they are not responsible, at common law or by statute, for ensuring the safety of medical devices."[30] Because the BAAA remedial scheme controlled, allowing the jury to apportion fault to Astro Seal pursuant to Kentucky law was improper.[31]

Recent caselaw has involved defendants' unsuccessful claims that a component manufacturer was improperly sued to defeat diversity jurisdiction, alleging that the BAAA exempts them from liability.[32] Given the limited case law interpreting the provisions of the BAAA[33], it will be interesting to watch for future developments in component supplier liability in the medical device context.

addition, they contended that Astro Seal could not be liable under the two remaining claims against Advanced Bionics: failure to test the device pursuant to 21 CFR 820.30(g) and failure to manufacture in conformity with the premarket approval supplement.

[26] Memorandum Opinion and Order, *Sadler v. Advanced Bionics*, No. 11-450 (W.D. Ky. April 16, 2013).

[27] In *CertainTeed*, 330 S.W. 3d at 73-74, the Kentucky Supreme Court ruled that empty chair defendants must be treated like participating defendants with regard to the proof required to apportion fault. The Court reasoned that it was unfair to allow a defendant to shift the blame and reduce its liability thereby reducing a plaintiff's recovery when the empty chair defendant could not be liable to the plaintiff. *Id.*

[28] Memorandum Opinion and Order, *Sadler v. Advanced Bionics*, No. 11-450 (W.D. Ky. April 16, 2013).

[29] *Id.*

[30] *Id.* (citing from U.S. Code Congressional and Administrative News).

[31] *Id.*

[32] *See, e.g., Bocock v. MedVenture Tech Corp.*, 2013 U.S. Dist. LEXIS 135086 (S.D. Ind. 2013), *In re Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, 2013 US. Dist. LEXIS 178317 (S.D. W. Va. 2013) (denying fraudulent joinder claims since Plaintiffs may prove the inapplicability of the BAAA and allowing discovery to move forward).

[33] *See Mattern v. Biomet, Inc*., 2013 U.S. Dist. LEXIS 44054 (D. N.J. March 28, 2013) (dismissing supplier of cast metal for hip implant under the BAAA); *Whaley v. Morgan Advanced Ceramics, Ltd.*, 2008 U.S. Dist. LEXIS 29918 (D. Colo. March 31, 2008) (discussing procedure for motion to dismiss under BAAA and granting motion as to supplier of femoral head for hip implant); *Marshall v. Zimmer*, 1999 U.S. Dist. LEXIS 23594 (S.D. Cal. Nov. 5, 1999) (denying motion to amend complaint to add material and component suppliers because amendment would be futile in light of the BAAA).

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