

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
LOUISVILLE DIVISION
CIVIL ACTION NO. 3:11-CV-00450-TBR

BRIAN SADLER and MICHELLE SADLER,
Individually and on behalf of their Minor Child, B.S.

Plaintiffs

v.

ADVANCED BIONICS, LLC

Defendant

MEMORANDUM OPINION AND ORDER

The parties to this litigation have thoroughly argued the issue as to whether the jury should be instructed on apportionment in accordance with Kentucky and federal law, both in briefs and oral argument. After an exhaustive consideration of the issue, the Court finds that an apportionment instruction is improper in this case.

I.

Advanced Bionics seeks an apportionment instruction under KRS § 411.182, which provides that “[i]n all tort actions, including products liability actions, involving fault of more than one (1) party to the action, including third-party defendants . . . the court, unless otherwise agreed by all parties, shall instruct the jury to answer interrogatories . . . indicating . . . the percentage of the total fault of all the parties to each claim that is allocated to each claimant, defendant, [and] third-party defendant.” Advanced Bionics asserted a third party complaint against Astro Seal earlier in the litigation, which was ultimately dismissed for this Court’s lack of personal jurisdiction over Astro Seal. Under Kentucky law, the Court may provide an apportionment instruction against a dismissed defendant. *Ky. Farm Bureau Mut. Ins. Co. v. Ryan*, 177 S.W.3d 797, 803-04 (Ky. 2005). However, Kentucky law prohibits an apportionment

jury instruction where the Court dismissed the nonparty on the merits. *Barnes v. Owens-Corning Fiberglas Corp.*, 201 F.3d 815, 827 (6th Cir. 2000). The Kentucky Supreme Court extended this rule in *CertainTeed v. Dexter*, 330 S.W.3d 64, 74 (Ky. 2010), to provide for apportionment of fault to an empty-chair defendant only where the active defendant shows that the empty-chair defendant was liable for Plaintiffs' injuries. *Id.* ("Though the empty-chair defendant will not actually be held liable in the trial, since it is literally not on trial, a participating defendant must still prove liability on the part of the tortfeasor onto whom it seeks to shift some of the blame.").

In a case such as this where the defendant is trying to transfer responsibility to an empty-chair defendant, the burden of proof shifts to the active defendant to show that the empty-chair defendant legally caused Plaintiffs' injuries. *Id.* at 73. The Kentucky Supreme Court reasoned that such a requirement is necessary to avoid the inconsistent effect of a contrary rule, whereby a plaintiff would have to prove a case against a defendant at a higher standard of proof to obtain recovery than a defendant would have to prove against an empty chair defendant to shift fault and thereby reduce plaintiff's recovery. *Id.* at 73-74. In such a case, an empty chair defendant could be not liable to the plaintiff, but the defendant can effectively reduce its liability to plaintiff by shifting the blame. Because of this inequity, the Kentucky Supreme Court ruled that "[e]mpty-chair defendants . . . are to be treated no differently than participating defendants in regard to what must be proved to apportion fault against them." *Id.* at 74.

Under this rule, in order for Advanced Bionics to apportion fault to Astro Seal, Advanced Bionics must prove Astro Seal's liability to Plaintiffs. However, Advanced Bionics conceded in argument that it did not prove Astro Seal's liability, because according to the Biomaterials Access Assurance Act ("BAAA"), a component part manufacturer

shall not be liable for harm to a claimant caused by an implant unless such supplier is liable –

- (1) as a manufacturer of the implant . . .;
- (2) as a seller of the implant . . . ; or
- (3) for furnishing . . . component parts for the implant that failed to meet applicable contractual requirements or specifications

21 U.S.C. § 1604(a). Advanced Bionics admits that Astro Seal is a component manufacturer under the BAAA and that it did not present evidence to prove that Astro Seal falls into one of these three exclusions as they are further defined in § 1604. Thus, the BAAA provides “suppliers of ‘raw materials and component parts’ of medical devices that are permanently implanted in the human body to save or enhance lives with immunity from suit under ‘any’ legal theory.” *Marshall v. Zimmer*, 1999 WL 34996711, *1 (S.D. Cal. Nov. 4, 1999). Treating Astro Seal as if it were a participating defendant, Advanced Bionics cannot prove the case for Astro Seal’s liability to Plaintiffs, because Advanced Bionics cannot overcome the shield from liability the BAAA confers upon Astro Seal.¹

II.

The Court declines to submit an apportionment instruction to the jury on another ground—express preemption under the BAAA. Express preemption “exists where either a federal statute or regulation contains explicit language indicating that a specific type of state law is preempted.” *State Farm Bank v. Reardon*, 539 F.3d 336, 341-42 (6th Cir. 2008). Two provisions of the BAAA necessitate a finding against submitting an apportionment instruction because of express preemption. First, Congress provided that the BAAA preempts any state or federal laws to the contrary. 21 U.S.C. § 1603(c). As noted in a previous order in this case, “the

¹ This holding should not be read as an extension of the Kentucky Supreme Court decisions in *Jefferson County Commonwealth Attorney’s Office v. Kaplan*, 65 S.W.3d 926 (Ky. 2001) and *Lexington-Fayette Urban County Government v. Smolcic*, 142 S.W.3d 128 (Ky. 2004). In these cases, the Kentucky Supreme Court seemed to recognize an exception from KRS § 411.182 where the court dismissed the empty-chair defendants under absolute immunity. Here, the Court finds that Advanced Bionics is unable to prove that Astro Seal is liable to Plaintiffs for their injuries, and therefore under *CertainTeed*, apportionment is inappropriate.

purpose of Congress is the ultimate touchstone in every pre-emption case.” *Wyeth v. Levine*, 555 U.S. 555, 565 (2009).

Congress enacted the BAAA to protect companies that manufacture component parts for implant devices from suit, 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. Nonetheless, when a medical device is alleged to have caused harm, biomaterials suppliers are often named along with manufacturers as defendants in lawsuits alleging inadequate design and testing or inadequate warning related to the use of the device.

H. Rep. No. 105-549(I), at *9-10 (1998), *reprinted in* 1998 U.S.C.C.A.N. 390, 377. Congress intended the BAAA to eliminate most component part manufacturer liability and to streamline the dismissal process for component part manufacturers.²


Second, 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. 21 U.S.C. § 1606. The BAAA thus sets up a specific remedial scheme akin to joint and several liability. Plaintiffs are to sue the manufacturer, and the manufacturer may then, where appropriate, implead the component part manufacturer for contribution or indemnity. Plaintiffs have no direct means of obtaining recovery from the component part manufacturer when the BAAA applies.³ However, plaintiffs are made whole by a judgment against the manufacturer, which may then implead the component supplier and seek contribution or indemnity.

² The BAAA excludes from this liability shield component part manufacturers that are also the final product manufacturer, are also a seller of the finished product, or fail to comply with specifications or contractual provisions. 21 U.S.C. § 1604. Advanced Bionics admitted at argument on the record that it has not presented evidence showing that Astro Seal fits within these exceptions.

³ Plaintiffs may only implead the component manufacturer where the plaintiffs are “unlikely to be able to recover the full amount of its damages from the remaining defendants.” 21 U.S.C. § 1606(a)(2).

Kentucky adopted comparative fault, codified in KRS § 411.182, as its remedial scheme for all tort liability, including products liability. *Ryan*, 177 S.W.3d at 802. In so doing, the legislature “eliminate[d], once and for all, joint and several liability [T]he adoption of comparative fault and its codification in KRS 411.182 were designed to prevent . . . a plaintiff [from] being able to allocate fault against a tortfeasor far in excess of that tortfeasor’s actual liability.” *Id.* Under KRS § 411.182, Kentucky therefore adopted several liability. *Degener v. Hall Contracting Corp.*, 27 S.W.3d 775, 779 (Ky. 2000). The remedial scheme of the BAAA, which manifested a congressional decision to protect component part manufacturers from liability, is irreconcilable with Kentucky’s adoption of several liability in all tort actions, including those actions against component part manufacturers. According to the express preemption provision of the BAAA, the BAAA’s remedial scheme controls. Advanced Bionics’ attempt to obtain an apportionment jury instruction under KRS § 411.182 is improper, because the operation of that statute is preempted in this case.

Advanced Bionics cites no other controlling authority mandating an apportionment instruction under the BAAA. Accordingly, Advanced Bionics’ motion for an apportionment instruction must be denied.


Thomas B. Russell, Senior Judge
United States District Court

April 16, 2013