PUBLISHED

UNITED STATES COURT OF APPEALS

FOR THE FOURTH CIRCUIT

American Cyanamid Company, Plaintiff-Appellee,

v.

No. 02-1235

St. Louis University,

 $Defendant\hbox{-}Appellant.$

Appeal from the United States District Court for the District of Maryland, at Baltimore.

J. Frederick Motz, District Judge.

(CA-99-1316-JFM)

Argued: January 22, 2003

Decided: July 16, 2003

Before NIEMEYER, LUTTIG, and TRAXLER, Circuit Judges.

Affirmed by published opinion. Judge Traxler wrote the majority opinion, in which Judge Niemeyer joined. Judge Luttig wrote a concurring opinion.

COUNSEL

ARGUED: Marc Simon Moller, KREINDLER & KREINDLER, New York, New York, for Appellant. David Patrick Donovan, WILMER, CUTLER & PICKERING, McLean, Virginia, for Appellee. **ON BRIEF:** Mark R. Dunn, HERZOG, CREBS & MCGHEE, L.L.P., St. Louis, Missouri; Stanley P. Kops, Bala Cynwyd, Pennsylvania; Rex Carr, CARR, KOREIN, TILLERY, KUNIN, MONTROY

& GLASS, East St. Louis, Missouri, for Appellant. Roger W. Yoerges, WILMER, CUTLER & PICKERING, Washington, D.C., for Appellee.

OPINION

TRAXLER, Circuit Judge:

St. Louis University ("SLU") paid a \$16 million Missouri state-court judgment to the family of a boy who became paralyzed after receiving Orimune, an oral polio vaccine, and SLU now seeks contribution from American Cyanamid Company, the parent company of the vaccine manufacturer. The district court granted summary judgment in favor of Cyanamid, and SLU appeals. We affirm.

I.

Much of the factual and procedural background relevant to this case is set out in our opinion in *St. Louis University v. United States*, No. 02-1351, which is also filed today. To the extent possible, we will not repeat that information in this opinion.

After SLU paid the judgment in the state court case, it filed various federal and state-court actions against Cyanamid. These actions were dismissed for procedural reasons. SLU ultimately filed a contribution action against the United States government in federal district court in Maryland (the "Government Contribution Action"). The district court in that action granted summary judgment in favor of the government in 1999. Cyanamid thereafter filed a declaratory judgment action in the same federal district court, seeking a declaration that the summary judgment order in the Government Contribution Action collaterally estopped SLU from seeking contribution against Cyanamid. The district court agreed with Cyanamid, gave collateral estoppel effect to its order in the Government Contribution Action, and granted summary judgment in favor of Cyanamid. SLU appealed the rulings in the declaratory judgment action and the Government Contribution Action. This court reversed and remanded both cases for further proceedings. See St. Louis Univ. v. United States, No. 99-2227 (4th Cir.

March 1, 2001); *American Cyanamid v. St. Louis Univ.*, No. 99-2224 (4th Cir. March 1, 2001). On remand, the district court concluded that the government could be held liable in contribution to SLU, but that Cyanamid was not liable in contribution.¹

II.

The district court concluded that SLU failed to establish that a defect in the vaccine proximately caused the injuries in the underlying state-court case. SLU's arguments on appeal largely track those it made in response to the government's appeal in *St. Louis University v. United States*, No. 02-1351. That is, SLU contends that the opinions of the district court and this court in the *Sabin* cases² are determinative of this case. The *Sabin* courts concluded that the government violated the neurovirulence regulations and that the government's actions proximately caused the injuries suffered by the *Sabin* plaintiffs, and SLU contends that the "rationale" of the *Sabin* opinions applies to Cyanamid as well as the government. Reply Brief at 6. SLU also contends that Cyanamid bears ultimate responsibility for the regulatory violations found in *Sabin*, and that these regulatory violations alone make Cyanamid liable in contribution to SLU.

As to SLU's reliance on the *Sabin* cases, we again find it to be misplaced. As we explained in our decision in No. 02-1351, the *Sabin*

¹SLU's argument that there is no live case or controversy involving Cyanamid because Cyanamid did not amend its complaint after our remand is wholly without merit. The post-remand conduct of the parties clearly indicated the question of whether Cyanamid could be held liable in contribution was tried by consent. See People for the Ethical Treatment of Animals v. Doughney, 263 F.3d 359, 367 (4th Cir. 2001) ("A party's failure to amend will not affect a final judgment if the issues resolved were tried by express or implied consent of the parties. Even without a formal amendment, a district court may amend the pleadings merely by entering findings on the unpleaded issues." (citations and internal quotation marks omitted)).

²In re Sabin Oral Polio Vaccine Prods. Liab. Litig., 743 F. Supp. 410 (D. Md. 1990); In re Sabin Oral Polio Vaccine Prods. Liab. Litig., 763 F. Supp. 811 (D. Md. 1991); In re Sabin Oral Polio Vaccine Prods. Liab. Litig., 774 F. Supp. 952 (D. Md. 1991), aff'd In re Sabin Oral Polio Vaccine Prods. Liab. Litig., 984 F.2d 124 (4th Cir. 1993) (per curiam).

cases involved questions of Maryland and Florida law. Because this case is governed by Missouri law, the *Sabin* decisions are not controlling. Thus, the issue we must resolve is whether, without regard to the *Sabin* decisions, SLU has carried its burden of demonstrating that Cyanamid can be held responsible for the injures suffered by Danny Callahan. We agree with the district court that SLU did not carry this burden.

Under Missouri law, SLU is entitled to contribution from Cyanamid only if Cyanamid can be held liable for Danny's injuries. *See Gramex Corp. v. Green Supply, Inc.*, 89 S.W.3d 432, 442 (Mo. 2002) (en banc). Liability is grounded in Missouri's product liability law, which follows the approach set forth in the section 402A of the *Restatement (Second) of Torts. See Keener v. Dayton Elec. Mfg. Co.*, 445 S.W.2d 362, 364 (Mo. 1969).

The essential elements of a strict product liability claim are (1) the defendant sold a product in the course of its business; (2) the product was then in a defective condition, unreasonably dangerous when put to a reasonably anticipated use; (3) the product was used in a manner reasonably anticipated; and (4) the plaintiff was damaged as a direct result of such defective condition as existed when the product was sold.

Lay v. P & G Health Care, Inc., 37 S.W.3d 310, 325 (Mo. Ct. App. 2000); see Restatement (Second) of Torts § 402A(1) (1965) ("One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer"). Assuming that the first three elements are satisfied, SLU has not satisfied the fourth element, causation.

SLU has simply failed to present any competent evidence showing that the defect in the vaccine — excessive neurovirulence — proximately caused Danny's injuries.³ SLU insists, however, that the mere

³The record does include an article discussing a particular genetic mutation in the vaccine that might be connected to cases of vaccine-associated poliomyelitis, but SLU offered no expert testimony to interpret the findings and explain the relevance of the findings to this case. The article, therefore, is insufficient to satisfy SLU's burden of showing proximate cause. The expert testimony in the record is likewise insufficient. As explained in our opinion in 02-1351, none of SLU's experts testified that increased neurovirulence led to increased incidence of vaccine-associated polio, nor were any qualified to render such an opinion.

fact that the neurovirulence regulations were violated entitles it to recovery. As we explained in No. 02-1351, SLU is simply wrong on this point. Even in cases where the violation of a statute amounts to negligence *per se*, Missouri law is unambiguous in its requirement that the plaintiff must still prove that the violation proximately caused his injuries. *See Sill v. Burlington No. R.R.*, 87 S.W.3d 386, 392 (Mo. Ct. App. 2002) ("If a submissible case is made under a negligence per se cause of action, a plaintiff could recover if a jury concluded that a statute was violated and the violation was the proximate cause of the injury."); *Friend v. Yokohama Tire Corp.*, 904 S.W.2d 575, 579 (Mo. Ct. App. 1995) ("One of the elements of a negligence per se action is that the violation of a statute was the proximate cause of the injury.").

SLU presented no expert testimony showing that Danny Callahan would not have contracted polio or would have contracted a less severe case of polio had he been given a vaccine complying with the neurovirulence regulations. The district court, therefore, properly rejected SLU's claim against Cyanamid. *See Klein v. General Elec. Co.*, 714 S.W.2d 896, 900 (Mo. Ct. App. 1986) ("To prevail under the doctrine of strict liability in tort, the plaintiffs must prove that the product was defective and dangerous . . . that the plaintiff sustained damage as a direct result of the defect.").

Accordingly, for the foregoing reasons, the district court's grant of summary judgment in favor of Cyanamid is hereby affirmed.⁴

AFFIRMED

⁴Proximate cause is an element of the plaintiff's cause of action. Because SLU failed to establish this essential element of its claim, SLU's argument that Cyanamid failed to prove its entitlement to the affirmative defense set forth in comment K to section 402A of the *Restatement* is irrelevant. *See, e.g., Farm Bureau Town & Country Ins. of Missouri v. Hilderbrand*, 926 S.W.2d 944, 948 (Mo. Ct. App. 1996) ("An affirmative defense seeks to defeat or avoid the plaintiff's cause of action. It avers that even if the petition is true, the plaintiff cannot prevail because there are additional facts that permit the defendant to avoid legal responsibility." (citation omitted)). Also irrelevant is SLU's pre-emption argument. The district court did not reject SLU's claim on pre-emption grounds, nor do we. Instead, the district court held, and we agree, that SLU failed to prove proximate cause, as required by Missouri law.

LUTTIG, Circuit Judge, concurring:

I concur in the judgment of the court. I do not fully join the majority opinion, however, for the same reasons that I dissent from the companion case in 02-1351. Again, the majority would have it that *Sabin IV* does not present binding law for this appeal. Again, I disagree. However, I join the judgment of the court in this case for the straightforward reason that SLU failed to proffer evidence of proximate causation sufficient to satisfy the Missouri tort standards.

In contrast to the companion case, the defendant here is being sued not for its conduct as an alleged defective product-approver, but for its conduct as an alleged defective product manufacturer. The straightforward defective product manufacturing proximate cause analysis therefore applies to this case. *See Nesselrode* v. *Executive Beechcraft, Inc.*, 707 S.W.2d 371, 375-76 (Mo. 1986) (en banc) (holding that the plaintiff in a product manufacturing defect case must prove the defect caused his injuries by proving that had the product been defect-free he would not have been injured).

Here, the defect in question is the defective manufacture of the vaccine. As the majority well points out, SLU proffered no evidence that the vaccine, had it been defect-free, would not have caused Danny Callahan's injuries. As such, SLU failed to create a genuine issue as to that central proximate cause question, without which it cannot survive appellee's summary judgment motion.

For these reasons I too would affirm the district court's judgment in this case.