

NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 24-3138

NOETIC SPECIALTY INSURANCE COMPANY n/k/a PROASSURANCE
SPECIALTY INSURANCE COMPANY d/b/a NOETIC SPECIALTY INSURANCE

v.

B. BRAUN MEDICAL, INC.; B. BRAUN OF AMERICA, INC.; B. BRAUN
CEGAT, LLC; B. BRAUN INTERVENTIONAL SYSTEMS, INC.

Appellants

On Appeal from the United States District Court
for the Eastern District of Pennsylvania
(D.C. No. 5:22-cv-02398)
District Judge: Honorable Jeffrey L. Schmehl

Submitted Pursuant to Third Circuit L.A.R. 34.1(a)
December 4, 2025

Before: CHAGARES, Chief Judge, FREEMAN and BOVE, Circuit Judges

(Opinion filed: December 30, 2025)

OPINION*

* This disposition is not an opinion of the full Court and, pursuant to 3d Cir. I.O.P. 5.7, does not constitute binding precedent.

CHAGARES, Chief Judge

When medical device manufacturer B. Braun faced numerous lawsuits alleging that it had exposed local residents to a harmful chemical, it asked its insurer to pay for its defense. The insurer, Noetic Specialty Insurance, refused and filed this lawsuit, seeking a declaratory judgment that it owed no duty to defend B. Braun in the underlying actions. The District Court agreed and entered a declaratory judgment in favor of Noetic. B. Braun now appeals. For the reasons set forth below, we will affirm.

I.

We write solely for the parties and so recite only the facts necessary to our disposition. B. Braun operates a manufacturing plant in Allentown, Pennsylvania. In 2019, local residents began filing lawsuits alleging that B. Braun and its related entities had exposed them to emissions of ethylene oxide (“EtO”), a chemical used by the company to sterilize its medical devices. These underlying cases included a class-action suit as well as dozens of individual complaints. All of them alleged that EtO is a known carcinogen. B. Braun then tendered the defense of these lawsuits to Noetic, urging that Noetic owed B. Braun a duty to defend and indemnify.

Noetic had issued three liability insurance policies to B. Braun. Each policy covered a one-year period from December 31, 2018 to December 31, 2021. The policies included identical provisions excluding coverage for bodily injury or property damage caused by “pollutants.” Appendix (“App.”) 319. The policies defined pollutants as “any solid, liquid, gaseous, or thermal irritant or contaminant.” App. 274. The policies also included a regulatory clearance exception, which provided that the pollution exclusion did not apply

where B. Braun’s “product” or “work” was cleared by a “governmental health authority or regulatory body for marketing with a specific indication for medical, diagnostic, or therapeutic use.” App. 319. Noetic invoked the pollution exclusion and disclaimed any duty to defend B. Braun in the underlying lawsuits. When B. Braun protested this decision, Noetic filed this lawsuit against B. Braun and its affiliates, seeking a declaratory judgment that it had no duty to defend or indemnify the company. After B. Braun filed a counterclaim seeking its own declaratory judgment to the contrary, both parties moved for judgment on the pleadings. The District Court granted Noetic’s motion and entered a declaratory judgment in its favor. B. Braun and its affiliates timely appealed.

II.¹

B. Braun argues that the District Court erred in finding both that the pollution exclusion applied and that the regulatory clearance exception did not apply. We disagree.

The District Court concluded that the policies’ definition of pollutants unambiguously applied to EtO based on the allegations in the underlying lawsuits. See Am. & Foreign Ins. Co. v. Jerry’s Sport Ctr., Inc., 2 A.3d 526, 541 (Pa. 2010) (“[T]he obligation to defend an action brought against the insured is to be determined solely by the allegations of the complaint in the action” (quoting Gen. Accident Ins. Co. of Am. v. Allen, 692 A.2d 1089, 1094 (Pa. 1997))). Those underlying complaints alleged that EtO

¹ The District Court had jurisdiction under 28 U.S.C. § 1332, and we have appellate jurisdiction under 28 U.S.C. § 1291. We exercise plenary review over a district court’s grant of a Rule 12(c) motion for judgment on the pleadings. E.I. DuPont de Nemours & Co. v. United States, 508 F.3d 126, 131–32 (3d Cir. 2007).

is a “powerful cancer-causing gas” that is “dangerous, toxic, carcinogenic and mutagenic,” App. 229, 233, “readily taken up by the lungs,” App. 233, and in the International Agency for Research on Cancer’s highest risk category for humans. Given that characterization, the District Court properly concluded that EtO is at least an “irritant,” thereby triggering the insurance policies’ pollution exclusion. See App. 328; Madison Constr. Co. v. Harleysville Mut. Ins. Co., 735 A.2d 100, 107 (Pa. 1999) (noting that underlying lawsuits alleged a floor sealant was harmful to humans if inhaled and holding that an insurance policy’s pollutant definition “including as it does ‘any . . . irritant,’ clearly and unambiguously applies to the product in question”).

The District Court also correctly declined to apply the regulatory clearance exception to the pollution exclusion. That exception provided that the pollution exclusion does not apply when either B. Braun’s “Product” or “Work” has been cleared by a regulatory authority “for marketing with a specific indication for medical, diagnostic, or therapeutic use.” App. 319. EtO is not B. Braun’s “Product.” See App. 275 (defining Product as something “designed, developed, manufactured, sold, handled, or distributed by” B. Braun); see also Hydro Sys., Inc. v. Cont’l Ins. Co., 717 F. Supp. 700, 703 (C.D. Cal. 1989), aff’d, 929 F.2d 472 (9th Cir. 1991) (“The [pollutant at issue] produced in the manufacturing process is not sold or marketed. Allowing such an emission to be considered a product would completely swallow the pollution exclusion.”). Moreover, even if the EtO sterilization process qualified as B. Braun’s “Work,” the two regulatory clearances B. Braun cites still do not satisfy the exception. App. 319. As the District Court observed, B. Braun’s permit from the Pennsylvania Department of Environmental

Protection for its EtO emissions makes no mention of marketing. And the FDA's clearance of B. Braun's medical device for marketing makes no mention of the company's EtO emissions.

In sum, the District Court correctly held that the pollution exclusion applies, but the regulatory clearance exception does not. The District Court thus properly entered a declaratory judgment in favor of Noetic.

III.

For the foregoing reasons, we will affirm the order of the District Court.