NONPRECEDENTIAL DISPOSITION
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United States Court of Appeals

For the Seventh Circuit
Chicago, Illinois 60604

Argued January 26, 2016
Decided February 3, 2016

Before

DIANE P. WOOD, *Chief Judge*

WILLIAM J. BAUER, *Circuit Judge*

RICHARD A. POSNER, *Circuit Judge*

No. 15-2411

MICHAEL HOUSTON,
Plaintiff-Appellant,

v.

UNITED STATES OF AMERICA, et al.,
Defendants-Appellees.

Appeal from the United States District Court for the Northern District of Illinois, Eastern Division.

No. 14 C 1042

Jorge Alonso,
Judge.

ORDER

Michael Houston is permanently disfigured as a result of a severe skin reaction called Stevens-Johnson Syndrome (SJS), which he developed after taking allopurinol, a prescription drug used to treat gout. Houston brought tort claims in state court against the federally funded health clinic where he was treated for gout, the physician's assistant who prescribed allopurinol, and the drug manufacturer. The United States removed the case to federal court and substituted itself as the defendant in place of the federal healthcare providers, as the Federal Tort Claims Act provides. *See* 28 U.S.C. § 2679. The United States then moved to dismiss Houston's claims against the United States for failing to exhaust his administrative remedies. *See* 28 U.S.C. § 2675(a). The drug manufacturer moved to dismiss, too, arguing that all of Houston's state-tort claims

against it are preempted by federal drug regulations. The district court granted the defendants' motions and dismissed the case with prejudice. Because the defects in Houston's amended complaint cannot be cured, we affirm.

Houston visited the Komed Holman Health Center in July 2011 for pain in his right toe. James Pecard, a physician's assistant, diagnosed Houston with gout and prescribed allopurinol. (Allopurinol is a generic form of Zyloprim and is used to treat gout by reducing uric acid in the body.) Pecard allegedly did not warn Houston that taking allopurinol risks SJS, blindness, and even death. One month later, Houston went to an emergency room because of severe eye pain, red eyes, and a small rash on his face. He was prescribed eye medication and sent home but returned two days later with persistent eye pain and a severe rash that had spread across his body. Houston was diagnosed with SJS and admitted to the intensive care burn unit, where doctors concluded that the allopurinol had triggered his SJS.[1]

Houston brought a complaint in Illinois court. He alleged medical malpractice claims against Pecard, the health clinic Komed and its parent company, and an unnamed doctor who allegedly failed to supervise Pecard (together, "the healthcare defendants").

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[1] According to the Mayo Clinic, SJS is a serious skin disorder. *Stevens-Johnson Syndrome: Treatments and Drugs*, MAYO CLINIC (Apr. 22, 2014), http://www.mayoclinic.org/diseases-conditions/stevens-johnson-syndrome/basics/treatment/con-20029623. If treated properly the syndrome can be eliminated within a few days of hospitalization, but severe cases may last several months. *Id.* SJS typically starts with flu or fever-like symptoms, and after a few days the skin begins to peel or blister, causing painful raw areas known as erosions that resemble severe hot water burns. *Stevens-Johnson Syndrome/Toxic Epidermal Necrolysis*, NAT'L INSTS. OF HEALTH, http://ghr.nlm.nih.gov/condition/stevens-johnson-syndrome-toxic-epidermal-necrolysis (reviewed July 2015). Those erosions usually start on the face and chest and then spread to the rest of the body. *Id.* For most people SJS damages the mucous membranes, including the lining of the mouth and airways, making it difficult to breathe and swallow. *Id.* Painful blistering can also occur in the urinary tract and genitals. *Id.* SJS often affects eyes, as well, causing redness in the mucous membranes that protect the white parts of the eye, and damaging the cornea. *Id.* SJS is a potentially life-threatening disease, with one in ten cases resulting in death. *Id.* Long-term side effects may include changes in skin coloring, dry skin and mucous membranes, excess sweating, hair loss, abnormal growth or loss of fingernails and toenails, impaired taste, difficulty urinating, and genital abnormalities. *Id.*

He also brought product-liability claims against the manufacturer of allopurinol, Qualitest Pharmaceuticals, for failing to warn about or better design the drug. He sought damages for mental and physical suffering associated with the skin disease. Houston states that he has incurred permanent physical injuries and disfigurement from SJS.

The United States removed the case to federal court, *see* 28 U.S.C. § 2679, and substituted itself for the healthcare defendants. The government certified that "at the relevant times" Komed was a federally funded entity, Pecard acted "within the scope of his employment" at Komed, and the healthcare defendants are therefore federal employees under the Public Health Service Act, 42 U.S.C. § 233. *See* 28 U.S.C. § 2679(d). Under the FTCA, it continued, federal employees are immune from tort claims arising from conduct within the scope of their jobs; claims against them are deemed actions against the United States only. *See* 28 U.S.C. § 2679.

Houston contested the government's certification that Pecard acted within the scope of his employment. After the court allowed Houston limited discovery on that issue, Houston amended his complaint. He asserted that Pecard acted outside the scope of his job at Komed because he, "at all times relevant … a physician's assistant," prescribed allopurinol without warning of its side effects or getting the signature of his supervising physician at Komed. Houston identified that supervising doctor as Syeda Shariff, adding that "at all times relevant" she worked at Komed.

The defendants moved to dismiss. The United States argued that Houston did not allege facts supporting the claim that Pecard and Shariff were acting outside the scope of their employment and thus not covered by the FTCA. Houston's claims, therefore, were against the United States and should be dismissed as unexhausted under the FTCA because he never filed an administrative claim. *See* 28 U.S.C. § 2675(a). Qualitest also moved to dismiss. It argued that under the Supreme Court's recent decisions in *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 133 S. Ct. 2466 (2013), and *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), all of Houston's state-law claims are preempted by federal laws that regulate generic-drug manufacturers.

The district court granted the motions. It agreed with Qualitest that the product liability claims are preempted. The court explained that federal drug regulations impose a duty of "sameness" on generic drug manufacturers to ensure that the generic versions of drugs have the same active ingredients, route of administration, dosage form, strength, and labeling as the brand name drug. *See Bartlett*, 133 S. Ct. at 2475; *Mensing*, 131 S. Ct. at 2576. It would be impossible, the court reasoned, for the company to comply

with a state-law duty to change the label or design of allopurinol while complying with its federal duty to keep the label and design the same. The court also ruled that, because the acts attributed to the healthcare defendants occurred within the scope of federal employment, the claims against them were deemed against the United States and must be dismissed as unexhausted.

The case ended there. Although the court did not enter the judgment on a separate document, Houston's appeal is timely because he filed it within 150 days after the court's final decision. *See* FED. R. CIV. P. 58(c)(2)(B); *Brown v. Fifth Third Bank*, 730 F.3d 698, 699–700 (7th Cir. 2013).

Turning first to the healthcare defendants, Houston argues that the district court erred in concluding that Pecard and Shariff acted within the scope of their employment; therefore it should not have deemed the claims against them to be against the United States and dismissed those claims as unexhausted. He relies on cases stating that a state employee is not shielded from tort liability under Illinois law if the employee's duty to the plaintiff arises outside of the employment context. *See, e.g.*, *Currie v. Lao*, 592 N.E.2d 977, 980–81 (Ill. 1992); *Janes v. Albergo*, 626 N.E.2d 1127, 1133 (Ill. App. Ct. 1993). But the FTCA immunizes federal employees who act within the scope of their employment, regardless of the source of the employee's duty to the plaintiff. *See* 28 U.S.C. § 2679(b)(1); *Osborn v. Haley*, 549 U.S. 225, 229 (2007). Pecard's and Shariff's duties to Houston may arise from the doctor–patient relationship rather than their employment with Komed. But they are nonetheless shielded from liability under the FTCA as long as they were acting within the scope of their employment at Komed. *Id.*

The question, then, is whether Houston has alleged facts to support his claim that Pecard and Shariff acted outside the scope of their employment. *See Taboas v. Mlynczak*, 149 F.3d 576, 582 (7th Cir. 1998). Under Illinois law, which the parties agree governs, "[a]n employee's action falls within the scope of employment if (a) it is of the kind he is employed to perform; (b) it occurs substantially within the authorized time and space limits; [and] (c) it is actuated, at least in part, by a purpose to serve the master." *Id.* (quoting *Pyne v. Witmer*, 543 N.E.2d 1304, 1308 (Ill. 1989)) (internal quotation marks omitted). When the court, as here, dismisses a complaint based on the government's certification that its employees acted within the scope of employment, the plaintiff must point to facts suggesting that, based on this scope-of-employment formula, the certification is wrong. *Taboas*, 149 F.3d at 582.

Houston's factual allegations suggest that Pecard and Shariff acted *within* the scope of their work. He alleges that "at all times" Pecard was a physician's assistant at Komed. A physician's assistant may prescribe drugs once a supervising physician has delegated that power to the assistant. *See* 720 ILCS 570/303.05(a)(1). Having received discovery on the matter, Houston needed to allege (if it was true) that no supervising physician at Komed delegated prescribing power to Pecard. But he has not. Likewise Houston also alleges that Shariff was "at all times" Pecard's supervisor at Komed. But he does not allege that she (or Pecard) acted after work hours or offsite or that they were motivated by personal reasons rather than on behalf of the health center. Thus no factual allegations suggest that they acted outside the scope of their work.

Houston offers two unavailing replies. First, he argues that, because Pecard negligently prescribed him allopurinol without warning him of possible side effects and Shariff negligently failed to supervise Pecard or sign the prescription, they exceeded their job authority. But an allegation of negligence is not enough to remove actions from the scope of employment. *See Sellers v. Rudert*, 918 N.E.2d 586, 591–92 (Ill. App. Ct. 2009). Second, Houston argues that Pecard and Shariff cannot be deemed federal employees because, as medical professionals, they exercise judgment. But the use of judgment is irrelevant to federal employment status. *See, e.g.*, *Arteaga v. United States*, 711 F.3d 828, 830–31, 835 (7th Cir. 2013); *Alexander v. Mount Sinai Hosp. Med. Ctr.*, 484 F.3d 889, 891 (7th Cir. 2007). Therefore, because they acted as employees of Komed, the United States was the proper defendant under the FTCA. And because Houston does not dispute his failure to exhaust, the district court correctly dismissed the claims against the government. *See* 28 U.S.C. § 2675(a); *McNeil v. United States*, 508 U.S. 106, 113 (1993); *Smoke Shop, LLC v. United States*, 761 F.3d 779, 786–88 (7th Cir. 2014).

As for his claims against Qualitest, Houston argues first that, once the United States was dismissed, those claims should have been remanded to state court because they do not fall within the district court's original or supplemental jurisdiction. *See* 28 U.S.C. § 1441(c). But the claims against Qualitest are part of the "same case or controversy" as the claims against the United States—that Houston developed SJS after taking allopurinol—and thus the claims fall within the court's supplemental jurisdiction. *McCoy v. Iberdola Renewables, Inc.*, 760 F.3d 674, 682–83 (7th Cir. 2014) (quoting *United Mine Workers v. Gibbs*, 383 U.S. 715, 725 (1966)); *see* 28 U.S.C. § 1367(a). Moreover, the parties are diverse (Houston is a citizen of Illinois and Qualitest is a citizen of Delaware and Alabama); and although Houston did not quantify his damages, based on the severity of SJS the amount in controversy likely exceeds $75,000.

Houston next argues that the district court wrongly dismissed his state-law claims against Qualitest as preempted by federal law. He is incorrect. Federal law imposes on Qualitest an "ongoing duty of sameness" to ensure that allopurinol's chemical design and labeling are the same as its brand-name counterpart, Zyloprim. *See* 21 U.S.C. § 355(j)(2)(A)(ii)–(v); *Mensing*, 131 S. Ct. 2575. The duty preempts a state-law claim against a generic manufacturer if, as here, that claim would require the manufacturer to redesign its drug, change its labeling, or exit the market in order to avoid liability. *See Bartlett*, 133 S. Ct. at 2474–77; *Mensing*, 131 S. Ct. at 2578, 2581; *see also Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1139 (8th Cir. 2014); *Drager v. PLIVA USA, Inc.*, 741 F.3d 470, 476 (4th Cir. 2014).

Houston offers three replies, none persuasive. First he argues that his state-law claims do not necessarily require Qualitest to change allopurinol's design or label. But this argument is self-defeating because his suit alleges that under state law Qualitest should have labeled or designed the drug differently. Without a different label or design, the only way that Qualitest could avoid liability would be to exit (or never have entered) the generic market. But generic-drug makers benefit consumers when they bring FDA-approved drugs to market. For that reason, market exit is precisely the outcome that the duty of sameness and *Mensing's* preemption principle are designed to prevent. *Mensing*, 131 S. Ct. at 2578.

For the same reason, Houston's claims for defective design, negligence, consumer fraud, battery, and breach of express and implied warranties are also preempted. *See, e.g.*, *Brinkley*, 772 F.3d at 1140–41 (design-defect and implied-warranty claims); *Johnson v. Teva Pharm. USA, Inc.*, 758 F.3d 605, 612–13 (5th Cir. 2014) (design-defect and express-warranty claims); *Eckhardt v. Qualitest Pharm., Inc.*, 751 F.3d 674, 678–80 (5th Cir. 2014) (same); *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II)*, 751 F.3d 150, 165 (3d Cir. 2014) (strict-liability design-defect claim); *Drager*, 741 F.3d at 476–79 (claims for negligence, design defect, breach of implied and express warranties, negligent misrepresentation and fraudulent concealment); *Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 394–97 (6th Cir. 2013) (claims for breach of implied warranty, fraud and misrepresentation, and design defect); *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1286–89 (10th Cir. 2013) (claims for breach of express and implied warranties).

Second, Houston argues that his claims should survive preemption under the Supreme Court's decisions in *Altria Group, Inc. v. Good*, 555 U.S. 70 (2008), *Bates v. Dow Agrosciences, LLC*, 544 U.S. 431 (2005), and *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992). But the claims in those cases, which accused cigarette and pesticide makers of

deceptive advertising, did not require manufacturers to violate any federal duty. *See Altria Group*, 555 U.S. at 87; *Bates*, 544 U.S. at 446, 452; *Cipollone*, 505 U.S. at 530–31. By contrast, Houston's claims do.

Third, Houston argues that *Mensing* and *Bartlett* do not apply here because his claims arose after the passage of the Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007). Those amendments, he explains, give the FDA authority to negotiate changes in drug labeling with generic-drug manufacturers. Although the Supreme Court reserved ruling on the effect of that legislation, *Mensing*, 131 S. Ct. at 2574 n.1, the amendments still forbid a generic-drug maker from violating the duty of sameness without FDA permission. *See generally* Pub. L. No. 110-85, 121 Stat. 823 (2007); *see also Mensing*, 131 S. Ct. at 2581 ("[W]hen a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes."). And nothing in the amendments or other laws *requires* a manufacturer to seek that permission, the receipt of which would be speculative anyway.

Two loose ends remain. Houston challenges the denial of his request to add claims against a new party, the manufacturer of the brand-name version of allopurinol, Zyloprim. This court has not addressed whether a consumer of a generic drug may sue the brand-name manufacturer, though others have. *Compare Dolin v. Smithkline Beecham Corp.*, 62 F. Supp. 3d 705, 720–21 (N.D. Ill. 2014) (allowing generic consumer to pursue negligence claim against brand-name manufacturer), *with Smith v. Wyeth, Inc.*, 657 F.3d 420, 423–24 (6th Cir. 2011) (brand-name manufacturers owe no duty to generic consumers), *and Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 170–71 (4th Cir. 1994). We need not takes sides. Even if Houston could otherwise pursue a claim against the brand-name manufacturer, the two-year statute of limitations for personal-injury claims in Illinois has already run, *see* 735 ILCS 5/13-202, and the brand-name manufacturer did not receive notice of this suit within the time that would allow any amendment to relate back to the date of the original complaint, *see* FED. R. CIV. P. 4(m), 15(c)(1)(C).

Finally, Qualitest moved this court to take judicial notice of information on the FDA's website. Qualitest says the information shows that the FDA approved allopurinol to treat gout, that allopurinol and Zyloprim have the same active ingredients, route of administration, dosage form and effect, and labeling, and that the labels for both products include the same warnings about SJS. This court may take judicial notice of any fact that "can be accurately and readily determined from sources whose accuracy cannot

reasonably be questioned," FED. R. EVID. 201(b)(2), including public records, *Henson v. CSC Credit Servs.*, 29 F.3d 280, 284 (7th Cir. 1994), and agency determinations, *Fornalik v. Perryman*, 223 F.3d 523, 529 (7th Cir. 2000). Although information on the FDA's official website reflects the agency's determinations, the information is unnecessary to resolve this appeal and thus the motion is DENIED.

Therefore we AFFIRM the judgment of the district court.