In the

United States Court of Appeals

For the Seventh Circuit

No. 19-2547

WENDY B. DOLIN, Individually and as Independent Executor of the Estate of STEWART DOLIN, Deceased,
Plaintiff-Appellant,

v.

GLAXOSMITHKLINE LLC,
Formerly Known as SMITHKLINE BEECHAM CORPORATION,
Defendant-Appellee.

Appeal from the United States District Court for the
Northern District of Illinois, Eastern Division.
No. 1:12-cv-6403 — **William T. Hart**, *Judge*.

ARGUED JANUARY 22, 2020 — DECIDED MARCH 6, 2020

Before WOOD, *Chief Judge*, and SYKES and HAMILTON, *Circuit Judges*.

HAMILTON, *Circuit Judge*. This appeal presents two questions: first, whether we should reopen our court's prior judgment in this case, see *Dolin v. GlaxoSmithKline LLC*, 901 F.3d 803 (7th Cir. 2018) ("*Dolin I*"), and second, whether we should impose sanctions against appellant Wendy Dolin or her

counsel for pursuing this appeal. Our decisions are not to re-open the judgment and not to impose sanctions on Mrs. Dolin or her counsel.

I. *Factual and Procedural Background*

This case stems from a tragic suicide. In June 2010, Stewart Dolin was prescribed Paxil, the brand-name version of the drug paroxetine, to treat his depression. The prescription was filled not with brand-name Paxil but with a generic paroxetine product. Six days after beginning to take the medication, Mr. Dolin died by suicide. Federal law would have preempted a state-law claim against the generic manufacturer of the pills Mr. Dolin actually took on the theory that the federally approved label was inadequate because it failed to warn of the danger of adult suicide associated with the drug. See *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 609 (2011). Mrs. Dolin sued GlaxoSmithKline (GSK), the manufacturer of brand-name Paxil, on the theory that GSK was legally responsible for the content of the labeling for all paroxetine; no matter who made and sold it; that GSK had negligently omitted an adult suicide risk on the drug label, and that the negligent omission had caused her husband's death. Mrs. Dolin won a $3 million jury verdict in federal district court.

On appeal, we reversed the judgment. The appeal raised several issues, including whether Illinois law might hold GSK responsible for harm caused by paroxetine that someone else manufactured and sold, based on the contents of the label. We did not reach that issue. Instead, we found that Mrs. Dolin's claim was preempted by federal law governing the contents of the label for paroxetine. *Dolin I*, 901 F.3d at 803. Our opinion provided background on the complex regulation of drug labels in general and Paxil/paroxetine's label in particular. 901

F.3d at 806–10. We will not repeat it except to highlight that under the "changes being effected" or CBE regulation, 21 C.F.R. § 314.70(b)(2)(v)(A), "GSK needed FDA permission to change the paroxetine label unless three things were true: (1) GSK had newly acquired information about paroxetine (2) that showed a causal association (3) between the drug and an effect that warranted a new or stronger warning." 901 F.3d at 806. Further, the "FDA reviews CBE submissions and can reject label changes even after the manufacturer has made them." *Id.*, citing 21 C.F.R. § 314.70(c)(6) & (7). GSK attempted to change the Paxil label under the CBE regulation in 2007 to add an adult suicide warning. The FDA rejected that change. GSK had additional communications with FDA about the accuracy of the label's suicide risk warnings between 2007 and 2010, when Mr. Dolin died, but had not added a warning of adult suicide risk.

Under controlling precedent, "state-law claims based on labeling deficiencies are not preempted if the manufacturer could have added the warning unilaterally under the CBE regulation." *Dolin I*, 901 F.3d at 811, citing *Wyeth v. Levine*, 555 U.S. 555, 573 (2009). Applying *Wyeth*, we held in *Dolin I* that, "as a matter of law, (1) there is clear evidence that the FDA would have rejected the warning in 2007 [when it ordered GSK to remove its Paxil-specific adult-suicidality warning and instead use a class-wide SSRI warning], and (2) GSK lacked new information after 2007 that would have allowed it to add an adult-suicidality warning under the CBE regulation." *Dolin I*, 901 F.3d at 812. We therefore held that Mrs. Dolin's state-law claims against GSK were preempted. Mrs. Dolin filed a petition for certiorari at the Supreme Court, which was denied on May 28, 2019. 139 S. Ct. 2636 (2019).

The denial of certiorari in *Dolin I* came eight days after the Supreme Court decided another case, *Merck Sharp & Dohme Corp. v. Albrecht*, that picked up where *Wyeth* left off, further explaining *Wyeth*'s "clear evidence" standard for impossibility preemption for prescription drug labels. 139 S. Ct. 1668 (2019). After *Albrecht* was decided, Mrs. Dolin returned to the district court and filed a motion under Federal Rule of Civil Procedure 60(b)(6). Her motion argued that the 2018 final judgment should be set aside on the ground that *Albrecht* changed the law so that GSK could not establish its defense of impossibility preemption. The district court denied that motion. Mrs. Dolin has appealed.

We have jurisdiction of this appeal under 28 U.S.C. § 1291. The district court originally had subject-matter jurisdiction over the case under 28 U.S.C. § 1332(a)(1). Mrs. Dolin is a citizen of Illinois, and to the extent she is suing as representative of Mr. Dolin's estate, he was also a citizen of Illinois. See 28 U.S.C. § 1332(c)(2) (citizenship of legal representative of estate). GSK's only member is a corporation organized under Delaware law with its principal place of business in Delaware. The amount in controversy exceeds $75,000.

The district court had jurisdiction when Mrs. Dolin filed her Rule 60(b)(6) motion in June 2019. We had returned jurisdiction to the district court when we issued our 2018 mandate to that court to enter judgment in GSK's favor. The district court denied the motion and entered a written order to that effect on July 11, 2019. Mrs. Dolin appealed, and during the briefing, GSK filed a motion for sanctions, asserting that the appeal is frivolous. We deferred ruling on that motion until briefing and argument on the merits.

We review a district court's Rule 60(b) decision for abuse of discretion. *LAJIM, LLC v. General Electric Co.*, 917 F.3d 933, 949 (7th Cir. 2019). "[R]elief under that rule has been described as 'an extraordinary remedy … granted only in exceptional circumstances.'" *Davis v. Moroney*, 857 F.3d 748, 751 (7th Cir. 2017), quoting *Bakery Machinery & Fabrication, Inc. v. Traditional Baking, Inc.*, 570 F.3d 845, 848 (7th Cir. 2009).

II. *Sanctions*

We first address the question of sanctions, however. Federal Rule of Appellate Procedure 38 provides: "If a court of appeals determines that an appeal is frivolous, it may, after a separately filed motion or notice from the court and reasonable opportunity to respond, award just damages and single or double costs to the appellee." GSK's motion argues that Mrs. Dolin's appeal is frivolous. Its Rule 38 motion seeks fees and costs. We deny this motion.

"We do not invoke Rule 38 lightly." *Harris N.A. v. Hershey*, 711 F.3d 794, 801 (7th Cir. 2013). As we have often explained, our business is deciding appeals brought by reasonable lawyers and parties who disagree in good faith on the application of law in a particular case. Federal courts exist to decide such disputes, including good-faith efforts to convince the courts to extend, modify, or even reverse existing law. See, e.g., Fed. R. Civ. P. 11(b)(2) (explicitly endorsing "nonfrivolous argument[s] for extending, modifying, or reversing existing law or for establishing new law" as proper subject of legal filing); *Nisenbaum v. Milwaukee County*, 333 F.3d 804, 809 (7th Cir. 2003) ("[C]ourts do not penalize litigants who try to distinguish adverse precedents, argue for the modification of existing law, or preserve positions for presentation to the Supreme Court."); *Hartmarx Corp. v. Abboud*, 326 F.3d 862, 867 (7th Cir.

2003) ("[S]anctions are to be imposed sparingly, as they can have significant impact beyond the merits of the individual case and can affect the reputation and creativity of counsel.") (cleaned up); *In re Drexel Burnham Lambert Group Inc.*, 995 F.2d 1138, 1147 (2d Cir. 1993) ("Sanctions of course are not imposed merely because one side does not prevail in a given case."); *Fleming Sales Co., Inc. v. Bailey*, 611 F. Supp. 507, 519 (N.D. Ill. 1985) ("Rule 11 should be applied with some caution, given its potential for chilling legitimate advocacy. Even in its more expansive form as amended in 1983, it was not designed to penalize litigants because they choose to fight uphill battles[.]"); Fed. R. Civ. P. 11 Advisory Committee's Note to 1983 Amendment ("The rule is not intended to chill an attorney's enthusiasm or creativity in pursuing factual or legal theories. The court is expected to avoid using the wisdom of hindsight and should test the signer's conduct by inquiring what was reasonable to believe at the time the pleading, motion, or other paper was submitted.").

By contrast, appeals that are hopeless efforts to harass the opposing parties or to delay the inevitable may warrant sanctions, as in *Harris N.A. v. Hershey*, 711 F.3d at 803 (appellant-defendant was sophisticated borrower who offered no plausible reason to set aside district-court judgment enforcing eight-figure loan and guaranty), and *Spiegel v. Continental Illinois Nat'l Bank*, 790 F.2d 638 (7th Cir. 1986) (appellant brought frivolous appeal from dismissal of his civil RICO claims that were collateral attacks on state-court decision refusing his effort to become sole trustee of valuable trust established by his father).

In deciding whether to impose sanctions, we first consider whether the appeal is frivolous. "Frivolous," we stress, is not

a synonym for "unsuccessful," or "unlikely to succeed." See *NLRB v. Lucy Ellen Candy Div.*, 517 F.2d 551, 555 (7th Cir. 1975) ("A frivolous appeal means something more to us than an unsuccessful appeal."). GSK suggests that because Mrs. Dolin lost her Rule 60(b) motion in the district court, and because our review of such a denial is "extraordinarily deferential," it was almost by definition frivolous for her to challenge that denial in our court. We do not see it that way. Deferential standards of review may be hard for appellants to overcome, but they have the right to try.

"An appeal can be frivolous, though, 'when the result is obvious or when the appellant's argument is wholly without merit.'" *Harris N.A.*, 711 F.3d at 801–02, quoting *Spiegel*, 790 F.2d at 650. We disagree with Mrs. Dolin's argument *on* the merits, but that does not mean it is utterly *without* merit. One way to frame the legal question at the center of Mrs. Dolin's Rule 60(b) motion is whether *Albrecht* set a new standard or merely clarified the *Wyeth* standard. There are reasonable, and certainly colorable, arguments on both sides. We ultimately agree with the district court that *Albrecht* is better understood as clarifying *Wyeth,* but that is not the "foregone conclusion" that GSK makes it out to be.

Second, even if we thought that Mrs. Dolin's appeal were frivolous, and we do not, we would not automatically award sanctions. "When an appeal is frivolous, Rule 38 sanctions are not mandatory but are left to the sound discretion of the court of appeals to decide whether sanctions are appropriate." *Harris N.A.*, 711 F.3d at 802, citing *Burlington Northern R.R. Co. v. Woods*, 480 U.S. 1, 4 (1987). "How we exercise [our] discretion may turn on our perception of whether an appellant acted in bad faith." *Berwick Grain Co. v. Illinois Dep't of Agric.*, 217 F.3d

502, 505 (7th Cir. 2000). Mrs. Dolin has been vigorous in pursuing her arguments, and she has had every right to be. We see no indication of bad faith here. The fact that she has lost on the merits does not mean that her Rule 60(b) motion and her appeal of its denial in the face of a deferential standard of review were filed in bad faith. See, e.g., *Smeigh v. Johns Manville, Inc.*, 643 F.3d 554, 566 (7th Cir. 2011) (denying Rule 38 sanctions: "We find that this case is too close to the line to warrant monetary sanctions."), citing *Ross v. RJM Acquisitions Funding LLC*, 480 F.3d 493, 499 (7th Cir. 2007). We deny GSK's motion for attorneys' fees and costs. Mrs. Dolin has already lost her husband and a $3 million jury verdict. She need not lose anything more.

III. *The District Court's Decision Under Rule 60(b)*

The district court did not abuse its discretion in denying Mrs. Dolin's Rule 60(b) motion. We begin by exploring the discretion the district court was afforded under the circumstances. The district judge was aware of the range of options available to him and justified his ruling appropriately. We then look more closely at *Albrecht* and *Wyeth* and conclude that our decision in *Dolin I* would have been the same even if decided under *Albrecht*. We close by emphasizing the importance of finality.

A. *The District Court's Exercise of Discretion*

As noted, we review a district court's denial of a Rule 60(b) motion for abuse of discretion. *LAJIM, LLC*, 917 F.3d at 949. "A motion under Rule 60(b) often puts to a court a question without a right answer," calling on the district judge to "weigh incommensurables." *Metlyn Realty Corp. v. Esmark, Inc.*, 763 F.2d 826, 831 (7th Cir. 1985). "Dealing with these

intersecting planes of legal argument is a task of great subtlety, calling on all the skills of the district judges. It is not, however, a task that gives rise to 'error' … unless the judge leaves something important out of his analysis. This is why we have been so deferential in Rule 60(b) cases to decisions not to reopen." *Id.*

Our deference here is heightened by the fact that Mrs. Dolin's motion was filed under Rule 60(b)(6). In paragraphs (b)(1) through (b)(5), Rule 60 specifies five particular grounds for relief "from a final judgment, order, or proceeding," such as fraud, mistake, and newly discovered evidence. Paragraph (b)(6) provides a sixth, catchall ground: "any other reason that justifies relief." Mrs. Dolin's *Albrecht* argument falls into this catchall, making the district court's task here as incommensurable as one can imagine.

Nevertheless, where the law gives a court discretion that the court does not recognize and exercise, "The failure of the trial court to exercise its discretion at all … constitutes an abuse of discretion." *Brown-Bey v. United States*, 720 F.2d 467, 471 (7th Cir. 1983), quoted in *Childress v. Walker*, 787 F.3d 433, 443 (7th Cir. 2015). Mrs. Dolin argues that the district judge erred by failing to exercise discretion. She points to this statement by the judge at the hearing on her motion:

> I might have disagreed with the Seventh Circuit. But after they have spoken, I have to follow the Seventh Circuit. I'm a District Judge, I'm not a Court of Appeals Judge or a Supreme Court Judge. I can only do what I'm told by the upper court. If they don't tell me, I do the best I can without them. But now I've got their direction, and I am sworn to follow the law.

Mrs. Dolin's counsel then asked the court to "take a hard look at the law around Rule 60 because I think that the law actually gives you significantly more discretion than you realize." Judge Hart replied that he had "read the cases and everything that was called out to my attention," and he proceeded to engage in a detailed back-and-forth with counsel about the relevant precedents. See, e.g., *E.E.O.C. v. Sears, Roebuck & Co.*, 417 F.3d 789, 796 (7th Cir. 2005); *LSLJ Partnership v. Frito-Lay, Inc.*, 920 F.2d 476, 478 (7th Cir. 1990).

The transcript shows that Judge Hart knew well the relevant procedural and substantive law. We interpret his statement that "after they have spoken, I have to follow the Seventh Circuit" to indicate that he felt bound to follow our *Dolin I* ruling as to the interpretation of *Wyeth v. Levine*. Though he may have disagreed with that interpretation, it is binding circuit law and the law of the case. Because he understood *Albrecht* to be a clarification of *Wyeth*, the result would not change. This was a straightforward application of the hierarchical and precedential principles that organize our entire legal system.

Based on that legal analysis, and with no other equitable factors weighing in favor of reopening the judgment, the district judge held that "this is not one of those cases where I think a District Judge should grant a 60(b) motion." Note: "*should* not," not "*can*not." The district judge knew that he had discretion, and he exercised it to deny the motion.

B. *Albrecht and Wyeth*

We agree with the district court that *Albrecht* is better understood as a clarification of the impossibility standard in *Wyeth* rather than as a repudiation of it. We decided *Dolin I* on

the basis of the Supreme Court's teaching in *Wyeth* that "absent clear evidence that the FDA would not have approved a change to [the drug]'s label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements." 555 U.S. at 571. In *Wyeth*, the Supreme Court held that the drug company had not provided such "clear evidence" for two reasons: first, it had not shown that it "supplied the FDA with an evaluation or analysis concerning the specific dangers" underlying the appropriate warning; and second, it had not shown that it had "attempted to give the kind of warning required by [state law] but was prohibited from doing so by the FDA." *Id.* at 572–73. *Wyeth* did not establish a general definition of the "clear evidence" standard.

In *Albrecht*, the Court clarified that standard, writing that "'clear evidence' is evidence that shows the court that the drug manufacturer fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve a change to the drug's label to include that warning." 139 S. Ct. at 1672. *Albrecht* included two other important holdings: first, that the preemption question is a matter of law to be decided by the judge, not the jury; and second, that "the only agency actions that can determine the answer to the preemption question … are agency actions taken pursuant to the FDA's congressionally delegated authority." *Id.* at 1672, 1679.

There is language in *Albrecht*, however, that could be interpreted as a significant modification of the *Wyeth* standard for applying the CBE regulation to preemption of labeling claims. *Wyeth* framed the issue as requiring the defense to offer "clear evidence that the FDA would not have approved a change to [the drug's] label." 555 U.S. at 571. The phrase

"would not have approved" implies that the defendant may be able to satisfy the standard without showing that it actually requested a change for the label and that the FDA rejected it. In *Albrecht*, the Court wrote that the "clear evidence" needed is "evidence that shows the court that the drug manufacturer fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve a change to the drug's label to include that warning." 139 S. Ct. at 1672. That language implies that the manufacturer must have actually requested a change and that the FDA rejected it.

In addition, further language in *Albrecht* can be read to signal that the FDA's rejection must have acted "pursuant to the FDA's congressionally delegated authority," citing as examples notice-and-comment rulemaking or a formal rejection pursuant to regulations or some other action "carrying the force of law." 139 S. Ct. at 1679. That language could be understood as indicating that less formal exchanges of correspondence, like some of the evidence in this case, are not enough to provide such "clear evidence."

The quoted language from *Albrecht* has helped to convince us that Mrs. Dolin's Rule 60(b)(6) motion and appeal are not frivolous. We are not persuaded, however, that she should prevail. *Albrecht* explicitly grounded its analysis in the Court's holdings in *Wyeth*. *Albrecht* began by citing the *Wyeth* "clear evidence" standard and formulated the question for decision in terms of the *Wyeth* framework. *Id.* at 1672, 1678. The Court noted that its "conclusions flow from our precedents on impossibility pre-emption and the statutory and regulatory scheme that we reviewed in *Wyeth*." *Id.* at 1678. The Court also presented its decision as a clarification of *Wyeth*: "We stated

in *Wyeth v. Levine* that state law failure-to-warn claims are pre-empted by the Federal Food, Drug, and Cosmetic Act and related labeling regulations when there is 'clear evidence' that the FDA would not have approved the warning that state law requires. We here decide that a judge, not the jury, must decide the pre-emption question. *And we elaborate Wyeth's requirements along the way*." *Id*. at 1676 (emphasis added) (citation omitted).

This is the language of ordinary evolution and clarification in case law, not reversal and overruling. In addition, the facts of both *Wyeth* and *Albrecht* offer relatively little to work with. In *Wyeth*, the manufacturer had not offered any evidence that might have satisfied the newly articulated "clear evidence" standard. And in *Albrecht*, the principal holding was that the "clear evidence" standard for the impossibility preemption defense is a question of law for a court to decide. To the extent the Supreme Court modified the *Wyeth* standard, the Court itself did not try to apply that modified standard but instead remanded the case to the lower courts to apply the legal standard. 139 S. Ct. at 1680–81. We agree with the district court that *Albrecht* brought the *Wyeth* "clear evidence" holding into sharper focus. It did not adopt a new rule of preemption law.

More fundamental, though, our decision in *Dolin I* would have been the same under *Albrecht*. The record showed (a) that GSK disclosed the relevant data underlying its desired adult-suicidality warning to the FDA in 2006, and (b) that the FDA unambiguously rejected a Paxil-specific warning in 2007 when it formally mandated that all SSRIs carry a uniform, class-wide warning label. *Dolin I*, 901 F.3d at 813–15. We also noted in *Dolin I* that "Plaintiff has failed to offer evidence that

GSK acquired new information after 2007, when the FDA rejected its proposal to add an adult-suicidality warning to the paroxetine label that would have justified a change in the label and thus undermine GSK's preemption defense." *Id.* at 815. As we read *Albrecht*, the 2007 formal requirement that all SSRIs carry the same warning label would qualify as "agency action[] taken pursuant to the FDA's congressionally delegated authority." 139 S. Ct. at 1679. Also, the method of FDA rejection was not squarely before the Court in *Albrecht* and thus does not bear on that aspect of the *Dolin I* decision for purposes of Rule 60(b)(6). See *id.* at 1679–81. In short, *Albrecht* provided important guidance but did not break new ground that would change the result in this case.

C. *Rule 60(b), Finality, and Extraordinary Circumstances*

Judgments "may not be reopened under Rule 60(b) except in compelling and extraordinary circumstances." *Metlyn Realty Corp.*, 763 F.2d at 831. The "need for the finality of judgments is an overarching concern." *Cincinnati Ins. Co. v. Flanders Elec. Motor Service, Inc.*, 131 F.3d 625, 628 (7th Cir. 1997). Rule 60(b) recognizes this concern. Its "framers … set a higher value on the social interest in the finality of litigation." *Merit Ins. Co. v. Leatherby Ins. Co.*, 714 F.2d 673, 682 (7th Cir. 1983). Courts therefore approach Rule 60(b) motions with great caution.

Even if we agreed with Mrs. Dolin that *Albrecht* changed the law more dramatically than its elaboration of the *Wyeth* "clear evidence" standard, we would be mindful that "[i]ntervening developments in the law by themselves rarely constitute the extraordinary circumstances required for relief under Rule 60(b)(6)." *Agostini v. Felton*, 521 U.S. 203, 239 (1997). Mrs. Dolin presents no extraordinary circumstances here. In sum,

we do not see a compelling reason to disturb the final judgment in this case.

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The district court's denial of relief under Federal Rule of Civil Procedure 60(b)(6) is AFFIRMED. Appellee GlaxoSmithKline's motion for fees and costs under Federal Rule of Appellate Procedure 38 is DENIED.